ASME NQA-1–2015

(Revision of ASME NQA-1–2012)

Quality Assurance Requirements for Nuclear Facility Applications

AN AMERICAN NATIONAL STANDARD

The American Society of Mechanical Engineers

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Quality Assurance Requirements for Nuclear Facility Applications

AN AMERICAN NATIONAL STANDARD

The American Society of Mechanical Engineers

Two Park Avenue • New York, NY • 10016 USA

Date of Issuance: February 20, 2015

The next edition of this Standard is scheduled for publication in 2017.

ASME issues written replies to inquiries concerning interpretations of technical aspects of this Standard. Interpretations are published on the ASME Web site under the Committee Pages at http://cstools.asme.org/. Interpretations are also included with each edition.

Errata to codes and standards may be posted on the ASME Web site under the Committee Pages to provide corrections to incorrectly published items, or to correct typographical or grammatical errors in codes and standards. Such errata shall be used on the date posted.

The Committee Pages can be found at http://cstools.asme.org/. There is an option available to automatically receive an e-mail notification when errata are posted to a particular code or standard. This option can be found on the appropriate Committee Page after selecting "Errata" in the "Publication Information" section.

The American Society of Mechanical Engineers
Two Park Avenue, New York, NY 10016-5990

CONTENTS

(A detailed Contents precedes each NQA Part.)

FOREWORD

This Standard is intended to serve the global nuclear industry responsible for the safety and quality of nuclear facilities and activities.

It is intended to be applied to any structure, system, component, activity, or organization that is essential to the safe, reliable, and efficient performance of a nuclear facility and any activities independent of a facility that may affect performance. It is also intended to be applied to all phases of a nuclear facility life cycle and to related activities.

This Standard reflects industry experience and current understanding of the quality assurance requirements necessary to achieve safe, reliable, and efficient utilization of nuclear energy and management and processing of radioactive materials. The Committee on Nuclear Quality Assurance (NQA) actively endorses the growing worldwide movement toward rational, cost-effective quality assurance practices — practices that focus on results. The NQA Committee also maintains liaison with national and international groups that have similar interests in quality to assure consistency and maximum applicability of the Standard in a global setting. Consequently, the NQA Committee has regularly updated and revised the Standard since its first edition was issued in 1979 to improve its utility, effect on nuclear safety, and value to the nuclear industry.

This Standard includes requirements and guidance and is organized in the following four parts:

(a) Part I contains requirements for a Quality Assurance Program for nuclear facility applications.

(b) Part II contains additional quality assurance requirements for the planning and conduct of specific work activities conducted under a Quality Assurance Program developed in accordance with Part I.

(c) Part III contains guidance for implementing the requirements of Parts I and II.

(d) Part IV contains guidance for the application of NQA-1 and comparisons of NQA-1 with other quality requirements.

Early in 1975, the American National Standards Institute (ANSI) assigned overall responsibility for coordination among technical societies and development and maintenance of nuclear power quality assurance standards to the American Society of Mechanical Engineers (ASME). The ASME Committee on NQA was constituted on October 3, 1975, and assumed responsibility for the ANSI/ASME N.45 series documents. Currently, the NQA Committee operates under the ASME requirements for Nuclear Codes and Standards Development Committees.

This Committee initially prepared

ANSI/ASME NQA-1–1979	Quality Assurance Program Requirements for Nuclear Power Plants
ANSI/ASME NQA-2–1983	Quality Assurance Requirements for Nuclear Power Plants
ANSI/ASME NQA-3–1989	Quality Assurance Requirements for High Level Waste Management

For a detailed history of the NQA Committee and evolution of the Standard, go to: http://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=O10500000&Action=16897.

Requests for interpretation or suggestions for improvement of this Standard should be submitted in accordance with the Preparation of Technical Inquiries to the Nuclear Quality Assurance Committee contained in the preface of this Standard.

For a listing of the NQA publication history, refer to the following table:

Historical Listing of NQA Publications

NQA-1			NQA-2			NQA-3		
Editions and Addenda	Designator	Issued	Editions and Addenda	Designator	Issued	Editions and Addenda	Designator	Issued
1st Ed.	**NQA-1–1979**	8/31/1979		...	...		...	...
Add.	NQA-1a–1981	4/30/1981		...	...		...	...
Add.	NQA-1b–1981	1/31/1982		...	...		...	...
2nd Ed.	**NQA-1–1983**	7/1/1983	1st Ed.	**NQA-2–1983**	8/31/1983		...	...
Add.	NQA-1a–1983	12/31/1983	Add.	NQA-2a–1985	10/15/1985		...	...
Add.	NQA-1b–1984	3/15/1985		...	...		...	...
Add.	NQA-1c–1985	12/31/1985		...	...		...	...
3rd Ed.	**NQA-1–1986**	7/1/1986	2nd Ed.	**NQA-2–1986**	7/1/1986		...	...
Add.	NQA-1a–1986	2/15/1987	Add.	NQA-2a–1986	2/15/1987		...	...
Add.	NQA-1b–1987	3/15/1988	Add.	NQA-2b–1987	4/15/1988		...	...
Add.	NQA-1c–1988	2/28/1989	Add.	NQA-2c–1988	2/28/1989		...	...
4th Ed.	**NQA-1–1989**	9/15/1989	3rd Ed.	**NQA-2–1989**	9/30/1989	1st Ed.	**NQA-3–1989**	3/23/1990
Add.	NQA-1a–1989	3/31/1990	Add.	NQA-2a–1990	5/31/1990		...	...
Add.	NQA-1b–1991	4/15/1991	Add.	NQA-2b–1991	5/12/1992		...	...
Add.	NQA-1c–1992	9/30/1992		...	...		...	...
5th Ed.	**NQA-1–1994** [Note (1)]	7/29/1994		...	...		...	...
Add.	NQA-1a–1995	1/19/1996		...	...		...	...
6th Ed.	**NQA-1–1997**	12/31/1997		...	...		...	...
Add.	NQA-1a–1999	5/25/1999		...	...		...	...
7th Ed.	**NQA-1–2000**	5/21/2001		...	...		...	...
Add.	NQA-1a–2002	12/6/2002		...	...		...	...
8th Ed.	**NQA-1–2004**	12/22/2004		...	...		...	...
Add.	NQA-1a–2005	5/3/2006		...	...		...	...
Add.	NQA-1b–2007	6/1/2007		...	...		...	...
9th Ed.	**NQA-1–2008**	3/14/2008		...	...		...	...
Add.	NQA-1a–2009	7/20/2009		...	...		...	...
Add.	NQA-1b–2011	1/4/2011		...	...		...	...
10th Ed.	**NQA-1–2012**	3/15/2013		...	...		...	...
11th Ed.	**NQA-1–2015**	2/20/2015		...	...		...	...

GENERAL NOTE: NQA editions and addenda prior to 1989 were titled ANSI/ASME NQA.

NOTE:

(1) This edition is a consolidation of NQA-1 and NQA-2.

PREPARATION OF TECHNICAL INQUIRIES TO THE NUCLEAR QUALITY ASSURANCE COMMITTEE

INTRODUCTION

The ASME Nuclear Quality Assurance Committee will consider written requests for interpretations and revisions to NQA Standards and develop new requirements or guidance if dictated by technological development. The Committee's activities in this regard are limited strictly to interpretations of the requirements and guidance, or to the consideration of revisions to the present Standard on the basis of new data or technology. As a matter of published policy, ASME does not "approve," "certify," "rate," or "endorse" any item, construction, proprietary device, specific organizations, individual titles, or activity and, accordingly, inquiries requiring such consideration will be returned. Moreover, ASME does not act as a consultant for specific engineering problems or for the general application or understanding of the Standard requirements. If, based on the inquiry information submitted, it is the opinion of the Committee that the inquirer should seek assistance, the inquiry will be returned with the recommendation that such assistance be obtained.

All inquiries that do not provide the information needed for the Committee's full understanding will be returned.

INQUIRY FORMAT

Inquiries shall be limited strictly to interpretations of the requirements and guidance, or to the consideration of revisions to the present Standard on the basis of new data or technology.

Inquiries shall be submitted in the following format:

(a) Scope. The inquiry shall involve a single requirement/guidance or closely related requirements/guidance. An inquiry letter concerning unrelated subjects will be returned.

(b) Background. State the purpose of the inquiry, which would be either to obtain an interpretation of the Standard or to propose consideration of a revision to the present Standard. Provide the information needed for the Committee's understanding of the inquiry concisely, being sure to include reference to the applicable Standard, Edition, Addenda, Requirements, Parts, Subparts, Appendices, paragraphs, figures, and tables. If illustrations are provided, they shall be limited to the scope of the inquiry.

(c) Inquiry Structure

(1) Proposed Question(s). The inquiry shall be stated in a condensed and precise question format, omitting superfluous background information, and, where appropriate, composed in such a way that "yes" or "no" (perhaps with provisos) would be an acceptable reply. The inquiry statement should be technically and editorially correct.

(2) Proposed Reply(ies). State what it is believed that the Standard requires. If, in the inquirer's opinion, a revision to the Standard is needed, recommended wording shall be provided.

(d) Submittal. The inquiry shall be submitted in typewritten form; however, legible, handwritten inquiries will be considered. It shall include the name and mailing address and telephone number of the inquirer and be mailed to the following address:

Secretary
ASME Nuclear Quality Assurance Committee
Nuclear Department
Two Park Avenue
New York, NY 10016-5990

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(As of April 23, 2014)

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INTRODUCTION (15)

This Standard is to be applied to any structure, system, component, activity, or organization that is essential to the safe, reliable, and efficient performance of a nuclear facility and any activities independent of a facility that may affect performance (e.g., transportation of nuclear materials) of those activities. The extent to which this Standard should be applied depends upon the specific type of facility, items, or services involved and the nature, scope, and relative importance of the activity being performed. It is also to be applied to all phases of a nuclear facility life cycle (e.g., siting, design, construction, operation, and decommissioning) and all types of activities (e.g., training, testing, software development or use).

The Standard also applies to activities that could affect the quality of nuclear material applications, structures, systems, and components of nuclear facilities.

Examples of nuclear facilities are those for power generation, spent fuel storage, waste management, fuel reprocessing, nuclear material processing, fuel fabrication, nuclear research, and other related facilities. Examples of activities include siting, designing, procuring, developing or using software, fabricating, constructing, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and decommissioning.

This Standard is organized in the following four parts:

(a) Part I contains requirements for developing and implementing a Quality Assurance Program for nuclear facility applications.

(b) Part II contains additional quality assurance requirements for the planning and conduct of specific work activities under a Quality Assurance Program developed in accordance with Part I.

(c) Part III contains guidance for implementing the requirements of Parts I and II.

(d) Part IV contains guidance for application of NQA-1 and comparisons of NQA-1 with other quality requirements.

The arrangement of the requirements in Parts I and II and the guidance in Parts III and IV permit the judicious application of the Standard or portions of the Standard. Applicable requirements of Parts I and II are to be implemented to ensure conformance with NQA-1. The application of this Standard, or portions thereof, shall be invoked by written contracts, policies, procedures, specifications, or other appropriate documents.

This Standard reflects industry experience and current understanding of the quality assurance requirements necessary to achieve safe, reliable, and efficient utilization of nuclear energy and management and processing of radioactive materials. The Standard focuses on the achievement of results, emphasizes the role of the individual and line management in the achievement and sustainment of quality, and fosters the application of these requirements in a manner consistent with the relative importance of the item or activity (i.e., a “graded approach”).

ASME NQA-1–2015
SUMMARY OF CHANGES

Following approval by the ASME Standards Committee on Nuclear Quality Assurance and ASME, and after public review, ASME NQA-1–2015 was approved by the American National Standards Institute on January 12, 2015.

ASME NQA-1–2015 consists of NQA-1–2012; editorial changes, revisions, and corrections; as well as the following changes identified by a margin note, **(15)**.

Page	*Location*	*Change*
ix	Introduction	Added
4–7	Part I Introduction	Revised in its entirety
9	Part I, Requirement 2, 300	Second paragraph revised
	Part I, Requirement 2, 301	Second word revised
10	Part I, Requirement 2, 303	Revised
11	Part I, Requirement 2, 400	Revised in its entirety
	Part I, Requirement 2, 500	First sentence deleted
12	Part I, Requirement 3, 401	Revised in its entirety
14	Part I, Requirement 3, 800	(1) Revised (2) Sections 801 and 802 deleted
23	Part I, Requirement 11, 200	Subparagraph (d) deleted
	Part I, Requirement 11, 400	Revised in its entirety
24	Part I, Requirement 11, 602	Revised in its entirety
30, 31	Part I, Requirement 17, 601	Spelling of second word corrected in subparagraph (b)
32	Part I, Requirement 18, 200	Revised in its entirety
34–36	Part II Contents	Updated
37	Part II Introduction, 100	Revised
	Part II Introduction, 200	Revised
	Part II Introduction, 300	Revised
39	Part II, Subpart 2.1	Title revised
	Part II, Subpart 2.1, 100	Revised
	Part II, Subpart 2.1, 101	Definitions of *cleaning* and *sensitized corrosion-resistant alloy* revised
41	Part II, Subpart 2.1, 302.1	ASTM designations updated
	Part II, Subpart 2.1, 302.2	ASTM designations updated
42	Part II, Subpart 2.1, 302.4	Subparagraph (d) revised
44–47	Part II, Subpart 2.1, 400	Third paragraph revised
	Part II, Subpart 2.1, 600	Last paragraph revised

Page	*Location*	*Change*
	Part II, Subpart 2.1, 801	First and last paragraphs revised
	Part II, Subpart 2.1, 802	Paragraphs 802.1 and 802.2 revised
	Part II, Subpart 2.1, 1000	Second paragraph revised
63	Part II, Subpart 2.4	Deleted
75	Part II, Subpart 2.7, 100	Footnote 1 added
	Part II, Subpart 2.7, 102	Definition of *change control* added
76–78	Part II, Subpart 2.7, 201	Title revised
	Part II, Subpart 2.7, 202	Title revised
	Part II, Subpart 2.7, 203	Revised in its entirety
	Part II, Subpart 2.7, 302	Revised
	Part II, Subpart 2.7, 400	Sections 400 through 404 revised
102	Part II, Subpart 2.16	Deleted
103	Part II, Subpart 2.18, 201	Subparagraph (c) revised
116, 117	Part III Contents	Updated
118	Part III Introduction, 100	Revised in its entirety
	Part III Introduction, 200	Subparagraph (a) and last paragraph revised
131–134	Part III, Subpart 3.1-3.1, 100	Subparagraph (g) added
	Part III, Subpart 3.1-3.1, 200	(1) Subparagraph (q) revised (2) Subparagraph (ii) added
	Part III, Subpart 3.1-3.1, 300	Subparagraph (a)(11) added
	Part III, Subpart 3.1-3.1, 400	Revised in its entirety
135	Table 401.4	Added
	Part III, Subpart 3.1-3.1, 600	Last paragraph added
144	Part III, Subpart 3.1-7.1, 705	Added
154, 155	Part III, Subpart 3.1-18.1, 204	(1) Added, and remaining paragraphs redesignated (2) Paragraphs 203.1, 203.2, and previous 206 deleted
156	Part III, Subpart 3.1-18.1, 600	Revised in its entirety
	Part III, Subpart 3.1-18.1, 700	Revised in its entirety
157	Part III, Subpart 3.1-18.2	Added
161	Part III, Subpart 3.2-2.7.1	Designation revised
	Part III, Subpart 3.2-2.7.1, Introduction	Spelling of “Subpart” corrected
166–173	Part III, Subpart 3.2-2.7.2	Added
175	Part III, Subpart 3.2-2.14, 300	First paragraph revised

Page	*Location*	*Change*
180	Part III, Subpart 3.2-2.14, 900	Designation of last EPRI report corrected
194–196	Part IV Contents	Updated
197	Part IV Introduction, 100	Revised in its entirety
245–256	Part IV, Subpart 4.1.5	Added
258, 259	Part IV, Subpart 4.2.1, 200	Revised
270	Part IV, Subpart 4.2.3, 404	Last paragraph added
272	Part IV, Subpart 4.2.4, 501	(1) Revised (2) Sections 502 and 503 deleted
281–284	Part IV, Subpart 4.2.7	Added

SPECIAL NOTE:

The interpretations to ASME NQA-1 are included in this edition as a separate section for the user's convenience.

PART I: REQUIREMENTS FOR QUALITY ASSURANCE PROGRAMS FOR NUCLEAR FACILITIES
(FROM FORMER NQA-1)

CONTENTS

(15)

PART I
INTRODUCTION

This Standard reflects industry experience and current understanding of the quality assurance requirements necessary to achieve safe, reliable, and efficient utilization of nuclear energy, and management and processing of radioactive materials. The Standard focuses on the achievement of results, emphasizes the role of the individual and line management in the achievement of quality, and fosters the application of these requirements in a manner consistent with the relative importance of the item or activity.

100 PURPOSE

Part I — this Part — establishes requirements for the development and implementation of a Quality Assurance Program (QAP) for nuclear facility applications. It is arranged by Requirements 1 through 18.

Part II contains additional quality assurance requirements for the planning and conduct of specific work activities under a Quality Assurance Program developed in accordance with Part I. It is arranged by Subparts.

Part III contains guidance for implementing the requirements of Parts I and II. It is arranged by Subparts.

Part IV contains guidance for application of NQA-1 and comparisons of NQA-1 with other quality requirements. It is arranged by Subparts.

200 APPLICABILITY

This Part — Part I — is to be applied using a graded approach to any structure, system, component, activity, or organization that is essential to the safe, reliable, and efficient performance of a nuclear facility and to any activities independent of a facility that may affect performance (e.g., transportation of nuclear materials) of those activities. It is also to be applied using a graded approach to all phases of a nuclear facility life cycle (e.g., siting, design, construction, operation, and decommissioning) and to all types of activities (e.g., training, testing, software development and use). A Quality Assurance Program developed in accordance with Part I is to be applied when implementing Part II requirements.

300 RESPONSIBILITY

The organization invoking this Part shall be responsible for specifying applicable requirements and appropriately relating them to specific items, activities, and services. The organization implementing this Part and applicable Part II requirements shall be responsible for complying with the specific requirements to achieve quality results in compliance with this Standard.

400 TERMS AND DEFINITIONS

The following definitions are provided to assure a uniform understanding of select terms as they are used in this Standard:

acceptance criteria: specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

assessment: an all-inclusive term that may include review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

audit: a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

audit, external: an audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.

audit, internal: an audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

audit finding: a condition adverse to quality identified during an audit requiring follow-up by or for the auditing organization.

Certificate of Conformance: a document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

certification: the act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

characteristic: any property or attribute of an item, process, or service that is distinct, desirable, and measurable.

commercial grade item:[1, 2] a structure, system, component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

commercial grade item:[1, 3] an item satisfying the following:

(a) not subject to design or specification requirements that are unique to those facilities or activities

(b) used in applications other than those facilities or activities

(c) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., a catalog)

commercial grade item:[1, 4] a structure, system, component, or part thereof, that affects its safety function, that was not designed and manufactured in accordance with the requirements of this Standard.

commercial grade service:[1] a service that was not provided in accordance with the requirements of this Standard.

computer program:[5, 6, 7] a combination of computer instructions and data definitions that enables computer hardware to perform computational or control functions.

condition adverse to quality: an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one that, if uncorrected, could have a serious effect on safety or operability.

configuration: the physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing facility.

configuration item (software):[6] a collection of hardware or software elements treated as a unit for the purpose of configuration control.

configuration management: the process that controls the activities, and interfaces, among design, construction, procurement, training, licensing, operations, and maintenance to ensure that the configuration of the facility is established, approved, and maintained.

corrective action: measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

critical characteristics: important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.

design, final: approved design output documents and approved changes thereto.

design authority: the organization having the responsibility and authority for approving the design bases, the configuration, and changes thereto.

design bases: that information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be

(a) restraints derived from generally accepted "state-of-the-art" practices for achieving functional goals; or

(b) requirements derived from analysis (based on calculations and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals.

design change: any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

design input: those criteria, performance requirements, codes and standards, design bases, regulatory requirements, or other design requirements upon which detailed final design is based.

design output: drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs.

design process: technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

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[1] See Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services for other definitions related to the dedication of commercial grade items.

[2] This definition is applicable to nuclear power plants and activities licensed pursuant to 10 CFR Part 30, 40, 50, 52, or 60.

[3] This definition is applicable to nuclear facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72.

[4] This definition is applicable to Department of Energy nuclear facilities and activities regulated under 10 CFR 830, Nuclear Safety Management.

[5] Computer programs covered by this Standard are those used for

(a) design analysis

(b) operations or process control, or

(c) data base or document control registers when used as the controlled source of quality information for (a) or (b) above

[6] This definition has been copied from ANSI/IEEE 610.12-1990, Glossary of Software Engineering Terminology, with the permission of IEEE.

[7] To the extent that computer programs are a physical part of plant systems (e.g., digital reactor protection systems, digital instrumentation), they are included in the term *item*.

design review: a critical review to provide assurance that the final design is correct and satisfactory.

deviation: a departure from specified requirements.

document: any written, pictorial, or electronic information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a quality assurance record until it satisfies the definition of a quality assurance record as defined in this Standard.

document control: the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.

electronic document: a document stored in a form (e.g., magnetic or optical media) that is typically accessible only by a computer.

graded approach:[8] the process employed, once the applicability of the requirement to the scope of the organization's activity has been determined, to ensure that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with the following:

(a) the relative importance to nuclear safety
(b) the magnitude of any hazard involved
(c) the life-cycle stage of a facility or item
(d) the mission of a facility
(e) the particular characteristics of a facility or item
(f) the relative importance to radiological and nonradiological hazards
(g) any other relevant factors

guidance: a suggested practice that is not mandatory in programs intended to comply with this Standard. The word *should* denotes guidance, the word *shall* denotes a requirement, and the word *may* denotes permission.

inspection: examination or measurement to verify whether an item or activity conforms to specified requirements.

inspector: a person who performs inspection activities to verify conformance to specific requirements.

item:[9] an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

may: see *guidance*.

measuring and test equipment (M&TE): devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

nonconformance: a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

objective evidence: any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

Owner:[9] the organization legally responsible for the construction and/or operation of a nuclear facility including but not limited to one who has applied for, or who has been granted, a construction permit or operating license by the regulatory authority having lawful jurisdiction.

procedure: a document that specifies or describes how an activity is to be performed.

procurement document: purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

Purchaser: the organization responsible for establishment of procurement requirements and for issuance or administration, or both, of procurement documents.

qualification, personnel: the characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

qualified automated means: automated methods of controlling or monitoring processes that have been demonstrated to produce required quality within controlled limits.

qualified procedure: an approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

quality assurance (QA):[9] all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

quality assurance record: a completed document that furnishes evidence of the quality of items and/or activities affecting quality. Types of record media may include paper, electronic (e.g., magnetic or optical), or specially processed media, such as radiographs, photographs, negatives, and microforms. The term *record*, as used throughout the Standard, is to be interpreted as quality assurance record.

quality standard: a code or standard that provides design inputs, acceptance criteria, or other criteria necessary to assure the quality of the designated item.

receiving: taking delivery of an item at a designated location.

repair:[9] the process of restoring a nonconforming characteristic to a condition such that the capability of an

[8] When used with Subpart 2.22 of this Standard, the definition in 10 CFR 830 shall apply.

[9] When used with ASME Section III, the definition in NCA-9000 shall apply.

item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.

rework:[9] the process by which an item is made to conform to original requirements by completion or correction.

right of access: the right of a Purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or quality assurance audit.

safety function: the performance of an item or service necessary to achieve safe, reliable, and effective utilization of nuclear energy and nuclear material processing.

service:[9] the performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

shall: see *guidance.*

should: see *guidance.*

software:[6] computer programs and associated documentation and data pertaining to the operation of a computer system.

special process: a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

supplier: any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels.

surveillance: the act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

survey, commercial grade:[1] a documented evaluation of an organization's ability to perform activities as verified by a determination of the adequacy of the organization's

(a) quality program and/or

(b) ability to meet specified requirements

testing: an element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

traceability: the ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

use-as-is:[9] a disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use.

verification: the act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

waiver: documented authorization to depart from specified requirements.

REQUIREMENT 1
Organization

100 GENERAL

Responsibilities for the establishment and implementation of the quality assurance program shall be defined. The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented.

200 STRUCTURE AND RESPONSIBILITY

201 General

The organizational structure and responsibility assignments shall be such that

(a) senior management establishes overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result

(b) quality is achieved and maintained by those assigned responsibility for performing work

(c) quality achievement is verified by those not directly responsible for performing the work

(d) those responsible for assuring that an appropriate quality assurance program has been established and those verifying activities affecting quality have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform this function, including sufficient independence from cost and schedule when opposed to safety function considerations. These verification functions include the following:

(1) identifying quality problems

(2) initiating, recommending, or providing solutions to quality problems through designated channels

(3) verifying implementation of solutions

(4) assuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

202 Delegation of Work

The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain responsibility thereof.

300 INTERFACE CONTROL

Where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented.

The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.

REQUIREMENT 2
Quality Assurance Program

100 GENERAL

(a) A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Part (Part I), or portions thereof. The program shall identify the activities and items to which it applies. The program shall provide control over activities affecting quality to an extent consistent with their importance. The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.

The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality. The organization shall establish and implement processes to detect and correct quality problems.

(b) The program shall provide for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to ensure that suitable proficiency is achieved and maintained.

(c) Management shall regularly assess the adequacy and effective implementation of the quality assurance program.

200 INDOCTRINATION AND TRAINING

Indoctrination and training shall be commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person.

201 Indoctrination

Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.

202 Training

The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities. On-the-job training shall be used if direct hands-on applications or experience is needed to achieve and maintain proficiency.

300 QUALIFICATION REQUIREMENTS (15)

The responsible organization shall designate those activities that require qualification of personnel and the minimum requirements for such personnel. The responsible organization shall establish written procedures for the qualification of personnel, and for the assurance that only those personnel who meet the requirements are permitted to perform these activities.

Specific qualification requirements for personnel performing nondestructive examination, inspection and tests to verify quality, and auditing are specified in paras. 301 through 304 of this Requirement.

301 Nondestructive Examination (NDE) (15)

This paragraph specifies requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MP), ultrasonic (UT), liquid penetrant (PT), electromagnetic (ET), neutron radiographic (NR), leak testing (LT), acoustic emission (AE), and visual testing (VT) to verify conformance to the specified requirements. The American Society of Nondestructive Testing (ASNT) Recommended Practices or Standards provide acceptable qualification requirements for NDE personnel. Applicable Codes and Standards or design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable ASNT qualification requirement and edition or to specify an equivalent alternative requirement.

302 Inspection and Test

The initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration. The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 yr. Reevaluation shall be by evidence of continued satisfactory performance or redetermination

of capability in accordance with the requirements of section 200 of this Requirement. If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in the qualified area for a period of 1 yr shall be reevaluated.

(15) **303 Lead Auditor**

The Lead Auditor organizes and directs audits, reports audit findings, and evaluates corrective action. An individual shall meet the requirements of paras. 303.1 through 303.4 of this Requirement prior to being designated a Lead Auditor. Lead Auditors shall maintain proficiency in accordance with the requirements of para. 303.5 or requalify in accordance with the requirements of para. 303.6, as applicable.

303.1 Communication Skills. The prospective Lead Auditor shall be capable of communicating effectively, both in writing and orally. These skills shall be attested to in writing by the Lead Auditor's employer.

303.2 Training. Prospective Lead Auditors shall receive training to the extent necessary to assure auditing competence including

(a) knowledge and understanding of this Standard and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable

(b) general structure of quality assurance programs as a whole and applicable elements as defined in this Standard

(c) auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings

(d) planning audits of activities affecting quality

(e) on-the-job training to include applicable elements of the audit program

303.3 Audit Participation. Prospective Lead Auditors shall participate in a minimum of five quality assurance audits within a period of time not to exceed 3 yr prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to qualification.

Participation in independent assessments including team assessment activities such as operations readiness reviews and regulatory inspections/surveys may be used to satisfy up to four of the five required quality assurance audits, provided that the activities can demonstrate the following:

(a) independence from the functional areas being assessed

(b) planning that establishes the scope of the activities and associated evaluation criteria

(c) performance by technically qualified and experienced personnel

(d) results that are documented and reported to management

(e) appropriate corrective action initiated and tracked to resolution

Such participation shall be subject to review and acceptance by the organization responsible for quality assurance audits and/or the certifying authority prior to their use for qualification.

303.4 Examination. Prospective Lead Auditors shall pass an examination that shall evaluate comprehension of and ability to apply the body of knowledge identified above. The examination may be oral, written, practical, or any combination thereof.

303.5 Maintenance of Proficiency. Lead Auditors shall maintain their proficiency through one or more of the following:

(a) regular and active participation in the audit process

(b) review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing

(c) participation in training program(s)

Based on annual assessment, management may extend the qualification, require retraining, or require requalification.

303.6 Requalification. Lead Auditors who fail to maintain their proficiency for a period of 2 yr or more shall require requalification. Requalification shall include retraining in accordance with the requirements of para. 303.2 of this Requirement, reexamination in accordance with para. 303.4 of this Requirement, and participation as an Auditor in at least one nuclear quality assurance audit.

304 Auditors

Auditors are participants in an audit. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the following methods:

(a) orientation to provide a working knowledge and understanding of this Standard and the auditing organization's procedures for implementing audits and reporting results.

(b) general and specialized training in audit performance where the general training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing and the specialized training shall include methods of examining,

questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

(c) on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.

305 Technical Specialists

The responsible auditing organization shall establish the qualifications and requirements for use of technical specialists to accomplish the auditing of quality assurance programs.

(15) 400 RECORDS OF QUALIFICATION

(a) The qualification of inspection, test, and Lead Auditor personnel shall be certified in writing and include the following information:

(1) employer's name

(2) identification of person being certified

(3) activities certified to perform

(4) signature of employer's designated representative

In addition to the requirements above, specific requirements for each qualification/certification that are to be certified in writing are specified in paras. 401 and 402 of this Requirement.

The employer may delegate qualification examination activities to an independent certifying agency but shall retain responsibility for conformance of the examination and its administration. Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the employer in accordance with the requirements of section 500 of this Requirement.

401 Inspection and Test Personnel

Additional requirements to those listed in para. 400 shall include the following:

(a) education

(b) work experience

(c) training

(d) demonstration of capabilities

(e) date of certification/recertification

(f) any special physical requirements needed in the performance of each activity, including the need for initial and subsequent physical examination

(g) certification expiration

402 Lead Auditor Personnel

Additional requirements to those listed in para. 400 shall include the following:

(a) education

(b) work experience

(c) training

(d) audit participation

(e) examination results

(f) date of certification/recertification

(g) annual assessment of proficiency maintenance

500 RECORDS (15)

Records of indoctrination and training shall include one or more of the following:

(a) attendance sheets

(b) training logs

(c) personnel training records

The employer shall establish and maintain records for indoctrination and training, Auditor and Lead Auditor qualification and requalification, and inspection and test personnel qualification and requalification.

REQUIREMENT 3
Design Control

100 GENERAL

The design shall be defined, controlled, and verified. Design inputs shall be specified on a timely basis and translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by individuals other than those who designed the item or computer program. Design changes shall be governed by control measures commensurate with those applied to the original design.

200 DESIGN INPUT

Applicable design inputs shall be identified and documented, and their selection reviewed and approved. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

300 DESIGN PROCESS

(a) The responsible design organization shall prescribe and document the design activities to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. Design documents shall support facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.

(b) The design methods, materials, parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.

(c) The final design shall

(1) be relatable to the design input by documentation in sufficient detail to permit design verification.

(2) specify required inspections and tests and include or reference appropriate acceptance criteria.

(3) identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall meet the requirements of Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services.

Critical characteristics to be verified are those that provide reasonable assurance that the item will perform its intended safety function. If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

400 DESIGN ANALYSES

Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

401 Use of Computer Programs (15)

Each computer program used for design analysis shall be accepted for use and controlled by applying the applicable requirements of Parts I and II prior to use, or the computer program's results shall be independently verified with the design analysis for each application.

The acceptance of controlled computer programs used for design analysis, and verification methods applied to the results of unproven programs, shall meet the following requirements:

(a) The computer program, or the verification method applied to the computer program results, shall be shown to produce correct solutions for the applied mathematical model within defined limits for each parameter employed.

(b) The applied mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.

402 Documentation of Design Analyses

Documentation of design analyses shall include the following:

(a) the objective of the analyses

(b) design inputs and their sources

(c) results of literature searches or other applicable background data

(d) assumptions and indication of those assumptions that must be verified as the design proceeds

(e) identification of any computer calculation, including identification of the computer type, computer program name, and revision, inputs, outputs, evidence of

or reference to computer program verification, and the bases (of reference thereto) supporting application of the computer program to the specific physical problem

(f) review and approval

500 DESIGN VERIFICATION

(a) The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be documented with the identification of the verifier clearly indicated. Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided

(1) the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or

(2) the supervisor is the only individual in the organization competent to perform the verification.

Cursory supervisory reviews do not satisfy the intent of this Standard.

(b) Design verification shall be performed prior to releasing the design for procurement, manufacture, construction, or use by another design organization, except where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.

(c) If the design is modified to resolve verification findings, the modified design shall be verified prior to release or use.

(d) Extent of Design Verification. The extent of the design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proved designs. Where the design has been subjected to a verification process in accordance with this Part (Part I), the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standard or previously proved designs and their effects on other features shall be considered. The original design and associated verification documentation shall be referenced in records of subsequent application of the design.

501 Methods

Acceptable verification methods include, but are not limited to, any one or a combination of the following:

(a) design reviews

(b) alternate calculations

(c) qualification testing

501.1 Design Reviews. Design reviews shall provide assurance that the final design is correct and satisfactory by addressing, where applicable, paras. 501.1(a) through (g) of this Requirement.

(a) Were the design inputs correctly selected?

(b) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?

(c) Were appropriate design methods and computer programs used?

(d) Were the design inputs correctly incorporated into the design?

(e) Is the design output reasonable compared to design inputs?

(f) Are the necessary design inputs for interfacing organizations specified in the design documents or in supporting procedures or instructions?

(g) Have suitable materials, parts, processes, and inspection and testing criteria been specified?

501.2 Alternate Calculations. Alternate calculations shall use alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions; input data used; and the computer program, its associated computer hardware and system software, or other calculation method used shall also be reviewed.

501.3 Qualification Tests. Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design.

600 CHANGE CONTROL

(a) Changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based. The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities.

Changes shall be approved by the same affected groups or organizations that reviewed and approved the original design documents. When the organization originally responsible for review and approval of the orginal design documents is no longer responsible, the owner or his designee shall have responsibility or designate a new responsible organization. The design organization approving the change shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

(b) When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate.

(c) Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

601 Configuration Management of Operating Facilities

Procedures implementing configuration management requirements shall be established and documented at the earliest practical time prior to facility operation. These procedures shall include the responsibilities and authority of the organizations whose functions affect the configuration of the facility including activities such as operations, design, maintenance, construction, licensing, and procurement.

601.1 Configuration management requirements shall include measures to ensure changes that may affect the approved configuration are recognized and processed.

601.2 The configuration shall be established and approved at the earliest practical time prior to initial operation of the facility, and maintained for the life of the facility.

601.3 The configuration shall include, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, operating and maintenance requirements, and other applicable sources.

601.4 Interface controls shall include the integration of activities of organizations that can affect the approved configuration.

601.5 Documentation shall identify the design bases and the approved configuration for the approved modes of operation.

601.6 Measures shall be established and implemented to ensure that proposed changes to the configuration are evaluated for their conformance to the design bases.

601.7 The implementation sequence for approved configuration changes shall be reviewed to determine that the configuration conforms to the design bases.

601.8 Approval by the design authority shall be required prior to implementation of a change to the design bases.

601.9 The configuration of the facility shall be documented in drawings, specifications, procedures, and other documents that reflect the operational status of the facility. The process used to control the current revision and issuance of these documents shall take into account the use of the document and the need for revision in support of operation.

700 INTERFACE CONTROL

Interface controls shall include assignment of responsibility and establishment of procedures among participating design organizations for review, approval, release, distribution, and revision of documents involving design interfaces.

Design information transmitted across interfaces shall identify the status of the design information or document provided, and identify incomplete items that require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

800 SOFTWARE DESIGN CONTROL (15)

The requirements of Part II, Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications, apply to computer software design control and shall be used instead of section 200, Design Input; section 300, Design Process; section 500, Design Verification; and section 600, Change Control.

900 DOCUMENTATION AND RECORDS

Design documentation and records shall include not only final design documents, such as drawings and specifications, and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design.

REQUIREMENT 4
Procurement Document Control

100 GENERAL

Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require Suppliers to have a quality assurance program consistent with the applicable requirements of this Standard.

200 CONTENT OF THE PROCUREMENT DOCUMENTS

Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the Purchaser.

201 Scope of Work

Procurement documents shall include a statement of the scope of the work to be performed by the Supplier.

202 Technical Requirements

Technical requirements shall be specified in the procurement documents. These requirements shall be specified, as appropriate by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. The procurement documents shall identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.

203 Quality Assurance Program Requirements

Quality assurance program requirements shall be specified in the procurement documents. These requirements shall be consistent with importance and/or complexity of the item or service being procured. The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in subtier procurement documents.

204 Right of Access

The procurement documents shall provide for access to the Supplier's and subtier Supplier's facilities and records for surveillance, inspection, or audit by the Purchaser, its designated representative, and others authorized by the Purchaser.

205 Documentation Requirements

The procurement documents shall identify the documentation required to be submitted for information, review, or approval by the Purchaser. The time of submittal shall also be established. When the Purchaser requires the Supplier to maintain specific records, the retention times and disposition requirements shall be prescribed.

206 Nonconformances

The procurement documents shall specify the Purchaser's requirements for the Supplier's reporting of nonconformances.

207 Spare and Replacement Parts

The procurement documents shall specify the Supplier's requirements to identify spare and replacement parts or assemblies and the related data required for ordering these parts or assemblies.

300 PROCUREMENT DOCUMENT REVIEW

A review of the procurement documents, and changes thereto, shall be made and documented prior to award to assure that documents transmitted to prospective Supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements.

Technical or quality assurance program changes made as a result of bid evaluations or negotiations shall be incorporated into the procurement documents prior to their issuance to the Supplier.

Procurement document review shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

400 PROCUREMENT DOCUMENT CHANGES

Procurement document changes affecting the technical or quality assurance program requirements shall be subject to the same degree of control as utilized in the preparation of the original documents.

REQUIREMENT 5
Instructions, Procedures, and Drawings

100 GENERAL

Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for, and level of detail in, written procedures or instructions shall be determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).

REQUIREMENT 6
Document Control

100 GENERAL

The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to ensure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

200 DOCUMENT CONTROL

The following controls shall be applied to documents and changes thereto:

(a) the identification of controlled documents

(b) the specified distribution of controlled documents for use at the appropriate location

(c) the identification of individuals responsible for the preparation, review, approval, and distribution of controlled documents

(d) the review of controlled documents for adequacy, completeness, and approval prior to distribution

(e) a method to ensure the correct documents are being used

300 DOCUMENT CHANGES

301 Major Changes

Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval.

302 Minor Changes

Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.

REQUIREMENT 7
Control of Purchased Items and Services

100 GENERAL

The procurement of items and services shall be controlled to ensure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.

200 SUPPLIER EVALUATION AND SELECTION

Prior to award of a contract, the Purchaser shall evaluate the Supplier's capability to provide items or services in accordance with the requirements of the procurement documents. Supplier evaluation and selection and the results therefrom shall be documented and shall include one or more of the following:

(a) Supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The Supplier's history shall reflect current capability.

(b) Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.

(c) Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the Supplier's quality assurance program.

300 BID EVALUATION

If bids are solicited, the bid evaluation shall include a determination of the Supplier's capability to conform to the technical and quality assurance requirements. Prior to the award of the contract, the Purchaser shall resolve or obtain commitments to resolve unacceptable technical and quality assurance conditions resulting from the bid evaluation.

400 CONTROL OF SUPPLIER-GENERATED DOCUMENTS

Controls shall be implemented to ensure that the submittal and evaluation of Supplier-generated documents and changes are accomplished in accordance with the procurement document requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria.

500 ACCEPTANCE OF ITEM OR SERVICE

501 General

Prior to offering the item or service for acceptance, the Supplier shall verify that the item or service being furnished complies with the procurement requirements. The extent of the verification activities by the Purchaser shall be a function of the relative importance, complexity, and quantity of the item or services procured and the Supplier's quality performance. Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement requirements shall be available at the nuclear facility site prior to installation or use.

502 Methods of Acceptance

Purchaser methods used to accept an item or service from a Supplier shall be a Supplier Certificate of Conformance, source verification, receiving inspection, or postinstallation test at the nuclear facility site, or a combination of these methods.

503 Certificate of Conformance

When a Certificate of Conformance is used, the minimum criteria of paras. 503(a) through (f) of this Requirement shall be met.

(a) The certificate shall identify the purchased material or equipment, such as by the purchase order number.

(b) The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.

(c) The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.

(d) The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the Purchaser's or Supplier's quality assurance program.

(e) The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the

certificates, shall be described in the Purchaser's or Supplier's quality assurance program.

(f) Means shall be provided to verify the validity of Supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.

504 Source Verification

When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and shall include monitoring, witnessing, or observing selected activities. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon Purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the Purchaser, and to the Supplier.

505 Receiving Inspection

When receiving inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the Supplier. Receiving inspection shall verify by objective evidence such features as

(a) configuration
(b) identification
(c) dimensional, physical, and other characteristics
(d) freedom from shipping damage
(e) cleanliness

Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

506 Postinstallation Testing

When postinstallation testing is used, postinstallation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier.

507 Acceptance of Services Only

In cases involving procurement of services only, such as third-party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, the Purchaser shall accept the service by any or all of the following methods:

(a) technical verification of data produced
(b) surveillance and/or audit of the activity
(c) review of objective evidence for conformance to the procurement document requirements

600 CONTROL OF SUPPLIER NONCONFORMANCES

Methods for control and disposition of Supplier nonconformances for items and services that do not meet procurement document requirements shall include paras. 600(a) through (e) of this Requirement:

(a) evaluation of nonconforming items.

(b) submittal of nonconformance notice to Purchaser by Supplier as directed by the Purchaser. These submittals shall include Supplier-recommended disposition (e.g., use-as-is or repair) and technical justification. Nonconformances to the procurement requirements or Purchaser-approved documents, which consist of one or more of the following, shall be submitted to the Purchaser for approval of the recommended disposition:

(1) technical or material requirement is violated

(2) requirement in Supplier documents, which has been approved by the Purchaser, is violated

(3) nonconformance cannot be corrected by continuation of the original manufacturing process or by rework

(4) the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired

(c) Purchaser disposition of Supplier recommendation.

(d) verification of the implementation of the disposition.

(e) maintenance of records of Supplier-submitted nonconformances.

700 COMMERCIAL GRADE ITEMS AND SERVICES

When commercial grade items or services are utilized, the requirements of Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services, shall apply and are an acceptable alternative to sections 200 through 600 of this Requirement, except that Supplier evaluation and selection, where determined necessary by the Purchaser, shall be in accordance with section 200 of this Requirement.

800 RECORDS

Records shall be established and maintained to indicate the performance of the following functions:

(a) supplier evaluation and selection
(b) acceptance of items or services
(c) supplier nonconformances to procurement document requirements, including their evaluation and disposition

REQUIREMENT 8
Identification and Control of Items

100 GENERAL

Controls shall be established to assure that only correct and accepted items are used or installed.

Identification shall be maintained on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained.

200 IDENTIFICATION METHODS

201 Item Identification

Items of production (batch, lot, component, part) shall be identified from the initial receipt and fabrication of items up to and including installation and use. This identification shall relate an item to an applicable design or other pertinent specifying document.

202 Physical Identification

Physical identification shall be used to the maximum extent possible. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed. Identification markings shall be applied using materials and methods that provide a clear and legible identification and do not degrade the function or service life of the item. Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coating unless other means of identification are substituted.

300 SPECIFIC REQUIREMENTS

301 Identification and Traceability of Items

When codes, standards, or specifications include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), the program shall provide such identification and traceability control.

302 Limited Life Items

Items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.

303 Maintaining Identification of Stored Items

Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as

(a) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging

(b) protection of identifications on items subject to excessive deterioration due to environmental exposure

(c) provisions for updating existing plant records

REQUIREMENT 9
Control of Special Processes

100 GENERAL

Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

200 PROCESS CONTROL

201 Special Processes

Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Special process instructions shall include or reference procedure, personnel, and equipment qualification requirements. Conditions necessary for accomplishment of the process shall be included. These conditions shall include proper equipment, controlled parameters of the process, specified environment, and calibration requirements.

202 Acceptance Criteria

The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in procedures or instructions.

203 Special Requirements

For special processes not covered by existing codes and standards or where quality requirements specified exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment shall be specified or referenced in procedures or instructions.

300 RESPONSIBILITY

It is the responsibility of the organization performing the special process to adhere to the approved procedures and processes.

400 RECORDS

Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process.

REQUIREMENT 10
Inspection

100 GENERAL

Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed. Characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.

200 INSPECTION REQUIREMENTS

Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.

300 INSPECTION HOLD POINTS

If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.

400 INSPECTION PLANNING

401 Planning

Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process.

402 Sampling

Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval.

500 IN-PROCESS INSPECTION

Inspection of items under construction or otherwise in process shall be performed as necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. Process monitoring shall be performed by qualified personnel or qualified automated means. Both inspection and process monitoring shall be provided when control is inadequate without both.

600 FINAL INSPECTIONS

601 Resolution of Nonconformances

Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections.

602 Inspection Requirements

Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements.

603 Modifications, Repairs, or Replacements

Any modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

604 Acceptance

The acceptance of the item shall be approved by authorized personnel.

700 INSPECTIONS DURING OPERATIONS

Periodic inspections (e.g., in-service inspections) or surveillances of structures, systems, or components shall be planned and executed to ensure the continued performance of their required functions.

800 RECORDS

Appropriate records shall be established, maintained, and, as a minimum, identify the following:

(a) item inspected
(b) date of inspection
(c) inspector
(d) type of observation
(e) results or acceptability
(f) reference to information on action taken in connection with nonconformances

REQUIREMENT 11
Test Control

100 GENERAL

Tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated.

(15) 200 TEST REQUIREMENTS

(a) Test requirements and acceptance criteria shall be provided or approved by the responsible design organization. Required tests (other than for computer programs) including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, and operational tests shall be controlled. Computer program tests including, as appropriate, software design verification, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled. Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria. The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.

(b) Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design documents or other pertinent technical documents that provide approved requirements.

(c) If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority is required prior to performing the test.

300 TEST PROCEDURES (OTHER THAN FOR COMPUTER PROGRAMS)

(a) Test procedures shall include or reference the test configuration and test objectives. Test procedures shall also include provisions for assuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed. Prerequisites shall include the following, as applicable:

(1) calibrated instrumentation
(2) appropriate equipment
(3) trained personnel
(4) condition of test equipment and the item to be tested
(5) suitable environmental conditions
(6) provisions for data acquisition

(b) As an alternative to para. 300(a) of this Requirement, appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, may be used. Such documents shall include or be supplemented with appropriate criteria from para. 300(a) to assure adequate procedures for the test are used.

400 COMPUTER PROGRAM TEST PROCEDURES (15)

Requirements for computer program test procedures are defined in Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications.

500 TEST RESULTS

Test results shall be documented and maintained. Test results shall be evaluated by the responsible authority to ensure that test requirements have been satisfied.

600 TEST RECORDS

Test records shall be established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements. Test records vary depending on the test type, purpose, and application, but shall contain the following information, as a minimum, for the specified application identified in paras. 601 and 602.

601 Test Records

(a) item tested
(b) date of test
(c) tester or data recorder
(d) type of observation
(e) results and acceptability

(f) action taken in connection with any deviations
(g) person evaluating test results

(15) **602 Computer Program Test Records**

Requirements for computer program test records are defined in Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications.

REQUIREMENT 12
Control of Measuring and Test Equipment

100 GENERAL

Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.

200 SELECTION

Selection of measuring and test equipment shall be based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements.

300 CALIBRATION AND CONTROL

301 Calibration

Measuring and test equipment shall be calibrated, at prescribed times or intervals and whenever the accuracy of the measuring and test equipment is suspect. Calibration shall be against and traceable to certified equipment or reference standards having known valid relationships to nationally recognized standards, or to international standards known to be equivalent to and verified against corresponding nationally recognized standards. Where no such standards exist, the basis for calibration shall be defined.

302 Reference Standards

Reference standards shall have a minimum accuracy four times greater than that of the measuring and test equipment being calibrated to ensure that the reference standards contribute no more than one-fourth of the allowable calibration tolerance. Where this 4:1 ratio cannot be maintained, the basis for selection of the standard in question shall be technically justified.

303 Control

Calibration procedures shall identify or reference required accuracy and shall define methods and frequency of checking accuracy. The calibration method and interval of calibration shall be based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting performance. Measuring and test equipment, which is overdue for calibration or found to be out-of-calibration, shall be tagged and/or segregated, or removed from service, and not used until it has been recalibrated. Measuring or test equipment consistently found to be out-of-calibration shall be repaired or replaced.

303.1 Application. Measuring and test equipment shall be traceable to its application and use.

303.2 Corrective Action. When measuring and test equipment is lost, damaged, or found to be out-of-calibration, the validity of previous measurement, inspection, or test results, and the acceptability of items previously inspected or tested shall be evaluated. This evaluation shall be from at least the last acceptable calibration of the M&TE. The evaluation and resulting actions shall be commensurate with the significance of the condition.

303.3 Handling and Storage. Measuring and test equipment shall be properly handled and stored to maintain accuracy.

303.4 Environmental Controls. Measuring and test equipment shall be used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy and precision are maintained.

303.5 Precalibration Checks. Measuring and test equipment and reference standards submitted for calibration shall be checked and the results recorded before any required adjustments or repairs are made.

303.6 Status Indication. Measuring and test equipment shall be suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records.

304 Commercial Devices

Calibration and control measures are not required for commercial equipment such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy.

400 RECORDS

401 General

Records shall be established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform its intended function.

402 Reports and Certificates

Calibration reports and certificates reporting the results of calibrations shall include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements.

REQUIREMENT 13
Handling, Storage, and Shipping

100 GENERAL

Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.

200 SPECIAL REQUIREMENTS

When required, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified and provided and their existence verified.

300 PROCEDURES

When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

400 TOOLS AND EQUIPMENT

Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at specified time intervals or prior to use.

500 OPERATORS

Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment.

600 MARKING OR LABELING

Marking or labeling shall be utilized as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls.

REQUIREMENT 14
Inspection, Test, and Operating Status

100 GENERAL

The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified. Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.

REQUIREMENT 15
Control of Nonconforming Items

100 GENERAL

Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

200 IDENTIFICATION

Nonconforming items shall be identified by legible marking, tagging, or other methods not detrimental to the item, on either the item, the container, or the package containing the item.

300 SEGREGATION

(a) Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.

(b) When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.

400 DISPOSITION

401 Control

Nonconforming items shall be evaluated and recommended dispositions shall be proposed. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and an approved disposition by authorized personnel.

402 Responsibility and Authority

The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined. Responsibility for the control of further processing, delivery, installation, or use of nonconforming items shall be designated in writing.

403 Personnel

Personnel performing evaluations to determine a disposition shall have

(a) demonstrated competence in the specific area they are evaluating

(b) an adequate understanding of the requirements

(c) access to pertinent background information

404 Disposition

A disposition, such as use-as-is, reject, repair, or rework of nonconforming items shall be made and documented. Technical justification for the acceptability of a nonconforming item dispositioned repair or use-as-is shall be documented. Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. Required as-built records shall reflect the use-as-is or repair condition.

405 Reexamination

Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria.

Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.

REQUIREMENT 16
Corrective Action

100 GENERAL

Conditions adverse to quality shall be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Completion of corrective actions shall be verified.

REQUIREMENT 17
Quality Assurance Records

100 GENERAL

The control of quality assurance records shall be established consistently with the schedule for accomplishing work activities. Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements. Quality assurance records shall be identified, generated, authenticated, and maintained, and their final disposition specified. Record control requirements and responsibilities for these activities shall be documented.

200 GENERATION OF RECORDS

(a) Records shall be legible.

(b) Records shall be traceable to associated items and activities and accurately reflect the work accomplished or information required.

(c) Records to be generated, supplied, or maintained shall be specified in applicable documents, such as design specifications, procurement documents, test procedures, and operational procedures.

300 AUTHENTICATION OF RECORDS

(a) Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Corrections to documents shall be reviewed and approved by the responsible individual from the originating or authorized organization.

(b) Electronic documents shall be authenticated with comparable information as in para. 300(a), as appropriate

(1) with identification on the media or

(2) with authentication information contained within or linked to the document itself.

400 CLASSIFICATION

Records shall be classified as *lifetime* or *nonpermanent* and maintained by the Owner, or authorized agent, in accordance with the criteria given in paras. 401 and 402 of this Requirement and consistent with applicable regulatory requirements.

401 Lifetime Records

401.1 Lifetime records are those that meet one or more of the following criteria:

(a) those that would be of significant value in demonstrating capability for safe operation

(b) those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item

(c) those that would be of significant value in determining the cause of an accident or malfunction of an item

(d) those that provide required baseline data for in-service inspections

401.2 Lifetime records are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use.

402 Nonpermanent Records

Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. Nonpermanent records shall be maintained for the identified retention period.

500 RECEIPT CONTROL OF RECORDS

Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing receipt controls for permanent and temporary storage. Receipt controls shall provide a method for identifying the records received, receipt and inspection of incoming records, and submittal of records to storage.

600 STORAGE

601 General (15)

(a) Records shall be stored at a predetermined location(s) in facilities, containers, or a combination thereof, constructed and maintained in a manner that minimizes the risk of loss, damage, or destruction from

(1) natural disasters such as winds, floods, or fires

(2) environmental conditions such as high and low temperatures and humidity

(3) infestation of insects, mold, or rodents

(4) dust or airborne particles

(b) Activities detrimental to the records shall be prohibited in the storage area.

(c) Access to the processing, storage, and retrieval of records shall be limited to authorized personnel.

(d) Provisions shall be made to prevent damage from harmful conditions (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media utilized for record storage.

602 Facility Types

There are two equally satisfactory methods of providing storage, single or dual.

602.1 Single storage consists of a storage facility, vault, room, or container(s) with a minimum two-hour fire rating. The design and construction of a single storage facility, vault room, or container shall be reviewed for adequacy by a person competent in fire protection or contain a certification or rating from an accredited organization.

602.2 Dual facilities, containers, or a combination thereof shall be at locations sufficiently remote from each other to eliminate the chance exposure to a simultaneous hazard. Facilities used for dual storage are not required to satisfy the requirements of para. 602.1, but shall meet the requirements of para. 601.

603 Temporary Storage

When temporary storage of records (such as for processing, review, or use) is required, the storage facility or container shall provide a one-hour fire rating, unless dual storage requirements of para. 602.2 are met.

700 RETENTION

(a) Record retention periods shall be documented.

(b) Records shall be maintained for their retention periods.

800 MAINTENANCE OF RECORDS

(a) Records shall be protected from damage or loss.

(b) Record controls shall provide for retrievability within planned retrieval times based upon the record type or content.

(c) The methods for record changes shall be documented.

(d) Provisions shall be established to ensure that no unacceptable degradation of the electronic record media occurs during the established retention period.

(e) Provisions shall be made to ensure that the records remain retrievable after hardware, software, or technology changes.

(f) Provisions shall be established to ensure the following when records are duplicated or transferred to the same media or to a different media for the purposes of maintenance or storage:

(1) duplication or transfer is appropriately authorized

(2) record content, legibility, and retrievability are maintained

REQUIREMENT 18
Audits

100 GENERAL

Audits shall be performed to verify compliance to quality assurance program requirements, to verify that performance criteria are met, and to determine the effectiveness of the program. These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.

(15) 200 SCHEDULING

Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

A grace period of 90 days may be applied to scheduled audits and annual evaluations of supplier performance. When the grace period is used, the next scheduled date for the activity shall be based on the activity schedule date and not on the date the activity was actually performed. If the activity is performed early, the next schedule date shall be based on the date the activity was actually performed.

201 Internal Audits

Except where specific regulatory guidance exists or Code restrictions apply, organizations shall audit internal activities at the following intervals.

201.1 Nuclear Facilities Prior to Placing the Facility Into Operation. All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter.

201.2 Nuclear Facilities After Placing the Facility Into Operation. All applicable quality assurance program elements for each functional area[1] shall be audited within a period of 2 yr. For well-established activities, the period may be extended 1 yr at a time beyond the 2-yr interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. However, the internal audit interval shall not exceed a maximum of 4 yr.

201.3 Suppliers and Other Nuclear Support Organizations. All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter. This interval may be extended up to 2 yr based on the results of an annual evaluation and objective evidence that the activities are being satisfactorily accomplished in accordance with the applicable quality assurance program elements.

202 External Audits

External audits (e.g., Supplier audits) shall be performed on a triennial basis and supplemented by annual evaluations of the Supplier's performance to determine if the regular schedule audit frequency shall be maintained or decreased or if other corrective action is required. A continuous or ongoing evaluation of the Supplier's performance may be conducted in lieu of the annual evaluations, provided that the results are reviewed in order to determine if corrective action is required.

300 PREPARATION

301 Audit Plan

The auditing organization shall develop an audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

302 Personnel

Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

303 Selection of Audit Team

An audit team shall be identified prior to the beginning of each audit. This team shall contain one or more Auditors, one being designated Lead Auditor who organizes and directs the audit. The audit team shall have experience or training commensurate with the scope,

[1] "Functional area" denotes activities such as engineering, construction, procurement, operations, maintenance, radiological protection, chemistry, security, etc.

complexity, or special nature of the activities to be audited.

400 PERFORMANCE

Elements selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

500 REPORTING

The audit report shall be signed or otherwise endorsed by the Lead Auditor and issued to the audited organization. The contents of the report shall

(a) describe the audit scope

(b) identify Auditors and persons contacted

(c) summarize audit results, including a statement on the effectiveness of the elements audited

(d) describe each audit finding

600 RESPONSE

Management of the audited organization or activity shall investigate audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of action taken or planned. Audit responses shall be evaluated by or for the auditing organization.

700 FOLLOW-UP ACTION

Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.

800 RECORDS

Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.

(15)

PART II: QUALITY ASSURANCE REQUIREMENTS FOR NUCLEAR FACILITY APPLICATIONS

CONTENTS

PART II
INTRODUCTION

(15) 100 PURPOSE

Part I establishes requirements for the development and implementation of a Quality Assurance Program (QAP) for nuclear facility applications. It is arranged by Requirements 1 through 18.

Part II — this Part — contains additional quality assurance requirements for the planning and conduct of specific work activities under a Quality Assurance Program developed in accordance with Part I. It is arranged by Subparts.

Part III contains guidance for implementing the requirements of Parts I and II. It is arranged by Subparts.

Part IV contains guidance for application of NQA-1 and comparisons of NQA-1 with other quality requirements. It is arranged by Subparts.

(15) 200 APPLICABILITY

When invoked by an organization, regulation, contract, or other specifying document, the applicable Subparts of Part II are to be applied using a graded approach to any structure, system, component, activity, or organization that is essential to the safe, reliable, and efficient performance of a nuclear facility and any activities independent of a facility that may affect performance (e.g., transportation of nuclear materials) of those activities. It is also to be applied to all phases of a nuclear facility life cycle (e.g., siting, design, construction, operation, and decommissioning) and related activities (e.g., training, testing, software development or use). The Quality Assurance Program developed in accordance with Part I is to be applied to the implementation of Part II requirements.

(15) 300 RESPONSIBILITY

The organization invoking this Part shall be responsible for specifying all applicable requirements and appropriately relating them to specific items, activities, and services. Implementation of applicable Parts I and II requirements is necessary for the Quality Assurance Program to be in compliance with this Standard.

The organization implementing this Part shall be responsible for complying with the specific requirements for the specific work activity described in the applicable Subpart(s) in order to achieve quality results.

400 PLANNING AND PROCEDURES

401 Planning

A plan shall be developed outlining the work to be performed and the work procedures or instructions required to comply with the requirements of the defined work scope.

Planning for activities such as fabrication, installation, operation, modification, repair, maintenance, decommissioning, inspection, testing, and software verification and validation shall include a review of structure, system or component design and procurement specifications, materials lists, drawings, construction work plans, and schedules to ensure that appropriate activities have been incorporated; that the work can be accomplished as specified; and that time and resources, plus training, are sufficient to accomplish the work in accordance with the specified requirements.

Planning shall define the operations to be performed, the systematic sequential progression of operations, and the overall measures to be used to preserve the quality of the work.

402 Procedures

Procedures and work instructions identified during planning shall be prepared. Preparation and approval of the procedures/instructions shall be in advance of the need to use the documents. The documents shall be kept current and revised as necessary to assure that the work is performed in accordance with the latest approved information.

The documents shall include the following as applicable:

(a) personnel safety and structure or facility protection considerations

(b) precautions to be observed

(c) work requirements such as those included in specifications, procedures, and instructions for performing an activity

(d) sequence of activities to be followed and steps within a given activity

(e) prerequisites

(f) software verification and validation

(g) test and inspection objectives

(h) special equipment required

(i) identification of inspection and test equipment and related calibration requirements including recalibration dates

(j) sequence and frequency of activities for verification

(k) acceptance criteria and methods for verification

(l) responsibility and required qualifications of personnel

(m) approvals and authorizing or verifying signatures

(n) specific document references

(o) data or test report forms

(p) information to be collected for facility records

(q) processing inspection and test data and their analysis, evaluation, and final acceptance, including software verification and validation

500 DEFINITIONS

Definitions unique to the activities described in Part II are included in the section dealing with that activity. Definitions generic to quality assurance activities are included in Part I, Introduction, section 400, Terms and Definitions.

600 MULTIUNIT FACILITY PROVISIONS

For construction, outage, or decommissioning activities in nuclear facilities where one or more units are already operating or has reached a stage where the fuel has been loaded in the facility and associated systems energized, the following measures shall be taken in addition to the provisions defined elsewhere in this Part.

601 Planning and Preparation

Instructions, procedures, or drawings shall be prepared to control installation, maintenance, modification, decommissioning, inspection, and testing activities at areas of interface between units. These instructions, procedures, or drawings shall define the following, as applicable:

(a) the areas of interface between units

(b) access control and authority for work at these interface areas

(c) nature of potential hazards to or from the operating equipment; precautions required to be taken during installation, maintenance, modification, or decommissioning; supplementary objectives for inspection and testing

602 Documentation

602.1 The instructions, procedures, or drawings described in para. 601 of this Introduction shall be kept current.

602.2 The equipment or systems that are associated with the operating unit(s) that are electrically energized or charged with pressurized or radioactive fluids and that are in the vicinity of the construction, outage, or decommissioning activity associated with the new or nonoperating unit shall be properly tagged or identified as energized or operational.

602.3 The documents associated with activities described in para. 602.2 of this Introduction shall also include

(a) identification of the equipment or system defined in para. 602.2 above that poses a potential hazard in the vicinity of current construction, outage, or decommissioning activities

(b) identification of the potential hazard of neighboring energized systems such as voltage, radiation level, fluid pressure, or temperatures

602.4 Authorizations for access to and work at the area of interface between the new and existing units shall be documented.

603 Installation

603.1 Suitable protective barriers shall be erected, where needed, to prevent damage to equipment or systems associated with the existing unit(s).

603.2 When working in an area common to the new and existing units, care shall be exercised to avoid interference with existing facilities, to maintain required separation (where appropriate) between the systems associated with existing and new units, and to prevent disturbing the operation of equipment or systems associated with the existing unit(s); construction workers shall be instructed with regard to the hazards present.

604 Inspection

604.1 Inspection shall be performed to verify that the requirements have been satisfied and that the existing facilities are properly protected from construction activities.

SUBPART 2.1
Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Facilities

(15)

(15) 100 GENERAL

Subpart 2.1 provides amplified requirements for the management of cleaning and cleanness control of fluid systems and associated components for nuclear facilities during manufacturing, construction, repairs, and modifications. It supplements the requirements of Part I and shall be used in conjunction with applicable sections of Part I when and to the extent specified by the organization invoking Subpart 2.1. The sensitivity to contaminants of the systems/components involved should be considered when specifying cleanness requirements or invoking this Subpart.

(15) 101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in Subpart 2.1.

acid cleaning: the removal of metal oxides by either dissolution of the oxide or undercutting the oxide by dissolution of the base metal with an acid solution.

alkaline cleaning: the removal of organic contaminants by converting them to an emulsion with an alkaline solution such as trisodium phosphate.

chelate cleaning: the removal of slightly soluble compounds such as iron oxide, by complexing the metallic ions with organic chelating compounds such as ethylene diamine tetra-acetic acid (EDTA).

chemical conditioning: the addition of chemicals in low concentration to flush, rinse, or lay up water to inhibit precipitation of dissolved solids, corrosion, and other detrimental effects.

cleaning: the removal of any contaminants that might have a deleterious effect on operation of the facility.

contamination: any unwanted or undesirable foreign material on the surface of an item, in the atmosphere, or in process liquids or gases.

corrosion-resistant alloys: materials that inherently resist oxidation or chemical attack in water, air, and the operating environment, such as stainless steel, nickel-base alloys, or cobalt-base alloys.

crevice: a narrow opening in a surface or an open juncture between mating surfaces in which solutions or contaminants can be trapped and not readily removed during rinsing or flushing operations (for example, the annular spaces in threaded connections and socket assemblies, tube-to-tubesheet joints, and tube-to-tube support joints).

dead leg: an area that does not have flow during the cleaning operation or that cannot be drained without special provisions.

fluid: any gas or liquid.

flushing: flowing fluid through a component or system at adequate velocity to suspend and carry away anticipated contaminants.

inaccessible area: an area or opening in an item that is not directly accessible for cleaning or inspection.

inhibitor: a chemical additive that retards some specific chemical reaction.

layup: the protection of an item after it has been cleaned to prevent corrosion of interior surfaces while the item is out of service or awaiting subsequent operations.

mechanical cleaning: a method in which contaminant removal is accomplished solely by mechanical means, including wiping, abrasive blasting, high pressure water jetting, brushing, sanding, grinding, and chipping.

pitting: surface defects resulting from localized corrosion.

rinsing:

(a) filling and draining an item with water until soluble contaminants in the effluent water are reduced to some predetermined concentration; or

(b) flowing water through the system or component until water-soluble contaminants in the effluent water are reduced to some predetermined concentration.

rust: corrosion products consisting largely of iron oxide. Such oxides may vary in color from red to black and may form anything from a loosely adherent heavy covering to a tightly adherent light film. Pitting or general surface roughening may or may not be present.

sensitized corrosion-resistant alloy: a corrosion-resistant alloy that has been subjected to heating that causes intergranular precipitation of chromium carbides in sufficient quantities to be detected by Practice B, C, E, or F of ASTM A262-13, Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels.

solvent cleaning: removing contaminants with an organic solvent.

200 GENERAL REQUIREMENTS

The work and quality assurance requirements for the cleaning of components and systems and for the control of their cleanness shall be established in order to

(a) ensure the removal of deleterious contaminants

(b) minimize recontamination of cleaned surfaces

(c) minimize the cleaning required after installation, repair, or modification

The cleanness classification of each item shall be specified in accordance with para. 302 of this Subpart.

201 Planning

Cleaning and cleanness control activities for each phase (manufacturing, construction, modification, repair, etc.) shall be planned in accordance with the requirements of the Introduction to this Part (Part II). The plan(s) shall define the cleaning and inspection operations to be used, the system, the responsibilities of the parties concerned for each operation, and the measures to be employed to preserve the cleanness of cleaned surfaces. In addition, planning shall consider the following factors, as appropriate, recognizing that this list may neither be complete nor applicable to each phase covered by Part II:

(a) adequacy of vents, drains, inspection access points, and bypass or recirculation lines

(b) facilities for filters and flushing and drain connections in locations where dead legs are unavoidable

(c) design and installation of piping in a manner that minimizes the necessity for installing temporary piping during the cleaning operations, such as dividing the system into a number of separate cleaning circuits to facilitate cleanability

(d) sequencing of installation operations to provide for visual inspection of inside surfaces of large diameter piping

(e) control of installation operations so that piping and components that have already been installed are not subject to contamination when subsequent installation operations are performed

(f) adequacy of pumping and heating capacities when these are important factors in the cleaning operations

(g) disposal of cleaning solutions and waste water

(h) safety, fire protection, and other hazards

202 Procedures and Instructions

202.1 Written procedures and instructions for cleaning, cleanness control, inspections, and tests to verify cleanness of items shall be prepared in accordance with the requirements of the Introduction to this Part.

202.2 Preparation of the actual cleaning procedures or instructions shall consider the following:

(a) work practices, housekeeping, access control, and prevention of contamination and recontamination

(b) effectiveness of cleaning methods for removal of the contaminants

(c) effects of residual quantities of cutting fluids, liquid penetrants, weld fluxes, precleaning solutions, engineering test fluids, and other process compounds that may have been intentionally or advertently applied to the surface of the item during prior steps of manufacture, installation, or use

(d) corrosiveness of cleaning solutions in contact with the material of an item, particularly in the case of dissimilar metals and entrapment of cleaning solutions

(e) chemical composition, concentration, and temperature limits of cleaning solutions to avoid deleterious effects

(f) solution and metal temperatures, solution concentrations, velocity, and contact times during cleaning

(g) methods for monitoring cleaning solution concentration, temperatures, and velocities during cleaning operations

(h) identification of the items for which the procedures are to be used

(i) sequence of operations and methods of filling system circulation, draining, and flushing

(j) see below:

(1) equipment isolation

(2) location of

(-a) temporary piping and valves

(-b) strainers

(-c) temporary equipment

(-d) connections for filling, flushing, rinsing, and draining equipment

(k) activities to be prohibited or constrained before, during, and after cleaning operations

(l) methods for rinsing and neutralizing, including estimated number of rinses

(m) methods for verifying cleanness

(n) methods for drying and layup

(o) methods for protecting installed items that are not involved in the cleaning operation

(p) method of disposal of cleaning solution

203 Rectification of Unacceptable Cleanness

If indications of contamination in excess of specified limits are observed at the end of a cleaning operation or at any subsequent inspections for cleanness, the item shall be recleaned using an approved procedure. If such indications are observed at the anticipated end of a cleaning operation, continued cleaning shall be performed to reduce the level to the specified limit.

If necessary, an evaluation shall be made to determine the cause of the unacceptable cleanness and the actions required to preclude recurrence.

204 Control of Cleaning Solutions

Cleaning solutions shall be prepared in accordance with the applicable cleaning procedure and shall be checked for proper chemical composition and effectiveness of inhibitors, if used. Solution temperatures shall be maintained and controlled to ensure adequate cleaning and to prevent cleaning agent decomposition and possible damage to the item.

300 CLEANNESS CRITERIA

301 Cleanness Classification

The level of cleanness required for any particular application is a function of the particular item under consideration. The assignment of a cleanness classification shall consider the following:

(a) the function of the item to be cleaned

(b) the susceptibility of its materials of construction to various forms of corrosion, including intergranular cracking, or stress corrosion cracking under fabrication, installation, or operating conditions

(c) the consequences of malfunction or failure of the item

(d) the possibility of contaminants (introduced during fabrication, storage, installation, repairs, or service) contributing to or causing such malfunction or failure

Four classes of surface cleanness (Classes A, B, C, and D) with criteria for each are provided in this Subpart. The cleanness class or classes applicable to the item or specific parts of the item shall be established and specified in the applicable drawings, specifications, or other appropriate documents. Different cleanness classes may be assigned to internal and external surfaces, or to different parts of the same item based on the cleanness needs of the specific item. Guidelines for assigning cleanness classifications are listed in Part III, Subpart 3.2-2.1.

302 Cleanness Class Criteria

(15) **302.1 Class A.** A very high level of cleanness as evidenced by the freedom from all types of surface contamination, according to the acceptance criteria of the inspection methods specified in the procedures required by para. 202.1 of this Subpart. If close control of particulate contamination is required, a clean room, in accordance with para. 8.5.5 of ASTM A380/A380M-13, Practice for Cleaning and Descaling Stainless Steel Parts, Equipment, and Systems, shall be employed during the manufacturing, assembly, and installation operations when particulate contamination could occur. Gross and precision inspection methods applicable to Class A are described in paras. 7.2 and 7.3 of ASTM A380/A380M-13; other special tests shall be specified as necessary. Where the cleanness of internal surfaces is evaluated by flushing, criteria shall be specified in the cleaning procedure.

(15) **302.2 Class B.** A high level of cleanness as evidenced by the following characteristics:

(a) Corrosion-Resistant Alloys

(1) The surface shall appear metal clean and free of organic films and contaminants when examined in accordance with para. 7.2.1 of ASTM A380/A380M-13, Practice for Cleaning and Descaling Stainless Steel Parts, Equipment, and Systems, except light deposits of atmospheric dust are permissible and shall show no evidence of deleterious contamination when subjected to the wipe test of para. 7.2.2 of ASTM A380/A380M-13. When visual inspection is impossible but surfaces are accessible for wipe tests, sufficient wipe tests in different areas of the item shall be made to evaluate the general cleanness level of the surface. Scattered areas of rust are permissible, provided the aggregate area does not exceed 2 $in.^2$ in any 1 ft^2 area (14 cm^2 per 1 000 cm^2). Temper films and discolorations resulting from welding are acceptable.

(2) If flushing is the only practical means for evaluating the cleanness of internal surfaces, a 20-mesh (850 μm, ASTM E11-09, Standard Specification for Woven Wire Test Sieve Cloths and Test Sieves) or finer filter (or the equivalent) shall be installed and the item flushed with water or other fluid meeting the requirements of para. 304 of this Subpart. The item shall be flushed at the design velocity (or other flow velocity if specified in the procedure) until the screen shows no more than slight speckling (as specified in the procedure in qualitative or quantitative terms, such as the number of particles per unit surface of the screen) and no more than slight rust staining. There shall be no particles larger than $\frac{1}{32}$ in. × $\frac{1}{16}$ in. long (0.8 mm × 1.6 mm). In water-flushed systems there shall be no visual evidence of contamination (e.g., oil, discoloration) of the effluent flush water or screen.

(b) Carbon and Low-Alloy Steels

(1) The surface shall appear metal clean when examined in accordance with para. 7.2.1 of ASTM A380/A380M-13, except light deposits of atmospheric dust are permissible, and shall show no deleterious contamination when subjected to the wipe test of para. 7.2.2 of ASTM A380/A380M-13. Wipe tests shall be made prior to the application of any preservative film (some type of protective film may be required in order to maintain a clean carbon or low-alloy steel surface at Class B level). When visual inspection is impossible, but surfaces are accessible for a wipe test, sufficient wipes of different areas of the item shall be made to evaluate the general cleanness of the surface. Scattered areas of rust are permissible, provided the aggregate area does not exceed 2 $in.^2$ in any 1 ft^2 area (14 cm^2 per 1 000 cm^2).

(2) If flushing is the only practical means for evaluating the cleanness of internal surfaces, a 20-mesh (850 μm, ASTM E11-09, Standard Specification for Woven Wire Test Sieve Cloths and Test Sieves) or finer

filter (or the equivalent) shall be installed and the item flushed with water or other fluid meeting the requirements of para. 304 of this Subpart. The item shall be flushed at the design velocity (or other flow velocity if specified in the procedure) until the screen shows no more than slight speckling (as specified in the procedure in qualitative or quantitative terms, such as the number of particles per unit area of the screen) and no more than slight rust staining. There shall be no particles larger than $\frac{1}{32}$ in. × $\frac{1}{16}$ in. long (0.8 mm × 1.6 mm). In water-flushed systems there shall be no visual evidence of contamination (e.g., oil, discoloration) of the effluent flush water or screen.

NOTE: Class B cleanness should be specified for carbon steel and low-alloy steel surfaces only in special cases because of the difficulty in maintaining such surfaces in that condition after they have been cleaned.

302.3 Class C. An intermediate level of cleanness in which the surfaces meet the requirements for Class B, except:

(a) Corrosion-Resistant Alloys. Scattered areas of rust are permissible, provided the aggregate area does not exceed 15 in.^{2} per 1 ft^2 area (100 cm^2 per 1 000 cm^2).

(b) Carbon and Low-Alloy Steels. A uniform light rust bloom that can be removed by brushing or wiping is acceptable.

(c) Corrosion-Resistant Alloys and Carbon and Low-Alloy Steels. Screens installed for evaluation of internal surfaces by flushing may exhibit considerable particle speckling (as specified in the procedures in qualitative or quantitative terms, such as the number of particles per unit area of the screen) and considerable rust staining.

(15) **302.4 Class D.** A nominal level of cleanness in which the following are acceptable:

(a) rust films on both corrosion-resistant alloys and carbon and low-alloy steel surfaces

(b) tightly adherent mill scale on nonmachined carbon and low-alloy steel surfaces that resist removal by hand scrubbing with a stiff wire brush

(c) paint or preservative coatings on carbon or low alloy steel surfaces that will not peel or flake when subjected to cold water flushing

(d) particles no larger than $\frac{1}{16}$ in. × $\frac{1}{8}$ in. long (1.6 mm × 3.2 mm) on a 14-mesh (1.4 mm, ASTM E11-09) or finer filter (or the equivalent)

302.5 Summary. The cleanness classes are summarized in Table 302.5 of this Subpart.

303 Hydraulic, Instrument Control, and Lubrication Lines and Systems

The preceding cleanness classifications and criteria in para. 302 of Subpart 2.1 are primarily applicable to relatively large items that are generally amenable to visual inspection of internal surfaces at some time during manufacture and installation operations. Interior surfaces of hydraulic, instrument control, and lubrication systems are generally not accessible for visual inspection during manufacture and installation, and may have much more stringent requirements on particulate contamination than those specified in the preceding cleanness classes. Where special characteristics and specific requirements are needed for such systems, they shall be specified. Guidelines for classifying hydraulic, instrument, and lubrication cleanness are presented in Part III, Subpart 3.2-2.1.

304 Cleaning and Flushing Fluid Quality Requirements

304.1 Water. The water quality for mixing cleaning solutions, rinsing, and flushing shall be specified by the organization responsible for cleaning unless otherwise stipulated in procurement documents or approved procedures. Table 304.1 of this Subpart lists water quality requirements commonly used for such purposes in nuclear cleaning operations. The water quality for final flushes of fluid systems and associated components shall be at least equivalent to the quality of the operating system water. To minimize the possible adverse effects of halogens, the chemical requirements for water including the use of halogen stress-cracking inhibitors used on components or systems containing austenitic stainless steel or corrosion-resistant alloy shall be as determined by technical evaluation.

304.2 Gaseous Fluids. The requirements for gaseous fluids used for flushing are dependent upon the particular item being flushed. The requirements for any given item shall incorporate restrictions on particulate contaminants, organic contaminants, water-soluble contaminants, and water content as appropriate for the item.

304.3 Organic Fluids. Requirements for organic fluids used for flushing are dependent upon the particular item being flushed. The requirements for any given item shall incorporate restrictions on particulate contaminants, water-soluble contaminants, and water content as appropriate for the item.

304.4 Fluids for Hydraulic, Instrument Control, and Lubrication Systems. In addition to the requirements of para. 304.1, 304.2, or 304.3 of this Subpart, as applicable for the system being flushed, fluids used for final flushing or rinsing of components and installed systems covered by this paragraph shall meet the particulate contamination limits specified in Table 304.4 of this Subpart for the system class specified.

304.5 If acid cleaning is used, particular attention shall be given to

(a) avoidance of entrapment of acids in crevices

(b) effects on either welded or sensitized corrosion-resistant alloys and nonferrous materials

(c) complete removal of any residual acid solution from the item

Table 302.5 Summary Table for Cleanness Classes

Class	Surface Appearance	Rust	Paints or Preservatives	Mill Scale	Flushing Criteria
Class A					
Corrosion-resistant alloys	Metal clean	Note (1)	Note (1)	Note (1)	Specified in cleaning procedure
Carbon and low-alloy steels [Note (2)]	Metal clean	Note (1)	No paints; preservative if specified	Note (1)	Specified in cleaning procedure
Class B					
Corrosion-resistant alloys	Metal clean, but with temper films	2 $in.^2/1\ ft^2$ (Scattered) (14 $cm^2/1\ 000\ cm^2$)	Note (1)	Note (1)	No particles larger than $\frac{1}{32}$ in. × $\frac{1}{16}$ in. (0.8 mm × 1.6 mm)
Carbon and low-alloy steels [Note (2)]	Metal clean, but with temper films	2 $in.^2/1\ ft^2$ (Scattered) (14 $cm^2/1\ 000\ cm^2$)	No paints; preservative if specified	Note (1)	No particles larger than $\frac{1}{32}$ in. × $\frac{1}{16}$ in. (0.8 mm × 1.6 mm)
Class C					
Corrosion-resistant alloys	Metal clean, but with temper films	15 $in.^2/1\ ft^2$ (Scattered) (100 $cm^2/1\ 000\ cm^2$)	Note (1)	Note (1)	No particles larger than $\frac{1}{32}$ in. × $\frac{1}{16}$ in. (0.8 mm × 1.6 mm)
Carbon and low-alloy steels	No visible particles	Uniform soft film	No paints; preservative if specified	Note (1)	No particles larger than $\frac{1}{32}$ in. × $\frac{1}{16}$ in. (0.8 mm × 1.6 mm)
Class D					
Corrosion-resistant alloys	Note (1) (unless specified by purchaser)	Note (1)	Note (1)	Note (1)	No particles larger than $\frac{1}{16}$ in. × $\frac{1}{8}$ in. (1.6 mm × 3.2 mm)
Carbon and low-alloy steels	Note (1) (unless specified by purchaser)	Note (1)	Acceptable	Acceptable if adherent	No particles larger than $\frac{1}{16}$ in. × $\frac{1}{8}$ in. (1.6 mm × 3.2 mm)

NOTES:
(1) No requirement.
(2) While Classes A and B cleanness levels can be achieved on carbon and low-alloy steel surfaces, maintenance of these levels is very difficult. Assignment of Classes A and B levels to such surfaces should be made with discretion.

Table 304.1 Water Requirements

Fresh Water [Note (1)] — Minimum Requirements	
pH at 25°C (77°F)	6.5 to 8.5
Chloride	Less than 250 ppm
Fluoride	Less than 2 ppm
Sulfate	Less than 250 ppm
Total dissolved solids	Less than 500 ppm
High-Quality Water — Minimum Requirements at Point of Entry Into Item	
pH at 25°C (77°F)	5.5 to 8.0
Chloride	Less than 1 ppm
Fluoride	Less than 1 ppm
Sulfide	Less than 1 ppm
Conductivity at 25°C (77°F)	Less than 3 μmho/cm
Silica	Less than 0.05 ppm
Total suspended solids	Less than 3 ppm

NOTE:
(1) Fresh water that meets U.S. Environmental Protection Agency, 40 CFR 143.3, Secondary Maximum Containment Levels (for Public Water Systems), may be utilized for any application where fresh water is specified.

Table 304.4 Flushing Requirements for Hydraulic, Instrument Control, and Lubrication Systems

System Class	Generic Description	Maximum Number of Particles Per 100 cc Particle Size				
		5–10 μm	10–25 μm	25–50 μm	50–100 μm	100 μm
0	Super clean	2 700	670	93	16	1
1	MIL-H-5606B	4 600	1 340	210	28	3
2	High reliability	9 700	2 680	380	56	5
3	Critical	24 000	5 360	780	110	11
4	Less critical	32 000	10 700	1 510	225	21
5	Moderate reliability	97 000	21 400	3 130	430	41
6	Industrial	128 000	24 000	6 500	1 000	92

GENERAL NOTES:
(a) Adapted from ASTM STP 491, Maintenance of Cleanliness of Hydraulic Fluids and Systems. Classes 2 and 5 of the table in STP 491 are described as Good Missile and Poor Missile, respectively. While these criteria are based on a specified volume of liquid (100 cc), they can also be applied to gaseous flushes. When used in this manner, the cleaning procedure shall specify the flushing velocity and time upon which the evaluation shall be based.
(b) The above system Class designations do not directly correspond to the cleanness class criteria classes of Subpart 2.1.

(d) neutralizing treatment followed by thorough rinsing or flushing

304.6 The use of contaminated tools shall be avoided. Tools that contain, or that may become contaminated with, materials that could contribute to stress-corrosion or intergranular cracking shall not be used on corrosion-resistant alloys.

(15) 400 MANUFACTURING PHASE CLEANNESS

The cleanness of an item at the point of manufacture is critical to the final cleanness level ultimately attained after installation. Where practicable, the cleanness classification of an item listed in the purchase specification shall be the same as that for final service. The capability of construction site cleaning operations may not be sufficient to upgrade the cleanness level of a complex item since a much wider variety of cleaning facilities and procedures are generally available for use at the manufacturer's shops than at the construction sites.

Purchase specifications shall specify the required as-shipped cleanness level for the item. Shop cleaning procedures shall be in accordance with para. 202 of this Subpart, and inspection and test results shall be documented, as appropriate, in accordance with approved procedures.

Listed below are cleaning considerations that are appropriate to all manufacturing operations. Additional

information is presented in ASTM A380/A380M-13; where applicable, it shall be considered.

(a) Operations that generate chemical or particulate contaminant, such as welding and grinding, shall be controlled during fabrication steps, after which removal of such contaminants becomes difficult because of limited access. Under such conditions, protection of openings shall be provided to prevent entry of contaminants, especially particulate contaminants. If practical, manufacturing sequence shall be based on considerations related to cleaning of individual items as the component is assembled, unless the component is readily cleanable in its final assembled state.

(b) Cleaning methods and materials used during manufacture shall be compatible with the materials of construction of the item being cleaned (see para. 202.2 of this Subpart). Cutting fluids, lubricants, liquid penetrants, marking materials, precleaning solutions, engineering test fluids, tools, and other materials and process compounds to be used on surfaces of items made from austenitic stainless steel or corrosion-resistant alloy during manufacture shall be evaluated from the standpoint of potentially harmful contaminants. Such contaminants include chlorides, fluorides, and low melting point materials such as sulfur, lead, zinc, copper, and mercury. Where potentially harmful quantities of such contaminants can be leached or are in a form in which they could be released by breakdown of the compound during subsequent manufacturing, installation, or operation, they shall not be used. Paint, chalk, scribing inks, and other temporary marking materials shall be removed from the affected surfaces prior to heat treatment or welding.

(c) Use of tools (such as those used for grinding, polishing, filing, deburring, and brushing) during manufacture shall be controlled when surface contamination of the item from such tools is considered an important factor.

(d) The quality of fluid used for final flushing or rinsing shall meet or exceed the requirements of para. 304.1 of this Subpart. Particular attention shall be paid to flushing of pockets, crevices, or dead legs to ensure that cleaning solutions are not trapped in such areas.

(e) Fresh water may be used for mixing oil cleaning solutions and for initial rinsing and flushing when permitted by approved procedures.

(f) The final cleaned item shall be sealed in a dried condition to prevent subsequent recontamination and then packaged in accordance with the requirements established in the procurement documents.

500 CLEANNESS PRIOR TO INSTALLATION

From a cleanness standpoint, consideration shall be given as to whether items should be delivered to the point of installation sooner than necessary, i.e., whether the installation location is a better storage area (see Subpart 2.2 of Part II). Inspections and tests, as appropriate, shall be made immediately prior to installation to determine the cleanness of the item. If potentially harmful contaminants are detected, they shall be removed if they will not be removed in subsequent cleaning operations. Items having surfaces to which temporary paint or preservative coatings have been applied shall be identified. The composition of the coating and methods for its removal shall be determined and removal of coatings, when required, recorded in the inspection report. Unless otherwise required by the job specifications, the temporary coatings shall be removed prior to installation of items.

600 CLEANNESS DURING INSTALLATION (15)

The installation process represents an opportunity for the introduction of contaminants into a cleaned item, and care shall be taken to minimize contamination. Operations that generate particulate matter, such as grinding and welding, shall be controlled. Cleanup of locally contaminated areas as installation progresses is recommended (rather than one cleanup operation when installation is completed). Consideration shall be given to sequencing of installation and erection operations to facilitate cleaning, cleanness control, and inspection. Insofar as practicable, internal surfaces of a portion of a system that can be blocked or obscured by subsequent operations shall be visually inspected and verified as being clean before the access points are closed. Openings and pipe ends shall be sealed at all times except when they must be unsealed to carry out necessary operations.

Precautions shall be taken to avoid contamination of crevices, blind holes, dead legs, undrainable cavities, and inaccessible areas. When grinding, sanding, chipping, or wire brushing, the item shall be so oriented that chips fall away from the openings, or covers shall be provided for the openings.

The use of cleaning methods and materials, cutting fluids, lubricants, liquid penetrants, marking materials, precleaning solutions, engineering test fluids, tools, and other materials and process compounds used during installation of items made from austenitic stainless steel or other corrosion-resistant alloys shall be subject to the limitations on such methods and materials specified in section 400 of this Subpart.

Surfaces shall be visually inspected upon completion of work on them, and obvious contamination removed before proceeding to the next installation or construction step. The use of mineral acids and organic acids to clean austenitic stainless steel and nickel alloys shall be evaluated and approved prior to use. Precleaning and postcleaning of weld joint areas and welds shall be performed by wire brushing and scrubbing with a solvent-moistened clean cloth unless otherwise specified.

Large openings shall be protected against falling and windblown contaminants.

700 MAINTENANCE OF INSTALLATION CLEANNESS

After any isolable item has been installed in a clean condition, cleanness control measures and access control shall be established to minimize the introduction of contaminants between the time of system isolation and preoperational testing. Where environmental contamination could cause degradation of quality, seals shall be installed to prevent contamination of interior surfaces. Materials used for sealing items made from austenitic stainless steel or other corrosion-resistant alloys shall be subject to the limitations specified in section 400 of this Subpart. Seals shall be installed in a manner to prevent accidental removal. Removal shall be only with proper authorization.

If access to such sealed items is required, precautions shall be taken to prevent introduction of contaminants. Such precautions include masking and tenting of surrounding areas with plastic film or tape, cleanup of the immediate surroundings to remove particulate matter that can be introduced into the opening, requiring personnel to wear clean outer clothing and shoe covers, etc. Control of tools, loose items, and access shall be maintained in accordance with applicable requirements.

When the necessary work is completed, the interior surface shall be locally cleaned, if necessary, to its original condition and the item resealed.

800 PREOPERATIONAL CLEANING

(15) 801 Preparations

Insofar as practicable, cleaning and flushing operations shall be scheduled so as to minimize interference from other facility operations. Areas in which cleaning operations are being performed shall be isolated and marked to the extent that personnel performing other construction phase operations are aware that the cleaning operations are being conducted.

Personnel shall be familiarized with the intended procedure and associated hazards. Means for communicating shall be provided between the local areas in which the cleaning is performed and any remote areas (e.g., control rooms) that may be related to the cleaning operations. Tools and other loose items in controlled areas shall be controlled as specified in section 700 of this Subpart.

The actual circulating flow path shall be checked for agreement with specified requirements with regard to location, position, and status of all components. Critical valves, controls, and switches shall be tagged to prevent inadvertent actuation during the cleaning operation. The interior of all accessible components (e.g., tanks) and large diameter piping shall be inspected for cleanness. All debris and contamination shall be removed.

Demineralizers, filters, instruments, valve internals, and other items that may be damaged by the cleaning process shall be blanked off, bypassed, or removed. Protective screens shall be installed on the suction side of all pumps and other components that may be subject to damage during the cleaning operations. Instrumentation (e.g., pressure, differential pressure temperature, and flow) shall be used as necessary to monitor flushing and circulatory cleaning operations. Instrumentation installed in the system but not used to monitor the cleaning operations shall be isolated where necessary. Cleaning of the reactor vessel and reactor vessel internals shall be completed before installation of fuel and control rods.

Provisions shall be made to collect liquid leakage and to prevent wetting of insulation.

Where the use of installed facility components such as pumps may be affected by the cleaning operations, recommendations shall be obtained from the component manufacturers regarding precautions to be taken for the use of their components. Procedures shall be established to protect or isolate installed components that could be adversely affected by cleaning or flushing operations.

802 Flushing and Cleaning Methods (15)

802.1 Flushing. If the intended level of cleanness has been maintained during erection of the facility, only flushing or rinsing will normally be required. The system shall be filled with fluid of the type and quality specified and flushed in accordance with approved procedures. Completion of flushing shall be determined by filter, turbidimetric or chemical analysis, or any combination of these, as applicable.

If flushes are directed toward the large components, provisions shall be made to prevent contaminants from collecting in areas where they cannot be removed in subsequent cleaning operations. Provisions shall be made to ensure that organics do not remain on the surfaces.

After system flushing is completed, but before draining, all pockets and dead legs shall be thoroughly flushed. Where conditioned water is used, particular attention should be given to ensure that large volumes of solvent do not remain trapped in the system.

After cleaning, the item shall be sealed where appropriate to prevent the subsequent entry of contaminants. If no further cleaning is required, system layup shall be performed if specified.

802.2 Alkaline Cleaning. Although it is the intent of those involved in erecting the nuclear facility to install piping systems and components in a clean condition, this may not be fully achieved. Common sources of organic contamination in items are lubrication oils from air tools, preservative films, and valve lubricants. When immediate local cleanup is not performed, full item cleaning to remove such organic contaminants may be necessary. Such cleaning shall be performed according

to the cleaning procedures established for the operation, and the procedure shall ensure that quantities of organic contaminants do not remain on the surfaces.

Alkaline cleaning consists of the circulation of an appropriately heated solution until a selected area represented by the worst contamination or a coupon contaminated with the expected contamination is cleaned by the cleaning solution to the specified cleanness level.

After item cleaning is completed, the item shall be flushed with water of the specified quality in accordance with para. 304.1 of this Subpart to remove the cleaning agents. In particular, all pockets and dead legs shall be flushed and attention given to ensure that large volumes of solution do not remain.

Where appropriate, the item shall be sealed to prevent subsequent contamination. If no further cleaning is required, system layup shall be performed, if specified.

Alkaline cleaning compounds that contain free caustic shall not be used on components or systems in which cleaning solutions may be entrapped. Cleaners based on compounds that produce alkaline solutions by hydrolysis, such as phosphate compounds, are acceptable. If heavy organic contaminants are present, the addition of an emulsifier and a wetting agent is required.

802.3 Chelate Cleaning. If chelate cleaning is used, attention shall be given to all pockets and dead legs to ensure that large volumes of solution do not remain in the item. Unless it is considered desirable to leave a film of chelating agent on the surfaces as a protective film, the item shall be flushed with water of a quality consistent with para. 304.1 of this Subpart to remove residual chelating agents.

Where appropriate, items shall be sealed to prevent subsequent contamination. If no further cleaning is required, layup shall be performed, if specified.

Acid-chelating agent shall not be used on welded or furnace-sensitized stainless steels and nickel-based alloys.

900 LAYUP AND POSTLAYUP CLEANING

Upon completion of preoperational cleaning, unless the item is to be released for the next series of operations or tests, the item shall be placed in layup condition by filling with dry, contaminant-free inert gas or air; the process fluid that will be used in the system during operation; fluid of purity equivalent to that used to make up the system; chemically conditioned fluid; or other specified method.

Prior to the next series of operations or tests, residual cleaning solutions or layup media shall be removed, if required, from the item by flushing or by draining and filling until the effluent fluid from the item meets the preoperational test fluid quality requirements for the system.

1000 POSTOPERATIONAL REPAIRS AND MODIFICATIONS (15)

Subpart 2.1 does not address radioactive decontamination operations that may be required prior to postoperational repairs or system modifications, although some of its requirements may be applicable to such decontamination operations. For the purposes of maintenance of cleanness as defined in this Subpart, postoperational repairs or system modifications shall be considered identical to preoperational installation procedures and treated in accordance with sections 500, 600, and 700 of this Subpart.

If system cleaning following repair or modification operations is deemed necessary, such cleaning shall be performed in accordance with section 800 of this Subpart, except that flushes directed toward equipment that is particularly sensitive to contaminants (e.g., reactor vessels) shall, to the extent possible, first be preceded with flushes directed away from the equipment until expected contamination is removed and the specified water quality level is achieved. If layup is deemed necessary, it shall be performed in accordance with section 900 of this Subpart.

1100 RECORDS

The following shall be prepared:

(a) record copies of procedures

(b) reports

(c) test equipment calibration records

(d) test deviation or exception records

(e) inspection or examination records

(f) other records necessary to document the cleaning and cleanness history of the items during manufacture, shipment, storage, installation, preoperational cleaning, modifications, and repairs

These records shall be retained with other project records as required by code, standard, specification, or project procedures.

SUBPART 2.2
Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Facilities

100 GENERAL

Subpart 2.2 provides amplified requirements for packaging, shipping, receiving, storage, and handling of nuclear facility items. Controls identified within Subpart 2.2 shall be applied to maintain acceptable equipment condition. Subpart 2.2 supplements the requirements of Part I and shall be used in conjunction with applicable sections of Part I when and to the extent specified by the organization invoking Subpart 2.2.

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in Subpart 2.2.

barrier: a material designed to withstand the penetration of water, water vapor, grease, or harmful gases.

carrier: the transporting agency.

classification: the organization of items according to their susceptibility to damage during shipping, receiving, and storage only. It does not relate to the function of the item in the completed system.

dynamic load test: a test wherein designated loads are hoisted, rotated, or transported through motions and accelerations required to simulate handling of the intended item.

storage: the act of holding items in storage facilities.

storage facilities: warehouse, yard, or other areas designated and prepared for holding of items.

transportation mode: a method identified by the conveyance used for transportation of items and includes any motor vehicles, ships, railroad cars, or aircraft. Each cargo-carrying body (trailer, van, boxcar, etc.) is a separate vehicle.

wrap: a flexible material formed around the item or package to exclude solid contaminants and to facilitate handling, marking, or labeling.

200 GENERAL REQUIREMENTS

Measures shall be established and implemented for the packaging, shipping, receiving, storage, and handling of specified items to be incorporated in nuclear facilities, and for the inspection, testing, and documentation to verify conformance to specified requirements.

201 Classification of Items

Requirements are divided into four levels with respect to protective measures to prevent damage, deterioration, or contamination of the items based upon the important physical characteristics, and not upon the important functional characteristics of the item with respect to safety, reliability, and operation. It should be recognized, however, that within the scope of each level there may be a range of controls, and that the detailed requirements for an item are dependent on the importance of the item to safety reliability. For example, even though a reactor vessel and structural steel are classified as Level D, the degree of protection and control over the reactor vessel should exceed that of the structural steel. Each of the specific items governed by Subpart 2.2 shall be classified into one of these four levels by the buyer or the contractor. The manufacturer's documented standard or minimum requirements shall be considered when classifying the items. Items, once classified at a level, shall be restricted to that level or a higher level for each of the packaging, shipping, receiving, storage, and handling operations. Any package unit or assembly made up of items of different levels shall be classified to the highest level designated for any of the respective items. If the unit is disassembled, a level shall be indicated for each part.

Items covered by Subpart 2.2 shall be categorized under the following levels.

201.1 Level A. Items classified to Level A are those that are exceptionally sensitive to environmental conditions and require special measures for protection from one or more of the following effects: temperatures outside required limits; sudden temperature changes; humidity and vapors; accelerating forces; physical damage; airborne contamination (e.g., rain, snow, dust, dirt, salt spray, fumes).

Types of items to be categorized under this classification level are

(a) special electronic/electrical equipment and instrumentation

(b) special materials, such as chemicals, that are sensitive to environmental conditions

(c) special nuclear material and sources

The requirements of the NRC fuel license and conditions and of other governmental agencies shall be met.

201.2 Level B. Items classified to Level B are those that are sensitive to environmental conditions and require measures for protection from the effects of temperature extremes, humidity and vapors, accelerating forces, physical damage, and airborne contamination, and do not require special protection required for Level A items.

Types of items to be categorized under this classification level are

(a) electronic equipment and instrumentation

(b) electrical equipment

(c) batteries

(d) welding electrode and wire (welding electrodes hermetically sealed in metal containers may be stored under conditions described for Level C, unless other storage requirements are specified by the manufacturers)

(e) control rod drives

(f) motor control centers, switchgear, and control panels

(g) motors and generators

(h) precision machine parts

(i) spares, such as gaskets, O-rings

(j) air-handling filters

(k) computers

201.3 Level C. Items classified to Level C are those that require protection from exposure to the environment, airborne contamination, acceleration forces, and physical damage. Protection from water vapor and condensation is not as important as for Level B items.

Types of items to be categorized under this classification level are

(a) pumps

(b) valves

(c) fluid filters

(d) reactor internals

(e) compressors

(f) auxiliary turbines

(g) instrument cable (unjacketed)

(h) refueling equipment

(i) thermal insulation

(j) fans and blowers

(k) cement

(l) fabricated fuel rods and assemblies

201.4 Level D. Items classified to Level D are those that are less sensitive to the environment than those for Level C. These items require protection against the weather, acceleration forces, airborne contamination, and physical damage.

Types of items to be categorized under this classification level are

(a) tanks

(b) heat exchangers and parts

(c) accumulators

(d) demineralizers

(e) reactor vessel

(f) evaporators

(g) steam generators

(h) pressurizers

(i) piping

(j) electrical cable (jacketed)

(k) structural items

(l) reinforcing steel

(m) aggregates

300 PACKAGING

301 General

This Section contains the requirements for packaging of items for protection against corrosion, contamination, physical damage, or any effect that would lower the quality or cause the items to deteriorate during the time they are shipped, handled, and stored. The degree of protection specified will vary according to conditions and duration of storage, shipping environment, and handling conditions.

Implementation of this section is accomplished by identifying the item and the appropriate packaging level, and then applying the appropriate criteria contained herein concerning cleaning, preservatives, desiccants, inert gas blankets, cushioning, caps and plugs, barrier and wrapping materials, tapes, blocking and bracing, containers, marking, other quality assurance provisions, and documentation. When more than one type of item is included in a package (such as equipment shipped with related parts like seals, gaskets, lubricants, or mounting hardware), precautions shall be taken to ensure smaller items are not introduced into openings or cavities of larger parts or equipment.

302 Levels of Packaging

The packaging requirements shall be based on the protection that is necessary during shipping, handling, and storage of the item to satisfy Levels A, B, C, and D protection requirements set forth below. The requirements herein are intended to be in addition to industry classifications or tariff rules for rail, truck, air, and water shipments and regulatory agency rules already established in the transportation industry; and in no way are they intended to reduce the minimum standards established by these regulatory agency rules.

The following packaging criteria are divided into four levels corresponding to the classification categories of para. 201 of this Subpart.

302.1 Level A Items. Level A items require the highest degree of protection and shall conform to the following criteria:

(a) Package design requirements shall be for extraordinary environmental protection to avoid the deleterious effects of shock and vibration, to control temperature or humidity within specified limits, or for any other special requirements.

(b) Items shall have been inspected for cleanness immediately before packaging. Dirt, oil residue, metal chips, or other forms of contamination shall have been removed by approved cleaning methods. Any entrapped water shall have been removed.

(c) Items that are not immediately packaged shall be protected from contamination.

(d) Items requiring protection from water vapor, salt air, dust, dirt, and other forms of contamination penetrating the package shall be packaged with a barrier.

(e) Items that require protection from damage during shipping and handling shall be packaged in containers or crates (see para. 307 of this Subpart).

(f) Items that can be damaged by condensation trapped within the package shall be packaged with approved desiccant inside the sealed waterproof and vapor-proof barrier or by an equivalent method.

(g) All openings into items shall be capped, plugged, or sealed. Weld end preparations shall be protected against corrosion and physical damage.

(h) Items packed in containers shall be blocked, anchored, braced, or cushioned to prevent physical damage to the item or barrier.

(i) Items and their container shall be identified by marking.

302.2 Level B Items. Level B items require a high degree of protection, and the package shall be designed to avoid the deleterious effects of shock, vibration, physical damage, water vapor, salt spray, condensation, and weather during shipping, handling, and storage. This packaging shall be equivalent to that for Level A, except that the package design requirements need not be equivalent to satisfy the level of extraordinary environmental protection indicated in para. 302.1(a) of this Subpart where such protection is not justified. Shipment of Level B items in fully enclosed vehicles or equivalent protective enclosure or packaging is acceptable, provided the above-stated high degree of protection for Level B items is maintained throughout shipment, and the shipment goes through to destination in the original vehicle and Level B storage facilities are available on site. If transfer becomes necessary to transit, transfer procedures shall be subject to purchaser acceptance.

302.3 Level C Items. Level C items require protection from exposure to salt spray, rain, dust, dirt, and other contaminants. Protection from water vapor and condensation is less important than for Level B items. The following criteria shall apply:

(a) Criteria (b), (c), (e), (g), (h), and (i) for Level A items shall apply to Level C items.

(b) Items shall be packaged with a waterproof barrier so that water, salt spray, dust, dirt, and other forms of contamination do not penetrate the item.

(c) Items subject to detrimental corrosion, either internal or external, shall be suitably protected.

302.4 Level D Items. Level D items require protection from physical and mechanical damage. The following criteria shall apply:

(a) Items, just before packaging, shall have been inspected for cleanness according to the requirements specified in the purchasing document. Dirt, oil residue, metal chips, or other forms of contamination shall have been removed by approved cleaning methods. Any entrapped water shall have been removed.

(b) All openings into items shall be capped, plugged, and sealed. Weld end preparations shall be protected from corrosion and physical damage.

(c) Items subject to detrimental contamination or corrosion, either internal or external, shall be suitably protected.

(d) Items packed in containers shall be blocked, braced, or cushioned to prevent damage.

(e) The identity of the item shall be maintained by marking or other appropriate means.

303 Cleaning

Cleaning includes the preparation of items for preservation or packaging, or both, to minimize the requirements for site cleaning. Items shall be inspected for cleanness immediately before packaging according to the cleaning requirements specified in the procurement documents. Any dirt, oil residue, metal chips, or other forms of contamination shall be removed by documented cleaning methods. Any entrapped water shall be removed.

The following general criteria shall apply as part of the manufacturing specifications for cleaning procedures:

(a) The cleaning process, including cleaning compounds chosen, shall in no way damage the item during cleaning or subsequent service when considering the composition, surface finish, complexity, or other inherent features, or other interface equipment after installation.

(b) The cleaning process or processes chosen shall remove loose mill and heat scale, oil, rust, grease, paint, welding fluxes, chalk, abrasives, carbon deposits, coatings used for nondestructive testing processes, and other contaminants that would render ineffective the method or preservation and packaging or other specified requirements.

(c) Item surfaces after cleaning shall be free of cleaning media, such as aluminum oxide, silica, grit, cleaning

cloth residual, chemical cleaning residue, and petroleum solvent residue, etc.

(d) After cleaning, the item shall be protected from contamination until preservation or packaging is complete.

304 Methods of Preservation

Items subject to deleterious corrosion shall be protected by using either contact preservatives, inert gas blankets, or vapor-proof barriers with desiccants.

304.1 Contact Preservations. Contact preservatives are compounds applied to bare metal surfaces to prevent surface corrosion during shipping and storage and generally require removal prior to installation.

The following criteria shall be used when considering the type of contact preservative to be used:

(a) The contact preservative shall be compatible with the material on which it is applied.

(b) Contact preservatives that are nondrying shall require a neutral greaseproof protective wrap when packaged.

(c) The procedure for applying contact preservatives shall not require disassembly of the item nor shall it be necessary to disassemble the item at the site for complete removal. An exception would be for long-term storage protection to be agreed upon by the Owner, Buyer, and Manufacturer.

(d) The method of contact preservative removal shall be accomplished with approved solvents and wiping cloths, or by flushing internal cavities with solvents that are not deleterious to the item or other interconnecting material. However, preservatives for inaccessible inside surfaces of pumps, valves, and piping for systems containing reactor coolant water shall be the water-flushable type.

(e) The name of the preservative used shall be provided to facilitate touch-up.

(f) When motors, pumps, turbines, etc., are shipped with oil reservoirs and bearing cavities filled with preservative oil, the item shall be so tagged and instructions for draining, flushing, refilling, and periodic rotation shall be included with the item.

(g) When it is anticipated that the item might require an extended storage period (6 months or longer), a preservative needed for the long-term protection of the item shall be applied or arrangements shall be made to periodically reapply the preservatives.

304.2 Inert Gas Blankets. Purging and pressurizing the interior of an item or its container, or both, with a dry inert gas provides a means of preventing moisture or corrosive atmospheres from acting on sensitive, bare metal surfaces or other materials. The item or its container shall be either evacuated prior to filling with the inert gas or adequately purged with the same gas prior to applying the gas blanket.

When inert gas blankets are used, the following criteria shall apply:

(a) Inert gas blankets shall be used only when the exterior shell of the item or its container can be tightly sealed or an inert gas blanket can otherwise be maintained.

(b) Only dry, oil free, inert gas shall be used.

(c) Provisions shall be made for measuring and maintaining the blanket pressure within the required range and within each pressurized purged item or container. Closures and seals, when used to maintain a static pressure, shall be tightly secured so that the absolute pressure (by mass) after final seal is maintained for 24 hr, without adding gas, prior to shipping the item from the manufacturer's plant.

(d) The item or container shall be marked in bold letters cautioning that an inert gas blanket has been used. The required pressure range also shall be marked on the item or container.

305 Caps, Plugs, Tapes, and Adhesives

These items shall be of materials that enable them to perform their intended function adequately, without causing deleterious effects on the items or system operation.

305.1 Caps and Plugs. Caps and plugs shall be used to seal openings in items having sensitive internal surfaces and to protect threads and weld end preparations.

Caps and plugs shall conform to the following criteria:

(a) Nonmetallic plugs and caps shall be brightly or contrastingly colored. Clear plastic closures are not to be used except when specified for a special purpose, e.g., as a window for humidity indicator cards. Special attention shall be given in the control of these closures.

(b) Metallic plugs and caps contacting metal surfaces shall not cause galvanic corrosion at the contact areas. Gasketing or other nonmetallic materials used in conjunction with metallic caps or plugs shall exhibit no corrosive effect on the material.

(c) Simplicity of installation, inspection, and removal without damage to the item shall be considered.

(d) Provisions shall be made to preclude the plug or cap from falling into or being pushed into the opening after its installation.

(e) Plugs or caps shall be secured with tape or other means as necessary to prevent accidental removal.

(f) All plugs and caps shall be clean and free of visible contamination such as, but not limited to, dust, dirt, stains, rust, discoloration, or scale.

(g) Plugs and caps used in contact with austenitic stainless steel or nickel alloys shall be made from nonhalogenated materials or stainless steel.

(h) Caps and plugs shall be clearly visible, e.g., not painted over, etc., during production processes. Caps

and plugs that have been painted over shall be replaced or otherwise be made clearly visible.

305.2 Tapes and Adhesives. Pressure-sensitive, removable tape shall be used in lieu of adhesives in contact with bare metal surfaces. Tapes or adhesives that could have damaging effects on the item or system shall not be used. Tapes near a weld shall be removed completely, immediately prior to performing a weld. Tapes used for identification rather than sealing that are not near a welding operation may remain until system testing is complete, but shall be removed before facility operations unless qualified for operating conditions.

Tapes and adhesives shall conform to the following criteria:

(a) When contacting austenitic stainless steel and nickel alloy surfaces

(1) tapes shall not be compounded from, or treated with chemical compounds containing elements in such quantities that harmful concentrations are leachable, or that they could be released by breakdown under expected environmental conditions and could contribute to intergranular cracking or stress corrosion cracking, such as those containing fluorides, chlorides, sulfur, lead, zinc, copper, and mercury [paperbacked (masking) tape shall not be used]

(2) upon removal of tape, all residual adhesive shall be removed by wiping with a nonhalogenated solvent (acetone, alcohol, or equal)

(3) starch, silicone, and epoxy tape material may be used for tape adhesive

(b) When contacting other surfaces and containers

(1) tapes and adhesives used to seal nonaustenitic materials, nickel alloys, or containers are not subject to the above restrictions

(2) tape shall be impervious to water and not subject to cracking or drying out if exposed to sunlight, heat, or cold

(c) When used on surfaces of items, tapes shall be visibly distinguishable from the materials on which they are used.

306 Barrier and Wrap Materials and Desiccants

Material thickness shall be selected on the basis of type, size, and weight of equipment or item to be protected, such that the barrier or wrap will not easily be damaged by puncture, abrasion, weathering, cracking, temperature extremes, wind conditions, and the like. Barrier and wrap materials shall be noncorrosive and shall not be otherwise harmful to the item packaged. When barrier and wrap materials are used in direct contact with austenitic stainless steels, the total and water leachable content of halogen shall not be harmful to the item packaged. Also, barrier and wrap materials shall not readily support combustion. Vapor-proof barrier materials used with desiccants constitute another preservation system that protects against potential damage by water vapor condensate.

306.1 Waterproof Barrier Material. Waterproof barrier material shall be resistant to grease and water; it shall protect items from airborne and windblown soils.

306.2 Vapor-Proof Barrier Material. Vapor-proof barrier materials shall be sealable, and the edge of the barrier that normally will be opened at destination shall be of sufficient area to permit at least two subsequent sealing operations. When maximum vapor protection is required, barrier material shall meet the maximum water vapor transmission rate of 0.05 g/100 $in.^2$ per 24 hr required by ASTM E96, Test Methods for Water Vapor Transmission of Materials, Procedure E, and shall be packaged with an approved desiccant. Vapor-proof barrier material should be colored to contrast with the material on which it is used.

306.3 Desiccants. Desiccants shall be used within a vapor-proof barrier when condensation or high humidity could damage an item by corrosion, mold, or mildew.

Desiccants shall consist of nondeliquescent, nondusting, chemically inert, dehydrating agents. The following criteria shall apply:

(a) The desiccant bag shall be made of puncture-, tear-, and burst-resistant material.

(b) When used with austenitic stainless steel and nickel alloy materials, tapes, desiccants, and the materials for the desiccant bag shall not be compounded from or treated with chemical compounds containing elements in such quantities that harmful concentrations are leachable, or they could be released by breakdown under expected environmental conditions and could contribute to intergranular cracking or stress corrosion cracking, such as those containing fluorides, chlorides, sulfur, lead, zinc, copper, and mercury.

(c) The reactivation temperature and time shall be marked on the desiccant container.

(d) Canisters used to contain desiccants shall be placed so as to cause no deleterious effects such as galvanic corrosion, even when the desiccant has reached its absorptive capacity for water vapor.

(e) Desiccant bags and canisters, when used, shall be secured to prevent movement, rupture of the bags, or damage to the item being protected.

(f) Waterproof and vapor-proof barriers shall be used to seal items containing desiccants. The included air volume within the barrier shall be kept to a minimum.

(g) Items that contain desiccants shall have all openings securely sealed. When flange connections are a part of the barriers, O-rings or gaskets shall be used with all bolts in place and tightened sufficiently to ensure a waterproof and vapor-proof seal. Weld end preparations, after capping, shall be covered with a waterproof and vapor-proof seal.

(h) Packages and items containing desiccants shall be marked. The total number of separate bags or containers of desiccants in the package shall be indicated.

(i) The minimum quantity of desiccant for use in each package shall be determined in accordance with Formula I or Formula II, as applicable.

(1) Formula I: to determine minimum units of desiccant for use with other than sealed rigid metal barrier:

$$U = 1.6A + XD \quad (1)$$

(2) Formula II: to determine minimum units of desiccant for use with sealed rigid metal barrier:

$$U = KV + XD \quad (2)$$

where

A = area of barrier, ft^2 ($m^2 \times 0.0929$)
D = dunnage (other than metal) within barrier, lb (kg × 2.2)
K = 0.0007 when volume is given in $in.^3$
= 1.2 when volume is given in ft^3
= 0.0000425 when volume is given in cm^3 (42.5 in m^3)
U = number of units of desiccant to be used (see Note)
V = volume within barrier in $in.^3$ or ft^3 (cm^3 or m^3)
X = 8 for hair felt, cellulosic material (including wood), and other material not categorized below
= 6 for bound fibers (animal hair, synthetic fiber, or vegetable fiber bound with rubber)
= 2 for glass fiber
= 0.5 for synthetic foams and rubber

NOTE: A *desiccant unit* is that quantity of desiccant, as received, that will absorb at equilibrium with air at 78°F (25°C) at least the following quantities of water vapor: 3.00 g at 20% relative humidity and 6.00 g at 40% relative humidity.

(j) A humidity indicator shall be included in every waterproof and vapor-proof envelope containing desiccant. As applicable, the indicator shall be located behind inspection windows or immediately within the closing edge, face, or cover of the barrier and, as far as practical, from the nearest unit of desiccant.

307 Containers, Crating, and Skids

307.1 Containers. Containers shall be used when maximum protection for the item or its barrier is required. Container types shall include, but not be limited to, the following:

(a) cleated, sheathed boxes [500 lb (227 kg) maximum net weight]
(b) nailed, screwed, or bolted wood boxes
(c) wood-cleated solid fiberboard boxes
(d) metal or fiber drums
(e) crates
(f) wire-bound boxes [200 lb (91 kg) maximum net weight]
(g) other specially designed containers for special equipment
(h) fiberboard boxes [120 lb (54.5 kg) maximum net weight]. The following criteria shall apply for fiberboard boxes used as exterior containers:

(1) Boxes shall be weather-resistant fiberboard preferably from the grade types (or compliance symbol): V2 s, V3 s, or V3 c (Federal Specification PPP-B-636).

(2) Box style shall be RSC regular slotted box (outer flaps meet, inner flaps and outer flaps are of equal length).

(3) Fiberboard boxes shall be securely closed with a water-resistant adhesive applied to the entire area of contact between the flaps. All seams and joints shall be further sealed with not less than 2 in. (5 cm) wide, water-resistant tape.

(4) Boxes shall be strapped with pressure-sensitive reinforced tape, lengthwise (top, bottom, and ends), girthwise (top, bottom, and sides), and horizontal sides and ends.

(5) Wood cleating on fiberboard boxes shall be fabricated from structurally sound, seasoned or treated lumber. Cleated boxes in excess of 50 lb (22.7 kg) shall be bound with steel strapping, or equivalent, around the container at not less than two places.

307.2 Crates and Skids. Crates or skids shall be used for equipment in excess of 500 lb (227 kg). Skids or runners shall be used on crates with a gross weight of 100 lb (45.5 kg) or more, allowing a minimum floor clearance for forklift tines as provided by 4 in. (10 cm) lumber.

308 Cushioning, Blocking, Bracing, and Anchoring

308.1 Cushioning. Cushioning shall be used where protection from shock and vibration is required. The cushioning materials shall have sufficient strength to perform this function.

Selection of cushioning material shall be based on the following:

(a) It shall exhibit no corrosive effect when in contact with the item being cushioned.
(b) It shall have low moisture content and exhibit low moisture absorption properties, or if the cushioning material has some moisture-absorbing capacity, the item shall be protected with a water-vaporproof barrier.
(c) It shall have negligible dusting characteristics.
(d) It shall not readily support combustion.

308.2 Blocking and Bracing. Blocking and bracing used for protection of the load to be supported shall be compatible with the size, shape, and strength of bearing areas of the shipment. The blocking and bracing used to prevent item movement shall withstand thrust and impact applied in any direction. Blocking and bracing used in direct contact with the item being blocked shall not have a corrosive effect on the item.

308.3 Anchoring. Anchoring of the item within a crate or on a skid shall adequately fasten the item during

shipment and protect the item from potential damage due to rough handling.

When bolts are used for anchoring, the following criteria shall apply:

(a) If precision bolt holes in the item are used for anchoring, precaution shall be taken to ensure that properly fitting bolts of the correct dimension and characteristics are used to prevent marring or elongation of the holes.

(b) Holes bored through containers or mounting bases shall provide a snug fit.

(c) When mounting items to container bases equipped with skids, bolts shall be extended through the skids whenever practical. In such instances, countersinking of the bolts in the sliding surface of the skid shall be done.

(d) Washers shall be used under the nuts to decrease the possibility of the bolt pulling through the wood.

(e) Nuts shall be properly tightened. To prevent their loosening during shipment, locknuts, lock washers, cotter pins, or staking shall be employed.

Temporary cushioning, blocking, bracing, or anchoring placed on an item for shipping protection that needs to be removed prior to operation of the item shall be identified by warnings placed in a conspicuous manner to affect proper removal of the packing material.

309 Marking

(a) To maintain proper identification and instructions, or both, during shipping, receiving, and storage and to provide for identification after the outside of the container has been removed, the item and the outside of the containers shall be marked. If equipment does not lend itself to marking, records shall be maintained that are uniquely identifiable to the item.

(b) Items shall be marked to preserve identity in accordance with the following criteria:

(1) The specified identification shall be stamped, etched, stenciled, or otherwise marked on the item or on tags to be affixed securely to the item in plain, unobstructed view. When metal stamps are employed, low stress stamps shall be used when the item proper is marked. When vibrating marking tools are used, they shall be fitted with carbide marking tip or its equivalent, and shall be designed to provide a rounded impression not to exceed 0.010 in. (0.25 mm) in depth. Etching shall not be used on nickel alloys, weld areas, or sensitized areas of stainless steel. Electric-arc marking pencils shall not be used.

(2) The marking shall neither be deleterious to the material nor violate any other section of this Subpart.

(3) When tags are employed, they shall be of a material that will retain the marking, withstand weathering deterioration, and other normal shipping and handling effects, and shall not be detrimental to the item.

(4) The English language shall be used. Duplicate marking may be made in other languages.

(5) References to weights shall be in avoirdupois units. Duplicate markings in other systems may also be indicated.

(c) Markings on the outside container shall be in accordance with the following criteria:

(1) Container markings shall appear on a minimum of two sides of a container, preferably on one side and one end.

(2) The English language shall be used. Duplicate marking may be made in other languages or in pictorial marking according to ISO Recommendation R780, Pictorial Markings for Handling of Goods (General Symbols) or ANSI MH6.1.

(3) References to weights shall be in avoirdupois or System International (SI) units. Duplicate markings in other systems may also be indicated.

(4) Container markings shall be applied with waterproof ink or paint in characters that are legible. When information relative to handling and special instructions is required, such information shall be preceded by the word CAUTION in letters that are at least $\frac{1}{2}$ in. (12.7 mm), as permitted by container size.

(5) Where tags or labels are used, they shall be affixed to the container using a waterproof adhesive, tacks where practical, or a corrosion-resistant wire.

(6) Container markings shall include the following information:

(-a) destination

(-b) return address

(-c) package numbers showing the purchase order number, followed by the package number and the total number of packages

(-d) material identification number

(-e) handling instructions (e.g., Fragile, Center of Gravity, Keep Dry, This Side Up, Sling Here, Do Not Freeze) and stacking limitations, as appropriate

(-f) weight of package [in excess of 100 lb (45.5 kg)]

(-g) special instructions (Desiccant Inside, Remove Items Packaged Inside Prior to Installation, Remove Caps and Plugs Prior to Installation, Special Inspection, Storage, Unpacking Restrictions, etc.) as appropriate; if items are repackaged for storage, provisions shall be made for retention or transfer of the special instructions

(d) Marking of items not within a container, such as pipe, tanks, and heat exchangers, shall exhibit specified information in a location that is in plain unobstructed view. Marking may be applied directly to bare metal surfaces, provided it has been established that the marking material is not deleterious to the item.

400 SHIPPING

401 General

This section covers the requirements for loading and shipment of items as defined in para. 201 of this Subpart.

The mode of transportation used shall be consistent with the protection classification of the item and with the packaging methods employed. Special shipping instructions from the manufacturer, approved alternatives should be addressed while meeting the requirements of section 400 of this Subpart.

402 Transportation Requirements

402.1 Open Carriers. For shipment on open carriers where items may be exposed to adverse environmental conditions, the following shall apply:

(a) Levels A, B, and C items shall be covered for protection from environmental conditions. Tarpaulins, when used, shall be fire retardant, and they shall be installed in a manner to provide drainage and to ensure air circulation to prevent condensation.

(b) Barrier and wrapped materials subject to transportation damage shall be covered with waterproof shrouds, such as tarpaulins, so that they are not exposed directly to the environment.

402.2 Closed Carriers. For shipment on closed carriers, the following shall apply:

When Levels A, B, and C items cannot be adequately protected from weather or environment on open carriers, closed carriers or fully enclosed vehicles shall be used.

402.3 Special Shipments. Items that exceed established weight or size limitations for railroads or highways or require special handling shall be given additional consideration in the following areas:

(a) The type of bracing and tie-down methods to be used with the mode of transportation selected for special shipments shall be specified.

(b) NO HUMPING shall be specified on rail shipments of these items, and NO HUMPING signs shall be prominently displayed.

(c) Use of impact recording devices shall be specified on shipments of heavy or relatively large items incorporating delicate factory-installed instrumentation. Devices, when specified, shall be installed prior to loading (to record any rough handling during loading). Procedures shall be established to interpret recorded data and to thoroughly check the integrity of an item when there is evidence of rough handling. A notice that impact recording devices are being used shall be prominently displayed. Special recording devices with operating time limits greater than the expected transit time shall be specified or, if the expected transit time exceeds the operating time limit of the recorders being used, provisions shall be made to service the devices during transit.

(d) For special shipments, the conveyance used for transport shall be certified to be structurally adequate to take the loads imposed during loading, while en route, and during unloading. Prior to shipment, the route shall have been investigated to ensure safe transit.

403 Precautions During Loading and Transit

403.1 Loading. The weight, lifting points, or center of gravity indicated by the shipper on the crate, skid, or package by the shipper shall be utilized to ensure proper handling during loading, transfer between carriers, and unloading.

403.2 Rigging. Carbon steel rigging equipment shall not come in direct contact with stainless steel, except when attached to lifting lugs, eyes, or pads in order to avoid surface damage.

403.3 Handling Precautions. All austenitic stainless steel and nickel-base alloy materials shall be handled in such a manner that they are not in contact with lead, zinc, copper, mercury, or other low melting point elements, carbon steel, alloys, or halogenated material having a water-leachable content harmful to the material.

403.4 Package and Preservative Coatings. Package or preservative coatings shall be visually inspected after loading and damaged areas repaired prior to shipment. Items shipped with desiccants shall be inspected after loading to ensure that sealed areas are intact.

403.5 Sealed Openings. Sealed openings shall be visually inspected after loading to ensure closures are intact. Materials used for resealing shall be in accordance with section 300 of this Subpart.

403.6 Stacking. Where special care is deemed necessary to avert damage, written instructions concerning the location or stacking limits for crates or boxes shall be marked on the containers.

403.7 Theft and Vandalism. Precautions shall be taken to minimize the possibility of theft and vandalism during shipment of items.

404 Identification and Markings

Identification and markings on the outside of all packages, skids, or protective covering shall be maintained.

405 Nuclear Material Shipments

Special nuclear material and sources shall be shipped as specified in the NRC fuel license and by other regulatory agencies.

500 RECEIVING

501 General

This section covers the requirements that shall be fulfilled by the organization(s) responsible for the receiving of items. Receiving starts when the items arrive at a storage facility or construction site before unloading or unpacking.

502 Receiving Inspection Requirements

502.1 Shipping Damage Inspection. Preliminary visual inspection shall be performed prior to or immediately after unloading to determine if any damage occurred during shipping. Observations for unusual conditions shall include the following:

(a) fire: charred paper, wood, or paint, indicating exposure to fire or high temperature

(b) excessive exposure: weather-beaten, frayed, rusted, or stained containers, indicating prolonged exposure during transit

(c) environmental damage: water or oil marks, damp conditions, dirty areas, or salt film, indicating exposure to sea water or winter road salt chemicals

(d) tie-down failure: shifted, broken, loose, or twisted shipping ties, and worn material under ties, indicating improper blocking and tie down during shipment

(e) rough handling: splintered, torn, or crushed containers, indicating improper handling

(f) review of impact recording device readings against established criteria

(g) review of humidity recording data against established criteria

502.2 Item Inspection

(a) Unless the package marking prohibits unpacking, the contents of all shipments shall be visually inspected to verify that the specified packaging and shipping requirements have been maintained. When items are contained in transparent, separate, moistureproof bags or envelopes, visual inspection without unpacking the contents shall be acceptable. Where specific inspection requirements can be achieved, statistical sampling methods may be used for groups of similar items. Care shall be taken to avoid contamination of the items during inspection. The inspection shall be performed in an area equivalent to the level of storage requirement for the item. If an appropriate area is not available, the inspection shall be performed in a manner and environment that does not endanger the required quality of the item. These inspections and examinations shall include the following, as appropriate:

(1) identification and marking: verification that identification and markings are in accordance with applicable codes, specifications, purchase orders, and drawings, and with requirements in this Part (Part II).

(2) manufacturing documentations: assurance that the item received was fabricated, tested, and inspected prior to shipment in accordance with applicable code, specification, purchase order, or drawings.

(3) protective covers and seals: visual inspection to ensure that covers and seals meet their intended function.

(4) coatings and preservatives: verification that coatings and preservatives are applied in accordance with specifications, purchase orders, or manufacturer's instructions.

(5) inert gas blanket: verification that the inert gas blanket pressure is within the acceptable limits.

(6) desiccant: verification that the desiccant is not saturated, as indicated, through the use of humidity indicators. Desiccants shall be regenerated or replaced as necessary in accordance with special instructions.

(7) physical damage: visual inspection to ensure that parts of items are not broken, cracked, missing, deformed, or misaligned, and that rotating parts turn without binding. Accessible internal and external areas shall be free of detrimental gouges, dents, scratches, and burrs.

(8) cleanness: visual inspection to ensure that accessible internal and external areas are within the specification requirements for dirt, soil, mill scale, weld splatter, oil, grease, or stains. If inspection for cleanness was performed prior to sealing and shipping, and inspection upon receipt indicates that there has been no penetration of the sealed boundary, then inspection for internal cleanness is optional.

(b) Unless the completed item was inspected at the source, it shall be inspected upon receipt to verify that the following characteristics conform to the specified requirements. These inspections shall include such items as

(1) physical properties: assurance that physical properties conform to the specified requirements and that chemical and physical test reports, if required, meet the requirements

(2) dimensions: random visual inspection to ensure that important dimensions conform with drawings and specifications, i.e., baseplate mounting holes, overall external size, and configuration and orientation of parts

(3) weld preparations: random verification that weld preparations are in accordance with applicable drawings and specifications

(4) workmanship: visual inspection of accessible areas to ensure that the workmanship is satisfactory to meet the intent of the requirements

(5) lubricants and oils: verification of presence of proper lubricants and oils, if required, by either specification, purchase order, or manufacturer's instructions

(6) electrical insulation: performance of insulation resistance tests for motors, generators, and control and power cable to ensure conformance with specifications

502.3 Special Inspection. Where receiving inspection in addition to that described above is required, the special inspection procedure, complete with documentation instructions, shall be attached to the item or container. This is in addition to the copy sent through normal channels. The special inspection shall be performed, and the results of the inspection shall be documented.

503 Disposition of Received Items

503.1 Acceptable. Containers and items inspected and found in conformance with specified requirements shall be identified as acceptable and placed in a storage area for acceptable items, or moved to the final location for installation or use.

503.2 Nonconforming. Items that do not conform to the specified requirements shall be controlled in accordance with Part I of this Standard.

503.3 Conditional Release. If the nonconformance that caused the item to be classified unacceptable can be corrected after installation, the item may be released for installation on a conditional release basis. A statement documenting the authority and technical justification for the Conditional Release of the item for installation shall be prepared and made part of the documentation.

504 Status-Indicating System

A status-indicating system is a system or method for identifying the status of items (e.g., an inventory management system, tagging, labeling, color coding, etc.) that clearly indicates whether items are acceptable or unacceptable for installation. A controlled physical separation is an acceptable equivalent method. The system shall provide for indication of the date the item was placed in the acceptable or unacceptable installation status and the conditional release of the items for installation pending the subsequent correction of the nonconformance. When tags are used, the stock shall be made from material that will not deteriorate during storage. The stock used shall not be deleterious to the item. Tags shall be securely affixed to the items and displayed in an area that is readily accessible.

505 Marking

Changing, correcting, or any other marking on nameplates shall be prohibited, unless authorized by the manufacturer of the item.

506 Documentation

A written record of the receiving inspection, package identification, tagging, corrective actions, and justification for conditional acceptance shall be prepared.

600 STORAGE

601 General

601.1 Scope. This section contains requirements that shall be fulfilled by the organization responsible for performing the storage of items. Levels and methods of storage are defined to minimize the possibility of damage or lowering of quality due to corrosion, contamination, deterioration, or physical damage from the time an item is stored upon receipt until the time the item is removed from storage and placed in its final location. Special storage instructions from the manufacturer, if specified, shall be addressed as part of the storage process for both short- and long-term storage of items.

601.2 Levels of Storage. Environmental conditions for items classified as Levels A through D shall meet the requirements as described in the following paragraphs:

(a) Level A items shall be stored under special conditions similar to those described for Level B items but with additional requirements such as temperature and humidity control within specified limits, a ventilation system with filters to provide an atmosphere free of dust and harmful vapors, and any other appropriate requirements.

(b) Level B items shall be stored within a fire-resistant, tear-resistant, weather-tight, and well-ventilated building or equivalent enclosure. Precautions shall be taken against vandalism. This area shall be situated and constructed so that it will not be subject to flooding; the floor shall be paved or equal, and well drained. Items shall be placed on pallets or shoring to permit air circulation. The area shall be provided with uniform heating and temperature control or its equivalent to prevent condensation and corrosion. The minimum temperature shall be 40°F (5°C), and the maximum temperature shall be 140°F (60°C) or less if so stipulated by the manufacturer.

(c) Level C items shall be stored indoors or in an equivalent environment with all provisions and requirements as set forth for Level B items, except that heat and temperature control is not required.

(d) Level D items may be stored outdoors in an area marked and designated for storage that is well drained, preferably gravel covered or paved, and reasonably removed from the actual construction area and traffic so that the possibility of damage from construction equipment is minimized. Items shall be stored on cribbing or equivalent to allow for air circulation and to avoid trapping water.

602 Storage Areas

Periodic inspections shall be performed to ensure that storage areas are being maintained in accordance with applicable requirements.

602.1 Access to Storage Areas. Access to storage areas for Levels A, B, and C items shall be controlled and limited only to personnel designated by the responsible organization. Access to storage areas involving Level D items shall be controlled as designated by the responsible organization.

602.2 Cleanliness and Housekeeping Practices. Cleanliness and good housekeeping practices shall be enforced at all times in the storage areas. The storage

areas shall be cleaned as required to avoid the accumulation of trash, discarded packaging materials, and other detrimental soil.

602.3 Fire Protection. Fire protection commensurate with the type of storage area and the material involved shall be provided and maintained.

602.4 Storage of Food and Associated Items. The use or storage of food, drinks, and salt tablet dispensers in controlled storage areas shall not be permitted.

602.5 Measures to Prevent Entrance of Animals. Measures shall be taken to prevent the entrance of rodents and other animals into indoor storage areas or equipment to minimize possible contamination and mechanical damage to stored material.

603 Storage Methods

Storage methods and procedures shall comply with the requirements described in paras. 603.1 through 603.6 of this Subpart.

603.1 Ready Access to Stored Items. All items shall be stored in such a manner as to permit ready access for inspection or maintenance without excessive handling to minimize risk of damage.

603.2 Arrangement of Items. Items stacked for storage shall be arranged so that racks, cribbing, or crates are bearing the full weight without distortion of the item.

603.3 Storage of Hazardous Material. Hazardous chemicals, paints, solvents, and other materials of a like nature shall be stored in well-ventilated areas and not in close proximity to important nuclear facility items.

603.4 Identification. Items and their containers shall be plainly marked so that they are easily identified without excessive handling or unnecessary opening of crates and boxes.

603.5 Coverings. Weatherproof coverings, when used for outdoor storage, shall be the flame-resistant type of sheeting or tarpaulins. They shall be placed so as to provide drainage and to ensure air circulation to minimize condensation. They shall be tied down to prevent moisture from entering laps and to protect the coverings from wind damage.

603.6 Outdoor Storage. Items stored outdoors shall be positioned or covered to avoid trapping moisture in pockets or internally. For example, valves shall be positioned such that water does not collect under the bonnet but can drain from the valve packing area.

604 Control of Items in Storage

Control of items in storage is described in paras. 604.1 through 604.3 of this Subpart.

604.1 Inspections. Inspections shall be performed and documented on a periodic basis to ensure that the integrity of the item and its container, as provided for under section 300 of this Subpart, is being maintained. Deficiencies noted shall be corrected and documented. The characteristics verified during this inspection shall include such items as

(a) identification and marking
(b) protective covers and seals
(c) coatings and preservatives
(d) desiccants and inert gas blankets
(e) physical damage
(f) cleanliness

604.2 Care of Items. Requirements for proper maintenance during storage shall be documented. Care of items in storage (includes storage in place) shall be exercised in accordance with the following:

(a) Items in storage shall have all covers, caps, plugs, or other closures intact. Methods used to seal openings shall be in accordance with section 300 of this Subpart. Covers removed for internal access shall be immediately replaced and resealed after completion of the purpose for removal.

(b) Temporary preservatives shall be left intact during storage. Should reapplication of preservatives be required at the site, only those previously approved shall be used.

(c) Items pressurized with inert gas shall be monitored at such a frequency as to ensure that the gas pressure is maintained within specified limits during storage. Desiccant humidity indicators shall also be monitored, and desiccants shall be changed or reprocessed when specified.

(d) Instrumentation racks shall be energized as specified by the manufacturer.

(e) Space heaters enclosed in electrical items shall be energized.

(f) Rotating electrical equipment shall be given insulation resistance tests on a scheduled basis.

(g) The shafts of rotating equipment shall be rotated on a periodic basis. The degree of turn shall be established so that the parts receive a coating of lubrication, where applicable, and so that the shaft does not come to rest in a previous position (90 deg and 450 deg rotations are examples).

(h) Other maintenance requirements specified by the manufacturer's instructions for the item shall be performed.

604.3 Post-Fire Evaluation. In the event that a fire should occur in the storage area at any time, each item known to have been heated to an ambient temperature of over 150°F (65°C) or subjected to smoke contamination shall be withheld from installation or use until it has been thoroughly examined, and the item has been verified to be in conformance with specified requirements.

605 Removal of Items From Storage

Only items that have been inspected and are considered acceptable for installation or use in accordance with the receiving inspection procedure shall be removed from storage for installation or use (see section 500 of this Subpart). Items released from storage and placed in their final locations and items stored in place within the nuclear facility shall be inspected and cared for in accordance with the requirements of paras. 604.1 and 604.2 of this Subpart and other standards, as applicable.

606 Storage Records

Written records shall be prepared that include such pertinent information as storage location, results of inspections, results of in-storage maintenance to include the results of configuration control activities for the item while in storage, protection requirements, changes in item ownership including (if applicable) certificates of conformance, and personnel authorized access to the storage location(s).

700 HANDLING

701 General

The requirements that shall be fulfilled by the organizations responsible for handling items are contained in Subpart 2.15.

800 RECORDS

Record copies of procedures, reports, personnel qualification records, test equipment calibration records, test deviation or exception records, storage and maintenance records, and inspection records shall be prepared as required by this Subpart. These records shall be retained with other project or operations records as required by code, standard, specification, or project procedures.

SUBPART 2.3
Quality Assurance Requirements for Housekeeping at Nuclear Facilities

100 GENERAL

Subpart 2.3 provides housekeeping requirements for the control of work conditions and environments that can affect the quality of important parts of a nuclear facility. It supplements the requirements of Part I and shall be used in conjunction with applicable sections of Part I when and to the extent specified by the organizations invoking Subpart 2.3.

200 GENERAL REQUIREMENTS

Housekeeping encompasses activities related to the control of cleanliness of the site area, the facility, materials, and equipment and fire prevention and protection, including collection and disposal of combustible material and debris, control of access to areas, and protection of equipment. Housekeeping activities shall include documented methods and techniques for control of the site area, the facility, and the materials and equipment being incorporated in the facility to preserve the requisite quality of the items being constructed or installed. Personnel working in zone-controlled areas shall be familiar with the necessities and requirements for cleanness control applicable to the various zones. Training programs shall be used for this purpose, where appropriate.

201 Planning and Procedures

Planning and procedure preparation shall be in accordance with the requirements of the Introduction to this Part (Part II). Procedures and instructions shall contain sufficient detail to provide for control of the site area, the facility, and the materials and equipment being incorporated in the facility to preserve the requisite quality of the item being constructed or installed. Procedures and instructions providing for the control of site areas, site preparation, fire prevention and protection, and records shall be in force with the start of the construction activity. Other procedures and instructions shall be prepared and approved no later than the start of equipment installation work.

202 Classification of Cleanness

Cleanness requirements for housekeeping activities shall be established on the basis of the following zone designations. The five zones are primarily for construction and generally not applicable for the operations. The timing for implementation of the zone designations shall be as required by the need for cleanness.

	Zones				
Restriction List	I	II	III	IV	V
Clothing change	Yes	No	No	No	No
Clean gloves, shoe covers, head covering	Yes	Yes	No	No	No
Filtered air	Yes	No	No	No	No
Material pre-cleaning	Yes	Yes	No	No	No
Material accountability	Yes	Yes	Yes	No	No
Personnel accountability	Yes	Yes	Yes	No	No
Use of tobacco or eating	Yes	Yes	Yes	Yes	No

(a) Zone I. Areas requiring the highest order of cleanness shall be equipped with a clean clothing change facility at the vestibule or entrance. Such areas shall provide for complete outer change of clothing by personnel, including the use of shoe covers, head covers, and gloves to protect all equipment surfaces from outside contamination. Material entering this zone shall have been appropriately cleaned prior to entry.

(b) Zone II. Intermediate cleanness requirements less restrictive than Zone I, but where foreign matter may have detrimental effects.

(c) Zone III. Areas less restrictive than Zones I and II, but requiring access control over personnel and materials.

(d) Zone IV. Areas where it is desired to regulate the use of tobacco and eating of food for material and equipment protection or for health and fire hazards.

(e) Zone V. Unrestricted construction areas requiring good construction site housekeeping practices only.

300 REQUIREMENTS

301 Control of Site Area

Areas for specific activities shall be assigned and regulated. Areas that shall be designated include, where appropriate, refuse and garbage dumps, refuse burning sites, storage locations, parking lots, eating places, nonsmoking areas, subcontractor work areas, common

areas, and waste collection container locations. Personnel entrance to controlled areas, admission of visitors to the work site, and identification of all personnel shall be controlled in accordance with established procedures and instructions.

For Zones I, II, and III a written record of the entry and exit of all personnel and material shall be established and maintained.

Grading, drainage, roads, construction facilities, facility fencing, and utilities shall be provided in accordance with specified requirements and shall be maintained as required in good condition throughout the construction phase or until replaced with the permanent facilities.

302 Control of Facilities

Control of work and storage areas where important items are handled shall be established and maintained to conform to the appropriate zone defined in para. 202 of this Subpart. Atmospheric control shall be provided where necessary.

The control of tools, equipment, materials, and supplies that are used in Zones I, II, and III shall be maintained to prevent the inadvertent inclusion of deleterious materials or objects in critical systems. Appropriate control measures shall be provided through use of such items as log books and tethered tools.

302.1 Cleanness. The work areas shall be kept sufficiently clean and orderly so that construction activity can proceed in an efficient manner that will produce and maintain quality in conformance with specified requirements. Where large accumulations of materials occur on a nonroutine basis, such as the stripping of concrete forms, the material shall be promptly removed or stored neatly. Garbage, trash, scrap, litter, and other excess materials shall be collected, removed from the job site, or disposed of in accordance with specified requirements or planned practices. Such excess material shall not be allowed to accumulate and create conditions that will adversely affect quality. The disposal of cleaning chemicals shall be accomplished so additional hazards are not created at the disposal site.

302.2 Environment. Areas of activity shall be adequately lighted, ventilated, protected, and accessible as appropriate for the work being performed. Temporary lighting may be used but shall be installed and maintained to provide good visibility. Ventilation shall be provided where necessary to prevent accumulation of dust, noxious fumes, and temperature extremes. Adequate working space for construction personnel shall be provided using proper work scaffolds and platforms having accessibility by stairs or ladders. Barriers, screens, shields, restricted access, or other protection shall be provided as necessary for isolation of areas where noise, welding arcs, dust, inclement weather, or other conditions may affect the quality of work being performed.

302.3 Fire Protection and Prevention. Equipment and instruction for the protection from, and prevention of, damage by fire shall be provided in accordance with the requirements of the NFPA National Fire Codes. Procedures or instructions for fire protection shall include provisions for fighting fires involving the use of available community fire departments, trained project brigades, and others. Procedures or instructions shall include plans for provision of water supplies, hydrants, automatic sprinklers, access for fire fighting, and distribution of extinguishers and fire-fighting equipment. Fire surveillance during and immediately following operations such as welding and heat treating shall be provided when materials are located where flames, flying sparks, weld spatter, or excessive heat resulting from the operation could cause combustion, with resulting damage to items of the nuclear facility. Fire protection facilities shall be in service beginning with the initial stages of permanent construction. Prefire planning shall be conducted as a requirement of the fire protection procedures or instructions, which shall include evacuation of confined areas.

303 Material and Equipment

Materials and equipment delivered to the work area shall be so positioned, or protected when necessary, to ensure that the quality of the item will not be degraded by the construction activity. The cleaning of important materials and equipment for the facility that is necessary during receiving, storage, and handling activities shall be in accordance with applicable requirements.

304 Construction Tools, Supplies, and Equipment

The use, location, and deployment of construction tools, supplies, and equipment shall be controlled to keep access and work areas clear and to prevent conditions that will adversely affect quality. These provisions shall include, but are not limited to, such items as the movement of materials to the work area, welding and stress-relieving leads, power leads, temporary heating equipment, pumps, air and water hoses, welding machines, air compressors, hoisting equipment, air tools, grinding tools, and burning tools.

305 Surveillance and Inspections

Periodic inspection of work areas and construction practices shall be performed at scheduled intervals to ensure adequacy of cleanness and housekeeping practices. These inspections shall include the following, as appropriate:

(a) inspection of construction site roads, access ways, and ramps for conditions that may result in damage to items being transported or handled

(b) inspection of storage and work areas for conformance to procedures and instructions in the following categories:

(1) adequacy of access control

(2) evidence of damage or deterioration

(3) adequacy of protection from fires, weather, movement of equipment, and other factors that may result in damage to stored and installed items

(4) adequacy of hazardous chemicals, paints, and solvent storage facilities

(c) inspection of work areas for maintenance of environmental conditions within specified limits

(d) surveillance of installed items to ensure the adequacy of

(1) maintenance of protection

(2) preservation of precautionary signs

(3) preservation of item identity

(4) protection from fire, weather, movement of materials or equipment, and other factors that may result in damage to installed items

400 RECORDS

Record copies of procedures, reports, personnel qualification records, zone control registries, fire and accident investigations, surveillance, and inspection records shall be prepared as required in this Part (Part II). These records shall be retained with other project records as required by code, standard, specification, or project procedures.

SUBPART 2.4
Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities

(15)

DELETED

SUBPART 2.5
Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Facilities

100 GENERAL

Subpart 2.5 provides amplified requirements for installation, inspection, and testing of structural concrete, structural steel, soils, and foundations. It supplements the requirements of Part I and shall be used in conjunction with applicable sections of Part I when and to the extent specified by the organization invoking Subpart 2.5.

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in Subpart 2.5.

class of concrete: identifies each individual concrete mix design.

correlation testing: comparison testing of two samples obtained from the same batch of concrete but from different sampling locations. Usually performed to check or confirm the effects of a conveyance system, such as a pump system, on plastic concrete properties specified at the point of placement.

curing: the process of maintaining a satisfactory moisture content and a favorable temperature in concrete during hydration of the cementitious materials so that desired properties of the concrete are developed.

delivery point: the point of discharge from a bulk concrete delivery container. These containers include a truck mixing unit/ready-mix truck, truck-agitating unit, or nonagitating unit. For sampling purposes, delivery point and placement point can be considered coincident when no conveyance system is used or if correlation testing shows no significant change to the concrete properties following conveyance.

NOTE: "Buckets" are not considered bulk delivery containers but rather are considered a conveyance system.

finishing: the process of obtaining specified surface characteristics of hardened concrete.

in-process tests: tests performed during the course of construction to determine compliance with specified requirements and maintain control of materials. These tests may be performed by the Purchaser (or his agent), constructor, manufacturer, or Supplier, but samples for these tests must be taken from the lot or batch of materials supplied and used at the site of construction.

mixing point: the point of discharge of plastic concrete from a central mix plant. For truck-mixed concrete, the mixing point and delivery point are defined as coincident. When a truck agitator unit is used in the transit of concrete, the delivery and mixing points are considered coincident when

(a) the delivery point is not more than a distance of 2 mi (3.22 km) and a maximum time of ½ hr in transit from the mixing point

(b) the delivered concrete commences to be placed within a maximum time of ½ hr from the time the transporting vehicle arrives at the delivery point

When a nonagitating unit is used, the delivery point and mixing point shall not be considered coincident.

nonagitating unit: containers, mounted on trucks or other vehicles, for delivering central-mixed concrete, not constructed or equipped to keep the mass of concrete in motion in the container.

NOTE: "Buckets" are not considered as nonagitating delivery units.

placement point: the point of discharge of plastic concrete into the forms. Except for pumped concrete, the placement point and the delivery point are considered coincident when 5 min or less is used in transit of the concrete from the delivery point to the placement point. Correlation testing may be employed to demonstrate that placement point and delivery point of pumped concrete are coincident.

qualification tests: tests performed to qualify the basic material source or manufacturer to ensure conformance to specification requirements.

ready-mix truck: concrete mixers on trucks or other vehicles, capable of uniformly mixing concrete ingredients after they have been batched at the plant.

truck-agitating unit: drums or containers, mounted on trucks or other vehicles, in which central-mixed concrete is kept sufficiently in motion during delivery to prevent segregation.

200 GENERAL REQUIREMENTS

The requirements of Subpart 2.5 apply to any organization or individual participating in work relating to production, preparation, placement, installation, inspection, and testing of structural concrete, structural steel, soils, and foundations, and applies to the following:

(a) formwork
(b) steel reinforcement
(c) embedded items
(d) foundation preparation
(e) concrete
(f) structural steel
(g) soils and earthwork
(h) special foundations, including piles and caissons as identified in para. 601
(i) foundation underpinning

300 REQUIREMENTS

Measures shall be established and implemented for documenting installation, inspection, and testing activities to verify conformance to specified requirements.

301 Planning and Procedures

Planning and procedure preparation shall be in accordance with the Introduction to Part II.

302 Control of Measuring and Test Equipment

Measuring and test equipment used to implement the requirements of Subpart 2.5 that affect quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits per Part I, Requirement 12. This includes, but is not limited to, thermometers, balances, scales, air entrainment meters, volumetric buckets, field measuring devices, pressure gages, and torque wrenches.

303 Laboratory Testing

Laboratory operations and testing associated with concrete and soils shall be controlled using a quality assurance program. Such testing laboratories shall conform to ASTM C1077 and D3740.

400 PRECONSTRUCTION VERIFICATION

401 General

Receipt and interim storage inspections shall be used to verify that items are in a satisfactory condition for installation. The verification shall include the following:

(a) visual inspection of material for proper identification, physical damage, and contamination
(b) review of manufacturer's documentation, test reports, or other evidence of quality conformance for correctness and compliance with specifications if not reviewed at time of receipt

402 Materials Suitability

To ensure that materials meet specified requirements, preconstruction qualification tests and inspections of the materials to be used and in-process tests of materials being used shall be conducted.

Qualification tests shall be performed and the results evaluated prior to the initial use of the material to establish conformance of the materials to the specified requirements. These tests are mandatory unless current documentary test data are available to establish complete confidence in conformance to specification requirements. The specifications shall identify the required qualification tests and the frequency for their repetition. The tests required for concrete, concrete constituents, materials for reinforcing systems, materials for prestressing systems, and welding materials shall be in accordance with the ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359).

Concrete mix designs shall be batched and mixed in accordance with ASTM C94, Standard Specification for Ready Mix Concrete, or ASTM C685, Standard Specification for Concrete Made by Volumetric Batching and Continuous Mixing.

Normal, heavyweight, and mass concrete mix designs shall be proportioned in accordance with ACI 211.1, Standard Practice for Selecting Proportions for Normal, Heavyweight, and Mass Concrete.

Lightweight concrete mix designs shall be proportioned in accordance with ACI 211.2, Standard Practice for Selecting Proportions for Structural Lightweight Concrete. Lightweight concrete aggregates shall be qualified by tests for conformance with ASTM C330. When splitting tensile strengths are required for lightweight concrete mix, the methods given in ASTM C330 shall be used. Additional tests may be required to qualify materials for special application.

403 Construction Processes

Inspections shall be performed to verify that the prerequisites for control of construction processes such as welding, structural bolting, mechanical splicing of reinforcement, and concrete measuring, mixing, transporting, placing, and curing have been accomplished. These inspections shall include verification of the following:

(a) the process has been qualified as required
(b) process controls are in effect
(c) approved procedures, instruction manuals, or both, if required for specific equipment, are available for use during construction
(d) the process is suitable for the particular application
(e) manpower, equipment (including measuring and testing equipment), and materials are readily available and adequate to perform the work in accordance with drawing and specification requirements

500 INSPECTION OF SOILS AND EARTHWORK

501 General

Inspection of soils and earthwork shall include preparations for earthwork, as well as in-process inspections of placing and compacting operation, to ensure conformance to specified requirements.

502 Materials

Inspections and qualification testing of stockpiles or borrow pits shall be performed to verify conformance to specified requirements. Qualification tests of soil fill materials shall be performed for

(a) grain size analysis using ASTM D422

(b) moisture-density relationship of soil using ASTM D698 or D1557

(c) maximum and minimum index density of soils using ASTM D4253 and D4254

(d) liquid limit, plastic limit, and plasticity index of soils using ASTM D4318

(e) unified soil classification using ASTM D653, D2487, and D2488

Other qualification tests of soil fill materials may be used when specified.

503 Placing and Compacting Equipment

Inspections shall be performed prior to compacting operations to verify the adequacy of compacting equipment. These inspections shall include the following:

(a) inspections to verify that compacting equipment has specified weight, if applicable

(b) inspections to verify that the specified type of equipment is available and in operating condition

(c) inspections of vibratory compaction equipment to verify proper functionality and that the correct vibration frequency setting is being used, if specified

504 Preplacement Preparations

Inspections of preparations for fill placement shall include the following:

(a) inspections to ensure compliance with site preparation requirements

(b) inspections to ensure that the subgrade surface is within specified limits

(c) inspections to ensure that the subgrade is free of deleterious materials and voids and in compliance with specified requirements

(d) inspections to ensure that the subgrade is free of excess moisture, snow, frost, or frozen lumps

(e) inspections to verify that subgrade preparation meets specified requirements

(f) documentation of the inspections required by paras. 504(a) through (e) of this Subpart shall be verified as being complete and indicating that all inspection results are satisfactory

505 Soil Compaction

Inspections of soil compaction during construction shall be performed to verify the following:

(a) fill material meets specified requirements

(b) segregation of the fill material does not occur as it is dumped and spread

(c) specified lift thicknesses are not exceeded

(d) when specified, a knitting technique is used when joining lifts and where fill is placed against existing earth slopes or adjacent to previously compacted fills

(e) proper location and installation of underdrains, where specified

(f) the compacting equipment makes the specified number of passes over each lift and that passes overlap

(g) heavy compaction equipment is not operated adjacent to concrete until concrete has achieved the appropriate specified strength prior to being subjected to compaction loads

(h) heavy compaction equipment does not exceed maximum loads specified for buried structures

(i) moisture control during compaction

506 In-Process Tests on Compacted Fill

In-process tests shall be performed during the course of construction to maintain control of soil compaction. A list of the in-process tests for soils is shown in Table 506 of this Subpart. The need for each specific test shall be established in the specifications. In-process tests shall be performed more frequently if the test results are erratic, or if the trend of results or an apparent change in material characteristics indicates that the frequency should be increased.

600 INSPECTION OF FOUNDATION PILE AND CAISSON CONSTRUCTION[1]

601 Piles

601.1 Pile Receiving, Handling, and Storage. Inspections shall be performed to verify that the specified material has been received and to verify the adequacy and proper handling techniques. These inspections shall include the following:

(a) receiving inspection

(b) inspection of handling procedure to verify that proper lifting points and lifting techniques are used

(c) inspection of storage procedure to verify that suitable storage areas have been designated, that blocking is adequately and properly located, and that piles can be rehandled without damage

(d) inspection of procedure for transporting piles from storage area to driving location to verify that

[1] Applicable for nonreactor containment structures only. This section is not applicable to reactor containment structures because piles and caissons are typically not used for U.S. commercial nuclear reactor containment structures.

Table 506 Required In-Process Tests for Compacted Fill

Material	Requirements	Test Method	Test Frequency
Soil	Moisture-density relationship of soils or maximum-minimum index density of soils	ASTM D698 or D1557; Method A, B, C, or D, or ASTM D4253 and D4254, as specified	At least one for each soil type and whenever soil type visually changes or is otherwise questionable
	Grain size	ASTM D422 hydrometer or sieve, as appropriate	One for each density relationship test
	Plasticity index	ASTM D4318	One for each density relationship test and when volume change characteristics are questionable
	Soil moisture	ASTM D6938 or ASTM D2216, as specified (ASTM D6938 shall be correlated to results obtained using ASTM D2216)	One for each field density test and when moisture content changes are questionable
	Field density test	ASTM D1556 or D2167, supplemented by ASTM D6938 or D2937, as specified	Test as specified in owner's specification with the following as minimum: *(a)* one for every 2,000 yd^3 of material placed for mass earthwork *(b)* one for every 1,000 yd^3 of material in relatively thin sections for canal or reservoir lining *(c)* one for every 200 yd^3 to 300 yd^3 of backfill in trenches or surrounding structures *(d)* at least one test for every lift of compaction operations on mass earthwork *(e)* one test whenever there is a suspicion of the quality of moisture control or effectiveness of compaction
	Fines content	ASTM D1140	One for each density relationship test and every 100,000 ft^2 (9 290 m^2)

GENERAL NOTE: These test frequencies shall be considered minimum unless documentary test data are available to establish adequate confidence in conformance with specification requirements.

proper support and lifting points are utilized, that proper lifting technique is used to position the pile for driving, and that the pile to be driven is undamaged and as specified

601.2 Pile Driving and Cast-in-Place Pile Construction. Pile driving and cast-in-place pile construction shall be inspected to verify that the specified piles are properly located from site baselines and elevation benches (located according to length and capacity), that the surface from which the piles will be driven has been properly prepared, excavated to the designated driving elevation, and drained or dewatered, as specified, and that pile driving equipment in compliance with the specification is available.

601.2.1 Installation of Wood, Steel, and Precast Concrete Piles, and Cast-in-Place Concrete Piles With Permanent Casing and Shell. The installation of wood, steel, and precast concrete piles, and the shells or casing for cast-in-place concrete piles shall be inspected to verify the following:

(a) the specified pile hammer is being used and is operating at the required speed (blows/minute) and stroke, if specified

(b) the pile being installed is the specified type and length

(c) the pile is installed within specified tolerances of locations, plumb, and rotation or to the specified batter and tip elevation, and that the blow counts are as specified

(d) the proper type of cushioning materials is used between the hammer and the pile and to ensure that piles are not being damaged during driving

(e) the follower used on piles with the final top elevation below the existing grade is compatible with the driving characteristics of the pile

(f) the piles that are adjacent to the pile being installed are checked for heave and reinstalled if required

(g) the sequence of pile installation is as specified in order to avoid displacement of piles in place

(h) documentation and reporting of any observed damage to adjacent structures that may have been caused or worsened due to pile-driving operations

(i) drilling and jetting are only done when specified and are performed in accordance with the specifications

(j) complete records are made of pile driving resistance

601.2.2 Concrete Placement in Cast-in-Place Piles With Permanent Casing. Prior to concreting cast-in-place concrete piles, inspection shall be performed to verify the following:

(a) the casing has not buckled or ruptured

(b) the casing is straight

(c) the casing is dewatered and cleaned to the tip elevation

(d) the reinforcement is installed and positioned as specified and is secured against displacement during concreting

(e) the volume of concrete used is consistent with the estimated required volume

The placement of concrete in the pile casing shall be inspected to verify that it conforms with paras. 705 and 707 of this Subpart, as applicable.

601.2.3 Concrete Placement for Cast-in-Place Piles Without Permanent Casing. The construction of cast-in-place piles without permanent casing shall be inspected to verify the following:

(a) the volume of concrete used is consistent with the estimated required volume

(b) the method for withdrawing the casing will not cause separation of the pile concrete, nor alter the position of the reinforcing steel

(c) the method for withdrawing the casing during the placing of the concrete maintains a level of concrete sufficiently above the bottom of the casing to avoid separation of the pile concrete, soil intruding or necking down the concrete pile, and movement of the reinforcing steel, if placed

(d) the placement of concrete in the pile casing conforms with paras. 705 and 707 of this Subpart

(e) grouting pressure or compaction energy used to form the pile is specified

601.2.4 Pile Splicing. The construction of composite piles and the splicing of piles with the specified section above and below the splice shall be inspected to verify the following:

(a) the top section is properly aligned with the bottom section

(b) the splice interface is clean and is properly prepared and spaced for application of the splicing material

(c) the pile is at the specified temperature limits for splicing and that the splice is installed in accordance with applicable standards and specifications

601.2.5 Inspection of Concrete Construction. Concrete construction of cast-in-place piles and protective concrete cast around piles shall be inspected in accordance with section 700 of this Subpart.

601.2.6 Test Piles. Test piles shall be inspected to verify that

(a) load tests are made on piles driven or cast-in-place in the same manner as production piles

(b) the driving or construction is in accordance with the applicable paragraphs above

(c) the performance of load testing and integrity testing is in accordance with ASTM D1143, Method of Testing Piles Under Static Axial Compressive Load

602 Caissons

602.1 Caisson excavation shall be inspected to verify that

(a) caissons are correctly located

(b) the caisson shaft is straight and plumb, or to the specified batter, and suitable means are employed to maintain the shaft diameter

(c) the bottom of the caisson is at the specified elevation and is level, or is excavated in steps as necessary to provide level and uniform bearing over the full base area

(d) there are no unacceptable voids, caverns, or strata of compressible material below the bottom of the caisson

(e) underreamed caissons have the specified bottom diameter and side slope

(f) the rock socket of drilled-in caissons is the specified diameter and depth

(g) the shear rings of friction caissons are the specified size and spacing

602.2 Caisson concrete construction shall be inspected in accordance with section 700 of this Subpart. Also, the performance of load testing and integrity testing shall be conducted in accordance with specified requirements.

In addition, caisson concrete shall be inspected to verify that

(a) all loose soil has been removed from the bottom of the caisson excavation prior to concreting

(b) the caisson excavation has been dewatered or that approved means of placing concrete underwater are employed

(c) sufficient head of concrete is maintained above the bottom of the casing while it is being withdrawn to avoid soil intrusion or necking down of the concrete shaft

(d) method of withdrawal of the casing prevents voids in or separation of the concrete shaft

(e) approved methods of proportioning and placing concrete are employed in slurry-stabilized caisson to prevent segregation or mixing with slurry and to ensure specified concrete strength

(f) the volume of concrete used is consistent with the estimated required volume

603 Required Qualification Tests

The required qualification tests are as follows:

(a) Wood piles shall conform to specifications such as ASTM D25, and AWPA C3, and ASTM D1760 for wood preservation treatment.

(b) Steel piles shall conform to specifications such as ASTM A252 for pipe, and ASTM A6 and A36 for structural shapes.

(c) Concrete piles (precast, cast in place, and prestressed) shall conform to approved specifications used in the manufacturer's certification (e.g., ACI 543, Design, Manufacture, and Installation of Concrete Piles), or as specified.

700 INSPECTION OF CONCRETE CONSTRUCTION

701 General

Inspection of concrete construction shall include inspection of preparations for concreting, as well as in-process inspections of concrete measuring, mixing, transporting, placement, curing, and protection to ensure conformance to specified requirements. The inspection of pretensioning or post-tensioning systems shall be included, if applicable. The inspection shall follow ACI Standard 311.4R, Guide for Concrete Inspection, and PCI MNL-116 and MNL-117.

702 Protection of Materials

Inspections shall be performed to verify the adequacy and proper maintenance of material storage conditions and handling techniques. These inspections shall include the following:

(a) inspection of cement storage facilities to verify weathertightness, cement temperature, and the absence of lumps, and review of records to verify type and age of cement

(b) inspection of aggregate stockpiles to verify that

(1) handling techniques are not resulting in segregation

(2) storage and handling adequately prevent contamination with deleterious substances or mixing with other aggregates

(3) specified temperature and uniform moisture control are maintained

(4) use of frozen materials is prevented

(c) inspection of admixture storage and handling facilities to verify that deterioration and contamination are prevented and that admixtures are protected from freezing

(d) inspection of water sources and cooling and heating facilities to verify the specified water quality and to ensure that the specifications for concrete temperatures are met

(e) inspection of reinforcing material, embedments, and prestressing systems materials (wire, strand, tendons, tendon tubes, and temporary or permanent anchor hardware) to verify protection against excessive corrosion, contamination, and physical damage

703 Measuring, Mixing, and Transporting Equipment

Concrete batching and mixing facilities shall be certified to be in accordance with the requirements of the National Ready-Mix Concrete Association (NRMCA). Inspections shall be performed prior to and during the production of concrete to verify the adequacy and proper operation of measuring, mixing, and transporting equipment in accordance with ACI 304, ASTM C94, and the NRMCA Plant Certification Checklist. These inspections shall include the following:

(a) inspection of measuring facilities for the specified accuracy of measuring, weighing, and weight recording devices to control the following:

(1) proportions of cement, water, and aggregates

(2) quantities of admixtures

(3) aggregate moisture compensation

(4) mixing time

(5) temperature control, heating or cooling of concrete

(6) method of adding water when batching lightweight aggregates in accordance with ACI Standard 301

(b) inspection of central mix plant and truck mixers for wear of drum blades, availability of revolution counter and water-measuring devices, proper speed of rotation, and ability to mix concrete completely in the specified time.

704 Preplacement Preparations

Inspection of preparations for concrete placement shall include the following:

(a) inspection of the compacted structural fill or undisturbed soil to verify correct condition

(b) inspection and field testing, in accordance with the specifications of all structural fill, undisturbed soil, and rock surfaces that will be in contact with structural concrete to verify surface cleanness, removal of loose rock and free water, correct contour, and specified subgrade condition

(c) inspection of previously placed concrete to verify proper joint preparation

(d) inspection of formwork to verify

(1) correct location and configuration, dimensional accuracy, and proper line and grade of formwork

(2) installation and integrity of water stops and membrane waterproofing

(3) condition of form material to produce the specified concrete finish, installation of ties, anchors, bracing, shoring, and supports to prevent movement during concrete placement

(4) correct location and dimensions of blockouts, proper form coating, and cleanness inspection of forms for tightness and placement of grout and vent pipes when preplaced aggregate concrete is used

(e) inspection of reinforcing steel, prestressing components (if applicable), and other embedded items to verify

(1) correct size, number, material (ASTM bar specification), location, position, cleanness, and leak tightness, if applicable

(2) proper stringing and absence of physical damage to pretensioning strands or tendons

(f) inspection of mechanical reinforcing bar splicing operations to verify conformance to the requirements or para. 712 of this Subpart

(g) inspection by use of a mandrel or similar device to ensure that the tendon conduits are open and remain open during the concrete placing operation

(h) inspection of pretensioning load cells and pressure gages for accuracy and calibration, if applicable

(i) inspection of pretensioning system strand vises for cleanness, proper lubrication, wear, distortion, and cracking, if applicable

(j) inspection of the pretensioning operation, if applicable, to verify

(1) initial tensioning of each strand to eliminate slack and to provide a uniform initial stress condition in all strands prior to final stressing

(2) proper measurement and correlation of jack pressure (or load cell reading) and strand or tendon elongation

(3) proper correction for elongation losses, due to strand slippage in the rises and movement of anchorage abutments

(k) inspection of groundwater control, as specified

(l) inspection for embedments

Documentation of the inspections required by paras. 704(a) through (l) of this Subpart shall be verified as being complete and indicating that all inspection results are satisfactory.

705 Concrete Placement

Inspection of concrete placement shall be performed to verify the following:

(a) specified tests of concrete have been performed

(b) adherence to specified requirements for class of concrete, time of placement from batching, mixing revolutions, rate of placement, lift height, placing sequence, concrete temperature, and hot or cold weather concreting practice (ACI Standard 305 or 306, respectively)

(c) proper use of adequate conveying and placing equipment

(d) materials harmful to the concrete are not used in covering or placing the concrete

(e) adequate concrete consolidation equipment and technique of operation (ACI Standard 309)

(f) neither embedded items are disturbed nor forms are displaced

706 Finishing and Repairs

Inspections shall be performed to verify that specified finishes are obtained, i.e., wood float, steel trowel, as cast, or other type. After forms have been removed, inspections shall be performed to verify that the formed surfaces have been repaired and finished in accordance with specified requirements.

Any indication of honeycomb, voids, or contamination, such as at a construction joint, shall be explored by physical removal of concrete, if necessary, to determine the extent of such voids or contamination. Appropriate repairs shall be made. Noncosmetic repairs, such as those extending behind reinforcement or damaged induced by loading or other type of stress, shall be as directed by the responsible design organization if not covered by approved repair procedures.

707 Curing

Qualification tests shall be performed on liquid membrane forming curing compounds and sheet materials for concrete curing for compliance with ASTM C309 or ASTM C171, as applicable.

Inspections shall be performed throughout the specified curing period to verify the following:

(a) correct curing method is used, i.e., use of ponding, fog spray, wet burlap, curing compound, or other methods in accordance with specified requirements

(b) concrete is kept continuously, i.e., not periodically, wet during the entire curing period, if one of the wet curing methods is used

(c) membrane curing compounds are specifically approved for use prior to application

(d) curing temperature is maintained within specified limits during the entire curing period

(e) shoring and forms are left in place, and precast concrete members are left in the forms until concrete has reached specified strength necessary to preclude the possibility of damage from construction loads

(f) concrete test cylinders are subjected to the same curing process as the placed concrete when field-cured cylinders are required to evaluate curing methods

708 Stress Transfer of Pretensioned Members

If applicable, inspections shall be performed to verify the following:

(a) the concrete strength, as indicated by test cylinders, is in accordance with the specified transfer strength prior to the transfer of prestressing load to the member

(b) stress transfer is performed within the specified temperature limits for heat-cured members

(c) forms, ties, inserts, hold downs, or other devices that would restrict longitudinal movement of the member(s) are removed, or loosened in a specific sequence to or in conjunction with stress transfer

(d) the stress transfer is performed following an approved stressing procedure and sequence

709 Post-Tensioning

Inspections shall be performed prior to and during post-tensioning, if applicable, to verify the following:

(a) the concrete strength, as indicated by test cylinders, is in accordance with the specified strength at the time of prestress or at the time of post-tensioning.

(b) the tendons and tendon ducts of ungrouted tendons have been treated with the specified lubricant, or corrosion-inhibiting compound, prior to tendon installation.

(c) the tendons are tensioned (from both ends if so specified) in accordance with the specified prestressing sequence.

(d) there is proper measurement and correlation of jack pressure (or load cell reading) and tendon elongation as well as proper correction for elongation, or prestress seating losses.

(e) the anchorage details (buttonheads, friction grip, wedge grip, threaded, etc.) are in accordance with the specified requirements both prior to and after tensioning.

(f) the grouted tendon ducts are free from excessive moisture prior to grouting. The grout material and the grouting operation are in accordance with specified requirements.

710 Shipping and Handling of Precast Concrete Members

Inspections shall be performed prior to and during erection to verify that

(a) members are handled only by means of approved devices at designated locations or pick-up points

(b) suitable foundations are provided for storage of precast members

(c) stacked members are separated and supported by battens placed across the full width of the designated bearing points

(d) cracking, spalling, and other defects caused by shipping and handling of the precast members do not exceed the specified limits

711 In-Process Tests on Concrete

In-process tests shall be performed during the course of construction to maintain control of structural, prestressed, and precast concrete. The tests that are required and the frequency shall be in accordance with the ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359) and Code Requirements for Nuclear Safety-Related Concrete Structures (ACI 349-06) and Commentary (ACI Standard 349), except as follows:

The ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359) test frequencies for the following tests shall be considered minimum, unless current documentary test data are available to establish adequate confidence in conformance of materials to specified requirements:

(a) for concrete materials: unit weight/yield

(b) for aggregate materials

(1) unit weight of aggregate

(2) fixed water and iron content of aggregate only for radiation-shielding concrete

(3) organic impurities

(4) flat and elongated particles

(5) lightweight particles

(6) specific gravity and absorption

(7) Los Angeles abrasion

(8) potential reactivity

(9) soundness

The reduction of frequency of testing must be documented, and referenced documentation must be representative of the material currently being certified with the results of prior testing.

Additionally, mixing water and ice, if not potable, shall be tested per the requirements and frequencies of ASTM C1602, Standard Specification for Mixing Water Used in the Production of Hydraulic Cement Concrete, for effect on compressive strength, deviation on time of set, chloride content, sulfate content, total dissolved solids, and alkalies.

In-process tests shall be performed more frequently if test results are erratic or if the trend of results indicates an apparent change in material characteristics.

In-process tests shall be performed on samples of concrete aggregates designated for construction use to ensure they conform to specifications prior to use. Periodic correlation tests shall be conducted to ensure the uniformity of the concrete aggregates is maintained from aggregate supply source to concrete batch plant.

Samples for in-process tests of concrete shall be taken following the procedures of ASTM C172, except as defined herein regarding location of sampling. No water or other ingredients may be added to any concrete batch after obtaining the in-process sample. Samples shall not be taken from concrete deposited in the form. Except as noted below, the sampling point for taking in-process test samples of plastic concrete shall be performed at the placement point or other points coincident thereto.

For sampling purposes, delivery point and placement point can be considered coincident when placement is by chute, wheelbarrow, or bucket, and time of conveyance to the forms does not exceed 5 min or when correlation testing shows no significant change to the concrete properties following conveyance (1-in. maximum variance in slump; 1.0% maximum variance in air content).

Where conveyance systems with the potential of significantly altering concrete properties are employed, correlation testing shall be conducted daily to establish concrete properties needed at the delivery point to provide concrete as specified at the point of placement. Correlation testing shall be repeated whenever the

equipment or conveyance delivery configuration significantly changes or whenever concrete quality is in question.

Where correlation tests of slump, air content, or temperature of concrete placed by a conveyance system show changes beyond specified allowances, repeat correlation testing every 100 yd^3 (75.6 m^3) or until changes return to allowable limits.

712 Mechanical Splice Testing

The mechanical splice testing for permitted splice systems shall be done in accordance with the requirements of the ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359) and Code Requirements for Nuclear Safety-Related Concrete Structures (ACI 349-06) and Commentary (ACI Standard 349).

713 Welded Reinforcing Bar Splices

Welded reinforcing bar splices shall be subject to the requirements of para. 805 of Subpart 2.5, except that provisions of the ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359), shall also apply.

714 Bending of Reinforcement

Bending of reinforcing bars shall comply with provisions of the ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359), Section CC-4320. Field bending of bars partially embedded in set concrete shall not be permitted except as specifically approved by the responsible design organization.

800 INSPECTION OF STEEL CONSTRUCTION

801 General

Structural steel qualification shall be documented by manufacturer's certification showing conformance to specifications such as ASTM A36, A441, or as otherwise specified.

Inspection of steel construction in accordance with the AISC 360, Specification for Structural Steel Buildings, shall include inspection of assembly and erection operations, fastening or connecting operations such as high strength bolting and welding, and finishing operations such as cleaning and protective painting or coating.

Inspection of steel construction shall include inspection of related items, such as anchor bolts and baseplates, that may be part of the supporting structure and installed as part of the structural concrete work.

802 Supporting Structures

Prior to erection of steel, anchor bolts, baseplates, and other structural embedments shall be checked for correct orientation, spacing, and elevation. Baseplate surfaces and supporting concrete surfaces shall be checked to verify satisfactory conditions for grouting.

Grouting of baseplates, beam pockets, etc., shall be controlled and inspected to verify that only specified materials are used, proportioned properly, placed correctly, and cured properly to achieve the specified compressive strength.

803 Assembly and Erection

Assembly and erection operations shall be inspected to verify compliance with installation procedures and work instructions. Alignment operations shall be carried out early enough and as often as is necessary as erection progresses to ensure that specified requirements are met.

Particular attention shall be given to verification of the condition of contact surfaces of friction-type connections and bolt hole alignment. Correction of fabrication errors shall be closely controlled to prevent correction of misaligned holes by reaming in excess of AISC tolerances. Burning of bolt holes is not permitted. Equipment used in connecting operations shall be inspected to verify conformance with specification requirements. For example, air compressors shall be of sufficient capacity to maintain the required operating pressures for impact tools.

Control and monitoring of type of contact surface coating (to provide adequate friction in slip critical joints) shall be conducted.

804 High-Strength Bolting

Installation of high-strength bolts shall be in accordance with Research Council on Structural Connections (RCSC), Specification for Structural Joints using ASTM A325 or A490 Bolts and with AISC N690, Specification for Safety-Related Steel Structures for Nuclear Facilities. Manufacturer's certifications for bolting materials shall be provided with each lot received.

For snug-tight installations, the inspector shall verify that proper bolting materials are used and that all plies of metal are brought together. Snug condition shall be verified by checking 10% or a minimum of two bolts at each connection, whichever is greater.

For fully tensioned connections, a calibrated tension-measuring device shall be required at all job sites. As verified by the inspector, the contractor shall demonstrate that required tension is achieved by the specified or selected installation method being employed.

Procedures for verifying tension installation and establishing a job inspection torque for checking installations in question shall be as given in the AISC document referenced above. The inspector shall monitor the installation of fully tensioned bolts to verify that the selected installation procedure is properly applied, proper bolting materials are used, and all plies of metal are brought together.

For turn-of-the-nut installations, a marking system shall be employed that allows confirmation of proper rotation from the snug-tight condition.

804.1 Inspection of Bolting. Inspection of bolting shall include visual inspection of bolting operations and torque wrench inspection of completed connections. Connection points shall be visually inspected for the following items:

(a) bolts are long enough as indicated by the point of the bolts being flush with or outside the face of the nuts

(b) correct type bolt is used as indicated by the manufacturer's marking on the head

(c) torque has been applied as indicated by the burnishing or peening of the corners of the nut

(d) turning elements are on the correct face; properly sized washers are used when required

Bolt tension inspection shall be as specified in the RCSC Specification and with AISC N690, Specification for Safety-Related Steel Structures for Nuclear Facilities. In addition, during the initial phase of bolting operations, all bolts tightened by each bolting crew shall be checked until the results are consistently acceptable.

804.2 Inspection Tools and Procedure. Hand torque wrenches used for inspection shall be controlled in accordance with Part I and shall be calibrated at least weekly, more often if deemed necessary. Impact torque wrenches used for inspection shall be calibrated at least twice daily. Feeler gauges used for inspection of direct-tension indicators shall be controlled.

805 Welding

Inspection of structural steel welding shall be performed in accordance with the provisions of Section 6.0 of AWS D1.1, Structural Welding Code — Steel. This inspection shall include visual examination of preparations, welding processes, postwelding operations, and, if deemed necessary, some NDE inspections that are appropriate to the application. Prior to welding, verification of welding procedure and welder qualification shall be documented and shall include all essential variables identified in the procedures. In-process inspections shall include acceptability of environmental conditions, joint fit-up prior to start of welding, preheat and interpass temperature requirements, filler metal, control of distortion, postweld heat treatment, and cleaning requirements. Procedures shall be established to control the purchase, receiving, distribution, storage, and use of welding electrodes.

Weld repairs necessitated by visual or nondestructive examinations shall be made in accordance with the procedure used to perform the original weld or a qualified repair procedure and reinspected by the same method that disclosed the repairable defect. All weld repairs necessitated by nondestructive examination shall be documented.

900 DATA ANALYSIS AND EVALUATION

901 General

Procedures shall be established for processing inspection and test data and their analysis and evaluation. These procedures shall provide for acquisitions and preparation of inspection and test data for prompt evaluation against acceptance criteria, operating limits, and performance standards. The data processing procedures shall provide for on-the-spot evaluation to determine the validity of the inspection and test results and the appropriateness of continuing the inspection or test. The data shall be analyzed and evaluated to verify completeness of results and achievement of inspection and test objectives; and to identify additional inspection and tests required, and necessary changes to the installation inspection or test procedures. Inspection and test results that include inspection and test data, together with a report of data analysis and evaluation, shall be provided as specified in section 1000 of this Subpart. When test data are found to not meet acceptance criteria, steps shall be taken to assess the implications of such and take appropriate corrective and preventive measures.

902 Concrete and Mechanical Splice Test Data Evaluation and Analysis

902.1 Evaluation of Concrete Test Results. Standard deviation data shall be developed, evaluated, and maintained for permanent records in accordance with ACI Standard 214. Concrete quality and acceptance criteria shall conform to the requirements of ACI Standard 318, Chapter 4.

902.2 Evaluation of Mechanical Splice Test Results. The evaluation of mechanical splice test results shall be in accordance with ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359).

902.3 Evaluations of Aggregate Test Results. When any aggregate tests specified fail to meet the specified requirements, two additional tests shall be made from samples of the same lot of aggregate. If one or both of the two additional tests fail to meet the specified requirements, the data shall be submitted to the responsible engineering organization for evaluation and corrective action.

903 Steel Construction Test Data Evaluation and Analysis

This data shall be evaluated for conformance to project specifications of the AISC M011, Manual of Steel Construction and AWS D1.1, Structural Welding Code — Steel.

904 Soils Test Data Evaluation and Analysis

This data shall be evaluated daily during progress of the work for conformance to project specifications. The

control techniques given in the specifications, such as specific test methods for the type of soil compacted, shall be verified. Data shall include determination of parameters specified, including use of proper materials, amounts and uniformity of soil moisture, and thickness of layers being placed. In-place compacted fill density shall be determined using standard approved methods and the results evaluated for compliance to specified requirements. Data shall include verification that the soils are fully compacted or consolidated to contours and the grades specified. When statistical methods are required by the specification, the desired level of confidence shall be specified.

1000 RECORDS

Record copies of procedures, reports, personnel qualification records, test equipment calibration records, test deviation or exception records, and inspection and examination records shall be prepared. These shall be retained with other project records as required by code, standard, specification, or project procedures.

SUBPART 2.7
Quality Assurance Requirements for Computer Software for Nuclear Facility Applications

(15) 100 GENERAL

Subpart 2.7 provides requirements for the acquisition, development, operation, maintenance, and retirement of software. The appropriate requirements of this Subpart shall be implemented through the policies, procedures, plans, specifications, or work practices, etc., that provide the framework for software engineering activities. Subpart 2.7 supplements the requirements of Part I and shall be used in conjunction with applicable Requirements of Part I when and to the extent specified by the organization invoking the Subpart.[1]

101 Software Engineering

The scope of software engineering activities includes the following elements, as appropriate:

(a) software acquisition method(s) for controlling the acquisition process for software and software services

(b) software engineering method(s) used to manage the software life-cycle activities

(c) application of standards, conventions, and other work practices that support the software life cycle

(d) controls for support software used to develop, operate, and maintain computer programs

(15) 102 Definitions

acceptance testing, also known as *software validation:* the process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment.

baseline: a specification or product that has been formally reviewed and agreed upon, that thereafter serves as the basis for use and further development, and that can be changed only by using an approved change control process.

change control:[2] an element of configuration management consisting of the evaluation, coordination, approval or disapproval, and implementation of changes to configuration items after formal establishment of their configuration identification.

configuration item:[2] a collection of hardware or software elements treated as a unit for the purpose of configuration control.

configuration management (software): the process of identifying and defining the configuration items in a system (i.e., software and hardware), controlling the release and change of these items throughout the system's life cycle, and recording and reporting the status of configuration items and change requests.

control point: a point in the software life cycle at which specified agreements or controls (typically a test or review) are applied to the software configuration items being developed, e.g., an approved baseline or release of a specified document or computer program.

error: a condition deviating from an established baseline, including deviations from the current approved computer program and its baseline requirements.

operating environment: a collection of software, firmware, and hardware elements that provide for the execution of computer programs.

regression testing:[2] selective retesting to detect errors introduced during modification of the computer program or to verify that the modified computer program still meets its specified requirements.

software design verification: the process of determining if the product of the software design activity fulfills the software design requirements.

software development cycle:[2] the activities that begin with the decision to develop a software product and end when the software is delivered. The software development cycle typically includes the following activities:

(a) software design requirements

(b) software design

(c) implementation

[1] Regulatory Guides 1.152, Criteria for Use of Computers in Safety Systems of Nuclear Power Plants, and 1.168, Verification, Validation, Reviews, and Audits for Digital Computer Software Used in Safety Systems of Nuclear Power Plants, provide guidance for nuclear power plant licensees and their suppliers on acceptable methods and techniques.

[2] This definition has been copied or adapted from ANSI/IEEE Std. 610.12-1990, Glossary of Software Engineering Terminology, with the permission of IEEE.

(d) test

(e) sometimes installation

software engineering:[2]

(a) the application of a systematic, disciplined, quantifiable approach to the development, operation, and maintenance of software; that is, the application of engineering to software

(b) the study of approaches as in (a)

software life cycle:[2] the period of time that begins when a software product is conceived and ends when the software is no longer available for use. The life cycle typically includes a concept phase, requirements phase, design phase, implementation phase, test phase, installation and checkout phase, operation and maintenance phase, and, sometimes, retirement phase. These phases may overlap or be performed iteratively, depending on the software development approach used.

software tool:[2] a computer program used in the development, testing, analysis, or maintenance of a program or its documentation. Examples include comparators, cross-reference generators, compilers, CASE (Computer Aided Software Engineering) tools, configuration and code management software, decompilers, disassemblers, editors, flowcharters, monitor test case generators, and timing analyzers.

system software:[2] software designed to enable the operation and maintenance of a computer system and its associated computer programs.

test case: a set of test inputs, execution conditions, and expected results developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement.

testing (software): the process of

(a) operating a system (i.e., software and hardware) or system component under specified conditions

(b) observing and recording the results

(c) making an evaluation of some aspect of the system (i.e., software and hardware) or system component in order to verify that it satisfies specified requirements and to identify errors

test plan (procedure): a document that describes the approach to be followed for testing a system or component. Typical contents identify the items to be tested, tasks to be performed, and responsibilities for the testing activities.

200 GENERAL REQUIREMENTS

The following general requirements shall be applied to the software engineering elements described in para. 101 of this Subpart.

(15) 201 Documentation and Records

The appropriate software engineering elements, described in para. 101 of this Subpart, shall define the baseline documents that are to be maintained as records, in accordance with Part I, Requirement 17. Although multiple documentation requirements are specified within this Subpart, they can be provided as separate or as combined documents.

202 Verification (15)

The appropriate software engineering elements, described in para. 101 of this Subpart, shall define the control points and associated reviews. Reviews of software shall ensure compliance with the approved software design requirements. Although multiple review requirements are specified within this Subpart, the reviews may be performed and documented separately or combined, as appropriate, to the defined software engineering method. The following two reviews are required:

(a) One review shall consider the requirements related to the activities of preparing the computer program for acceptance testing. This review can be combined with or be part of the software design verification.

(b) The other review shall provide assurance of the satisfactory completion of the software development cycle including acceptance testing. This review can be combined with or be part of software design verification. Individual(s) familiar with the design detail and the intended use of the computer program shall be included in the review.

Reviews shall identify the participants and their specific review responsibilities. Documentation of review comments and their disposition shall be retained until they are incorporated into the updated software. Comments not incorporated and their disposition shall be retained until the software is approved for use. When review alone is not adequate to determine if requirements are met, alternate calculations shall be used, or tests shall be developed and integrated into the appropriate activities of the software development cycle.

Tests performed in support of a review can be used to complement acceptance testing. The tests and test results shall be included in the acceptance testing documentation. Such tests shall be subjected to the same criteria as the acceptance tests. These tests do not substitute for performing the comprehensive, end of development, acceptance test.

203 Software Configuration Management (15)

Software configuration management includes, but is not limited to, configuration identification, change control, and configuration status control. Configuration items shall be maintained under configuration management until the software is retired.

The appropriate software engineering elements, described in para. 101 of this Subpart, shall identify when configuration baselines are to be established.

203.1 Configuration Identification. A labeling system for configuration items shall be implemented that

(a) uniquely identifies each configuration item

(b) identifies changes to configuration items by revision

(c) provides the ability to uniquely identify each configuration of the revised software available for use

203.2 Configuration Change Control

(a) The software configuration change control process shall include

(1) initiation, evaluation, and disposition of a change request

(2) control and approval of changes prior to implementation

(3) requirements for retesting (e.g., regression testing) and acceptance of the test results

(b) A software baseline shall be established at the completion of each activity of the software design process. Approved changes created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recently approved software configuration. Configuration items to be controlled as part of the baseline shall include, as appropriate

(1) documentation (e.g., software design requirements, instructions for computer program use, test plans, and results)

(2) computer program(s) (e.g., source, object, backup files)

(3) support software

(c) Changes to software shall be formally documented. The documentation shall include

(1) a description of the change

(2) the rationale for the change

(3) the identification of affected software baselines

The change shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. Only authorized changes shall be made to software baselines. Appropriate verification activities shall be performed for the change. The change shall be appropriately reflected in documentation, and traceability of the change to the software design requirement shall be maintained. Appropriate acceptance testing shall be performed for the change.

203.3 Configuration Status Control. The status of configuration items resulting from software design shall be maintained current. Configuration item changes shall be controlled until they are incorporated into the approved product baseline. The controls shall include a process for maintaining the status of changes that are proposed and approved but not implemented. The controls shall also provide for notification of this information to affected organizations.

204 Problem Reporting and Corrective Action

(a) Method(s) for documenting, evaluating, and correcting software problems shall

(1) describe the evaluation process for determining whether a reported problem is an error or other type of problem (e.g., user mistake)

(2) define the responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation

(b) When the problem is determined to be an error, the method shall provide, as appropriate, for

(1) how the error relates to appropriate software engineering elements

(2) how the error impacts past and present use of the computer program

(3) how the corrective action impacts previous development activities

(4) how the users are notified of the identified error, its impact, and how to avoid the error, pending implementation of corrective actions

The problem reporting and corrective action process shall address the appropriate requirements of Part I, Requirement 16.

300 SOFTWARE ACQUISITION

Software acquisition includes software or software services procured in accordance with Part I, or otherwise acquired for use in activities within the scope of Part I.

301 Procured Software and Software Services

Part I, Requirements 4 and 7 for items and services shall be applied to the procurement of software and software services. The Purchaser shall be responsible for the appropriate requirements of this Subpart upon acceptance of the software or related item (e.g., programmable device). Procurement documents shall identify requirements for Supplier's reporting of software errors to the Purchaser and, as appropriate, the Purchaser's reporting of software errors to the Supplier.

302 Otherwise Acquired Software (15)

Part I, Requirement 7, and Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services, shall be applied to acquired software that has not been previously approved under a program consistent with Part I of this Standard for use in its intended application. This includes computer programs not obtained using the procurement requirements of Part I, such as freeware, shareware, and computer programs from corporate repositories.

Otherwise acquired computer programs whose results are verified with the design analysis for each application as specified in Part I, Requirement 3, para. 401 are excluded from the requirements of Part II, Subpart 2.14.

Otherwise acquired computer programs shall be identified and controlled during the dedication process. The dedication process shall be documented and include the following:

(a) identification of the capabilities and limitations for intended use as critical characteristics

(b) utilization of test plans and test cases as the method of acceptance to demonstrate the capabilities within the limitations

(c) instructions for use (e.g., user manual) within the limits of the dedicated capabilities

The dedication process documentation and associated computer program(s) shall establish the current baseline.

Subsequent revisions of the software shall be dedicated in accordance with this section.

(15) 400 SOFTWARE ENGINEERING METHOD

Software engineering method(s) shall be documented. The selected software engineering method shall ensure that software life-cycle activities are planned and performed in a traceable and orderly manner.

The software design process shall be documented, approved by the responsible design organization, and controlled. This process shall include the activities described in paras. 401 through 404.

401 Software Design Requirements

Software design requirements shall specify technical and software engineering (i.e., para. 101 of this Subpart) requirements, including security features (e.g., vulnerability protection and cybersecurity).[3] Identify applicable reference drawings, specifications, codes, standards, regulations, procedures, or instructions that establish software design requirement test, inspection, and acceptance criteria. Security requirements shall be specified commensurate with the risk from unauthorized access or use. The software requirements shall identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program. Software design requirements shall be traceable throughout the software life cycle. Software design requirements shall be identified and documented and their selection reviewed and approved.

402 Software Design

An integral part of software design is the design of a computer program that is part of an overall system. Thus, the software design shall consider the computer program's operating environment. Measures to mitigate the consequences of problems, as identified through analysis, shall be an integral part of the design. These potential problems include external and internal abnormal conditions and events that can affect the computer program.

The software design shall be documented and shall define the computational sequence necessary to meet the software requirements. The documentation shall include, as applicable, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, process structures, and the applicable relationships between data structures and process structures. This documentation may be combined with the documentation of the software design requirements or the computer program listings resulting from implementation of the software design.

402.1 Software Design Verification. Software design verification shall evaluate the technical adequacy of the design approach and ensure internal completeness, consistency, clarity, and correctness of the software design and shall verify that software design is traceable to the software design requirements. Software design verification shall include review of test results. The software design verification shall be completed prior to approval of the computer program for use. The requirements for the software design verification activity shall be documented in the software engineering method.

Software design verification shall be performed by a competent individual(s) or group(s) other than those who developed and documented the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided

(a) the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design, or

(b) the supervisor is the only individual in the organization competent to perform the verification

Cursory supervisory reviews do not satisfy the intent of this Standard.

The results of verification shall be documented with the identification of the verifier indicated. Software verification methods shall include any one or a combination of design reviews, alternate calculations, and tests performed during computer program development. The extent of verification and methods chosen are a function of the complexity of the software, degree of standardization, similarity with previously proved software, and importance to safety.

403 Implementation

The software design shall be translated into computer program(s) using the programming organization's or design organization's programming standards and conventions.

[3] See IEEE Std 7-4.3.2-1993, IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations.

The implementation process shall result in software products such as computer program listings and instructions for computer program use. A review shall be performed in accordance with para. 202 of this Subpart.

404 Acceptance Testing

The acceptance testing activity shall demonstrate that the computer program adequately and correctly performs all intended functions (i.e., specified software design requirements). Computer program tests including, as appropriate, software design verification, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled.

Test requirements and acceptance criteria for computer programs shall be provided by the organization responsible for the use of the computer program and shall include the following, as applicable:

(a) Software design verification testing shall demonstrate the capability of the computer program(s) to provide valid results for test problems encompassing the range of documented permitted usage.

(b) Computer program acceptance testing shall consist of the process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment.

(c) In-use computer programs testing shall demonstrate required performance over the range of operation of the controlled function or process.

404.1 Test Coverage. Acceptance testing shall demonstrate, as appropriate, that the computer program

(a) properly handles abnormal conditions and events as well as credible failures

(b) does not perform adverse unintended functions

(c) does not degrade the system either by itself or in combination with other functions or configuration items

Acceptance testing shall be performed prior to approval of the computer program for use. Configuration items shall be under configuration change control prior to starting acceptance testing. Acceptance testing shall be planned and performed for all software design requirements. Acceptance testing ranges from a single test of all software design requirements to a series of tests performed during computer program development. Performance of a series of tests provides assurance of correct translation between activities and proper function of individual modules. Testing shall include a comprehensive acceptance test performed in the operating environment prior to use.

404.2 Test Plans and Procedures. The requirements of this section apply to testing of computer programs and, as appropriate, the computer hardware and operating system.

Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements. For those computer programs used in design activities, computer program test procedures shall provide for ensuring that the computer program produces correct results. For those computer programs used for operational control, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process. The procedures shall also provide for evaluating technical adequacy through comparison of test results from alternative methods, such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature.

In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. In-use test procedures shall be performed after the computer program is installed on a different computer or when there are significant changes in the operating system. Periodic in-use manual or automatic self-check tests shall be prescribed and performed for those computer programs in which computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance.

The test plans, test cases, and test results shall be documented, reviewed, and approved prior to use of the computer program.

Test procedures or plans shall specify the following, as applicable:

(a) required tests and test sequence

(b) required ranges of input parameters

(c) identification of the stages at which testing is required

(d) criteria for establishing test cases

(e) requirements for testing logic branches

(f) requirements for hardware integration

(g) anticipated output values

(h) acceptance criteria

(i) reports, records, standard formatting, and conventions

Observations of unexpected or unintended results shall be documented and dispositioned prior to test result approval. Test results shall be evaluated by the responsible authority to ensure that test requirements have been satisfied.

404.3 Computer Program Test Records. Test records shall be established and maintained to indicate the ability of the computer program to satisfactorily perform its intended function or to meet its documented requirements. Test records shall include

(a) computer program tested, including system software used

(b) computer hardware used

(c) test equipment and calibrations, where applicable

(d) date of test

(e) tester or data recorder

(f) simulation models used, where applicable
(g) test problems
(h) results and applicability
(i) action taken in connection with any deviations noted
(j) person evaluating test results
(k) acceptability

404.4 Acceptance Testing of Changes. The acceptance testing of changes to the computer program shall be subjected to selective retesting to detect unintended adverse effects introduced during the change. Such testing shall provide assurance that the changes have not caused unintended adverse effects in the computer program and shall verify that a modified system(s) or system component(s) still meets specified software design requirements.

405 Operation

After the software is approved for use and installed in the operating environment, the use of the software shall be controlled in accordance with approved procedures and instructions. These include, as appropriate
(a) application documentation (e.g., application log)
(b) access control specifications
(c) computer system vulnerability protections
(d) problem reporting and corrective action
(e) in-use tests
(f) the configuration change control process

406 Maintenance

The appropriate software engineering elements, as described in para. 101 of this Subpart, shall identify how changes to the software are controlled. Typically, changes are in response to any of the following:
(a) enhancement requests from the user community
(b) revisions to software based on software design requirements
(c) changes to the operating environment and changes to computer system vulnerability protections
(d) reported software problems that must be corrected

407 Retirement

During retirement, support for the software product is terminated, and the routine use of the software shall be prevented.

500 STANDARDS, CONVENTIONS, AND OTHER WORK PRACTICES

As appropriate, the software engineering method, software acquisition method, or both shall establish the need for standards, conventions, and other required work practices to facilitate software life-cycle activities (e.g., software design and implementation activities). Standards, conventions, and other required work practices shall be documented.

600 SUPPORT SOFTWARE

Support software includes software tools and system software. As appropriate, the software engineering method, software acquisition method, or both shall establish the need for software tools.

601 Software Tools

Software tools shall be evaluated, reviewed, tested, and accepted for use and placed under configuration control as part of the software development cycle of a new or revised software product. Software tools that do not affect the performance of the software need not be placed under configuration control.

In cases involving modifications of software products using the software tools, the configuration of the support software associated with that modification shall be managed. Changes to the software tool shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

602 System Software

System software consists of the on-line computer programs used to provide basic or general functionality and facilitate the operation and maintenance of the application computer program. Examples include lower level software layers, assemblers, interpreters, diagnostics, and utilities.

System software shall be evaluated, reviewed, tested, and accepted for use as part of the software development cycle of a new or revised software product. System software shall be placed under configuration change control. Changes to the system software shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

700 REFERENCES

The following is a list of publications referenced in this Standard:

ANSI/IEEE Std. 610.12-1990, Glossary of Software Engineering Terminology

IEEE Std. 7-4.3.2-1993, IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations

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SUBPART 2.8
Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Items for Nuclear Facilities

100 GENERAL

Subpart 2.8 provides amplified requirements for installation, inspection, and testing of mechanical items. It supplements the requirements of Part I and shall be used in conjunction with applicable Requirements of Part I when and to the extent specified by the organization invoking Subpart 2.8.

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in Subpart 2.8.

checks: the tests, measurements, verifications, or controls placed on an activity by means of investigations, comparisons, or examinations to determine satisfactory condition, accuracy, safety, or performance.

engineering limitations: restrictions that, if disregarded, may result in damage to the item, shortening the life of the item, or preventing the item from functioning as intended.

examination: an element of inspection consisting of investigation of materials, components, supplies, and services to determine conformance to those specified requirements that can be determined by such investigation. Examination is usually nondestructive and includes simple physical manipulation, gaging, and measurement.

mechanical items: parts, components, or systems that function primarily for pressure retaining, mass moving, or heat exchange purposes. Examples of mechanical items are rotating equipment (motors, pumps, blowers), handling equipment (cranes, hoists, conveyors), piping systems (pipe, valves, hangers), fuel handling systems, and waste effluent systems.

200 GENERAL REQUIREMENTS

Measures shall be established and implemented for documenting the necessary installation, inspection, and testing to verify conformance to specified requirements.

201 Planning and Procedures

Planning and procedure preparation shall be in accordance with the requirements of the Introduction to Part II.

202 Prerequisites

The following minimum conditions shall have been met, or evidence thereof shall be available as applicable, before the requirements set forth in Subpart 2.8 are applied:

(a) Qualification of individuals, organizations, and procedures has been completed in accordance with the requirements of applicable codes and standards.

(b) Mechanical items have been designed and engineered in accordance with applicable codes, standards, and specifications.

(c) Materials have been selected and equipment has been fabricated and assembled in accordance with the design specifications and the applicable published codes and standards, the conformance to which has been demonstrated by the responsible organization.

(d) Engineering limitations, as applicable, have been incorporated in the procedures and instructions. These limitations and requirements shall include, as a minimum, installation, testing, and on-site fabrication processes such as cleaning, welding, nondestructive examination, and parameters such as pressure, flow, speed, load limits (static and dynamic), travel limits, physical clearances, control and alarm settings, and environmental and thermal limits, which are included in design specifications, manufacturer's data sheets, instruction manual, and design reports.

(e) To substantiate paras. 202(b) and (c) of this Subpart, the following documents relating to the specific stage of installation activity for the mechanical item shall be available at the work site:

(1) the latest applicable approved drawings

(2) equipment/design specifications

(3) manufacturer's installation instructions

(4) installation procedures

(5) evidence of compliance by manufacturer with purchase requirements, including quality assurance requirements

(6) evidence that engineering or design changes are documented and approved prior to installation

(7) records of inspections and tests during on-site receiving, storage, and handling

(8) release of mechanical items for installation

(9) evidence that nonconformances have been satisfactorily resolved or controlled

300 PREINSTALLATION VERIFICATION

301 General

Prior to the actual installation of mechanical items, there are certain preliminary inspections, checks, and similar activities that shall be completed to verify that the item and the installation area conform to specified requirements, and the necessary resources are available to ensure that the quality of the mechanical item will be maintained as the installation proceeds.

The quality requirements and quality assurance actions that are necessary during installation shall be reviewed and planned so that they are understood by responsible individuals.

302 Identification

Checks shall be made to verify that the identity of received mechanical materials and equipment has been maintained and is in accordance with the latest approved drawings, equipment lists, specifications, and established procedures. If these checks disclose apparent loss of identification, the identity shall be reaffirmed prior to release for installation.

Checks shall be made to verify that a control system for maintaining identification of mechanical items through installation has been established, including provisions for control of substitution or exchange of equipment or materials. The procedures for control of identification shall provide a system of traceability to drawings, specifications, or other records when identification or markings must be destroyed, hidden, or removed from an item.

303 Installation Process Control

Consistent with the installation activities schedule, inspections or checks shall be performed to verify that processes are ready when needed for use in the installation of mechanical items. These inspections or checks shall include, but not be limited to, the following verifications:

(a) Approved procedures, drawings, manuals, or other work instructions are provided to the installer at the work site.

(b) Special instructions and checklists as required are available at the installation area or attached to the item.

(c) Approved procedures and instructions for special processes such as coating, welding, heat treating, and nondestructive examination are available at the site.

(d) Where applicable, personnel, procedures, and instructions shall have been qualified through the preparation of workmanship standards, samples, or mockups that simulate actual job conditions.

(e) Installation preparations have been completed, including such tasks as removal of packaging, conditioning, cleaning, and preliminary positioning.

(f) Jigs, fixtures, and equipment for special processes, if required, are available at the site and conform to specified requirements.

(g) Equipment for handling and placement of mechanical items is available at the site and is adequate to perform the work in accordance with specified requirements.

(h) Warnings and safety notices appropriate to the activity are posted.

(i) Inspection hold/witness points are identified in work instructions.

(j) The status of installation, inspections, examinations, or tests is clearly indicated or identified.

(k) The installation, inspection, and testing sequences are being maintained.

(l) Identification, appropriate segregation, and disposition of nonconforming items are being maintained.

(m) As-built information is being captured and processed.

(n) Documents such as installation records and inspection and test reports are current, accurate, and complete.

304 Physical Condition

Inspections or checks, as appropriate, shall be performed to verify that mechanical items at installation are in accordance with the specified requirements and that quality has been maintained.

These inspections or checks shall include, but not be limited to, the following verifications:

(a) Protective measures and physical integrity during storage have been maintained in conformance with specified requirements.

(b) Nonconformances have been satisfactorily dispositioned or controlled.

(c) Items have been cleaned in accordance with specified requirements.

305 Installation Area Conditions

Inspections or checks, as appropriate, shall be performed to verify that conditions of the installation area conform to specified requirements and precautions have been taken to prevent conditions that will adversely affect the quality of the items during installation. These inspections or checks shall include, but not be limited to, verification of the following:

(a) Protection from adjacent activities is being provided, including implementation of appropriate exclusion and area cleanness requirements.

(b) Protection from inclement weather and other ambient conditions adverse to quality is being provided.

(c) Materials that may be deleterious to the mechanical items being installed are controlled.

(d) Installation of the mechanical item will not adversely affect the subsequent installation of materials

and equipment, and repair or rework on any nonconforming items can be performed satisfactorily.

(e) Adequate permanent or approved temporary supports and mountings have been installed that will properly interface with the mechanical item.

(f) Controls for foreign material exclusion (FME) are in place.

(g) Mating parts, such as couplings and flanges, are properly positioned and conditioned.

(h) Servicing or maintenance activity related to installation has been performed.

400 INSTALLATION INSPECTIONS

401 General

Checking and examination of testing activities shall be performed during the installation of mechanical items to ensure that the required quality is being obtained in accordance with prescribed procedures. These activities shall be performed in a systematic manner to ensure surveillance throughout the installation process. A procedure shall be provided for the coordination and sequencing of these activities at established inspection points in successive stages of installation.

A method shall be implemented to ensure that engineering and design changes during installation are documented and controlled.

402 Process and Procedures Control

Inspections shall be made to verify that a system of controls has been established and is being maintained at the construction site to ensure that

(a) the applicable revision of approved procedures, drawings, and instructions is being followed

(b) qualified and approved processes, materials, tools, and other equipment are being used by qualified personnel

(c) the status of installation, inspections, examinations, or tests is clearly indicated or identified in inspection reports

(d) the installation, inspection, and testing sequences are being maintained

(e) identification, appropriate segregation, and disposition of nonconforming items are being maintained

(f) as-built information is being processed

(g) inspection and test reports are current, accurate, and complete

403 Inspection

Inspections of the work areas and the work in progress shall be performed to verify that mechanical items are being located, installed, assembled, or connected in compliance with the latest approved drawings, manufacturer's instructions, and procedures. Inspections performed shall include as appropriate, but not be limited to, the following:

(a) identification

(b) location and orientation of components

(c) leveling and alignment

(d) clearances and tolerances

(e) tightness of connections and fastenings

(f) fluid levels and pressures

(g) absence of leakage

(h) physical integrity

(i) cleanness

(j) welding operations, including materials and process controls, adequate purging, and the removal of purge dams on completion

(k) adequacy of protective measures to ensure that the item will not be damaged during installation

(l) adequacy of housekeeping, barriers, and protective equipment to ensure that items will not be damaged or contaminated as a result of adjacent activities

404 Installation Checks

Checks shall be performed to verify that mechanical items have been correctly installed and will function properly so that the initial starting of items and preoperational testing can proceed with a minimum amount of problems and delays. If construction or an associated activity affects the results of these checks, the checks shall be repeated, if necessary, to ensure that the quality has not been adversely affected.

These activities shall include as appropriate, but not be limited to, the following:

(a) Procedures are prepared and approved to verify correctness of installation and ability to function per design.

(b) Proper greasing or lubrication has been completed.

(c) Protection strainers are installed where necessary.

(d) Rotation of prime movers is correct.

(e) Item is correctly valved and isolated.

(f) Casings, reservoirs, etc., are primed, vented, and filled.

(g) Piping system alignment is correct.

(h) Pipe hangers are installed per design.

(i) Seismic anchors and restraints are properly installed.

(j) Valve glands and packing are installed.

(k) Pneumatic lines are verified free of debris and dry.

(l) Valve stroking, actuation, and settings are proper.

(m) Pump seals and packing are properly installed.

404.1 Cleaning. Mechanical items shall be cleaned, flushed, and conditioned according to applicable requirements. Special attention shall be given to the following requirements:

(a) Chemical Conditioning. Procedures shall be prepared including the scope, acceptance criteria, sequence, temperatures, soak periods, and neutralizing solutions to be used. Checks shall be made to verify that the proper

chemicals at the designated strength and temperature are being used in the conditioning operations.

Other operations shall be performed as specified in para. 403.1(c) of this Subpart.

(b) Flushing. Procedures shall be prepared including routes, boundaries, velocities and acceptance criteria, restoration, and layup for high integrity systems, where appropriate. Checks shall be made to verify that mechanical items are being flushed in accordance with specified requirements so that contaminants or flow velocities will not adversely affect subsequent operations.

Other operations shall be performed as specified in para. 403.1(c) of this Subpart.

(c) Process Controls. Checks shall be performed to verify that controls are functioning for the following:

(1) removal and installation of parts or components such as metering devices, orifice plates, and valve internals that are removed from the system to facilitate flushing

(2) installation and removal of temporary strainers, blind flanges, and piping

(3) isolation of sensitive instrumentation

(4) water and chemical quality

(5) acceptance data, specimens, or progressive samples, if required

Where appropriate for disassembly and reassembly of mechanical items, procedures or instructions shall be prepared or manufacturer's technical manuals shall be used to ensure adherence to match marks, protection of seats, and proper reassembly and to preclude damage to the mechanical item.

404.2 Pressure Testing. Checks shall be made to verify that mechanical items are being pressure tested in accordance with specified requirements to ensure that the strength and integrity of the installed systems or portions thereof conform to specified requirements. The purpose of the test, scope, test boundary, duration for inspection, acceptance criteria, restoration, and layup shall be clearly established and documented. Checks shall include, but not be limited to, the following:

(a) Appropriate pressures, temperatures, water chemistry, and pressure test cycles are established.

(b) Sufficient time at test pressure is specified to determine acceptance.

(c) Provisions are available to protect and isolate instrumentation during hydrostatic testing.

(d) Items external to test boundary are protected to prevent inadvertent overpressurization.

(e) Relief devices are controlled to prevent overpressurization.

(f) Gagging and ungagging of relief valves has been performed.

(g) Piping and equipment supports have hydrostatic pins installed where applicable for testing and are to be removed upon completion of testing.

(h) Evidence of calibration of measuring and test equipment has been determined.

405 Care of Mechanical Items

Items on which inspection and testing activities are performed shall be protected from personnel traffic, weather, and adjacent activities such as sandblasting, acid cleaning, welding, jack hammering, chipping, burning, and stress relieving, which would adversely affect the quality of the item or test results. Such protection shall be provided through good cleanliness and housekeeping practices, temporary packaging, erection of barriers, protective covers, and walkways, as required.

Temporary use of equipment or facilities to which this Part applies, which are to become part of the completed project, may be desirable. Authorization for such usage shall be as provided for in the contract or by written approval from the responsible organization. Such temporary use shall not subject the mechanical items to conditions for which they were not designed.

The temporary use authorization shall include

(a) conditions of use or operation

(b) maintenance requirements

(c) inspections and tests as required to maintain operability and quality during the period of temporary use of item

When temporary use is completed, conditions of temporary use shall be evaluated to verify that the permanent equipment continues to satisfy specified requirements.

500 SYSTEMS TURNOVER INSPECTION AND TESTS

501 General

Following the installation of mechanical items, the checking, inspection, and testing activities shall be performed to verify that the completed systems are in conformance with specified requirements. This is a final verification that the requirements defined by licensing commitments, drawings, specifications, and other contract documents are reflected in the completed installation. It is also a time to verify that field modifications and other changes made and controlled during installation activities have been incorporated in the as-built documents.

Controls shall be provided for the identification, documentation, and resolution of nonconformances disclosed by inspections or tests.

Tests shall be conducted on completed plant systems. Test procedures shall identify prerequisites for system testing including required completed construction activities. The test procedures shall identify and describe any temporary or simulated condition or equipment. If not previously planned, a documented notice shall be prepared and issued with approval of the responsible organiztaion stating the substitutions that existed for the test.

Written verification shall also be provided that temporary installations have been satisfactorily replaced by permanent installations.

Checks and inspections shall be performed to verify the operational readiness and completeness of components and systems. These systems or partial systems shall be identified, tagged, and released for operational testing. These checks and inspections shall be performed to verify the following as a minimum:

(a) Equipment and materials have not sustained external physical damage.

(b) The installation has been made in accordance with specified requirements.

(c) All nonconforming conditions have been satisfactorily dispositioned.

(d) Internal and external restrictions and obstructions to flow and full travel have been removed.

(e) Supports and restraints are properly installed.

(f) Interfacing connections with adjacent systems are compatible.

(g) Original materials and component identification have been preserved with provisions for traceability throughout the installed systems.

(h) Safety features such as interlocks, cable separations, guards, warning devices, and lockouts have been installed, are being used, and comply with applicable codes and regulations.

(i) Temporary connections, such as jumpers and bypass lines, and temporary trip points of control equipment are identified and documented so that their final condition can be verified.

(j) System water chemistry is appropriate for operational testing.

(k) External surface chemistry requirements have been maintained.

(l) Permits and authorizations have been obtained.

502 Preoperational Testing

This testing involves the operation of all items in a system(s) or partial system(s) to ensure that operation is in accordance with the design criteria and functional requirements. The testing shall include, but not be limited to, the following:

(a) systems integrity

(b) in-line instrument installation is consistent with specified flow directions

(c) sensing lines are phased correctly to in-line elements and sensors

(d) service requirements for initial operation such as flow alignments, limiting flow orificing, and relief devices have been performed

(e) operation of controls, valves, dampers, operators, and load limiting devices

(f) rotating equipment (motors, pumps, blowers), rotation, speed, vibration, noise, and no-load operation

(g) handling equipment (load tests of cranes, hoists, conveyors, hooks, handling adapters, and accessories)

(h) containment systems

(i) air handling systems

(j) fuel storage and handling systems

(k) reactor component handling systems

(l) instrument air systems

(m) fluid service systems

(n) waste effluent systems

(o) auxiliary building systems

Where mechanical equipment and systems interface with, and their operation must coordinate with, nonmechanical equipment or systems, the test performed shall include verifying the compatibility of interfacing equipment and functions.

503 Cold Functional Tests

Typically, a nuclear facility will have a cold startup process where nonradioactive materials or gases are used to check the system, followed by a hot startup when radioactive materials are used. These tests follow preoperational testing of individual systems, including reactor coolant systems. This testing shall be performed to obtain operational data of equipment and maximum allowable simultaneous operation of interfacing systems and equipment, and the final verification of functional performance of these systems.

503.1 Reactor Coolant System Hydrostatic Tests. As applicable to reactor system type, hydrostatic tests to verify conformance to specified requirements, when performed on the reactor coolant system, shall include all or parts of connected systems that cannot be isolated from the test pressure. The applicable test requirements are contained in Section III of the ASME Boiler and Pressure Vessel Code.

503.2 Functional and Flow Testing. The required individual systems shall be tested to demonstrate cold functional operability of individual components, subsystems, and systems, and to demonstrate compatibility with other systems. These tests, where appropriate, shall demonstrate the following:

(a) system pressure drop

(b) flow rate

(c) controls and throttling device settings

(d) function of interlocks, alarms, and automatic features

(e) instrument calibration

(f) setting of meter biases

(g) system stability

(h) adequacy of pipe and equipment support settings

(i) heat runs on rotating equipment

(j) adequacy of ventilation, lubrication, and cooling systems under sustained operating conditions

(k) ability to meet water chemistry requirements

504 Hot Functional Tests

Typically, a nuclear facility will use radioactive materials for hot startup. These tests are not applicable to BWR and HTGR nuclear plants because these plants use nuclear heat to produce the system temperatures. Hot functional tests for PWR plants follow cold functional tests and simulate plant operating conditions at elevated temperatures and pressures. All auxiliary and support systems exclusive of those required for precriticality testing must be available for these tests. If any of these systems is not available, the responsible organization shall specifically authorize exclusion of these systems from testing and document those exceptions.

These systems shall include the following as a minimum:

(a) system pressure drop
(b) flow rate
(c) controls and throttling device settings
(d) function of interlocks, alarms, and automatic features
(e) instrument calibration
(f) setting of meter biases
(g) system stability
(h) adequacy of pipe and equipment support settings
(i) heat runs on rotating equipment
(j) verification of heat exchanger performance
(k) verification of boron control system performance
(l) thermal insulation effectiveness
(m) set points of temperature, pressure, and level devices
(n) system heatup tests
(o) system cooldown tests
(p) hot flow tests
(q) setting protective devices
(r) hot clearances
(s) vibration measurements of major equipment and piping, as applicable

600 DATA ANALYSIS AND EVALUATION

Procedures shall be established for processing inspection and test data and their analysis, evaluation, and final acceptance. These procedures shall identify individuals or organizations responsible for documentation of inspection and test data and evaluation against acceptance criteria, operating limits, and performance standards. The data processing procedure shall provide for preliminary evaluation to determine the validity of the inspection and test results and the appropriateness of continuing the inspection or test. The data shall be analyzed and evaluated to verify completeness of results, achievement of inspection and test objectives, and operational proficiency of equipment and systems; to identify additional inspection or test requirements or both; and to identify necessary changes to the installation inspection or test procedures. Inspection and test results supported by the inspection and test data, together with a report of data analysis and evaluation, shall be provided as specified in section 700 of this Subpart.

700 RECORDS

Record copies of procedures, reports, required qualification records, test equipment calibration records, test deviation or exception records, and inspection, examination, and check records shall be prepared. These records shall be retained with other project records as required by code, standard, specification, or project procedures.

SUBPART 2.14
Quality Assurance Requirements for Commercial Grade Items and Services

100 GENERAL

Subpart 2.14 provides amplified requirements to provide reasonable assurance that a commercial grade item (CGI) or service will perform its safety function. These requirements are intended to supplement the requirements of Part I and shall be used in conjunction with the applicable requirements of Part I by organizations performing commercial grade dedication for accepting items or services.

The amplified requirements specified in this Subpart are considered adequate for nuclear facilities identified in Part I, Introduction, section 200, Applicability.

101 Definitions[1]

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in Subpart 2.14.

basic component: a structure, system, component, or part thereof that affects its safety function, that was designed and manufactured in accordance with the requirements of this Standard, or commercial grade items which have successfully completed the dedication process.

commercial grade item:[2] a structure, system, component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

commercial grade item:[3] an item satisfying the following:

(a) not subject to design or specification requirements that are unique to those facilities or activities

(b) used in applications other than those facilities or activities

(c) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., a catalog)

commercial grade item: [4] a structure, system, or component, or part thereof, that affects its safety function, that was not designed and manufactured in accordance with the requirements of this Standard.

commercial grade service: a service that was not provided in accordance with the requirements of this Standard that affects the safety function of a basic component.

critical characteristics: important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.

dedicating entity: the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or by the facility.

dedication: an acceptance process performed in accordance with this Standard to provide reasonable assurance that a commercial grade item or service will perform its intended safety function and, in this respect, is deemed equivalent to an item or service designed and manufactured or provided under the requirements of this Standard. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hold-points at the manufacturer's facility, and analysis of historical records for

[1] United States (U.S.) nuclear facilities are regulated and licensed under the Code of Federal Regulation (CFR) based on the facility function or purpose. Regulations can vary based on the type of facility, applicable CFR, and regulatory agency. Regulation 10 CFR Part 21, Reporting of Defects and Noncompliance, establishes criteria for commercial grade item definition and dedication activities that are based on the facility types per 10 CFR Parts 30, 40, 50, 52, 60, 61, 63, 70, 71, and 72, unless specifically provided otherwise in the regulations. United States licensed facilities and other entities supporting the licensed facilities are required to comply with the appropriate regulations. It is the responsibility of the U.S. facility management to determine the applicability of this Subpart to meet the U.S. facility regulatory requirements, including all pertinent definitions.

[2] This definition is applicable to nuclear power plants and activities licensed pursuant to 10 CFR Part 30, 40, 50, 52, or 60.

[3] This definition is applicable to nuclear facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72.

[4] This definition is applicable to Department of Energy nuclear facilities and activities regulated under 10 CFR 830, Nuclear Safety Management.

acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of Part I.

equivalency evaluation: a technical evaluation performed to confirm that a replacement item (not identical to the original) can satisfactorily perform its intended functions, including its safety functions.

equivalent replacement: a replacement item not physically identical to the original. These replacement items require an equivalency evaluation to ensure that the intended functions, including its safety function, will be maintained.

identical item: an item that exhibits the same technical and physical characteristics (physically identical).

like-for-like replacement: the replacement of an item with an item that is identical.

200 CGI DEFINITION APPLICATIONS

A facility utilizing commercial grade items or services shall utilize the appropriate commercial grade item definitions to determine if the item or service can be procured commercial grade. An item or service performing a safety function that does not meet the commercial grade definition is subject to the requirements in Part I of the Standard.

300 UTILIZATION

To utilize a commercial grade item or service, controls shall be implemented to provide reasonable assurance that the item or service will perform its intended safety function. These controls shall include the following:

(a) determination that the item or service performs a safety function

(b) confirmation that the item or service meets the applicable commercial grade item definitions

(c) identification and documentation of the critical characteristics, including acceptance criteria

(d) selection, performance, acceptance, and documentation of the dedication method(s) for determining compliance with the critical characteristic acceptance criteria.

Only items or services that perform a safety function and meet the commercial grade definitions shall be considered for commercial grade dedication. A dedication plan shall be developed for the item or service that identifies the critical characteristics and dedication methods, including acceptance criteria. Dedication plans may be developed for a specific item, service, or for a generic group of items or services. Dedication requirements shall be included in applicable procurement and technical documents as necessary to support the dedication.

Items or services that successfully complete the dedication process are subsequently subject to the controls of Part I and Part II of the Standard.

400 TECHNICAL EVALUATION

401 General

The technical evaluation(s) shall be performed by the responsible engineering organization to

(a) determine the safety function(s) of the item or service

(b) identify performance requirements, the component/part functional classification, and applicable service conditions

(c) confirm that the item or service meets the commercial grade definition criteria

(d) identify the critical characteristics, including acceptance criteria

(e) identify the dedication method(s) for verification of the acceptance criteria

(f) determine if a replacement item is a like-for-like or equivalent item

The requirements of this Subpart are only applicable to commercial grade items or services that perform a safety function. Design output documents, supplier technical information, and other relevant industry technical and operating experience information, as appropriate, shall be utilized to prepare the technical evaluation.

Components that perform a safety function can contain items that do not perform a safety function. Replacement items shall be evaluated to determine their individual safety function in relation to the component or equipment.

The credible failure modes of an item in its operating environment and the effects of these failure modes on the safety function shall be considered in the technical evaluation for the selection of the critical characteristics. Services shall be evaluated to determine if the failure or improper performance of the service could have an adverse impact on the safety function of equipment, materials, or the facility operations.

If the design criteria for the commercial grade item are known by the dedicating entity, then the item may be dedicated to these criteria in lieu of defining a specific safety function. In this case, consideration of failure modes is not required and the item's design parameters and allowables become the critical characteristics and acceptance criteria.

If the design criteria or safety function of the original item have changed, the replacement item must meet the new design criteria and safety function. Like-for-like and equivalent items are not a design change subject to Part I, Requirement 3, section 600, Change Control.

402 Like-for-Like Items

Items may be considered identical or like-for-like if one of the following applies:

(a) The item is provided from the original equipment manufacturer (successor companies that maintain equivalent quality controls are acceptable), and has not been subject to design, materials, manufacturing, or nomenclature changes.

(b) The item was purchased at the same time and from the same supplier, as determined by the purchase date, shipping date, date code, or batch/lot identification.

(c) Evaluation of the item confirms that no changes in the design, materials, or manufacturing process have occurred since the procurement of the original item.

A like-for-like determination shall not be based solely on the selection of a commercial-grade vendor with items manufactured to meet the same industry standards of the original item. Meeting the same industry standards may be a necessary condition, but is not a sufficient condition for a like-for-like determination.

If the dedicating entity can demonstrate that the replacement item is identical, then the safety function, design requirements, and critical characteristics need not be re-determined. However, verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.

403 Equivalent Items

When difference(s) exist from the original item, an equivalency evaluation is required to determine if any changes in design, material, manufacturing process, form, fit, or function could prevent the replacement item from being interchangeable under the design condition of the original items and performing its required safety function.

The equivalency evaluation shall be documented and include the following:

(a) identification of the change(s) in design, material, manufacturing process, configuration, form, fit, or function of the replacement item that is different from the original item

(b) evaluation of the change(s)

(c) confirmation that the change(s) does not adversely affect the current design or safety function of the item

If the change(s) adversely affects or is not bounded by the current approved design bases, the replacement item is not equivalent and must be rejected or processed as a design change in accordance with Part I, Requirement 3, section 600, Change Control.

Equivalency evaluations can determine the acceptability of the difference in the item to perform its safety function and identify critical characteristics for acceptance for the replacement item. Equivalency evaluations are not to be used as the sole basis to accept a commercial grade item. Selection and verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.

500 CRITICAL CHARACTERISTICS

Critical characteristics selected for acceptance shall be identifiable and measurable attributes based on the complexity, application, function, and performance of the item or service for its intended safety function. Critical characteristics of an item for acceptance shall include the part number, physical characteristics, identification markings, and performance characteristics, as appropriate. The critical characteristic acceptance criteria shall include tolerances, when appropriate. An item's part or catalog number shall be considered a critical characteristic if it provides a method to link the item with the manufacturer's product description and published data. The dedication process shall not rely on the part number alone as the only critical characteristic to be verified. Commercial grade items or services can have numerous characteristics that are related to the composition, identification, or performance of the item or service. However, for acceptance, not all of these characteristics need to be verified to provide reasonable assurance that the item or service will perform its intended safety function.

The manufacturer's published product description or additional technical information typically identifies technical criteria or performance characteristics inherent in the design and manufacturing of the item. The manufacturer can employ standard tests or inspections as part of the manufacturing process and utilize a quality program to assure that appropriate controls are applied. This type of information is an example to be considered in the selection of critical characteristics and the related acceptance criteria.

In cases where the critical characteristics and acceptance criteria cannot be determined from the manufacturer's documentation or other documentation, the dedicating entity may perform an engineering evaluation, examination, or test (or any combination thereof) of the original item to develop the critical characteristics and acceptance criteria.

Critical characteristics selected for acceptance shall include criteria related to the location/design basis conditions (or manufacturing design limits) of the item in the facility or criteria addressing the most severe location criteria/design basis conditions (or manufacturing design limits) of the item in the facility, unless controls are in place to prevent usage in undesignated locations.

Commercial grade items designated for installation or installed in seismically or environmentally qualified equipment or in locations which require such qualification shall include the selection of appropriate critical characteristics required to maintain the qualification of the component or equipment.

600 METHODS OF ACCEPTING COMMERCIAL GRADE ITEMS AND SERVICES

601 Dedication

(a) To provide reasonable assurance that a commercial grade item or service will perform its intended safety function, the dedicating entity shall verify that the commercial grade item or service meets the acceptance criteria for the identified critical characteristics by one or more of the following dedication methods:

(1) Method 1: inspections, tests, or analyses performed after delivery

(2) Method 2: commercial grade survey of the supplier

(3) Method 3: source verification of the item or service

(4) Method 4: acceptable supplier/item performance record

(b) Prior to classifying the item or service as acceptable to perform its safety function, the dedicating entity shall determine that the following have been successfully performed, as applicable:

(1) Damage was not sustained during shipment.

(2) The item or service has satisfied the specified acceptance criteria for the identified critical characteristics.

(3) Specified documentation was received and is acceptable.

(c) The dedication method(s) described in paras. 602 through 605 shall provide a means to assure that the commercial grade item or service meets the acceptance criteria for the selected critical characteristics. The selection of acceptance method(s) shall be planned and based on the type of critical characteristics to be verified, available supplier information, quality history, and degree of standardization. If a critical characteristic cannot be verified by the selected dedication method, the dedicating entity may select another or combination of dedication methods to verify the critical characteristic.

(d) The organization that performs or directs the dedication activity and determines the item or service has satisfactorily met the acceptance criteria for the selected critical characteristics is the dedicating entity. The dedicating entity can be the manufacturer, a third-party organization, the purchaser, or the nuclear facility organization.

602 Method 1: Special Test(s), Inspection(s), and/or Analyses

Special test(s), inspection(s), or analyses either individually or in combination shall be conducted upon or after receipt of an item to verify conformance with the acceptance criteria for the identified critical characteristics. The special test(s), inspection(s), and/or analyses may include post-installation testing and may be performed utilizing a sampling plan, when appropriate.

Special inspections may include receipt inspection activities to verify adequate criteria associated with procurement activities. The receipt inspection activities may be included in the dedication plan.

Sampling plans utilized to select items for special test(s), inspection(s) and/or analyses shall be based upon standard statistical methods with supporting engineering justification and shall consider lot/batch traceability, homogeneity, and the complexity of the item.

When post-installation test(s) are used to verify acceptance criteria for the critical characteristics, the commercial grade item or service shall be identified and controlled to preclude inadvertent use prior to satisfactory completion of the dedication activities.

When critical characteristics acceptance criteria is based on certified material test reports or certificates of conformance, the criteria of Part I, Requirement 7, section 503 shall be met.

Services can result in a deliverable product that can be evaluated upon receipt or result in an activity that can be evaluated during or at the conclusion of its performance.

603 Method 2: Commercial Grade Survey of the Supplier

(a) A commercial grade survey is a method to verify critical characteristics by evaluating the adequacy and effectiveness of the supplier's commercial quality controls. A commercial grade survey is performed in accordance with a checklist or plan at the supplier's facility and includes or addresses the following:

(1) identification of the item(s), or product line, or service included within the scope of the survey

(2) identification of the critical characteristics to be controlled by the supplier

(3) verification that the supplier's processes and quality program controls are effectively implemented for control of the critical characteristics

(4) identification of the survey methods or verification activities performed with results obtained

(5) documentation of the adequacy of the supplier's processes and controls

(b) A commercial grade survey shall not be employed as a method for accepting commercial grade items or services from suppliers with undocumented quality programs or with programs that do not effectively implement the supplier's own specified processes and controls. After a supplier's processes and controls have been determined to be adequate, the dedicating entity shall invoke or reference the verified processes and controls including revision level as a part of the purchase order or control requirements for the commercial grade item or service and require the supplier to provide a Certificate of Conformance attesting to the implementation of the identified processes and controls.

(c) When critical characteristics acceptance criteria is based on certified material test reports or certificates of conformance, the criteria of Part I, Requirement 7, section 503 shall be met.

(d) Surveys shall not be employed as a method for accepting items from distributors unless the survey includes the manufacturer and the survey confirms adequate processes and controls by both the distributor and the manufacturer. A survey of the distributor may not be necessary if

(1) the distributor acts only as a broker and does not warehouse or repackage the items

(2) in cases where traceability can be established by other means such as verification of the manufacturer's markings or shipping records

(e) Surveys performed by organizations other than the dedicating entity may be used as a basis for acceptance if the survey results of the critical characteristics, survey scope, supplier's processes and controls, and acceptance criteria are evaluated by the dedicating entity to be acceptable and consistent with the dedicating entity's dedication requirements.

(f) The scope of the survey shall be determined by the dedicating entity based upon the item or service and critical characteristics to be verified. The survey shall be specific to the scope of the commercial grade item or service being procured. When several items or services are purchased from a supplier, a survey of representative groups of commercial grade items or services can be sufficient to demonstrate that adequate processes and controls exist. The survey report shall provide objective evidence that the critical characteristics are verified and controlled by the supplier.

(g) If the scope of the survey cannot verify a designated critical characteristic due to controls by the supplier's subsupplier(s), the dedicating entity shall extend the survey to the subsupplier(s) or select another dedication method(s) to verify the critical characteristic.

(h) Organizations performing surveys shall develop criteria for the personnel qualifications and processes used to perform surveys. The survey documentation shall provide objective evidence that the processes and controls for the identified critical characteristics were observed and evaluated for acceptance. Deficiencies identified in the supplier's process or controls shall be corrected, if the survey is used for acceptance of the identified critical characteristic(s).

(i) The dedicating entity shall establish a survey frequency to ensure that process controls applicable to the critical characteristics of the item or service procured continue to be effectively implemented. Factors to be considered in determining the frequency of commercial grade surveys include the complexity of the item or service, frequency of procurement, receipt inspection, performance history, and knowledge of changes in the supplier's process and controls. The survey frequency interval may be the same used for supplier audits, but shall not exceed the frequency interval for supplier audits.

604 Method 3: Source Verification

Source verification is a method of acceptance conducted at the supplier's facility or other applicable location to verify conformance with the identified critical characteristics and acceptance criteria. The scope of the source verifications shall include activities such as witnessing the fabrication and assembly processes, nondestructive examinations, performance tests, or final inspections, as applicable. It shall also include verification of the supplier's design, procurement, calibration, and material process and control methods employed for the particular commercial grade item or service being purchased, as applicable to the identified critical characteristics.

Organizations performing source verification shall develop criteria for the personnel qualifications and processes used to perform source verification. Source verification documentation shall provide objective evidence that the supplier's activities for the identified characteristics were observed and evaluated for acceptance.

Source verification is only applicable to the actual item(s) or service(s) that are verified at the supplier's facility or other applicable location. Source verification shall be performed in accordance with a checklist or plan with the documented evidence of the source verification furnished to the dedicating entity and shall include or address the following:

(a) identification of the item(s) or service(s) included within the scope of the source verification

(b) identification of the critical characteristics, including acceptance criteria, being controlled by the supplier

(c) verification that the supplier's processes and controls are effectively implemented for the identified critical characteristics

(d) identification of the activities witnessed during the source verification and the results obtained

(e) identification of mandatory hold points to verify critical characteristics during manufacture and/or testing for those characteristics that cannot be verified by evaluation of the completed item

(f) documentation of the adequacy of the supplier's processes and controls associated with the critical characteristics and acceptance criteria

605 Method 4: Acceptable Supplier Item or Service Performance Record

A documented supplier item or service performance record is a method of acceptance to verify conformance with the identified critical characteristics and acceptance criteria of a commercial grade item or service against the supplier's performance record for identical or similar services. This allows the dedicating entity to have reasonable assurance of the item's or service's performance

based upon historical performance gained from the successful utilization of other acceptance methods, and/or pertinent industry-wide performance data.

Acceptable data for historical performance may be compiled utilizing monitored performance of the item, industry product tests, certification to national codes and standards (non-nuclear specific), and other industry records or databases. The supplier item or service performance record or data shall be from the condition of service, environmental condition, failure mode, maintenance program, testing, or other conditions equivalent to the intended application of the commercial grade item or service.

(a) An acceptable supplier item or service performance record shall include the following:

(1) identification of the supplier item or service being evaluated

(2) identification of previously established critical characteristics specific to the supplier item or service

(3) identification of data examined to evaluate the supplier item or service

(4) identification of basis for determining that performance data substantiates acceptability of the supplier item or service

(5) documentation of the adequacy and acceptance of the supplier/item/service performance record

(b) An acceptable item or service performance record shall not be employed alone as a method of acceptance unless

(1) the established historical record is based on industry-wide performance data that is directly applicable to the critical characteristics and the intended facility application, i.e., single sources of information are not adequate to demonstrate satisfactory performance.

(2) the manufacturer's/supplier's measures for the control of applicable design, process, and material change have been accepted by the dedicating entity, as verified by survey.

Continued application of an acceptable supplier/item/service performance record as a method of acceptance shall include a documented periodic update and review to assure the supplier/item/service maintains an acceptable performance record.

606 Supplier Deficiency Correction

Deficiencies with the supplier's processes and controls identified by the acceptance method(s) shall be corrected by the supplier if it affects the acceptance criteria for critical characteristic(s) utilized for commercial grade dedication. Corrective actions shall be evaluated for acceptability by the dedicating entity. Uncorrected deficiencies in processes or controls may result in the selection of another dedication method for determining acceptance.

700 COMMERCIAL GRADE SERVICES

Some examples of services that may be provided as commercial grade include training, calibration, testing, engineering, computer software support, and other technical support activities. Services on equipment or items, including installation, repair, cleaning, or maintenance, that do not physically alter an item's critical characteristics are additional examples. Personnel qualification, activity controls, independent certifications, and documents are typical examples of critical characteristic for dedication of services.

Part I, Requirement 7, section 507 shall be reviewed to determine if this requirement is applicable before considering the dedication of a service. As an alternative to commercial grade dedication, services may be performed under the dedicating entity's or other organization's quality program and procedures that meet the requirements of this Standard.

Physical, mechanical, or other service activities that alter or create new critical characteristics of an item that can be used to determine the acceptability of the service that produced the critical characteristic shall not be considered a commercial grade service. For example, if a plate is rolled to a defined radius, the new critical characteristic produced is the radius of the rolled plate and not the rolling process or service that produced the curvature. Original critical characteristics of the plate material and the plate thickness can remain unchanged or be specified by the design organization for the rolled plate. Another example of a commercial grade service is the repair or calibration of an installed instrument by the manufacturer's service representative. The instrument could have been previously dedicated, but now requires service using special tools from the manufacturer that does not have a quality assurance program that meets the requirements of this Standard. The successful results of the calibration service to return the item to the original performance characteristics can be verified by the dedicating entity for acceptance of the commercial grade service.

800 DOCUMENTATION

Documentation of the commercial grade item or service dedication process shall be traceable to the item, group of items, or services and shall contain the following types of documents, depending on the applicable dedication method:

(a) dedication plans or procedures including the essential elements of the dedication process

(b) commercial grade item or service procurement documents

(c) technical evaluations

(d) critical characteristic identification and acceptance criteria

(e) test reports or results, inspection reports, analysis reports

(f) commercial grade survey reports

(g) source verification reports

(h) historical performance information

(i) dedication report containing sufficient data to accept the item or service

900 REFERENCES

The following is a listing of documents and publications utilized in the development of this Subpart.

10 CFR Part 21, Reporting of Defects and Noncompliance

Generic Letter 89-02, Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products, Washington, DC., March 21, 1989

Generic Letter 91-05, Licensee Commercial-Grade Procurement and Dedication Programs, Washington, DC. April 9, 1991

NRC Inspection Procedure (IP) 38703, Commercial-Grade Dedication

NRC Inspection Procedure (IP) 43004, Inspection of Commercial-Grade Dedication Programs

Publisher: U.S. Nuclear Regulatory Commission (NRC), 11555 Rockville Pike, Rockville, MD 20852-2738 (www.nrc.gov)

EPRI NP-5652, Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)

EPRI NP-7218, Guideline for the Utilization of Sampling Plans for Commercial-Grade Item Acceptance (NCIG-19)

EPRI Technical Report 1008256, Plant Support Engineering: Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants Revision 1 (Revision of EPRI NP-6406)

Publisher: Electric Power Research Institute (EPRI), 3420 Hillview Avenue, Palo Alto, CA 94304 (www.epri.com)

U.S. Department of Energy Guide G 414.1-2a

Publisher: U.S. Department of Energy, Office of Safety Appraisals, 1000 Independence Avenue, SW, Washington, DC 20585 (www.doe.gov)

SUBPART 2.15
Quality Assurance Requirements for Hoisting, Rigging, and Transporting of Items for Nuclear Power Plants

100 GENERAL

Subpart 2.15 provides requirements for the design, manufacture, acceptance, testing, and use of hoisting, rigging, and transporting equipment to maintain the quality of designated nuclear power plant items that require special handling. It supplements the requirements of Part I and shall be used in conjunction with applicable Requirements of Part I when and to the extent specified by the organization invoking Subpart 2.15.

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in Subpart 2.15.

accepted industry standard: a standard established by a group representing individual members from various facets of an industry who normally are those engaged in manufacturing. This standard is accepted by the responsible organization. Examples are American Gear Manufacturers Association (AGMA), American Institute of Steel Construction (AISC), and Association of Iron and Steel Engineers (AISE).

consensus standard: a standard established by a group representing a cross section of a particular industry or trade, or a part thereof. A cross section includes those who purchase or use products of the industry or trade, as well as those who produce these products.

dynamic load test: a test in which designated loads are hoisted, lowered, rotated, or transported through motions and accelerations required to simulate handling of the intended item.

equipment: manufactured assemblies that are used for the handling of items.

failure stress: that stress at which failure is imminent due to direct loads, excessive deflections or vibrations, or permanent deformations that may lead to unsafe conditions.

handled load: the weight of the item to be lifted plus the weight of any required rigging, such as lifting beam, slings, hooks, and blocks.

handling: hoisting, rigging, or transporting of items for nuclear power plants.

person-in-charge (PIC): the person who has overall responsibility for handling operations for his organization.

principal load-carrying members: those components of a system whose structural integrity must be maintained to ensure a safe operation.

principal structural welds: those welds that join or affect the integrity of principal load-carrying members.

responsible organization: a company that is in direct charge of the equipment and manpower actually engaged in a handling operation.

system: a combination of components arranged for a handling operation.

200 GENERAL REQUIREMENTS

The requirements of Subpart 2.15 apply to any organization or individual participating in work relating to hoisting, rigging, and transporting. Hoisting equipment used for handling shall be certified by the manufacturer. The certification shall indicate the various parameters for the maximum load to be handled. Measures shall be established and implemented to perform handling activities for nuclear power plant items (see Subpart 2.2, para. 202) and to perform the inspections, examinations, testing, and documentation to verify conformance to specified requirements. These measures are applicable to items that require special handling because of weight, size, susceptibility to shock damage, high nil-ductility transition temperatures, or any other conditions that warrant special instructions to preserve the quality of items and container. Where this Subpart references the use of consensus standards, these measures shall include the applicable requirements of the ASME/ANSI B30 series, Safety Standards for Cableways, Cranes, Derricks, Hoists, Hooks, Jacks, and Slings, and of ANSI A10.5, Safety Requirements for Material Hoists. Subpart 2.15 applies from the time these items are ready for delivery.

Use of permanent plant handling equipment during the construction phase is prohibited unless specifically authorized by the plant Owner and conducted in accordance with the plant Owner's quality assurance program. If such equipment is to be used during the construction phase, it shall be reviewed to ensure that

such use conforms to paras. 401, 402, 403, 501, 502, 503, 601, 602, and 603, and section 700, as applicable, in addition to the other requirements of Subpart 2.15.

After construction use and prior to release to the Owner, the permanent plant handling equipment shall be restored to its design configuration, and it shall be inspected and tested as specified in a procedure furnished by the Owner or his designee.

During subsequent use, the testing, inspection, and maintenance shall be performed as specified by applicable standards.

The requirements of Subpart 2.15 may also be extended to other appropriate parts of nuclear power plants when specified in contract documents, or to modifications involving operating plants. For other requirements, see applicable sections of Subpart 2.2.

201 Planning and Procedures

Planning and procedure preparation shall be in accordance with the requirements of the Introduction to Subpart 2.15. Procedures and instructions shall contain sufficient detail, such as center of gravity, weights, sling locations, balance points, methods of attachment, maximum hoist line speeds, ground loading, and other pertinent features considered necessary for safe handling, to govern handling operations, inspection thereof, and documentation in accordance with this Subpart. Planning shall provide for compliance with applicable federal, state, and local regulations.

202 Classification of Items Handled

The requirements for activities covered by Subpart 2.15 are based on classifying the items into three categories according to their important physical characteristics. It is recognized that within the scope of each category there may be a range of controls, and that the need for, and extent of, detailed handling requirements for an item is dependent on the importance of the item to safe, reliable operation of the plant and the complexity of the operation. Pertinent manufacturer's requirements shall be considered when classifying the items. Items for which handling activities are covered by this Subpart shall be classified into one of the three categories (paras. 202.1 through 202.3) below. An item shall not be reclassified to a lower status without approval by the responsible organization that assigned the original category.

202.1 Category A. Items classified in Category A are those that require specially selected equipment and detailed procedures for handling operations because of large size and weight. Examples of items that may be assigned to this category are

(a) reactor vessels
(b) steam generators
(c) major components of reactor vessels internals
(d) primary system pressurizers
(e) spent fuel casks
(f) subassemblies requiring specially selected equipment

202.2 Category B. Items classified in Category B are those that may be handled with conventional handling equipment but that require detailed procedures because of the susceptibility to damage. Examples of items that may be assigned to this category are

(a) reactor vessel head
(b) primary and intermediate coolant pumps and their internals
(c) designated instrument cabinets and control boards
(d) control rod drive mechanisms
(e) helium circulators
(f) fuel-handling equipment
(g) purification equipment
(h) fuel
(i) core components (small)

202.3 Category C. Items classified in Category C are those that may be handled with conventional equipment using sound rigging practice. Included in this category are both construction and permanent plant items not included in Category A or B.

300 TYPES OF HANDLING EQUIPMENT

Equipment used for handling of items, as covered by this Subpart, can be divided into four general types. Paragraphs 301, 302, 303, and 304 of this Subpart define these four types of handling equipment and list some examples.

301 Standard Manufactured Component

Handling equipment classed as a standard manufactured component is equipment that is available from several sources. This equipment is normally a catalog item, generally kept in stock, and normally used as a component of a handling system. Examples of standard manufactured components are

(a) chains and chain accessories such as hooks, shackles, and links
(b) fiber ropes and accessories
(c) hooks such as link or eye type, single, sister, and miscellaneous
(d) transporting devices such as casters, rollers, shoes, and wheels
(e) wire rope and wire rope accessories such as blocks, clamps, sockets, thimbles, and turnbuckles
(f) miscellaneous items such as cribbing, eyebolts, pads, swivel devices, links, shackles, and sheaves

302 Commercial Standard Design Equipment

Commercial standard design equipment for handling is equipment that is available as an item of standard design and manufacture. Examples of commercial standard design equipment are

(a) gantry, mobile, overhead, and jib cranes

(b) guys and stiffleg derricks

(c) hoists, winches, and trolleys

(d) jacks and jacking systems

(e) transporting devices such as forklift trucks, rail cars, tractors, trailers, and transporters

(f) elements of commercial standard design equipment such as booms, masts, and struts

(g) other optional standard accessories and adaptations available from the equipment manufacturer

303 Special Design Equipment

Special design equipment for handling is equipment that is not available from a commercial source as a catalog or standard designed item, or equipment for which no generally accepted consensus standard exists. This type of equipment may be designated and fabricated by using standard manufactured components and commercial standard designed equipment, or by using a combination of nonstandard and standard equipment. Examples of special designed equipment are

(a) special gin poles, derricks, and jacking towers

(b) special crane supports such as runways, columns, and frames

(c) rigging devices such as spreader beams, strongbacks, up end and down end devices, bolsters, and yokes

(d) transporting systems such as dollies, special rail cars, and transporters

304 Permanent Plant Handling Equipment

Permanent plant handling equipment employed for handling nuclear plant items is equipment that is intended primarily for maintenance and operation of the nuclear power plant, but which may also be used for construction. It may consist of standard manufactured components as defined in para. 301 of this Subpart, commercial standard design equipment as defined in para. 302 of this Subpart, or special designed equipment as defined in para. 303 of this Subpart. Examples of permanent plant handling equipment are

(a) fuel handling equipment

(b) overhead and gantry cranes for reactor and auxiliary (spent fuel) buildings

400 DESIGN REQUIREMENTS

Due to the wide range of equipment normally used in the handling of items for nuclear plants, it is appropriate that different criteria be used for designing different types of handling equipment. This section describes specific design criteria that are appropriate for most applications and that are recommended for general use. If it can be shown that these criteria are not appropriate for a specific application, the engineer responsible shall select compatible criteria and document the justification. It is recognized that some items are also covered by other standards, which may be more stringent than this Subpart, and items must meet requirements of both. Hoisting, rigging, and transporting equipment that is to be used exclusively during the construction phase shall be designed in accordance with paras. 401, 402, and 403 of this Subpart. Permanent plant handling equipment is designed and selected in accordance with other standards.

The organization responsible for the design shall establish a program for ensuring that the handling equipment conforms to the design requirements of the applicable portions of this Subpart.

401 Standard Manufactured Components

Standard manufactured components shall be selected to safely perform the intended operations structurally, mechanically, and electrically. They shall have been designed to conform to accepted industry standards.

402 Commercial Standard Design

Commercial standard design equipment shall be selected to perform the intended operations structurally, mechanically, and electrically. They shall have been designed to conform to consensus standards or, when a consensus standard is not totally adequate, to accepted standards.

403 Special Design Equipment

Special design equipment shall be designed to safely perform the intended operations structurally, mechanically, and electrically. Standard manufactured components or commercial standard design equipment, or elements thereof, incorporated into the total system, shall meet the requirements of paras. 401 and 402 of this Subpart, respectively, with safety factors as recommended by the manufacturer of the components and equipment.

403.1 Structural

(a) Structural design of the equipment, except as noted in paras. 403.1(a)(1) through (10) of this Subpart, shall be in accordance, as applicable, with the latest accepted edition of Manual of Steel Construction of the American Institute of Steel Construction, Timber Construction Manual of the American Institute of Timber Construction, and Building Code Requirements for Reinforced Concrete (ACI 318) of the American Concrete Institute.

(1) Equipment components shall be designed for the appropriate combination of vertical and horizontal loads.

(2) The effects of seismic activity need not be included in combination with lifting or transporting operations during construction.

(3) Winds in excess of 50 mph (80.5 km/h) normally need not be considered in combination with lifting or transporting operations as these operations are normally suspended before winds exceed 50 mph (80.5 km/h). If

historical wind data indicate the likelihood of operations occurring during winds greater than 50 mph (80.5 km/h), such data shall be used as the basis of design. ANSI A58.1, Minimum Design Loads for Buildings and Other Structures, shall be used to determine appropriate wind loads. If these forces have not been considered in design, lifting and transporting activities shall be suspended before winds reach 50 mph (80.5 km/h).

(4) Special designed equipment normally is designed for a limited number of operations. Fatigue factors shall be included where applicable.

(5) Vertical impact shall be considered in the design, and selection of loads shall be supported by analysis. In no case shall vertical impact load be less than 10% of maximum handled load, excluding test load.

(6) Longitudinal and transverse horizontal forces shall be determined by the maximum acceleration or deceleration that can be delivered by the complete hoisting or transporting system, the maximum grades or slide slopes encountered, maximum out-of-plumb lift, wind, and similar loads. In no case shall longitudinal or transverse horizontal forces be less than 2% of maximum handled load.

(7) For the entire system considered as a whole, the ratio of failure stress to calculated stress shall be no less than 1.67. This minimum ratio shall exist after considering such factors as unequal load distribution, stability, slenderness ratios, and joint efficiencies.

(8) Calculated stress developed by handling the combination of dynamic test load and vertical impact, plus longitudinal or transverse horizontal loads, if applicable, shall not exceed 133% of allowable stress.

(9) Nondestructive examinations to be performed during manufacture and the acceptance criteria for these examinations shall be specified by the responsible design organization. Particular attention shall be given to lamellar tearing, highly restrained connections, and welds joining load-carrying members.

(10) Guys and guyed systems, such as column-supported girders with traveling hoists, gallows, frames, guyed derricks, and similar equipment, shall be designed to provide system stability and restraint by

(-a) maintenance columns, poles, or masts in the desired position and within desired tolerances

(-b) providing capability to resist forces caused by handling operations, impact, wind, opposing guys, eccentricity, and similar causes

(b) The design shall consider the following as a minimum:

(1) handled load.

(2) height of column and column capability.

(3) slope of the guys.

(4) load sharing of multiple guyed systems.

(5) pretension requirements.

(6) physical characteristics or wire rope, such as area, modulus of elasticity, and spring constant.

(7) footing and anchorage adequacy.

(8) secondary loads caused by stretch of guys.

(9) safety factors.

(10) end connections.

(11) nil-ductility transition temperatures. Design criteria shall be selected by the organization responsible for the design.

403.2 Mechanical. The following special conditions apply to the mechanical design:

(a) Special designed equipment normally is designed for a single operation, or for a limited number of operations. Life, durability, and fatigue factors shall be included where applicable.

(b) Gearing shall be designed by use of American Gear Manufacturers Association formulas, or equivalent formulas, for strength only.

(c) Each independent wire rope or chain and sprocket hoisting unit shall have at least one holding brake. At the place where the brake is applied, the minimum static torque rating shall be 150% of the torque required to hold the maximum load to be handled, excluding the test load.

(d) Engines, gear boxes, torque converters, couplings, hydraulic jacks, pumps, valves, fittings, lines, and similar components used for hoisting operations shall be designed in conformance with the consensus standard and shall be sized to

(1) handle load, excluding test load, within the manufacturer's rated capacity

(2) operate continuously during the specified duty cycle

(3) safely resist maximum loads imposed by emergency braking

(e) Hydraulic circuit design shall take into consideration the need for design features that minimize possibilities of unexpected lowering of loads.

(f) Engines, electric motors, brakes, gear boxes, cylinders, bearing housings, and similar components that support any part of the load shall be secured to the main structure in such a way that the entire system, including components, meets structural requirements to adequately support the load.

(g) Rigidity of machinery base, shafts, and similar components shall be adequate to permit proper functioning of the equipment under operating conditions.

403.3 Electrical. The following special conditions apply to the electrical design:

(a) Electrical components and wiring used for hoisting operations shall be designed in conformance with consensus standards and shall be sized to

(1) lift the handled load, excluding test load, within the manufacturer's rated capacity

(2) operate continuously during the specified duty cycle

(3) be compatible with mechanical requirements for brakes in accordance with para. 403.2(c) of this Subpart

(b) Electrical circuits shall contain provisions for proper grounding and shall incorporate design features to minimize possibilities of unexpected lowering of load.

500 ACCEPTANCE CRITERIA FOR MANUFACTURED HANDLING EQUIPMENT

This section contains the requirements for manufacture and acceptance of manufactured equipment, structures, and accessories used in the handling of nuclear power plant items.

501 Standard Manufactured Components

Standard manufactured components shall be manufactured and accepted in accordance with accepted industry standards.

502 Commercial Standard Design

Commercial standard design equipment shall be manufactured and accepted in accordance with applicable consensus standards.

503 Special Design Equipment

Special design equipment shall be based upon one of the following criteria (paras. 503.1 and 503.2).

503.1 Acceptance of existing equipment shall be based upon one of the following criteria:

(a) historical data that show satisfactory performance in handling loads within the design capability, which are equal to or greater than the intended loads. This history would include records of test, inspections, and maintenance performed on the equipment, along with the record of actual handling operations.

(b) a load test in accordance with section 600 of this Subpart.

(c) recognition of capability by an engineer or other qualified materials handling individual when the equipment is handling Category C items only.

503.2 Acceptance criteria for new equipment and modifications to existing equipment shall conform to the following requirements:

(a) The design shall have been performed in accordance with section 400 of this Subpart.

(b) Standard manufactured components or commercial standard design equipment incorporated in the total system shall meet the requirements of para. 501 or 502 of this Subpart.

(c) Structural steel elements shall be fabricated and erected in accordance with the latest edition of AISC Code of Standard Practices for Buildings and Bridges. The following additional items shall be required:

(1) Principal load-carrying members shall be designated by the design organization responsible for either or both the design and application of the equipment. Materials of principal load-carrying members shall meet any one of the following three qualifications:

(-a) record of meeting the minimum mechanical properties as documented by certified material test reports

(-b) mechanical test report of a sample of the material showing adequate mechanical properties (this may be made by the manufacturer or a testing laboratory)

(-c) conservatism of design, documented by engineer's calculations [this option is acceptable only in emergency situations, when last-minute changes have proved necessary by field conditions, and when options specified in paras. 503.2(c)(1)(-a) and (c)(1)(-b) of this Subpart are not available]

(2) Structural welds shall be made by qualified welders using qualified procedures in accordance with the applicable requirements of the AWS D1.1, Structural Welding Code — Steel.

(3) Welds joining principal load-carrying members shall be inspected as described in section 600 of this Subpart.

(4) Structural elements of material other than steel shall be constructed in accordance with applicable consensus or accepted industry standards.

(d) Operational tests of the entire system shall be conducted in accordance with section 600 of this Subpart.

(e) Recognition of capability by an engineer or other qualified materials-handling individual will suffice in lieu of paras. 503.2(a), (c)(1), and (d) of this Subpart when the equipment is handling Category C items only.

600 TESTING, INSPECTION, AND MAINTENANCE

This section defines requirements for testing, inspection, and maintenance to ensure that the equipment will perform as required for the safe handling of items at nuclear facilities.

601 Testing

A test program shall be established to demonstrate that the handling component or equipment will perform satisfactorily in service. Testing may involve either operational or load-type tests, or a combination of the two. Operational-type tests ensure structural and mechanical capability. Test loads shall normally be handled at the same speeds and rates of acceleration (deceleration) as planned for the intended item. When dynamic test loads greater than 100% are designated, the rates of acceleration (deceleration) may be adjusted as long as the impact load does not exceed the maximum designed impact load. The combination of load and rate of acceleration (deceleration) shall not be lower than 100% dynamic load test. In addition, requirements specified in paras. 601.1 through 601.4 of this Subpart shall apply as applicable.

601.1 Standard Manufacturing Components. One of the following will satisfy the requirements for testing of these components:

(a) tests as required by applicable accepted industry standards

(b) actual proof load tests by the manufacturer

(c) dynamic load tests as part of the system being tested to 110% of the maximum load to be handled

601.2 Commercial Standard Design Equipment. One of the following will satisfy the requirements for testing of this equipment:

(a) tests as required by applicable consensus standard

(b) a dynamic load test equal to 110% of the maximum load to be handled

601.3 Special Design Equipment. Requirements for testing of this equipment shall be as follows:

(a) An operational test shall be performed. This test shall be over the portion of the motions applicable to the handling system tested.

(b) A dynamic load test equal to 110% of the maximum load to be handled by the complete system shall be performed, except that documented proof of equivalent handling ability as described in para. 503.1(a) of this Subpart may be substituted. Transport equipment tests shall demonstrate adequacy of braking, drawbar pull, stability, and other similar factors. Testing shall take place with equipment in the location where it will be used for actual handling of the item, except that in cases in which the test would interfere with, or needlessly endanger an existing item or the item to be lifted, testing may be conducted at another location, on or near the construction site. Where practical and useful, load tests shall be applied over the entire range of motions required for the actual handling of the item, with the following exceptions:

(1) Spreader bars, jacks, slings, or similar items whose loading is independent of travel may be tested in test fixtures at locations other than the construction site.

(2) Transporting vehicles need not be tested over the entire length of travel.

During subsequent use, the testing, inspection, and maintenance shall be performed as specified by other standards.

601.4 Rerated Equipment. For special lifts, hoisting equipment may be rerated, or modified and rerated, upon approval by the manufacturer or, if the manufacturer's specifications are not available, the limitations assigned to the equipment shall be based on the determinations of a qualified engineer competent in this field and such determination shall be documented and recorded appropriately.

Rerated equipment shall be given a dynamic load test over the full range of the lift using a test weight at least equal to 110% of the lift weight. A dynamic test includes raising, lowering, and traversing the load, in contrast to a static test, in which the test weight may be increased incrementally with no movement.

602 Inspection

Handling equipment in use shall be subjected to inspection. Inspections as detailed herein include three types: frequent, periodic, and major. Evidence of inspections and the results of periodic and major inspections shall be documented.

602.1 Frequent Inspections. Frequent inspections are those performed on a day-to-day or similarly frequent basis. The inspections shall conform to the consensus standards and federal, state, and local health and safety regulations. The inspection coverage shall include parts essential to safe operation plus those parts recommended by the manufacturer. A checklist shall be used to perform the inspections. These inspections shall be performed by the individual responsible for the operation of the particular equipment or by another competent individual.

602.2 Periodic Inspections. Periodic inspections are those performed on a preset interval. The inspections shall conform to the consensus standards and federal, state, and local safety regulations. The inspection coverage shall include parts essential to safe operation plus those parts recommended by the manufacturer. If a system or component is not included in established codes or standards, it shall be included in a planned, scheduled inspection program developed by the organization responsible for its use and operation. Personnel qualified by experience or special training, as determined by the organization responsible for the inspection, shall perform such inspections. Results of periodic inspections shall be documented.

602.3 Major Inspections. Major inspections are those performed on an as-specified basis and shall conform to a procedure prepared by the responsible organization. The procedure shall also state when the inspections are to be performed. Inspection coverage shall include recommendations of the manufacturer or designer. Visual examinations or nondestructive examinations shall be used for these inspections as deemed necessary by the designer of the component or system and by the organization responsible for its use and operation. Particular attention shall be paid to the following as applicable:

(a) welds at joints between highly stressed members

(b) welds at joints in principal load-carrying members and highly restrained members

(c) excessive deformation in principal load-carrying members or parts

(d) adequacy of brakes under both static and dynamic loadings

(e) response and positiveness of controls

(f) accuracy and response of load indicators

(g) overheating of power supply

Welds to be inspected shall be inspected in accordance with the applicable requirements of AWS D1.1, Structural Welding Code — Steel. Nondestructive examinations performed during these inspections shall be performed by an individual certified in accordance with Requirement 2 of Part I.

Other parts of these inspections shall be performed by personnel qualified by experience or special training, as determined by the organization responsible for the inspections. Results of major inspections shall be documented.

603 Maintenance

A maintenance program shall be established to ensure that the handling equipment is maintained in good operating condition. The program shall provide for adequate protection of equipment that is used in an environment other than the environment for which it is designed. Those responsible for operation of equipment shall be responsible for maintenance.

603.1 Service. Equipment shall be serviced at specified intervals in accordance with the manufacturer's recommendations, severity of service, and environment. Items damaged or worn sufficiently to affect operation of equipment shall be repaired or replaced before continuing operations. Replacement parts shall meet or exceed the specifications of the part being replaced.

603.2 Records. Maintenance shall be documented and the records kept current. These records shall show lubrication, servicing, adjustments, repairs, and replacement of the equipment.

700 CONTROL OF THE USE OF HANDLING EQUIPMENT

This section contains requirements to be fulfilled by the organizations that will have operational control of the handling equipment in use at a nuclear power plant. These organizations shall appoint a person-in-charge (PIC). The PIC shall ensure that procedures are provided as required, and shall provide surveillance over the activities of personnel associated with the handling operations to ensure that the procedures are being followed, that specified quality assurance requirements are being met, and that good handling practices are being followed.

701 Handling Category A Items

701.1 Prerequisites. Prior to the handling of a specified item and initial use of equipment, it shall have been verified that

(a) design and manufacture of the equipment are in accordance with sections 400 and 500 of this Subpart

(b) the load-carrying capability has been established in accordance with section 600 of this Subpart, and it equals or exceeds the load to be handled

(c) the equipment has been maintained in accordance with section 600 of this Subpart

(d) handling and moving clearances have been investigated and are satisfactory

(e) set down and installation areas have been cleared and prepared as required and are ready to receive the item

701.2 Procedures. The handling of Category A items shall be in accordance with written approved procedures, and associated instructions or drawings, as applicable. The procedures shall include the following as a minimum:

(a) Responsibilities shall be defined for organizations and key responsible individuals. Their qualifications shall be in accordance with section 800 of this Subpart.

(b) Handling equipment to be used shall be identified, and its selection shall be based on its capability to handle the load. Loads handled shall not exceed the loads used in the design of the equipment.

(c) Manufacturer's instructions and conditions of operation shall be followed for the handling equipment and items to be handled.

(d) Work instructions shall be issued for tasks that, because of their relationship to each other, must be accomplished in a certain sequence.

(e) Where applicable, acceptance criteria shall be specified for determining when a task has been satisfactorily completed.

(f) Inspection checkpoints shall be included when documentation by specific individuals is required as proof of satisfactory completion. Final documentation review and sign-off shall be made to verify that the operations have been performed in accordance with the procedures.

(g) Procedures shall identify maximum safe loads that are permissible and shall describe specific methods for ensuring that these safe loads are not exceeded. Load-indicating devices, properly calibrated, shall be used in systems in which the primary source of power has the capability of imposing excessive loads on the equipment, component, or item being handled.

(h) The need for soils tests shall be considered. (See Part III, Appendix 2.15, section 300.)

701.3 Variations. Variations from the procedures shall be approved and documented. Some situations may require emergency variations from the procedure. The individual with authority to act in emergencies shall have been previously identified (see para. 701.2 of this Subpart). Such variations shall be documented after the fact.

702 Handling Category B Items

702.1 Prerequisites. Prior to the actual handling of a specified item, it shall have been determined that the prerequisites of paras. 601 through 604 of this Subpart have been implemented. Handling and moving clearances shall have been investigated.

702.2 Procedures. The handling of Category B items shall be in accordance with written procedures as set forth under paras. 701.2(b) through (d) of this Subpart.

702.3 Variations. Variations from the procedure shall be in accordance with para. 701.3 of this Subpart.

703 Handling Category C Items

703.1 Prerequisites. Evidence of maintenance in accordance with para. 603 of this Subpart shall be verified.

703.2 Procedures. Written detailed procedures are not required.

Category C items shall be handled by experienced personnel in accordance with good rigging and handling practices as described in safety handbooks, consensus standards, and corporate or contractor standards designated for the job, and in compliance with regulations. Manufacturer's load charts and general safe rigging manuals shall be available to personnel.

800 QUALIFICATIONS OF PERSONNEL

This section contains minimum qualifications for certain key personnel involved in ensuring safe handling of nuclear power plant items. Qualifications of these personnel shall be verified by objective evidence and documented.

801 Person-in-Charge (PIC)

The PIC of handling operations shall be designated by his management. He shall have demonstrated supervisory experience in the hoisting, rigging, and transporting activities for which he is responsible, to the satisfaction of the cognizant management.

802 Engineer

The engineer responsible for the design, selection, or application of special equipment, or a combination of these, shall have demonstrated capability in the technical aspects of similar work. This capability shall be achieved through education and experience. He shall be an engineering graduate of an accredited college or university, or a Professional Engineer registered to practice in an applicable discipline.

803 Inspector

The inspector of hoisting, rigging, and transporting equipment shall have demonstrated experience in the activity for which he is responsible. Nondestructive examiners shall meet the qualifications of Requirement 2 of Part I.

900 RECORDS

Record copies of procedures, reports, personnel qualification records, test equipment calibration records, test deviation or exception records, and inspection and examination records shall be prepared. These records shall be retained with other project records as required by code, standard, specification, or project procedures.

(15)

SUBPART 2.16
Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities

DELETED

SUBPART 2.18
Quality Assurance Requirements for Maintenance of Nuclear Facilities

100 GENERAL

Subpart 2.18 provides amplified requirements for the maintenance of nuclear facility components and systems. Maintenance consists of actions necessary to maintain or restore an item to acceptable conditions. This Subpart supplements the requirements of Part I and shall be used in conjunction with applicable sections of Part I when and to the extent specified by the organization invoking Subpart 2.18. This Subpart does not apply to controlling modifications that may be determined to be needed during the performance of maintenance.

200 GENERAL REQUIREMENTS

Design or modification information shall be available to the operating organization so that it can review the adequacy of provisions for the maintenance program in accordance with the requirements of Subpart 2.18.

(15) 201 Responsibilities

Responsibilities shall be assigned for establishing and implementing the maintenance program. These responsibilities shall include

(a) the review of the maintenance program to ensure that changes to plant design or modifications are taken into consideration

(b) the development and updating of appropriate maintenance plans, procedures, and schedules

(c) the review of planned maintenance activities to ensure that radiation exposures to personnel will be as low as reasonably achievable

(d) the conduct of the program of maintenance activities and other inspections and tests as necessary to verify satisfactory performance

(e) the assurance that activities are performed by qualified personnel, using approved processes and calibrated test equipment and tools

(f) the assurance that properly controlled and identified materials are used

(g) the assurance that environmental or seismic qualification requirements of equipment are not compromised

(h) the development of provisions for installation and removal of temporary conditions (e.g., jumpers, transferring of control switch position) and returning equipment and systems to service

(i) the recording of all maintenance examination and test results including corrective actions required and actions taken

(j) the assessment and evaluation of the results of maintenance, examinations, postmaintenance tests, and equipment history

(k) the development and trending of performance indicators

(l) the retention of records

202 Procedures

(a) Procedures and/or written instructions shall be established for performance of maintenance activities. Requirements for procedure format and content shall be established. Additional guidance regarding procedural requirements are contained in ANS 3.2.

(b) Checks shall be made to verify that

(1) procedures and/or written instructions with an appropriate level of detail have been provided

(2) procedures include applicable format and content elements

(c) All changes, including temporary changes, shall be controlled

(d) Provisions shall be made for documenting data to assist in ensuring satisfactory completion of the work. Such data shall include, as applicable:

(1) parts used (e.g., serial no., part no., lot no.)

(2) identification number of measuring and test equipment used

(3) "as found" condition

(4) "as left" condition

(5) adjustments, repairs, replacements made

(6) postmaintenance clean-up and final inspection

(7) postmaintenance testing and acceptance results

Recorded data shall be reviewed for completeness and acceptability. The review shall be conducted by personnel who are familiar with the design and operation of the equipment, including acceptance criteria for its design features and operating characteristics. Administrative procedures shall require documentation of the acceptance of results.

203 Cleanness Control

(a) Controls to minimize the introduction of foreign materials and to maintain cleanness during maintenance shall be in accordance with Subpart 2.1 of this Part

(Part II). Verification methods shall be established to ensure that these requirements are met.

(b) Immediately prior to closure of equipment, the absence of foreign materials shall be verified. The results of the verification shall be documented.

204 Environmental and Seismic Qualifications

Procedures shall be established to ensure that environmental and/or seismic qualification of equipment is not voided in performing maintenance. Such procedures shall include identification of the qualified items, methods for reestablishing qualifications, and verification of qualification status.

205 Work Authorization

(a) Procedures shall be established for the authorization of maintenance work. The work authorization shall be documented and serve as the identification of authorized work for the purposes of work planning, scheduling, and control.

(b) The work authorization shall contain the following information as a minimum:

(1) unique work authorization identifier or number

(2) description of work, including identification and quality designation of the specific equipment on which the work is to be performed

(3) identification of performing organizations and their specific roles

(4) approval by authorized personnel

(c) Interface concerns such as plant operations, health physics/as low as reasonably achievable (ALARA), security, industrial safety, effluent control, fire protection and quality control requirements shall be considered for applicability by authorized individuals prior to approval of the work authorization document.

(d) The description of work shall reference the applicable maintenance procedure(s). If a separate procedure is not required, the work authorization shall contain or reference necessary and sufficient information (design drawings, equipment manuals, etc.) to perform the work.

(e) Provision shall be made for verifying the completeness of work authorization documents prior to starting the maintenance work.

(f) The work authorization approval process shall provide for approving substantive changes in the work requirements commensurate with the original scope of work.

206 Equipment History

A system shall be established to identify equipment for which equipment history files shall be maintained. Files shall be established as early in the life of equipment as possible to maintain the history of maintenance activities on each specific item. Information to be entered in the files shall be specifically identified and mechanisms established for their incorporation into the files. The files shall be organized to facilitate information retrieval.

207 Verification of Maintenance Work

Verification shall be performed, as appropriate, to ensure that equipment on which maintenance has been performed conforms to specified requirements. This verification shall include inspection, testing, or document review as necessary.

Documentation of verification activities shall be in accordance with para. 202 of Subpart 2.18.

When maintenance involves installation, inspection shall be conducted in accordance with the applicable elements defined in Subparts 2.4, 2.5, and 2.8 of this Part (Part II).

208 Updating of Maintenance Procedures From Vendor Technical Manuals and Industry Bulletins

Controls shall ensure that updated information (vendor technical manuals, industry bulletins, etc.) is received, reviewed, and incorporated where appropriate into maintenance procedures.

300 PREVENTIVE MAINTENANCE

301 General

Preventive maintenance includes all those activities performed on designated equipment needed to maintain it within specified design limits.

302 Plans and Procedures

Plans and procedures shall be developed to identify the equipment that requires preventive maintenance, to establish the frequency and kind of preventive maintenance to be performed on the equipment, and to document those actions.

302.1 Equipment. Equipment shall be evaluated to determine its preventive maintenance requirements. That evaluation shall include the vendor recommendations as delineated in their technical manual and bulletins, applicable industry standards and operational experience, and maintenance experience and equipment history files. Equipment shall be monitored and evaluated for degradation of performance because of age, as appropriate.

Equipment that is purchased for future installation or spares shall be evaluated to determine the preventive maintenance requirements associated with its storage.

302.2 Frequency. A preventive maintenance schedule shall be established to uniquely identify the equipment, frequency, and preventive maintenance to be performed.

302.3 Evaluation. The effectiveness of preventive maintenance actions on equipment shall be evaluated.

The evaluation results shall be documented and be the basis for future preventive maintenance practices.

302.4 Corrective Action. When discrepancies or failures are identified as part of preventive maintenance activities, they shall be corrected in accordance with section 400 of Subpart 2.18.

400 CORRECTIVE MAINTENANCE

401 General

The following requirements apply to maintenance performed to restore an item to an intended condition following failure of the item. The term *failure*, as used herein, applies to any condition in which an item is determined to be unable to perform within its specified limits.

402 Identification, Reporting, and Documenting of Equipment or Systems Requiring Corrective Maintenance

Procedures shall be established for

(a) promptly identifying (e.g., tagging or other physical marking) the failed item and controlling it to preclude its inadvertent use

(b) documenting and reporting of failures, in accordance with preestablished criteria, to

(1) designated levels of management responsible for failure analyses, authorization of corrective action, and performance of corrective action

(2) Supplier and/or regulatory authority, as required

(c) entering the failure and the attributed cause in equipment history records

(d) verifying that failures are appropriately identified and reported as prescribed above to the extent necessary to ensure appropriate attention

403 Assessments and Evaluations

403.1 Assessment. An assessment of failure cause and required maintenance shall be made consistent with the type of item failure and the importance of the item. The assessment shall also include, as appropriate, the possibility of similar failure in other items. Assessments shall be performed in accordance with documented procedures and shall be appropriately reviewed.

403.2 Engineering Evaluation. For failures identified that could have serious effect on safety or operability, an engineering evaluation shall be performed and documented to substantiate or revise the failure assessment and corrective action planning.

404 Implementing Corrective Maintenance

404.1 Corrective maintenance shall be performed using work procedures developed in accordance with para. 202 of this Subpart.

404.2 Provisions shall be made for emergency maintenance work, e.g., work that must be performed immediately to eliminate a threat to the safety of personnel or facilities. These provisions shall be documented to identify

(a) the minimum controls applicable to the authorization, planning, and performance of the work

(b) requirements to ensure effective accomplishment of the work

Emergency work shall be reviewed and evaluated immediately after work accomplishment for adequacy.

500 RECORDS

(a) Maintenance records shall be maintained to establish an equipment history (see paras. 202 and 206 of this Subpart) and assist in performance evaluation and trend analysis. Maintenance records shall include work authorization documents and shall identify the equipment, type of maintenance performed, tools, measuring and test equipment, parts and material, date of performance, observation, failure cause, postmaintenance testing results, and the person who performed the maintenance.

(b) Records shall be maintained in accordance with Part I, Requirement 17.

SUBPART 2.20
Quality Assurance Requirements for Subsurface Investigations for Nuclear Facilities

100 GENERAL

Subpart 2.20 provides amplified requirements related to subsurface investigations but is not applicable to contaminated soil investigations. It supplements the requirements of Part I and shall be used in conjunction with applicable sections of Part I when and to the extent specified by the organization invoking Subpart 2.20.

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in Subpart 2.20.

borings: circular holes augered, washed, chopped, or drilled in or through soil or rock by the action of cutting tools for purposes of exploration.

geophysical survey: the use of geophysical instruments, methods, and techniques to determine subsurface conditions by measurement of seismic or electrical phenomena, or by measurement of the earth's gravitation or magnetic fields or by any other geophysical methods.

penetration and probes: cone penetration tests, dilatometer soundings, and vane shear testing in soil.

subsurface investigation: the determination, correlation, and interpretation of soil, rock, and groundwater features as disclosed or inferred by exploratory excavating (test pits), drilling, sampling, testing, direct push, and geophysical surveying.

subsurface model: a computer model, a physical, graphic, or descriptive representation depicting subsurface features identified in the subsurface investigation.

200 GENERAL REQUIREMENTS

The requirements of Subpart 2.20 apply to the work of any organization or individual participating in subsurface investigations such as drilling, coring, sampling, trenching, logging, geophysical methods, testing, or interpreting results of subsurface investigations. This Subpart is intended to apply to any of these activities that will be used to formulate design bases for the plant. The extent to which the individual requirements of this Subpart apply will depend on the nature and scope of work to be performed and the importance of the item or service involved.

Documentation of all program elements shall be made. These elements shall include, but not be limited to, program plan, organization and qualification of personnel, identification, control and storage of project documents and records, and use of procedures conforming to applicable specifications.

201 Planning

A plan shall be developed for outlining project-specific tasks for which procedures or work instructions will be required in accordance with the requirements of the Introduction to this Part (Part II).

In addition, planning shall include

(a) definition of work scope and tasks

(b) identification of roles and responsibilities

(c) identification of engineering data required for design

(d) identification of appropriate field and laboratory testing equipment

(e) identification of standard methods or procedures for field, laboratory, and engineering sampling, testing, and analysis activities

(f) definition of required records and documentation

(g) the preparation of exploratory work plans

The plan shall include provisions for control and documentation of any changes.

202 Procedures and Instructions

A program of procedures and work instructions shall be established and documented for those activities falling within the scope of this Subpart in accordance with the requirements of the Introduction to this Part. In addition, these documents shall include, as appropriate, the following:

(a) field exploration operations such as surveying, drilling, boring, excavating, sampling, classifying and logging activities, shipping of samples, and in-situ testing

(b) laboratory testing activities such as preparing, classifying, testing and storing samples; recording, calculating, verifying, and reporting test results; and controlling and calibrating measuring and test equipment

(c) engineering evaluation and analysis activities such as evaluation of field and laboratory data; analysis of subsurface conditions; development of conclusions

and recommendations; and preparations and presentation of the subsurface investigation report

(d) quality assurance activities such as audit plans and schedules, verification and surveillance procedures, and corrective action requirements

203 Results

Field activities and test results shall be documented in test reports and data sheets. Each report shall identify the activity to which it applies, the procedures or instructions followed in performing the task, and the identification of the following:

(a) pertinent test data such as identification of sample giving boring or test pit number, location, depth and elevation, test results, testing equipment identification, and description of sample

(b) date of test or activity

(c) test completion signatures

(d) results of test

(e) unusual conditions encountered

The signature of an approving reviewer (checker) constitutes a certification that the techniques used met the field and laboratory procedures. The evaluation regarding the adequacy of the results is covered in section 600 of this Subpart.

204 Personnel Qualifications

Personnel directing the overall program, including the performance of field activities and tests required by this Subpart, shall be qualified engineers and geologists with experience in subsurface investigations as described in section 200 of this Subpart. Personnel shall meet qualification requirements defined in ASTM D3740, Standard Practice for Minimum Requirements for Agencies Engaged in Testing and/or Inspection of Soils and Rock Used in Engineering Design and Construction, or equivalent alternative qualification requirements.

300 VERIFICATION

301 General

A quality assurance program shall require that frequency of checking and verifying field, laboratory, and engineering activities be established and be commensurate with the complexity of the soil/rock conditions being investigated and the volume of geotechnical activity. For example, procedures established for checking and verification of activities such as drilling and sampling equipment, field boring logs, boring locations, and sample storage and marking shall include provisions on frequency requirements of such activities.

302 Preinvestigation

Prior to the actual performance of subsurface explorations, it shall be verified that in-process and surveillance procedures have been established in accordance with the requirements of paras. 201 and 202 of this Subpart and that activities will be performed by appropriately qualified personnel, using specified equipment, in accordance with procedures. Verification shall establish that

(a) a complete and comprehensive program or design plan has been prepared

(b) the requirements and specifications of the plan have been translated into work instructions and procedures for all quality-related activities

(c) personnel have been qualified and certified as required in accordance with applicable procedures

(d) the equipment to be used meets applicable standards, specifications, or requirements

303 Field Investigation

During the actual performance of subsurface explorations, it is necessary to provide in-process surveillance to ensure that the activities are being performed according to procedures by qualified personnel using specified equipment. Checks of subsurface investigation activities shall be made at the site in accordance with procedures to ensure conformance to the requirements of sections 200 and 400 of this Subpart.

(a) Checks shall be performed prior to and during field operations to verify the adequacy, accuracy, and proper operation of field equipment. These checks shall, as a minimum, ensure that

(1) sampling, measuring, and test equipment meet the applicable ASTM standards or have been evaluated as being acceptable to the procedures, requirements, and specifications of section 200 of this Subpart

(2) drilling, coring, and excavating equipment meet applicable ASTM standards or have been evaluated as being acceptable to the procedures, requirements, and specifications of section 200 of this Subpart

(b) Checks shall be performed to verify that the organization, execution, and documentation of all field activities and operations are in accordance with applicable standards, procedures, and project requirements and specifications. The items and activities to be checked and verified shall include, but are not limited to, the following:

(1) general compliance with the program plan and procedures

(2) qualification of personnel

(3) identification and control of project documents

(4) surveying activities

(5) drilling and excavation operations

(6) soil, rock, and groundwater sampling and testing methods and activities

(7) classifying, logging, and reporting methods and activities

(8) identification, handling, storage of samples and materials, and verification of the quality of these samples

Records of field operation verification activities shall be verified as complete prior to the termination of field activities.

304 Laboratory Testing

During the actual performance of laboratory testing operations, in-process surveillance shall be performed to ensure that the activities are being conducted according to procedures by qualified personnel using specified equipment. Checks of testing activities shall be conducted at the laboratory in accordance with procedures to ensure conformance to the requirements of sections 200 and 500 of this Subpart.

Checks shall be performed to verify that the elements of the laboratory testing program are in compliance with the applicable technical and quality standards, specifications, and requirements. The elements to be checked and verified shall include, but are not limited to, the following:

(a) organization of the laboratory quality assurance program

(b) qualification of laboratory personnel

(c) control and calibration of measuring and test equipment

(d) identification, control, and storage of samples

(e) identification, control, and storage of project documents

(f) implementation of standard test methods or qualified test procedures conforming to applicable specifications and requirements

(g) documentation and verification of test data, results, conditions, and observations

Records of the laboratory test program verification activities shall be verified as complete prior to the termination of the laboratory test program.

305 Engineering Evaluation and Analysis

During the performance of engineering evaluation and analysis of the results of the field and laboratory operations, in-process (not necessarily continuous) surveillance shall be performed to ensure that the engineering activities are being conducted by qualified personnel according to procedures. Checks of engineering evaluation and analysis activities shall be made in accordance with approved procedures to ensure conformance to the requirements of sections 200 and 600 of this Subpart.

Checks shall be made to verify that the elements of the evaluation and analysis program are in compliance with applicable technical and quality standards, specifications, and requirements. The elements to be checked and verified shall include, but not be limited to, the following:

(a) organization of the quality assurance program

(b) qualification of personnel

(c) identification, control, and storage of project documents

(d) use of procedures conforming to applicable specifications and requirements

(e) documentation and verification of field and laboratory data and results, engineering calculations and analyses, conclusions, and recommendations

(f) preparation and presentation of reports of data, calculations, analyses, conclusions, and recommendations

Records of the verification of the engineering evaluation and analysis activities shall be verified as complete prior to presentation of the final subsurface investigation report.

400 FIELD INVESTIGATION

401 General

The organization that conducts the field exploration activities inherent to a subsurface investigation shall be controlled by a quality assurance program. This organization shall be responsible for establishing and implementing a documented quality assurance program, and shall furnish the necessary resources such as personnel, equipment, procedures and instructions, and other services necessary to implement the requirements of the quality assurance program.

402 Field Operations

The scope of the quality-related operations required as a part of a subsurface investigation will depend upon the purposes of the investigations and subsurface conditions encountered. The operations may consist of, but not be limited to, any or all of the following activities:

(a) review of existing geotechnical data

(b) surveying

(c) auger, wash, core borings, and direct push methods

(d) test pits, trenches, and excavations

(e) soil, rock, and groundwater in-situ testing

(f) geophysical surveys

(g) classifying, logging, mapping, and recording conditions encountered

Pertinent records of field activities shall be maintained as the work progresses, and shall be verified as being complete. Any unusual circumstances encountered during field activities shall be recorded and reported as required by the governing procedures and applicable ASTM standards. Checks of field activities shall be performed while the work is in progress to ensure compliance with technical and quality requirements and task specifications.

Standard and nationally recognized methods shall be used unless specified otherwise, in accordance with procedures identified in the requirements of para. 202 of

this Subpart. These may include, but not be limited to, applicable ASTM standards.

403 Field Equipment

The type of field equipment required for a subsurface investigation will depend upon the purposes of the investigation and the conditions encountered. Field equipment may consist of, but not be limited to, any or all of the following items:

(a) small hand tools

(b) surveying equipment

(c) hand and power augers, direct push equipment, hammer drills, and rotary drills

(d) power trenching and excavating equipment

(e) soil, rock, and groundwater sampling devices

(f) soil, rock, and groundwater in-situ testing devices

(g) geophysical survey equipment

(h) special sampling and testing equipment

(i) field support equipment and vehicles

Pertinent records of field equipment that have a direct bearing on the quality of the work shall be maintained as the work progresses and shall be verified as being complete. Any unusual or nonconforming equipment conditions shall be recorded and reported as required by the specifications. Checks of field equipment shall be performed as required before, during, and after the execution of related field activities to ensure compliance with technical and quality requirements and specifications.

404 Surveying

A permanent system of horizontal and vertical controls, such as baselines and benchmarks, shall be established, maintained, and used in accordance with procedures in order to obtain an accurate location and relocation of explorations, installations, and geological features.

Installations and explorations requiring accurate horizontal and vertical location shall include, but not be limited to, the following items:

(a) auger, wash, core borings, and direct push exploration points

(b) test pits, trenches, and excavations

(c) observation wells, piezometers, gages, and weirs

(d) changes in surface and subsurface soil, rock, and groundwater conditions

(e) soil, rock, and groundwater samples

(f) soil, rock, and groundwater in-situ tests

(g) geophysical surveys

(h) previous and existing structures

(i) unusual or unexpected conditions or occurrences that may affect the accuracy or interpretation of the survey results

Pertinent records of surveying activities shall be maintained as the work progresses and shall be verified as being complete. Checks of surveying activities shall be performed while the work is in progress to ensure compliance with requirements and specifications.

405 Boring and Excavating

The type and number of borings, excavations, and other subsurface explorations required for a field investigation will depend upon the purposes of the investigation and the subsurface conditions encountered. Subsurface explorations include, but are not limited to auger, wash, and core borings; direct push methods; test pits; trenches; shafts; and excavations.

All subsurface explorations shall be located with an accuracy commensurate with the program plan and instructions specified in section 200 of this Subpart. All explorations shall, after completion, be consistently and uniquely numbered or identified.

Unless otherwise specified in the program plan, instructions, or procedures, borings shall be advanced in such a manner as to satisfy the requirements of ASTM D420, ASTM D1452, ASTM D1586, ASTM D1587, ASTM D6151, ASTM D2113, ASTM D2573, ASTM D6635, ASTM D5778, or other accepted standards.

Pertinent records of boring and excavating operations shall be maintained as the work progresses and shall be verified as being complete. Checks of boring and excavating operations shall be performed while the work is in progress to ensure compliance with requirements and specifications.

406 Sampling and Testing

The type and number of samples and tests required during the field portion of the subsurface investigation will depend upon the purposes of the investigation and the subsurface conditions encountered. The soil, rock, and groundwater sampling and test operations may include, but not be limited to, any or all of the following activities:

(a) split barrel sampling

(b) thin-walled tube sampling

(c) core barrel sampling

(d) groundwater sampling for physiochemical analysis

(e) vane shear testing

(f) cone penetration testing

(g) standard penetration testing

(h) permeability testing

(i) water level determinations

(j) pressure testing

(k) geophysical logging

(l) dilatometer testing

Sampling and testing shall be performed in compliance with the applicable requirements, specifications, standards, instructions, procedures, and program plan.

407 Classification and Reporting

This paragraph develops the requirements for classifying, logging, and reporting of borings, excavations, samples, tests, surveys, and other field investigation activities. Classifying, logging, and reporting activities shall be performed in accordance with procedures identified in the requirements of section 200 of this Subpart.

A field log shall be developed for borings and excavations with a detailed record of the stratigraphic units encountered during the field operations. This log shall also describe the type, location, and condition of recovery of all samples or tests conducted. For example, the boring log shall include, but not be restricted to, a heading containing the following information: boring number and location; project; boring contractor; date started and date finished; names of driller and sample logger; elevation; and any pertinent groundwater information or other data that may affect the use of the site.

In addition, a description of the method of advancing the boring should be included. The body of the log should include, in particular, information as to size and location of casting used, in-situ test results, and drilling abnormalities such as loss of fluid or artesian groundwater conditions that are detected.

Samples shall be controlled and cataloged by field logs, lists, or summaries. Procedures and consistent formats shall be used to label and identify all samples. Samples shall be systematically and uniquely identified with respect to project, sample number, location sampled, type of sample, and date sampled. Samples shall be handled, shipped, and stored in accordance with procedures identified in the requirements of section 200 of this Subpart and in such a manner as to minimize or prevent disturbance or changes in material properties.

Classification of soils shall be based on ASTM D2488 or other recognized methods. It is not necessary for field logs to contain the refinements that can only be determined by laboratory testing; however, where possible, the system for classifying soils contained in ASTM D2487 should be used, except when geological classification is specified. The logging and classification of groundwater and rock samples and tests shall be performed in accordance with procedures.

The reports of field tests and other activities shall include all specified results and shall be reported in a form to include the following items:

(a) identification of the applicable standard methods or qualified procedures

(b) all pertinent data and notes

(c) test calculation results in the form of tables and curves where required

(d) discussion to include significant conditions encountered, such as any specific difficulties, errors introduced, accuracy of results, and any specific soil, rock, or groundwater characteristics observed

500 LABORATORY TESTING

501 General

The laboratory in which tests are conducted shall be controlled by a quality assurance program in conformance with the applicable requirements of Part I. The laboratory shall be responsible for establishing and implementing a documented quality assurance program. The laboratory shall furnish the necessary resources such as personnel, equipment, documented procedures and instructions, and other services necessary to implement the requirements of the quality assurance program.

Laboratories involved in subsurface investigations and testing of soil and rock materials shall be accredited or inspected for conformance to requirements of ASTM D3740 or equivalent.

502 Scope

Laboratory testing of subsurface materials shall be made to determine their properties to provide data for engineering design. This requires a reliable procedure and a systematic approach, which should include the elements specified in paras. 502.1 through 502.4 of this Subpart.

502.1 Soil Identification and Description. A unified soil classification standard, such as ASTM D2487, shall be used.

502.2 Storage of Soil/Rock Samples. Identification of samples shall be affixed to the sample tubes or containers, which will maintain the integrity of the samples for the specified period of storage. Samples shall be stored in locations where they will be protected from damage.

502.3 Handling of Undisturbed Samples. Labels shall be affixed to sample tubes with all pertinent information. Tube and boring numbers shall be marked in duplicate. Undisturbed samples shall be stored vertically in a suitably controlled environment in which the ambient temperature and humidity are maintained at predetermined levels to preserve critical sample characteristics. Samples shall be transported vertically and protected with suitable resilient packing material to reduce shock, vibration, and disturbance. Appropriate measurements or observations shall be made prior to and following transportation, and the samples shall be evaluated for disturbance. Test specimens shall be prepared in accordance with applicable ASTM standards unless otherwise specified.

502.4 Determination of Standard Properties for Engineering Evaluation. Soils classification and testing shall conform to guidelines established in paras. 202 and 407 of this Subpart.

503 Test Methods

Standard and nationally recognized test methods shall be used unless otherwise specified by procedure identified in accordance with the requirements of para. 202 of this Subpart. These may include but not be limited to the applicable and approved ASTM standards.

504 Report of Laboratory Tests

The report of tests made shall include all specified test results and shall be reported in a form to include the following items:

(a) identification of samples tested, date tested, test personnel, test equipment, and test procedures used

(b) laboratory test results

(c) test and calculation results in the form of tables and curves as required

(d) discussion to include significant conditions encountered in the testing, such as any specific difficulties, errors introduced, test accuracy, and any specific characteristics of soil observed during testing

600 ENGINEERING EVALUATION AND ANALYSIS

601 General

The organization that conducts the evaluations and analyses of the subsurface investigation and laboratory test data shall implement a quality assurance program in conformance with the applicable requirements of Part I. This organization shall be responsible for furnishing the necessary resources such as personnel, equipment, documented procedures and instructions, and other services necessary to implement the requirements of the quality assurance program.

602 Analysis of Subsurface Conditions

Procedures shall be established to develop a generalized model of the subsurface conditions at the site for use in performing various engineering design analyses and evaluations. The development of the subsurface model shall include, but not be limited to, consideration and assessment of the following areas:

(a) the basic seismic, geologic, geotechnical, and hydrologic features in the vicinity of the site

(b) the specific soil, rock, and groundwater conditions encountered at the site

(c) the static and dynamic engineering properties and loading responses of the materials and strata underlying the site

(d) the interrelationship of the above geophysical features, subsurface conditions, engineering properties, loading responses, and the structural foundations for the facilities at the site

603 Report of Evaluation and Analysis

An analysis and evaluation of the subsurface investigation and foundation aspects of the site shall be presented along with the basic data supporting all conclusions and recommendations. Sufficient information shall be provided to allow for independent analyses and evaluations for design verification consistent with Part I.

700 RECORDS

Record copies of procedures; program or design plans; qualified investigation procedures; procurement control records; measuring and test equipment control and calibration records; work instructions and orders; field and laboratory logs and test data; test deviations or exception records; results of engineering analyses and evaluations; checks, verifications, and examination records; reports; and other specified documents shall be prepared. These records shall be retained with other project records as required by code, standard, specification, or project procedures.

SUBPART 2.22
Quality Assurance Requirements for Management Assessment and Quality Improvement for Compliance With 10 CFR 830 and Department of Energy (DOE) Order 414.1 for DOE Nuclear Facilities

100 GENERAL

This Subpart establishes requirements for implementing Management Assessment and Quality Improvement quality criteria for the Department of Energy (DOE) activities and organizations supporting DOE. It supplements the following related requirements of Part I: 2, 4, 7, 15, 16, and 18, which do not fully address[1] DOE Management Assessment and Quality Improvement criteria.

This Subpart applies to DOE activities regulated under Title 10 CFR 830, Nuclear Safety Management, including Subpart A, Quality Assurance Requirements, and Subpart B, Safety Basis Requirements (DOE QA rule), and for activities performed DOE Order 414.1, Quality Assurance (DOE QA Order). DOE rule and Order quality Criterion 3, Quality Improvement, and Criterion 9, Management Assessment, are addressed in this Subpart.

This Subpart shall be used with Part I when and to the extent specified by DOE regulation or contract, or by the organization invoking Subpart 2.22. This Subpart is not applicable to nuclear generation facilities licensed to 10 CFR 50 or 10 CFR 52 and other specific activities regulated by the Nuclear Regulatory Commission.

101 Definitions

The following DOE-specific definitions are provided to supplement or replace the definitions in Part I, Introduction, Section 400 when implementing this Subpart.

assessment: a review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively. [1]

graded approach: the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement is commensurate with

(a) the relative importance to safety, safeguards, and security

(b) the magnitude of any hazard involved

(c) the life-cycle stage of a facility or item

(d) the programmatic mission of a facility

(e) the particular characteristics of a facility or item

(f) the relative importance of radiological and nonradiological hazards

(g) any other relevant factors [1, 2]

item: an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, product, software, structure, subassembly, subsystem, support system, system, or unit (replaces Part I definition for use in this Subpart). [1, 2]

management assessment: an assessment conducted by managers of their management processes to identify and correct problems that hinder the organization from achieving its objectives. [1, 2]

nonreactor nuclear facility: those facilities, activities, or operations that involve, or will involve, radioactive and/or fissionable materials in such form and quantity that a nuclear or a nuclear explosive hazard potentially exists to workers, the public, or the environment but does not include accelerators and their operations nor activities involving only incidental use and generation of radioactive materials or radiation, such as check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines. [1]

nuclear facility: a reactor or nonreactor facility where an activity is conducted for or on behalf of DOE and includes any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements established by 10 CFR 830. [1]

process: a series of actions that achieves an end or result. [1]

quality: the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations. [1]

quality assurance: all those actions that provide confidence that quality is achieved (replaces Part I definition for use in this Subpart). [1]

[1] Refer to Part IV, Subpart 4.1.2 for a detailed comparison.

quality improvement: an iterative, disciplined management process used to promote efficiency and prevent potential future problems by eliminating error precursors. Quality improvement consists of planning work, evaluating/measuring the work process implementation for potential improvements, identifying item services and processes needing improvement, modifying how work is performed based on factual information, and evaluating the effectiveness of the modifications.

work: a defined task or activity such as research and development; operations; environmental remediation; maintenance and repair; administration; safety software development, validation, testing, and use; inspection; safeguards and security; or data collection and analysis. [2]

200 MANAGEMENT ASSESSMENT REQUIREMENTS

201 General

Managers shall assess their management processes to identify and correct problems that hinder the organization from achieving its objectives. Management assessments shall determine how effectively the organization is in meeting performance expectations and mission objectives and shall identify strengths and weaknesses. Management assessments shall be used to enhance safety, identify problems, and contribute to the organization's overall improvement of quality. The management assessment process shall use a graded approach as determined by the manager to provide an appropriate degree of flexibility in the level of detail for assessment planning, implementation, documentation, and reporting.

202 Assessment Planning and Scheduling

202.1 Planning. Senior management is responsible for

(a) establishing and implementing the management assessment program

(b) emphasizing the importance of assessments to the management team

(c) setting overall expectations and schedule

(d) ensuring necessary resources (including personnel and training) are available to develop the program, perform the assessments, and act on results

(e) communicating assessment schedule to appropriate individuals in time to permit sufficient time to prepare

(f) participating in the evaluation of assessment results from subordinate managers

202.2 Topic Selection and Scheduling. Managers performing assessments are responsible for

(a) evaluating performance information from internal and external sources (e.g., regulators, audits, clients, performance metrics, etc.) and the relative importance of current and planned activities to the organization's objectives.

(b) selecting the management processes to be assessed. Processes or topics that influence performance that could be included are strategic and operational planning; work environment; human resource allocation; financial and material resource allocation; communications between customers, community, suppliers, and regulators; quality and safety culture; and internal and external organizational interfaces.

(c) determining the degree of formality necessary to plan, conduct, document, and report the assessment.

(d) coordinating interfaces when assessments involve multiple organizations.

(e) setting the assessment schedule.

202.3 Assessment Personnel. Management assessments shall be performed by managers of the organization, processes, or activities being assessed. Managers shall remain personally involved in conducting the assessment and shall be responsible for evaluating the results when employees and/or consultants are used to assist with the assessment.

203 Assessment Process

203.1 Assessment Focus Areas. Assessment focus areas to be considered during a management assessment shall include one or a combination of the following:

(a) Have critiques and/or self-assessments been performed by employees related to assessing the effectiveness of the organization?

(b) What is the level of management participation in QA program implementation?

(c) Are the plans and goals of the organization still appropriate and valid?

(d) Are managers regularly monitoring the organizational plans and goals and the achievement of these goals?

(e) Do individuals understand the organizational plans, goals, and objectives?

(f) Is the overall performance focused effectively on meeting plans and goals?

(g) What is expected of individuals in the organization, and are these expectations aligned with mission objectives?

(h) Are these expectations being met?

(i) What opportunities are there for enhancing safety and improving quality?

(j) Are there risk assessments or declining trends related to effective and safe performance?

(k) How could the organization make better use of its human resource allocations?

203.2 Issue Identification. Areas of weakness and strength and compliance issues are documented during a management assessment. Management assessment results are evaluated by the manager to determine

whether there are problems that are hindering the organization from achieving its objectives, goals, and plans. Actions are taken to resolve those problems. Senior managers shall ensure that any specific QA program compliance issues or environment, safety, and health issues are promptly entered into the corrective action tracking program (or similar tracking system) to facilitate a timely resolution.

203.3 Assessment Reporting. Management assessment results shall be shared with the next highest level of management to support effective problem resolution. The assessment results shall be documented in a report that includes

(a) the scope and criteria of the assessment

(b) strengths, weaknesses, and problems affecting mission achievement that require resolution

(c) a summary statement that describes how effectively the organization is in meeting its objectives and those quality performance expectations that assist in meeting its mission objectives, goals, and plans

204 Evaluation of Assessment Results

204.1 The manager performing the assessment determines which results warrant further action, either as improvement or corrective action.

204.2 Senior management shall ensure the management assessment results are used to improve the organization's performance, promote quality improvement, and remove barriers that inhibit the organization from achieving its objectives, goals, and plans. Indicators of the effectiveness of the assessment process include

(a) eliminating the recurrence of problems from previous assessments

(b) benchmarking of assessment performance with that of other internal and external organizations to determine whether assessments reflect best industry practices

(c) incorporating assessment results into organizational goals, strategies, objectives, plans, and processes

(d) periodically reviewing the results of assessments with individuals and organizations that may benefit from the results and improve their performance

300 QUALITY IMPROVEMENT

301 General

Measures shall be established and implemented to govern quality improvement activities. Quality improvement ensures work that affects quality is planned, performed, evaluated, and improved upon to increase effectiveness and prevent problems before they occur. Requirements for quality improvement are

(a) establish and implement processes to detect and prevent quality problems

(b) identify, control, and correct items, services, and processes that do not meet established requirements

(c) identify the causes of the problems, and work to prevent recurrence as a part of correcting the problem

(d) review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement

Management shall decide which work activities will be evaluated for quality improvements. Priority shall be given to those activities that are most important to the organization's mission and safety, those with known existing problems, and those where trending or performance metrics indicate the potential for future problems.

302 Evaluation of Work

Work shall be formally evaluated with a focus on identifying potential sources of errors that may impact quality. Evaluations shall consider procedures, equipment, materials, work environment, management, communication, resource allocation, human performance factors, and other attributes with the potential to adversely impact quality. Evaluation methods shall include, but are not limited to, the following:

(a) audits

(b) surveillances

(c) management assessments

(d) trending and analysis of performance metrics, error rates, or other measured data

(e) other established quality evaluation methods to determine the cause of the condition or issue

303 Quality Improvement Tools

Processes or tools shall be selected to assist organizations in improving quality performance. One or more of the following tools shall be used for this purpose:

(a) Benchmarking (Internal and External). The purpose of benchmarking is to improve performance. Benchmarking provides a mechanism to learn about an organization in relation to other similar organizations. Benchmarking can identify those organizations that perform effectively for similar activities.

(b) Brainstorming. Brainstorming is a way of developing creative solutions to a problem. It works by focusing on a problem statement and developing radical solutions to it. Ideas are generated by all participants in a brainstorming session. There should be no criticism of ideas. Brainstorming identifies possibilities and minimizes assumptions within the limits of the problem statement.

(c) Bar Charts. Bar charts are useful when comparing groups of data. By using bar charts, a class or group of data can be grouped into a single category of data, or they can be broken down further into multiple categories for greater depth of analysis.

(d) Cause-and-Effect (Fishbone) Diagrams. A cause-and-effect diagram is a picture composed of lines and words

in a fishbone design to represent a meaningful relationship between and possible causes and the effect (problem) in terms of people, methods, machines, materials, and environment.

(e) Five Whys. This simple technique is used to identify the real issue behind a problem by starting with the issue and asking why it occurred and then continuing to ask why until there is no further response to the question. This generally occurs around the fifth why, but can occur sooner or later.

(f) Lessons Learned. A lesson learned is a good work practice or innovative approach that is captured and shared to provide repeat application. A lesson learned may also be an adverse work practice or experience that is captured and shared to avoid recurrence.

(g) Flow Charts (also known as a Process Map). A flow chart is a map of a process that is simply a graphical way of representing the process flows and activities throughout a process using common symbols. It is used to document processes and helps analyze and standardize a process and plan improvements. It is a tool to understand a process.

(h) Failure Mode and Effect Analysis (FMEA). FMEA is a systematic approach that identifies potential failure modes in a system, a product, or manufacturing/assembling operation caused by design or manufacturing deficiencies. It also identifies critical or significant design or process characteristics that require special controls to prevent or detect failure modes. FMEA is a tool used to prevent problems from occurring.

(i) Gap Analysis (also known as Change Analysis). Gap analysis provides a detailed breakdown of both the qualitative and quantitative aspects of the difference between what is and what is desired.

(j) Gantt Project Timeline Charts (sometimes referred to as a bar chart). The Gantt chart offers a graphical display of activities and duration illustrating timelines for proposals and projects.

(k) Histograms. A graphical summary of the results from a checklist.

(l) Pareto Charts. A Pareto chart is used to graphically summarize and display the relative importance of the differences between groups of data. The basis for a Pareto chart is the 80-20 rule, where 80% of the problems result from 20% of the causes. It assists in determining significance and identifying the potential items to improve first.

(m) Plan-Do-Check-Act (PDCA). The PDCA cycle is the foundation for continual improvement and can be applied to the development or improvement of any process. "Plan" represents the need to think through exactly what you are going to do before you do it. "Do" represents the undertaking of the activity that has been planned and to ensure that it happens as planned. "Check" represents the need to review the results and impact of the activity in an objective and analytical manner. "Act" represents the need to make changes to future plans in order to incorporate the learning from the "Check" phase of the cycle.

304 Improvement Identification and Implementation

Management shall determine which of the identified problems or weaknesses warrant quality improvement. This determination shall consider the likelihood and significance of the potential problems, safety considerations, mission priorities, process efficiency, and resource availability. Alternate actions shall be explored to determine the best solution to address the error precursor. The determination shall be documented. Improvements will be incorporated as determined by management and may include equipment or facility modification, updated training, or changes to institutionalized work controls (such as policies, programs, plans, procedures, or guidelines).

305 Improvement Evaluation

Management shall ensure quality improvement initiatives are evaluated or periodically monitored to determine whether the intended results are achieved and to check for unforeseen adverse impacts. Effective implementation eliminates potential problems and/or reduces their adverse impact.

400 RECORDS

Records of management assessment and quality improvement activities are considered quality records and shall be controlled in accordance with the requirements of Part I, Requirement 17. Management assessment records include assessment schedules and reports. Quality improvement records include reports utilized to record and track improvements.

500 REFERENCES

The following is a list of publications referenced in this Standard.

[1] Title 10 Code of Federal Regulations Part 830, Nuclear Safety Management

[2] DOE Order 414.1D, Quality Assurance, dated April 25, 2011

(15)

PART III: GUIDANCE FOR IMPLEMENTING PARTS I AND II REQUIREMENTS

CONTENTS

PART III
INTRODUCTION

(15) 100 PURPOSE

Part I establishes requirements for the development and implementation of a Quality Assurance Program (QAP) for nuclear facility applications. It is arranged by Requirements 1 through 18.

Part II contains additional quality assurance requirements for the planning and conduct of specific work activities under a Quality Assurance Program developed in accordance with Part I. It is arranged by Subparts.

Part III — this Part — contains guidance for implementing the requirements of Parts I and II. It is arranged by Subparts. This part contains nonmandatory guidance on approaches and methods to implement the requirements of Parts I and II. Consistent with its intent to provide nonmandatory guidance, the terms *must*, *require*, and *shall* are not used in statements of action in this Part. Alternative approaches and methods may be used to satisfy Parts I and II requirements.

Part IV contains guidance for application of NQA-1 and comparisons of NQA-1 with other quality requirements. It is arranged by Subparts.

200 APPLICABILITY (15)

Application of this Part's — Part III — guidance may be achieved by either or both of the following approaches when implementing Parts I and II requirements:

(a) as content within the Quality Assurance Program document to provide details relevant to an organization's activities

(b) as content in policies, protocols, instructions, and procedures that establish controls for activities affecting quality

This Part contains details of proven methods and activities to achieve compliance with Parts I and II requirements and provides proven principles and practices that may be used to establish an efficient and cost-effective Quality Assurance Program. Part III reflects industry experience, proven methods of performance, technology changes and regulatory considerations, and insights into the intent of the NQA Committee in formulating Parts I and II requirements. It does not, however, limit the Standard user from utilizing alternate methods and activities that can be proven to provide results consistent with Parts I and II requirements.

SUBPART 3.1
Guidance for Implementing Part I Requirements

The following Subparts provide nonmandatory guidance that may be used in conjunction with the applicable Requirements of Part I.

SUBPART 3.1-1.1
Implementing Guidance for Part I, Requirement 1: Organization

100 GENERAL

This Subpart provides nonmandatory guidance on organization as specified in Requirement 1 of Part I.

200 ORGANIZATIONAL STRUCTURE

In structuring the organization and assigning responsibility, quality assurance should be recognized as an interdisciplinary function involving many organizational components and, therefore, should not be regarded as the sole domain of a single quality assurance group. The quality assurance group (or groups), however, should be designated to describe, integrate, and monitor the agreed-upon quality assurance activities of the various disciplines and functions.

Quality assurance encompasses many functions and extends to various levels in all participating organizations, from the top executive to workers, such as designers, computer programmers, welders, inspectors, facility operators, craftsmen, and Auditors, who perform activities affecting quality.

Different organizational structures may be effective, depending on the portion of the project or job in which the implementing organization is involved.

300 BASIC PRINCIPLES

301 Management Functions

Designated management should have the authority and responsibility to identify or approve

(a) quality assurance program scope and appropriate quality levels

(b) characteristics to be verified and acceptance criteria

(c) actions to resolve quality problems

(d) determination of the validity and disposition of nonconforming items and services

302 Quality Achievement Functions

Those performing quality achievement functions should have

(a) means or information, or both, to monitor or check the quality of their work

(b) authority and responsibility to identify and control defective work products

(c) responsibility to correct quality problems in their area of responsibility, whether self-identified or reported to them by others

(d) freedom to provide or recommend solutions to quality problems outside their area of responsibility

SUBPART 3.1-2.1
Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs

100 GENERAL

This Subpart provides nonmandatory guidance on Requirement 2 of Part I, Quality Assurance Program.

200 PROGRAM FORMAT

The format of NQA-1 has retained the original eighteen criteria. Other recently developed quality assurance requirements documents use different formats. One such format is management, performance, and assessment.

Another format is

(a) program
(b) personnel training and qualification
(c) quality improvement
(d) documents and records
(e) work processes
(f) design
(g) procurement
(h) inspection and acceptance testing
(i) management assessment
(j) independent assessment

Still another format uses twenty elements to describe a quality assurance program. Regardless of how the requirements are grouped and formatted, the important success factor is to adequately address all imposed requirements. This Standard does not restrict the development of quality assurance programs to the format of requirements specified herein, provided the technical contents of the requirements imposed by the organization invoking this Standard are met.

Frequently, one quality assurance program can be adapted to satisfy the needs of more than one standard, or customer. Because of its broad base of requirements, NQA-1 provides a core program that can be related to other standards and customer specifications. A relationship matrix can be used to demonstrate programmatic comparability with other source requirement documents. Accommodating multiple customer needs with one quality assurance program has several benefits: consistency of application to minimize performance errors, minimization of training, and process cost effectiveness.

300 PROGRAM DEVELOPMENT

301 Purpose and Scope

The quality assurance program should be developed to meet customer requirements and user needs. Application of management controls and the degree of program formality should be graded to satisfy criteria based on the defined risks associated with meeting specified requirements.

Most quality assurance applications will have multiple customers and users, and to meet the intended purpose of the quality assurance program, customer needs should be viewed individually and collectively. Customers can be internal or external to the quality assurance program applied to the work process. Internal users of the quality assurance program will have different needs (i.e., performance) than external customers, who are recipients of the products (i.e., items or services) of the work process to which the quality assurance program applies. A regulator should be viewed as a customer with a defined set of requirements and expectations to be met.

The quality assurance program should describe the organizational structure, functional responsibilities, authority levels and relationships, and communication interfaces needed to accomplish the work and quality objectives.

Generally, functional interfaces should be identified to link with key customer communication points. This will promote performance-based operations and reporting if used effectively to communicate performance status and resolution of issues.

302 Timing

The primary reason for establishing a quality assurance program is to ensure that items and services are developed and provided for use in compliance with specified requirements. To achieve this objective, control and verification measures should be planned, documented, and implemented at predetermined points throughout the life cycle of the work process. The program should provide control from initiation of activities through their completion.

The quality assurance program should specify an orderly and timely sequence for the implementation of applicable requirements and standards; for example, as a nuclear project moves through its various stages, activities affecting quality will change as the type of work dictates.

400 WORK REQUIREMENTS AND PERFORMANCE

401 Basis and Structure

The structure, graded content, and application of a quality assurance program should be based on a defined baseline of requirements to accomplish performance objectives. Tasks derived as the step-wise methods to achieve performance objectives can be logically collected into a work process to form the basis for defining work functions. These functions are the building blocks of an organization framework. Work task relationships are frequently described in work breakdown structure that relates process requirements, tasks, and work products and provides the basis for work scheduling, cost control, and performance measurement.

Each work requirement should be related to a work task, a work process, and a customer. Progress toward achieving a work product should be measurable to determine how effectively work objectives are met.

402 Planning

Work activities should be planned to ensure a systematic approach. Planning should result in the documented identification of methods and functional responsibilities. Planning should determine what is to be accomplished, who is to accomplish it, how it is to be accomplished, when it is to be accomplished, and how to measure performance and progress.

Planning should be performed as early as practicable and prior to the start of the activities to be controlled to ensure functional interface compatibility and satisfactory coverage of governing requirements.

Planning for a quality assurance program should take into consideration

(a) applicable quality and technical requirements, including governing specifications, codes, standards, and practices

(b) the need for special procedures, work instructions, controls, processes, equipment, qualifications, or certifications required to achieve quality requirements

(c) the documentation needed to demonstrate the quality of the work performed and the items and services provided for use

(d) the assignment of task and performance responsibilities

(e) the methods to be used to verify conformance with quality and technical requirements, and program effectiveness

500 WORK PROCESSES

501 Process Management

The input to a work process consists of requirements and the output is a product that meets those requirements. Quality assurance is the tool for ensuring that the product meets specified requirements and should be embedded in the work process for optimal effectiveness. Being embedded means that quality assurance is designed into all aspects of work planning, management, performance, validation, verification, documentation, close-out, and product delivery. Quality assurance provides a systematic approach for achieving performance objectives.

The quality assurance program should describe the scope (i.e., breadth and depth) of its application, including coverage of administrative services, if that is what is needed to meet customer performance expectations.

502 Graded Approach

Items and services may require varying degrees of control and verification to ensure compliance with requirements. Some factors that should be considered in determining appropriate levels of control and verification are

(a) the hazards associated with doing the work or using the results of the work

(b) the consequences of malfunction or failure of the item, or inappropriate use of the results of services provided

(c) the probability of the occurrence of the postulated consequences

(d) the design and fabrication complexity or uniqueness of the item, or difficulty to perform services

(e) the need for special controls and oversight of processes, equipment, and performance

(f) the degree to which functional compliance can be demonstrated by inspection, test, or performance verification

(g) the quality history and degree of standardization of items and services

(h) the difficulty of repair, replacement, or replication of the items and services

600 TRAINING AND QUALIFICATION

The definition of work requirements, individual work tasks, and their collection into a work process should be used to determine the individual and collective training and qualification needs.

The accumulation of knowledge and skills through experience is an effective way of becoming proficient in a work activity. On-the-job training (including mentoring) is an effective training method and should be documented as well as classroom training.

Demonstrated proficiency and consistent performance are two primary measures of good training and qualification practices. Controlling process variability may be a good indication that the training and qualification practices are adequate to reach performance objectives.

700 ASSESSMENT OF PERFORMANCE

Work task objectives should be clearly established with in-process and final acceptance criteria. Progress toward meeting objectives should be measured against parameters that are meaningful to the work process. If work task and performance objectives, and work responsibilities have been defined, performance measurement should automatically follow.

Those doing the work should have first-line responsibility for the acceptability of their work. Their managers should regularly assess work performance.

Management assessments can be continuous measurements of performance or periodic efforts, depending on the scope of the work and process complexity as well as risk management considerations.

A clear understanding of hazards and risks of achieving or not achieving work objectives should be used as the basis for establishing a management assessment process, and the nature of that process.

Frequently, a well-developed (and well-coordinated) management assessment process can be linked to customer reporting needs to avoid duplicate performance measurement programs.

Management may choose to use individuals who have no direct responsibility for accomplishing work tasks or objectives to assist in the management assessment process. Assessments can have a process or technical focus, depending on the nature and scope of the assessment. In either case, the individual performing the assessment should have assessment skills, and work process and product/customer understanding to conduct an effective assessment.

SUBPART 3.1-2.2
Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs, Lead Auditor Qualification

100 GENERAL

This Subpart provides nonmandatory guidance relative to the education and experience that may be used for the qualification of Lead Auditors. This Subpart may be used in conjunction with Requirement 2 of Part I.

200 EDUCATION AND EXPERIENCE

The prospective Lead Auditor should have verifiable evidence that a minimum of 10 credits under the following score system have been accumulated.

201 Education (4 Credits Maximum)

(a) Associate degree from an accredited institution: score 1 credit or, if the degree is in engineering, physical sciences, mathematics, or quality assurance, score 2 credits; or

(b) A bachelor's degree from an accredited institution: score 2 credits or, if the degree is in engineering, physical sciences, mathematics, or quality assurance, score 3 credits; in addition, score 1 credit for a master's degree in engineering, physical sciences, business management, or quality assurance from an accredited institution.

202 Experience (9 Credits Maximum)

Technical experience in engineering, manufacturing, construction, operation, or maintenance: score 1 credit for each full year with a maximum of 5 credits for this aspect of experience.

(a) If 2 yr of this experience have been in the nuclear field, score 1 additional credit; or

(b) If 2 yr of this experience have been in quality assurance, score 2 additional credits; or

(c) If 2 yr of this experience have been in auditing, score 3 additional credits; or

(d) If 2 yr of this experience have been in nuclear quality assurance, score 3 additional credits; or

(e) If 2 yr of this experience have been in nuclear quality assurance auditing, score 4 additional credits.

203 Other Credentials of Professional Competence (2 Credits Maximum)

For certification of competency in engineering science, or quality assurance specialties issued and approved by a state agency or national professional or technical society: score 2 credits.

204 Rights of Management (2 Credits Maximum)

The Lead Auditor's employer may grant up to 2 credits for other performance factors applicable to auditing, which may not be explicitly called out in this Subpart. Examples of these factors are leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and quality assurance training courses.

300 RECORDS

The sample form shown in Fig. 300 is provided for utilization as a record of Lead Auditor qualification.

Fig. 300 Sample Form for Record of Lead Auditor Qualification

RECORD OF LEAD AUDITOR QUALIFICATION	Name	Date
EMPLOYER:		
QUALIFICATION POINT REQUIREMENTS		**CREDITS**
Education – University/Degree Date	4 Credits Max.	_____
1. Undergraduate Level 2. Graduate Level		
Experience – Company/Dates	9 Credits Max.	_____
1. Technical (0–5 credits) and 2. Nuclear Industry (1 credit), or Quality Assurance (2 credits), or Auditing (3 credits)	Nuclear Quality Assurance (3 credits), or Nuclear Quality Assurance Auditing (4 credits)	
Professional Accomplishment – Certificate/Date	2 Credits Max.	_____
1. P.E. 2. Society		
Management – Justification/Evaluator/Date	2 Credits Max.	_____
Explain: Evaluated by: (Name and Title)	_____ Date	
	Total Credits:	_____
AUDIT COMMUNICATION SKILLS		
Evaluated by: (Name and Title)	_____ Date	
AUDIT TRAINING COURSES		
Course Title or Topic: 1. 2.		Date
AUDIT PARTICIPATION		

	Location	Audit	Date
	1.		
	2.		
	3.		
	4.		
	5.		

EXAMINATION:	**PASSED:**	**DATE:**
QUALIFICATION CERTIFIED BY: (Signature and Title)		**Date Certified**

ANNUAL EVALUATION (Signature and Date)					

SUBPART 3.1-2.3
Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs, Inspection and Test Personnel Qualification

100 GENERAL

This Subpart provides nonmandatory guidance on the qualifications and use of inspection and test personnel. This Subpart may be used in conjunction with Requirement 2 of Part I.

200 FUNCTIONAL QUALIFICATIONS

Three levels of qualification may be utilized depending on the complexity of the functions involved. The recommendations for each level are not limiting with regard to organizational position or professional status but, rather, are limiting with regard to functional activities.

201 Level I Personnel Capabilities

A Level I person should be capable of performing and documenting the results of inspections or tests that are required to be performed in accordance with documented procedures, acceptance standards, and/or industry practices as defined in user's written procedures.

202 Level II Personnel Capabilities

A Level II person should have all of the capabilities of a Level I person for the inspection or test category or class in question. Additionally, a Level II person should have demonstrated capabilities in planning inspections and tests; in setting up tests, including preparation and setup of related equipment, as appropriate; in supervising or maintaining surveillance over the inspections and tests; in supervising and certifying lower level personnel; and in evaluating the validity and acceptability of inspection and test results.

203 Level III Personnel Capabilities

A Level III person should have all of the capabilities of a Level II person for the inspection or test category or class in question. In addition, the individual should also be capable of evaluating the adequacy of specific programs used to train and certify inspection and test personnel whose qualifications are covered by this Subpart.

300 EDUCATION AND EXPERIENCE QUALIFICATIONS

These education and experience recommendations should be considered with recognition that other factors commensurate with the scope, complexity, or special nature of the activity may provide reasonable assurance that a person can competently perform a particular task. Other factors that may demonstrate capability in a given job are previous performance or satisfactory completion of capability testing. These factors and the basis for their equivalency should be documented.

301 Level I

(a) Two yr of related experience in equivalent inspection or testing activities; or

(b) High school graduation and 6 mo of related experience in equivalent inspection or testing activities; or

(c) Completion of college level work leading to an associate degree in a related discipline plus 3 mo of related experience in equivalent inspection or testing activities.

302 Level II

(a) One yr of satisfactory performance as a Level I in the corresponding inspection or test category or class; or

(b) High school graduation plus 3 yr of related experience in equivalent inspection or testing activities; or

(c) Completion of college level work leading to an associate degree in a related discipline plus 1 yr of related experience in equivalent inspection or testing activities; or

(d) Graduation from a 4-yr college plus 6 mo of related experience in equivalent inspection or testing activities.

303 Level III

(a) Six yr of satisfactory performance as a Level II in the corresponding inspection or test category or class; or

(b) High school graduation plus 10 yr of related experience in equivalent inspection or testing activities; or high school graduation plus 8 yr of experience in equivalent inspection or testing activities with at least 2 yr as a Level II and with at least 2 yr associated with nuclear facilities — or, if not, at least sufficient training to be

acquainted with the relevant quality assurance aspects of a nuclear facility; or

(c) Completion of college level work leading to an associate degree and 7 yr of related experience in equivalent inspection or testing activities with at least 2 yr of this experience associated with nuclear facilities — or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility; or

(d) Graduation from a 4-yr college plus 5 yr of related experience in equivalent inspection or testing activities with at least 2 yr of this experience associated with nuclear facilities — or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility.

400 USE OF INSPECTION AND TEST PERSONNEL

Prior to assigning personnel to perform inspection and test activities, supervision should determine that the individuals have the experience or training commensurate with the scope, complexity, or special nature of the activities. When a single inspection or test requires implementation by a team or a group, personnel not yet meeting the requirements of Part I, Requirement 2, section 300, may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual. Appropriate training, which may include on-the-job training, should be conducted as needed to qualify personnel to perform inspections and tests. The use of personnel performing inspections and tests during on-the-job training qualification should be performed under the observation and supervision of a qualified person, since the verification of conformance is the responsibility of a qualified person.

SUBPART 3.1-2.4
Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs, Management Assessment of the QA Program Using Surveillance

100 GENERAL

Requirement 2 of Part I establishes the requirement for management to regularly assess the adequacy and to ensure the effective implementation of the quality assurance program. This Subpart provides nonmandatory guidance on one method that may be used as an element in meeting this requirement.

Surveillance as used in this Subpart is an assessment technique that uses observation or monitoring to provide confidence that ongoing processes and activities are adequately and effectively performed. Surveillance can be used effectively to complement the audit, review, inspection, and test functions. Surveillance may be used by managers and supervisors as part of their routine assessment activities to provide timely data on performance and to identify quality issues before they have a significant impact on safety and reliability.

Surveillance has the following advantages:

(a) It is flexible, adaptable, and easy to use.

(b) It may be implemented quickly.

(c) It may be applied by line personnel as well as independent personnel.

(d) It is adaptable to a broad range of assessments including item acceptance and diagnostics for determination of extent and cause of nonconforming issues.

Examples of processes and activities suitable for surveillance include research and development, design, procurement, manufacturing, plant operations, modifications and maintenance, radiological and industrial safety, safeguards and security, sampling, laboratory, inspection, testing, calibration, hazardous waste management, materials management, and environmental management.

200 PLANNING AND SCHEDULING

Planning and scheduling should be used to determine those processes and activities that would most benefit from surveillance, when and how frequently it should be performed, as well as who should perform or lead it. Surveillance plans may be integrated into the overall assessment program complementing other evaluation techniques as deemed useful and appropriate for the process or activity being covered.

201 Planning

Planning efforts should precede scheduling arrangements to determine what processes, activities, or conditions are important and which prerequisites are needed. Planning should consider aspects such as regulatory impact, safety and reliability significance, experience and previous history, follow-up of previous concerns, management commitments, line supervisory concerns, and related industry experience. Industry experience may be derived from inspection results, industry standards and information networks. Selection of personnel to perform a surveillance should also be considered. Directly related experience is a desirable attribute for surveillance personnel. Consideration of other scheduled assessments also should be made to avoid duplication and to optimize timing of the surveillance.

202 Scheduling

Scheduling may be flexible and informal to implement the surveillance plans to coincide with ongoing activities. When used, schedules may be informally controlled, but detailed to the extent that opportunities are not missed and priorities are satisfied. Control of scheduling may be accomplished by simply indicating the month in which the surveillance is to be performed, who is assigned to perform the surveillance, and the need for additional technical expertise.

300 PREPARATION

A surveillance outline may be prepared that describes what will be observed or monitored including those actions or attributes to be assessed. The amount of detail in an outline should be commensurate with aspects such as the knowledge and experience of the personnel performing the surveillance and the complexity or uniqueness of the process or activity. The outline may be used as a tool to guide personnel through the surveillance and to ensure that the purpose or objective is accomplished. The extent of the surveillance and related preparation should be consistent with its purpose and the importance of the processes and activities being observed.

Each surveillance should have a purpose or objective. Familiarization with management expectations, governing procedures, specifications and other policy documents is desirable. The governing resource documents may include drawings, procedures, supplier manuals, system descriptions, license commitments, codes and standards, controls, research and experiment guidelines, as well as industry publications. Reports from other assessments, both internal and industrywide, should be considered. Additionally, reports that provide performance indicators, status, trends, and histories may also be useful.

Methods of surveillance should also be considered with preference given to direct observation of performance. Direct observation may be augmented by discussions with personnel, observation of results, and review of documents.

Other preparation considerations may include the following:

(a) surveillance commencement date to coincide with performance of the process or activity

(b) need for additional assistance to include subject matter experts who can make accurate and meaningful assessments of performance

(c) orientation of surveillance personnel not yet familiar with the performance of surveillances by clarifying the reporting processes and the need to pursue identified concerns

(d) the need for observing processes and activities of groups performing the activity during all work periods

(e) generic attributes that apply to many or all surveillances but that are not specifically outlined in each plan

400 PERFORMANCE

401 Notification

Prior to the surveillance, contact should be made with cognizant management or supervision of the area, process, or activity to be covered to discuss the planned scope and duration of the surveillance.

402 Conduct of Surveillance

402.1 Surveillance personnel should use the following guidelines, as appropriate:

(a) Allow observed processes and activities to continue without interference unless it is apparent that immediate corrective or preventive action is necessary in accordance with governing procedures.

(b) Prior to starting the surveillance, develop a clear understanding of the scope of the surveillance, the safety and reliability aspects of the work scope, the requirements and rules applicable to the work to be observed, and the communication and reporting agreements made with the organization responsible for performing the work.

(c) Inform personnel responsible for the activity or process why the surveillance is being conducted, the scope of the surveillance, communication and reporting agreements, the authority of the person performing the surveillance (particularly in the area of Stop Work), and that notes of observations will be recorded as necessary.

(d) Commence the surveillance, when practical, at the prejob briefing stage or early stage of research and development, when the fundamental bases for the ensuing work are established and communicated. This provides the opportunity to confirm that all personnel involved understand the work, their roles, the risks, interfaces, and preparedness by having the correct tools, apparatus, and paperwork to accomplish the work.

(e) Use checklists in addition to the surveillance outline when they will enhance the surveillance effort. However, a checklist or outline should not preclude the opportunity to observe an unanticipated or unexpected event that may have the potential to yield exceptional performance data. Nor should the checklist prevent the immediate follow-up of an important or significant observation or concern.

(f) Record observations for reference and follow-up.

(g) Pursue concerns and deficiencies sufficiently to characterize the nature and extent of each.

(h) Exercise care in keeping facts separated from opinions or judgments. Where possible, confirmation of observations or perceptions should be sought prior to forming conclusions. This may be achieved through nondisruptive inquiries of personnel involved in the activity or by review of results.

(i) Offer to review observations with the personnel involved at the end of the surveillance, noting the observed strengths, weaknesses, and recommendations for improvements. Indicate if formal corrective action is being considered and invite comments and questions. Finally, express appreciation for cooperation demonstrated during the surveillance.

402.2 Surveillances should consider the following, as appropriate:

(a) Upon arrival at the workplace, note

(1) the existence of any apparent hazards, such as radiation, chemicals, toxins, spills, electricity, leaks, tripping, combustibles and flammables, noise, overhead work, unsecured ladders or scaffolding, dangerous apparatus or tools, hot or cold surfaces or liquids, compressed gases, unguarded rotating equipment, and general housekeeping.

(2) the application of barriers, such as isolations, tags, clearances, warning signs, locked or roped-off areas, and segregation of nonconforming materials.

(3) the condition of facilities, such as cleanliness, ventilation, temperature, area alarms, public-address system, availability of protective and emergency equipment, and current status of testing for fire protection and lifting equipment.

(4) the availability and use of appropriate equipment and materials, such as apparatus and tools, calibrated tools and measuring and test equipment and instruments, shelf life, labeling and traceability of raw materials and samples.

(5) the availability and use of documentation, such as current reference documents, instructions, procedures, drawings, specifications and documentation required to authorize work or to record key results or data.

(6) Personnel. If not evaluated earlier under para. 402.1(d) of this Subpart, note such things as

(-a) supervisory involvement

(-b) worker preparedness and understanding of assigned tasks and associated risks

(-c) skills and expertise available

(-d) communications

(b) As the surveillance progresses

(1) the performance of the personnel conducting work and inspection should be observed. Some aspects that may be evaluated include

(-a) communications with supervision and supporting organizations

(-b) how accountability is established

(-c) adherence to rules and procedures

(-d) use of tools, apparatus, and equipment

(-e) handling of problems or unexpected events

(-f) inspection activities performed to verify that materials, parts, and components meet specifications

(2) the adequacy of procedures, specifications, and work instructions should be assessed.

(3) the adequacy of process controls used for activities that cannot be clearly delineated in procedures should be assessed. Controls for tests and experiments should support and validate a researcher's results and conclusions and provide sufficient data for replication and peer reviews when required. Controls during development, which are applied to the fabrication, construction, test, and operation of prototypes and test rigs, should support and validate the results and provide reliable data for subsequent production-line activities.

(c) On completion of the surveillance

(1) the observations should be evaluated by the individual who performed the surveillance with the assistance of cognizant personnel if necessary to assess their validity, importance and significance, and impact on quality, safety, and reliability both individually and collectively.

(2) care should be taken to identify trends and isolated incidents that may have generic implications so that they may be appropriately followed up.

(3) consideration should also be given to reviewing other surveillances of similar work activities for identification of trends. This evaluation may identify conditions adverse to quality, nonconforming items, and quality program inadequacies. These should be processed in accordance with applicable corrective action procedures.

(4) observed strengths and positive trends should also be identified.

(5) issues not included in the above considerations, such as industrial safety, cost effectiveness, and process efficiency, should also be identified.

500 REPORTING AND COMMUNICATION

Reporting and communication may take many forms within the organization. The following elements should be considered:

(a) reaching agreement on communicating results during surveillance

(b) providing immediate verbal feedback concerning strengths and weaknesses to first-line supervisors, managers, and workers, as appropriate

(c) notifying appropriate personnel of conditions adverse to quality in accordance with governing procedures

600 RESOLUTION OF ISSUES

601 Response to Surveillance Reports

Responses to identified issues should be made in a timely manner, with consideration given to the importance of the issue. When an issue is not understood, it should be discussed with responsible individuals and mutually agreed upon or escalated in accordance with governing procedures.

Issues should be resolved at the lowest level that can effectively resolve the concern and that has the authority to implement a resolution.

602 Follow-Up

Follow-up of important issues should be initiated as necessary to confirm their satisfactory resolution.

Results from surveillances should be provided as inputs to existing corrective action, trending, or quality improvement programs in accordance with governing procedures.

SUBPART 3.1-3.1
Implementing Guidance for Part I, Requirement 3: Design Control

(15) 100 GENERAL

This Subpart provides nonmandatory guidance on design control as specified in Requirement 3 of Part I.

Some factors to be considered in establishing the design control measures may include the following:

(a) nature of the organization, such as the facility Owner(s), major equipment designer(s) or facility designer, and the design interfaces among them

(b) importance of design activity to safety

(c) state of the art such as experimental, developmental, or standard design

(d) nature of design activity, such as conceptual, preliminary, detailed design, field engineering, or modifications to operating facilities

(e) nature of interaction between design, operation, and construction activities

(f) the effect of design change implementation on the safe operation of the facility

(g) nature of analysis, such as analysis supporting the design or predictive analysis of an existing design

(15) 200 DESIGN INPUT

Design inputs include many characteristics and functions of an item or system. These inputs vary depending on the application; however, the nuclear industry has found it desirable to consider at least the following listed inputs as they apply to specific items or systems:

(a) basic functions of each structure, system, and component

(b) performance requirements such as capacity, rating, and system output

(c) regulatory requirements, and commitments or responses to federal, state, and local regulations. For example, these may include, but are not limited to

(1) safety analysis report

(2) NRC's Safety Evaluation Report and supplements thereto

(3) environmental report

(4) NRC's environmental statement and supplements thereto

(5) technical specifications

(6) regulatory guides

(7) code of federal regulations

(8) NRC bulletins, circulars, notices, and generic letters

(9) commitments in correspondence with NRC

(d) codes and standards. For example, these may include, but are not limited to

(1) ASME Codes and Standards

(2) ACI, AISC, ANSI, ASNT, ASTM, AWS, IEEE, ISO, NFPA, and others by similar societies or organizations

(e) design conditions such as pressure, temperature, flow, fluid chemistry, and voltage

(f) loads such as seismic, wind, thermal, and dynamic; the cumulative effect of design changes on the analytical design basis, e.g., the addition of a load to an existing wall or the addition of an instrument to a cabinet

(g) environmental conditions anticipated during storage, construction, operation, and accident conditions, such as pressure, temperature, humidity, corrosiveness, site elevation, wind direction, exposure to weather, flooding, nuclear radiation, electromagnetic radiation, and duration of exposure; qualification test requirements; shelf or service life limitations

(h) interface requirements including definition of the functional and physical interfaces involving structures, systems, and components:

(1) the effect on existing plant equipment capability, such as DC battery loads, AC bus capacity, available stored water inventory, service instrument air capacity, water systems capability (intake, service, and component cooling water), and HVAC capability

(2) the effect of cumulative tolerances in the design

(3) the effect on design and safety analyses to ensure the analytical bases remain valid

(4) the compatibility with unimplemented design changes to specify any required sequence for implementation

(5) compatibility with technical specification requirements

(i) material requirements including such items as compatibility, electrical insulation properties, protective coating, and corrosion resistance

(j) mechanical requirements such as vibration, stress, shock, and reaction forces

(k) structural requirements covering such items as equipment foundations and pipe supports

(l) hydraulic requirements such as pump net positive suction heads (NPSH), allowable pressure drops, and allowable fluid velocities

(m) chemistry requirements including provisions for system flushing, batch sampling, and in-line sampling; power plant water chemistry treatment for primary systems, steam generator, and plant limitations on water chemistry

(n) electrical requirements such as source of power, load profile voltage, electrical insulation, motor requirements, physical and electrical separation of circuits and equipment; the effect of cable routing or rerouting on the cable tray system (loading, seismic capability, and capacity limitations)

(o) layout and arrangement requirements

(p) operational requirements under various conditions, such as startup, normal operation, shutdown, maintenance, abnormal or emergency operation, special or infrequent operation including installation of design changes, and the effect of system interaction

(q) instrumentation and control requirements including indicating instruments, controls, and alarms required for operation, testing, and maintenance, other requirements such as the type of instrument, installed spares, range of measurement, location of indication, and set point determination are included

(r) security requirements to include access and administrative control requirements and system design requirements including redundancy, power supplies, support system requirements, emergency operational modes, and personnel accountability

(s) redundancy, diversity, and separation requirements of structures, systems, and components

(t) failure effects requirements of structures, systems, and components including a definition of those events and accidents that they must be designed to withstand

(u) test requirements including preoperational and subsequent periodic tests and the conditions under which they will be performed

(v) accessibility, maintenance, repair, and preservice and inservice inspection requirements for the facility including the conditions under which these will be performed

(w) personnel requirements and limitations including the qualification and number of personnel available for operation, maintenance, testing and inspection, and radiation exposures to the public and facility personnel

(x) transportability requirements such as size and shipping weight, limitation, and I.C.C. regulations

(y) fire protection or resistance requirements:

(1) safe shutdown analyses, the introduction of safe shutdown equipment into fire areas

(2) routing of piping and electrical cables and the necessity for cable fireproofing and/or fire stops

(3) fire detection and fire suppression capability

(4) fire barrier capability including fire door installation

(5) fire dampers

(6) access to fire fighting and emergency equipment

(7) use of noncombustible materials

(8) introducing combustible materials into safe shutdown areas by design or during installation or operation

(9) smoke and toxic gas generation

(z) handling, storage, cleaning, and shipping requirements

(aa) other requirements to prevent undue risk to the health and safety of the public

(bb) materials, processes, parts, and equipment suitable for application

(cc) safety requirements for preventing personnel injury including such items as radiation safety, minimizing radiation exposure to personnel, criticality safety, restricting the use of dangerous materials, escape provisions from enclosures, and grounding of electrical systems

(dd) quality and quality assurance requirements

(ee) reliability requirements of structures, systems, and components including their interactions, which may impair functions important to safety

(ff) interface requirements between equipment and operation and maintenance personnel

(gg) requirements for criticality control and accountability of nuclear materials

(hh) load path requirements for installation, removal, and repair of equipment and replacement of major components

(ii) qualification test requirements

300 DESIGN PROCESS (15)

The design activities may be prescribed in job specifications, work instructions, planning sheets, procedure manuals, test procedures, or any other typed or written form that provides adequate control and permits reviewing, checking, or verifying the results of the activity.

(a) Subjects normally covered by procedures for the preparation and control of drawings include the following:

(1) drafting room standards

(2) standardized symbols

(3) identification system

(4) indication of status

(5) checking methods

(6) review and approval requirements

(7) issuance and distribution control

(8) storage and control of originals or master copies

(9) revisions

(10) as-built drawings

(11) control of computer-aided design and engineering tools

(b) Subjects normally covered by procedures for the preparation and control of specifications and other design documents include the following:

(1) format requirements
(2) identification system
(3) review and approval requirements
(4) issuance and distribution
(5) revisions
(6) indication of status
(7) storage and control of originals or master copies

(c) Design documents should include information that may subsequently be needed to support facility operations such as

(1) control room operations
(2) maintenance
(3) spare and replacement parts
(4) environmental qualification of equipment
(5) outage planning and scheduling
(6) safety evaluations
(7) facility modifications
(8) personnel training and qualification

(15) 400 DESIGN ANALYSIS

Design analysis should be performed in a planned, controlled, and documented manner. Design analysis should identify the purpose, methods, assumptions, design inputs, references, units used, and any restrictions or limitations on the use of the results. Calculations should be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and dates or by other data such that calculations are retrievable.

401 Use of Computer Programs

When a computer program is used in a design analysis, the correctness of the computer-generated results may be demonstrated in either of the following two ways:

(a) Case (1): by virtue of the program's acceptance testing and configuration management in its as-installed configuration (i.e., it is controlled) in accordance with the applicable requirements of NQA-1, Parts I and II prior to use, or

(b) Case (2): by applying a known trustworthy means to independently verify the computer-generated results with the design analysis for each application of the computer program, in accordance with Part I, Requirement 3, section 500

These two cases are further clarified below. Additionally, in either case, it is advisable to have a properly qualified person assess the reasonableness of the results in light of the analyzed conditions.

Computer programs that are used to preprocess input or postprocess output (such as scripts that are written in macro languages, such as Microsoft VBA, Python, and the command shell) used in a design analysis are subject to these same requirements.

401.1 Acceptance Prior to Use by Applying NQA-1 Software Requirements. Case (1) is applicable only if all of the following are satisfied:

(a) The computer program's acceptance testing documentation shows that it produces correct solutions for the applied mathematical model within defined limits for each parameter employed [i.e., Requirement 3, para. 401(a)].

(b) The applied mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application [i.e., Requirement 3, para. 401(b)].

(c) The design analysis uses the computer program in a manner consistent with the scope of its acceptance testing.

(d) The computer program's acceptance testing was performed in accordance with Subpart 2.7, para. 404 and, if applicable, Subpart 2.14.

(e) The computer program is maintained under configuration management in its as-installed configuration in accordance with Subpart 2.7, para. 203.

(f) The design analysis uses the computer program in a controlled environment equivalent (i.e., with an identical configuration item list) to that in which it was tested.

When all of the above conditions are met, a reference to the computer program's configuration management and acceptance testing record should be sufficient to justify its use in the analysis. Acceptance testing performed during either NQA-1 compliant software development or computer program commercial grade dedication processes may be used to satisfy the requirements of Part I, Requirement 3, paras. 401(a) and (b).

For computer programs that are developed under a QA program compliant with NQA-1 Parts I and II, verification and validation performed during the computer program's development should demonstrate its acceptability in accordance with Requirement 3, para. 401(a) within defined limits for each parameter employed. For computer programs acquired as commercial-grade, activities performed during the dedication process, including documented technical evaluations and acceptance activities, should provide evidence that the computer program correctly performs within its defined limits in accordance with Requirement 3, para. 401(a).

For each computer program either developed under an NQA-1 compliant program or procured as commercial-grade, acceptance activities must show that the applied mathematical model produces a valid solution to the physical problem in accordance with Requirement 3, para. 401(b). This may be performed

through literature searches, textbook references, qualification testing, comparison of computer program results against a reliable reference such as alternate mathematical model results or physical system measurements, or other such methods that provide assurance that the applied mathematical model in the computer program is appropriate for the physical problem being analyzed.

A spreadsheet calculation may be considered an accepted and controlled computer program if, in addition to satisfying the criteria specified above, all of the cells that contain formulas are locked and password-protected to prevent changes. Only the input parameter cells should allow user input.

401.2 Independent Verification of Computer Program Results for Each Application With the Design Process. Case (2) applies to computer programs for which any one or more of the criteria specified in Case (1) is not satisfied. The affected computer-generated results are verified through the design verification process for each application by applying either para. 501.2 or para. 501.3 of Part I, Requirement 3. The focus is on the results, which are verified by known trustworthy means that are both independent of the unproven computer program and demonstrated to be technically correct in accordance with Requirement 3, paras. 401(a) and (b).

It is not sufficient to compare the results with those of another computer program that has not undergone acceptance testing (i.e., is unproven) or is not properly maintained under configuration management. The reference against which the results are verified is justified by good engineering practice, such as hand calculations, measurements taken on a physical system similar to that being modeled, or another computer program that has been properly accepted for such use and controlled [i.e., a computer program that meets all of the requirements listed for Case (1)].

The verification methodology is shown to produce correct solutions for the applied mathematical model within defined limits for each parameter employed [i.e., Requirement 3, para. 401(a)], and the applied mathematical model is shown to produce a valid solution to the physical problem associated with that application [i.e., Requirement 3, para. 401(b)]. Such independent verification of results for a particular design analysis should satisfy the computer program verification requirement in Requirement 3, para. 402(e) for the current verified design analysis only; it is not sufficient evidence to qualify the computer program for use in other design analyses.

In addition to the above, the verification of a spreadsheet calculation should include confirmation that the mathematical model's formulas are properly represented in the spreadsheet's symbology and that the correct cell references are incorporated into each instance of each formula.

The software requirements in Subpart 2.7 of Part II are optional for computer programs whose results are verified with the design analysis for each application.

401.3 Changes to Computer Code or Defined Limits. Where changes to a previously accepted computer program are performed, the new version requires verification in accordance with Requirement 3, para 401.

Any use of an accepted and controlled computer program beyond the limits previously verified must be justified, either by performing additional acceptance testing, as in Case (1), for the newly defined limits or by independently verifying, as in Case (2), all results that could be affected by such usage. Justification should be provided for judging any results to be unaffected by the out-of-scope usage.

401.4 Documentation. Documentation of the computer program verification activities described above should be in accordance with Requirement 3, para. 402 of Part I.

Table 401.4 summarizes the acceptability of methods that may be used to meet the requirements of Requirement 3, paras. 401(a) and (b) for each of five hypothetical scenarios.

500 DESIGN VERIFICATION

The purpose of design verification is to provide a confirmatory check of design adequacy by a person(s) competent to have prepared the design being verified but sufficiently independent such that they are not verifying their own work. Accordingly, design verifiers may be a supervisor, a subordinate, or any other individual from inside or outside the organization, provided they are competent, they are not verifying their own work, and they have access to the necessary design information.

Design verification for some designs or specific design features may be achieved by suitable qualification testing of a prototype or initial production unit.

Qualification testing may be used in combination with other verification methods. For example, it may be most effective to verify that an instrumentation cabinet is designed to withstand the maximum earthquake-caused vibratory motions by actually subjecting the cabinet and its associated components to shaker tests that correspond to these vibratory motions. The shaker tests will not, however, verify that the circuitry is designed correctly or that the component in the cabinet will perform its intended function. Other tests or verification means are required to confirm that remaining design functions are adequately performed by the instrumentation and that those components perform the intended functions under the varying conditions to which they are subjected.

If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance,

Table 401.4 Scenarios for Use of Computer Programs in Design Analysis (15)

Scenario	Use of Computer Program for Design Analysis (Part I, Requirement 3, Para. 401)	Design Verification Method (Part I, Requirement 3, Section 500)	Acceptable?	Comment
1	Computer program controlled and accepted for use applied to physical problem	Design review, alternate calculation, or qualification testing	Yes	Satisfies Case (1) and meets Requirement 3, paras. 401(a) and (b) through prior acceptance testing for design analyses within the acceptance testing scope.
2	Computer program not controlled and/or accepted for use	Design review	No	Does not satisfy Case (1) or Case (2). The appropriate design inputs may be verified; however, a trustworthy method has not been used to verify results. Additional method required to verify correct solutions for the applied mathematical model and physical problem.
3	Computer program not controlled and/or accepted for use	Alternate calculation: another computer program, which has been controlled and accepted for use, applied to physical problem	Yes	Satisfies Case (2) and meets Requirement 3, paras. 401(a) and (b) through the verification method for the current verified design analysis.
4	Computer program not controlled and/or accepted for use	Alternate calculation: hand calculation	Yes	Satisfies Case (2) and meets Requirement 3, paras. 401(a) and (b) through the verification method for the current verified design analysis, provided that the hand calculation verifies the applicability of its mathematical model to the physical problem through textbook references, literature searches, or other reliable methods.
5	Computer program not controlled and/or accepted for use	Qualification testing	Yes	Satisfies Case (2) and meets Requirement 3, paras. 401(a) and (b) through the verification method for the current verified design analysis.

the modification should be documented and the item modified and retested or otherwise verified to ensure satisfactory performance.

(15) 600 CHANGE CONTROL

Design documents should be maintained current to ensure their availability to support facility design, construction, and operation. However, design changes may be approved without revision to the affected document(s). When this occurs, procedures should be established to ensure that a determination of the final design or as-built condition can be made, consistent with the user's needs. Since not all affected documents require revision, procedures should identify those design documents that are subject to revision. Measures may include, but are not limited to, imposing a time limit for updating the affected document(s), limiting the number of design changes allowed to accumulate prior to revising the affected document, or providing for a process that continually updates the affected document(s).

During the operational phase, attention should be given to system modifications, mechanical and electrical temporary alterations, and instrument setpoint changes to ensure that design changes are processed in accordance with design control requirements. Proposed modifications, alterations, and changes may overlap and may not be installed in the sequence that they were designed; therefore, it is incumbent upon the design organization and plant/facility Owner to control approved (but not installed) design changes to ensure that changes do not conflict with each other. Where modifications, alterations, or changes must be installed in a particular sequence, the sequence should be specified. Partial installation of design changes should be approved by the design organization. Controls should ensure that documents that are required to support operation reflect

the as-built condition of the facility. Temporary and permanent repair work and parts replacement should be reviewed to determine if these activities constitute design changes.

Assessment of the cumulative effects of individual changes should be conducted to determine the impact on the final design.

700 INTERFACE CONTROL

During the construction and operational phases, attention should be given to defining and controlling the design interfaces between organizations participating in design changes/modifications and to defining the responsibility for the overall control of the design. The responsibility for the design of the facility should be divided in a way that is suited to the individual capabilities of the participating organizations and the status ofconstruction or operations. Participating organizations may include

(a) Owner's design organization
(b) construction engineering group
(c) operating organization
(d) architect engineer
(e) reactor manufacturer (NSSS)
(f) equipment design
(g) other design contractor

The documentation of the assignment of design responsibilities may be accomplished in procedures, internal or external correspondence, contracts, or other suitable documents.

800 DOCUMENTATION AND RECORDS

The documentation and records for a facility should include provisions for as-built documentation. These provisions should address what documents are required, the depth of information required for the as-built documentation, the internal or other measure for updating, and the identification of those documents that are to become lifetime or nonpermanent records. As-built documents may include documents such as the following:

(a) drawings required for facility operation
(b) modification packages
(c) manufacturer operation and maintenance instructions
(d) manufacturer vendor manuals
(e) manufacturer technical bulletins
(f) equipment and instrumentation listings
(g) environmental qualification listings
(h) spare and replacement parts listings

The status of the approved design should be readily available to the participating design organization(s). In addition, for the operation phase, the as-built configuration and the status of modifications being implemented should be readily available to the operating organization.

SUBPART 3.1-4.1
Implementing Guidance for Part I, Requirement 4: Procurement Document Control

100 GENERAL

This Subpart provides nonmandatory guidance on controlling quality assurance requirements in procurement documents as specified in Requirement 4 of Part I.

200 PROCUREMENT DOCUMENT REVIEW

The review of procurement documents should be performed as early in the document preparation as practicable. Technical and quality assurance reviews should normally be performed on the procurement documents prior to issuance for bid.

Prior to contract award, reviews of changes made resulting from bid evaluations or negotiations should include consideration of the following:

(a) applicable provisions described in Part I, Requirement 4, section 200

(b) determination of any additional or modified design criteria

(c) analysis of exceptions or changes requested or specified by the bidder and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished

Documentation of reviews performed should provide objective evidence of satisfactory accomplishment of such reviews prior to contract award.

300 TYPICAL SCOPE OF PROCUREMENT EFFORT

The complexity of a nuclear facility dictates the need for a multitude of tasks that should be performed during various phases of design, construction, testing, and operations. One of the major tasks is the procurement of items and services. Each major phase involves a procurement effort that should be responsive to the special needs of that phase and that should provide items and services that meet code, regulatory, and special requirements. Examples of the items and services procured during these phases are given in paras. 301 and 302 of this Subpart.

301 Design, Construction, and Testing Phases

The following are examples of the items and services provided during design, construction, and testing phases:

(a) design and engineering services

(b) site investigations, such as those required to determine the engineering requirements for the structure (i.e., soil investigation, environmental studies, both field work and laboratory effort)

(c) long-lead items such as the nuclear steam supply, process equipment, including major equipment fabrication and test, and high-level waste storage tanks

(d) construction of the main structure of the facility, including structural steel erection and concrete production and placement

(e) specific site erection and installation tasks, such as piping and mechanical and electrical equipment;

(f) services for nondestructive examination and required laboratory tests

(g) hardware, such as valves, piping, tanks, and miscellaneous hardware

(h) software, such as development of facility operating procedures, technical manuals, and computer codes

(i) services of various consultants to assist in setting up management systems (i.e., quality assurance program and operator training)

(j) preoperational and start-up tests

(k) baseline inspection equipment or services

302 Operational Phase

The following are examples of the items and services provided during operational phases:

(a) fuel, equipment, and services for power plant fueling operations; special fuel grapples and cask yokes at reprocessing plants, fuel components, and subassemblies at fuel fabrication plants; chemicals used in fuel processing and reprocessing cycles; special packaging for nuclear materials, radioactive products, and radioactive by-products

(b) in-service inspection equipment or services

(c) items and services for facility maintenance, modifications, or changes

(d) special services such as environmental monitoring, radioactive waste disposal, and facility decontamination

The examples given in paras. 301 and 302(a) through (d) of this Subpart are not meant to be all inclusive but only indicative of the wide variety of procurements for the above phases. Similarly, it should be realized that the phases and types of procurements listed above are

not distinct in scope and timing and that there may be considerable overlap depending upon the needs of a particular situation.

400 CATEGORIZATION OF PROCUREMENT ACTIONS

The types of procurements listed in para. 302 of this Subpart may also be categorized in terms of what is supplied by the Supplier, i.e., hardware, services, installation, and total system supply or combinations thereof. Such a categorization, wherein the procurement efforts are grouped by what is supplied, can be of assistance in identifying the logical steps that should be performed in properly specifying the quality assurance requirements in the procurement documents. For example, the procurement of services, such as for soil investigations or pipe stress calculations, can have certain quality assurance program features in common that may be different for the program feature of a pure hardware procurement.

500 GENERAL LOGIC CONSIDERATIONS

The quality assurance requirements should be compatible with the particular type of item or service that is to be supplied. Certain items and services may require extensive controls throughout all stages of development, while others may require only a limited quality assurance effort in selected phases of development. The factors that determine the extent of a quality assurance effort are specified in paras. 501 through 505 of this Subpart.

501 Importance of Malfunction or Failure of the Item to Plant Safety

Each item to be procured should be evaluated to determine whether or not it is important to plant safety. For those items that are important to plant safety, applicable requirements of this Standard should be specified in the procurement document. This safety determination should be made by the engineering staff of the appropriate organization having primary responsibility for specifying the design requirements for the item.

502 Complexity or Uniqueness of the Item

In developing specific quality assurance requirements for a particular item, complexity and uniqueness should be considered.

502.1 The extent of controls needed to ensure the quality of those characteristics that are necessary for proper functioning and long-term performance may depend heavily upon the complexity of the item, the margin of safety incorporated into its design, and the industry experience, or lack thereof, in accomplishing the quality-related activity. If a design effort is required to develop the item or accomplish the activity, design quality assurance requirements should be included in the procurement document.

502.2 Items that require a complex manufacturing plan may require extensive control over important characteristics. The control over important characteristics should extend beyond the manufacturing phase when it is necessary to preclude damage to those characteristics during packaging, shipping, handling, and storage.

502.3 In determining the extent of quality assurance to be applied, past experience in the development of similar items should be considered. An item being developed for the first time will probably require much more control over important characteristics than one that has had a past history of successful performance. The complexity or uniqueness of the item may also affect the extent of personnel training and indoctrination required.

503 Need for Special Controls and Surveillance Over Processes and Equipment

503.1 Certain work operations require the use of special processes such as a welding, nondestructive examination, passivation, brazing and soldering, hardness and tensile testing, protective coating, and heat treatment.

503.2 Special processes may also include certain in-process operations such as chemical batch process, plating operating, and electric insulation impregnation. These processes should be accomplished under specially controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions, definitive procedures, qualified personnel, and assurance that prerequisites have been satisfied.

504 Degree to Which Functional Compliance Can Be Demonstrated by Inspection and Test

It may be possible to demonstrate the quality of certain characteristics of an item by an appropriate inspection or test. In such cases, the in-process control effort may be reduced if any appropriate inspection and test will be sufficient to provide assurance of quality. A limiting case is an end-product test that can properly assess the degrees of compliance to quality requirements, thereby eliminating the need for in-process control.

505 Quality History and Degree of Standardization of the Item

The ability to use historical data in evaluating the quality experience of an item is based in part upon the degree of standardization of the item. If a manufacturer has been producing a particular standard item for a long period and if the operational quality history of the item indicates that its significant characteristics perform satisfactorily, the quality assurance program may be tailored

to reflect this satisfactory performance history. Conversely, if certain characteristics are determined to be unsatisfactory based upon operational data, additional quality assurance effort may be required to correct these deficiencies.

The general logic considerations outlined above should be applied for each procurement action. If all or most of these considerations apply to a particular action, the overall method of para. 700(a) of this Subpart should be applied in specifying the quality assurance requirements in the procedure document. However, if these considerations have only limited applicability to a particular procurement action, the unique order method of para. 700(b) of this Subpart may be used to specify the quality assurance requirements of the procurement document.

600 LOGIC CHART

Figure 600 provides a pictorial illustration of the logic process described in section 500 of this Subpart. This chart illustrates an example for procurement of hardware items only; however, a similar logic flow can also be used for other types of procurements such as design, inspection, test, and installation services or total system supply. It should be noted that this chart is provided for guidance and illustration only, and does not necessarily present all considerations that have to be made for this type of procurement.

700 METHODS OF SPECIFYING QUALITY ASSURANCE PROGRAM REQUIREMENTS

There are various ways in which the Purchaser can specify and obtain suitable Supplier quality assurance program requirements. Two of the most prevalent methods are as follows:

(a) Overall Method. The Purchaser may incorporate into the procurement documents a complete quality assurance program standard, such as Part I, and require the Supplier to apply the requirements of the quality assurance standard as appropriate to the items or services being procured.

(b) Unique Order Method. The Purchaser may incorporate into the procurement documents selected portions of a quality assurance standard, such as Part I, that are unique to the items or services being procured. For example, when the Purchaser's order is limited to design work only, Requirements 1, 2, 3, 5, 6, 16, 17, and 18 of Part I could be applied.

701 Example of Specifying the Overall Method

For procurement actions where the scope of work requires a broad range of skills and facilities to be furnished by the Supplier, most or all of the requirements of Part I may apply in varying degrees to the item or service being procured. An example would be the procurement of a major primary coolant pump or valve, which requires the Supplier to design, manufacture, inspect, and test the equipment in accordance with the Purchaser's engineering specification.

EXAMPLE: For the example given in para. 701 of this Subpart, the overall method could be used to specify the quality assurance program required of the Supplier by use of the provisions given in (a) through (f) of this Example.

(a) The Supplier shall establish and maintain a quality assurance program conforming to this Standard.

(b) This Standard is applicable only to the extent that the Purchaser's order requires work that is governed by the sections and elements. For example, when the Purchaser's order does not require design work of the Supplier, the requirements of Requirement 3 of Part I do not apply.

(c) The Supplier shall document a quality assurance program sufficient to conform to the applicable requirements of Part I and to the Purchaser's technical and administrative requirements contained in the purchase order and referenced documents.

(d) The Supplier shall submit a description of his quality assurance program to the Purchaser with the Supplier's bid response for the Purchaser's review. If the Supplier's description of his quality assurance program has been previously submitted, the Supplier shall update it or submit a statement that the quality assurance program has not changed since the last evaluation. Where the Supplier holds a valid Certificate of Authorization for ASME Code Section III, the Supplier's ASME Quality Assurance Manual containing a copy of the Certificate of Authorization may be submitted to satisfy the requirements for a documented quality assurance program description. The Supplier's ASME Quality Assurance Program should be supplemented to extend the quality assurance requirements to other activities not covered by the Code as necessary to satisfy the Purchaser's procurement requirements.

(e) The Purchaser shall evaluate the program of the successful bidder and provide comments if modifications to the program are required. The Supplier should resolve the Purchaser's comments and implement them prior to the start of any work affected by the comments. Subsequent changes to the Supplier's program shall be subject to the same degree of Purchaser control.

(f) The Supplier shall identify and pass on to the subtier Suppliers all applicable quality assurance program requirements.

702 Example of Specifying the Unique Order Method

For procurement actions where the scope of work requires only limited, even though specialized, skills and facilities to be furnished by the Supplier, only part of the requirements of Part I may apply to the item or service being purchased.

EXAMPLE: An example of the scope of work described in para. 702 of this Subpart might be as in (a) through (d) of this Example.

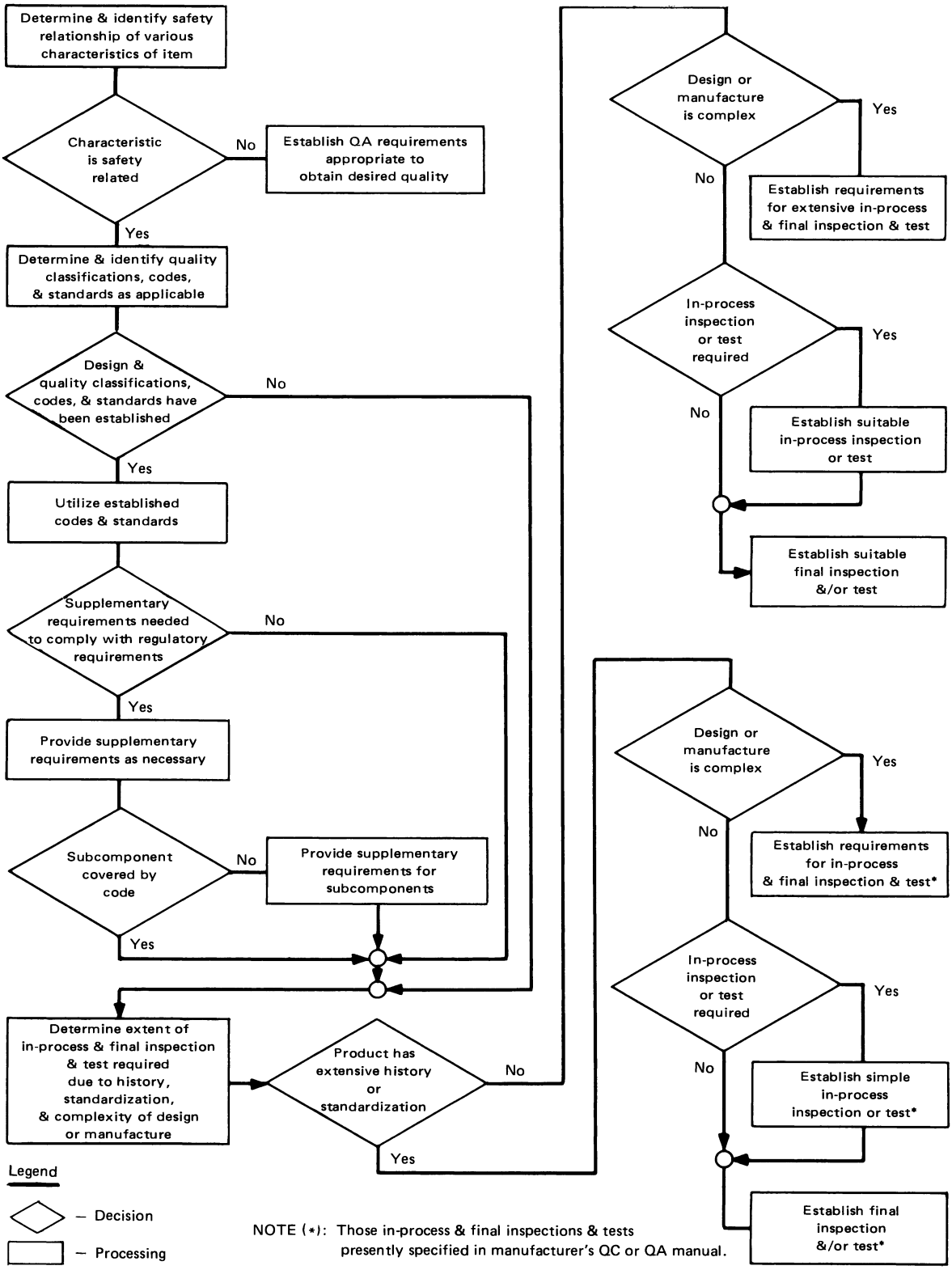
(a) Perform an independent design review of the following:

(1) the equipment described by the drawings and specifications referenced in this purchase order

(2) the equipment design and stress calculations submitted with this purchase order

(b) Establish a procedure and technique and conduct, subject to the Purchaser's approval, an experimental test to determine stress

Fig. 600 Logic Chart for Determining Appropriate Quality Requirements



levels at representative locations of the equipment under conditions corresponding to 100% system design pressure and coolant temperature of 100°F through 200°F. The Purchaser will provide the Supplier with the equipment to be tested.

(c) Prepare a complete report describing the work performed in (a) and (b) of this Example. The report should confirm whether the equipment meets the specified design requirements and make recommendations as to further investigations or design requirements considered necessary.

(d) For the above example, the unique order method could be used to specify the quality assurance program required of the Supplier by use of provisions given in (1) through (5) below.

(1) The Supplier shall establish and maintain a documented quality assurance program conforming to the Requirements of Part I, which are listed below. These Requirements shall be applied to the extent that the Purchaser's order requires work that is governed by the following Requirements:

1 Organization
2 Quality Assurance Program
3 Design Control
5 Instructions, Procedures, and Drawings
6 Document Control
11 Test Control
12 Control of Measuring and Test Equipment
15 Control of Nonconforming Items
16 Corrective Action
17 Quality Assurance Records
18 Audits

(2) The Supplier shall submit his quality assurance program description to the Purchaser with the Supplier's bid response for the Purchaser's review. If the Supplier's quality assurance program description has been previously submitted, the Supplier shall update it or submit a statement that the quality assurance program has not changed since the last evaluation.

(3) The Purchaser shall evaluate the program of the successful bidder and will provide comments if changes or supplements are required. The Supplier shall resolve the Purchaser's comments and implement them prior to the start of any work affected by the comments.

(4) The Supplier shall, during the performance of the order, submit all proposed changes of his quality assurance program to the Purchaser for information prior to implementing the changes to the Purchaser's order.

(5) The Supplier shall identify and pass on to the Supplier's subtier Suppliers all applicable quality assurance program requirements.

SUBPART 3.1-7.1
Implementing Guidance for Part I, Requirement 7: Control of Purchased Items and Services

100 GENERAL

This Subpart provides nonmandatory guidance on the control of procurement activities as specified in Requirement 7 of Part I, except for commercial grade items.

200 PROCUREMENT PLANNING

Procurement activities should be planned and documented to ensure a systematic approach to the procurement process. Procurement planning should result in the documented identification of procurement methods and organizational responsibilities.

Planning should consider the following: what is to be accomplished; who is to accomplish it; how it is to be accomplished; when it is to be accomplished.

Planning should be accomplished as early as practicable, and no later than at the start of those procurement activities that are required to be controlled, to ensure interface compatibility and a uniform approach to the procurement process.

Planning should result in the document identification of methods to be used in procurement activities, sequence of actions and milestones indicating the completion of these activities, and the preparation of applicable procedures prior to the initiation of each individual activity listed below. Planning would provide for the integration of paras. 200(a) through (i) of this Subpart.

(a) procurement document preparation, review, and change control

(b) selection of procurement sources

(c) bid evaluation and award

(d) Purchaser control of Supplier performance

(e) verification (surveillance, inspection, or audit) activities by Purchaser, including notification for hold and witness points

(f) control of nonconformances

(g) corrective action

(h) acceptance of item or service

(i) quality assurance records

300 SUPPLIER SELECTION

One method most commonly used to ensure the suitability of Supplier selection is source evaluation prior to selection. Where the evaluation involves more than one organization of the Purchaser, it is desirable to develop interface descriptions and sufficient program procedures to control the evaluations and define responsibilities.

There are many ways available for use in evaluating a potential Supplier. Some of the most common are given in paras. 301 through 303 of this Subpart.

301 Performance History

Evaluate the Supplier's history of providing a product that performs satisfactorily in actual use. Information evaluated should include either of the following:

(a) the experience of users of identical or similar products of the prospective Supplier

(b) the Purchaser's records that have been accumulated in connection with previous procurement actions and product operating experience

Quality performance is highly dependent upon the Supplier's personnel capabilities, the physical conditions of the manufacturing facility and equipment, and management attitude toward quality. Historical data should be representative of the Supplier's current capability. If there has been no recent experience with the Supplier or if he is a new Supplier, the prospective Supplier should be requested to submit information on a similar item or service for evidence of his current capabilities.

302 Quality Records

Objectively evaluate the Supplier's current quality records supported by documented qualitative and quantitative information. This may include review and evaluation of the Supplier's quality assurance program, manual, and procedures, as appropriate.

303 Facility Survey

Evaluate the Supplier's technical quality capability, which is determined by a direct evaluation of his facilities and personnel, and the implementation of his quality assurance program.

400 BID EVALUATION

The bid evaluation should consider the following performance and schedule considerations, which have the potential to affect the procurement quality:

(a) Supplier's personnel

(b) Supplier's production capability

(c) Supplier's past performance
(d) Supplier's alternates and exceptions

500 PURCHASER/SUPPLIER COMMUNICATIONS

Depending on the complexity or scope of the item or service, the Purchaser may initiate preaward and postaward activities. These activities may take the form of meetings or other communications to establish that the Supplier understands the procurement requirements; the intent of the Purchaser in monitoring and evaluating the Supplier's performance; and the planning and manufacturing techniques, tests, inspections, and processes to be employed by the Supplier in meeting procurement requirements. When Purchaser notification points, including hold and witness points, are required, they should be identified at this time. The depth and necessity of preaward and postaward communication depend on the uniqueness, complexity, and frequency of procurement with the same Supplier, and past Supplier performance for the specific items or services covered by the procurement document.

600 CONTROL OF CHANGES IN ITEMS OR SERVICES

601 Bid Evaluation Changes

Changes agreed upon by the Purchaser and Supplier during the bid evaluation process should be incorporated into a revision of the appropriate procurement documents.

602 Control of Changes

Changes to procurement documents should be subject to the same level of controls utilized for their development, except for editorial, price, delivery, or other minor changes that do not affect technical or quality requirements.

603 In Process Control of Deviations

Supplier-generated requests for deviations, changes, or exceptions to procurement documents should be controlled in accordance with para. 702 of this Subpart. The Purchaser should evaluate the need to maintain agreement between the procurement documents, and approved Supplier and Purchaser changes.

700 PRODUCT ACCEPTANCE

Among the methods used in the nuclear industry to accept an item or service from a Supplier are source verification, receiving inspection, Supplier Certificate of Conformance, postinstallation test at the nuclear power plant site, or a combination thereof.

701 Source Verification

Acceptance by source verification may be most desirable when the item or service is one of the following:
(a) vital to plant safety
(b) difficult to verify quality characteristics after delivery
(c) complex in design, manufacture, and test

Source verification may not be necessary when the quality of the item can be verified by review of test reports, inspections upon receipt, or other means.

The source verification activities may include the following checks.

701.1 Documentation has been submitted as required and provides verification of approvals, material, applicable inspections, and tests.

701.2 Fabrication procedures and processes have been approved and complied with and the applicable qualifications, process records, and certifications are available.

701.3 Components and assemblies have been inspected, examined, and tested as required and applicable inspection, test, and certification records are available.

701.4 Nonconformances have been dispositioned as required.

701.5 Components and assemblies are cleaned, preserved, packed, and identified in accordance with specified requirements.

702 Receiving Inspection

Acceptance solely by receiving inspection should be considered only when the items or services are as follows:
(a) relatively simple or standard in design, manufacture, and test
(b) adaptable to standard or automated inspections and/or tests of the end product to verify quality characteristics after delivery
(c) such that receiving inspection does not require operations that could adversely affect the integrity, function, or cleanness of the item

703 Certificate of Conformance

In certain procurement actions that do not involve source verification by the Purchaser, the Purchaser may accept an item or service from a Supplier based on a receiving inspection and a Supplier's Certificate of Conformance stating that the specified requirements have been met. However, specific supplemental documentation, such as material certificates or reports of tests performed, may be required by procurement documents. Acceptance by this method is satisfactory when the item or service is of simple design and involves standard materials, processes, and tests. Such items may be fabricated subject to selected qualification, sample, or batch testing to establish or maintain maximum quality.

704 Postinstallation Testing

Acceptance by postinstallation test is satisfactory when performed following the accomplishment of at least one of the preceding methods and when

(a) it is difficult to verify the quality characteristics of the item without it being installed and in use

(b) the item requires an integrated system checkout or test with other items to verify its quality characteristics or

(c) the item cannot demonstrate its ability to perform its intended function except when in use

(15) **705 Determining Authenticity**

Measures to ensure products are authentic and reduce the risk of introducing counterfeit or fraudulent items include

(a) procedures for detection and prevention of counterfeit and fraudulent items

(b) instructing staff on the issue of counterfeit and fraudulent items and providing information on incidents of suspected counterfeit items that have been received or experienced by others

(c) purchasing items directly from the manufacturer or an authorized manufacturer's distributor/representative

(1) confirming with the manufacturer or via other independent means that the item supplier is currently authorized by the manufacturer for the scope or type of item to be provided

(2) requiring additional receipt inspection for items being procured from a source other than the item manufacturer or the manufacturer's authorized distributor/representative

(d) inspecting items upon receipt for signs of potential counterfeiting or fraud. Inspections should include the following checks for indications that the item may not be authentic:

(1) nameplates, labels, and tags for signs of alteration, which can be an indication that items may not be authentic

(2) obvious attempts at beautification

(3) evidence of hand-tool marks on fasteners and other parts of an assembly

(4) use of dissimilar parts in the same application

(5) poor fit between assembled items

(6) evidence of handmade parts

(7) software identifiers, such as version numbers that do not match

(e) processing of returned items, including the following:

(1) inspection and screening for authenticity

(2) rejecting returns of items in quantities greater than those originally purchased by the customer

(f) when an item suspected of being counterfeit or fraudulent is identified, measures including segregation and control of the suspect item as nonconforming material

SUBPART 3.1-10.1
Implementing Guidance for Part I, Requirement 10: Inspection

100 GENERAL

This Subpart provides nonmandatory guidance on the inspection, monitoring, and in-service inspection activities as specified in Requirement 10 of Part I.

200 INSPECTION AND PROCESS MONITORING

When inspection and process monitoring are used, they should be performed in a systematic manner to ensure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process.

Controls, where required, should be established and documented for the control and sequencing of these activities at established inspection points during successive stages of the conducted process or construction.

Process monitoring may be advantageous when acceptance inspection may introduce significant delays or process interruptions or inhibit effective material control. When process monitoring is performed by personnel responsible for performing the process operation, results of monitoring should be verified by sampling inspection or surveillance.

300 IN-SERVICE INSPECTION

Inspection methods should be established and executed to verify that the characteristics of an item continue to remain within specified limits. Inspection methods should include evaluations of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.

SUBPART 3.1-16.1
Implementing Guidance for Part I, Requirement 16: Corrective Action

100 GENERAL

This Subpart provides nonmandatory guidance on corrective action as specified in Requirement 16 of Part I. While conditions adverse to quality are required to be identified promptly and corrected as soon as practicable, Requirement 16 also calls for a response to conditions adverse to quality appropriate to their significance.

200 CORRECTIVE ACTION

Corrective action should be integrated into all aspects of the quality assurance program. It consists of the following basic elements:

(a) identification and documentation
(b) determination of extent of condition
(c) significance classification
(d) cause determination
(e) corrections
(f) follow-up
(g) effectiveness review
(h) trend analysis

Corrective action activities should be documented and provide adequate control over the basic elements in a manner that permits the review, verification, and evaluation of the resulting effectiveness of the activities.

300 BASIC CORRECTIVE ACTION ELEMENTS

This section provides additional guidance on the basic elements of corrective action processes. Figure 300 depicts a representative corrective action process as described in sections 300 and 400 of this Subpart.

301 Identification and Documentation

Conditions adverse to quality (see definition in Introduction) should be promptly identified, documented, and corrected.

Where conditions adverse to quality have been identified, the extent to which other items and activities may be affected should be evaluated so that appropriate action may be taken, including measures to control any affected work in process, if necessary.

The extent of the condition may be identified by internal or external organizations and may include documentation resulting from audits, inspections, tests, design reviews, individual observations, operational events, maintenance activities, and other information that could indicate conditions adverse to quality.

302 Classification

302.1 Criteria for classifying conditions and trends adverse to quality as to significance should be established and, as a minimum, as conditions adverse to quality and significant conditions adverse to quality. Classifying the conditions should consider the following:

(a) impact on health and safety of the public, workers, or the environment

(b) impact on reliability, availability, or maintainability, or safety function of the equipment or facility

(c) impact and likelihood of not meeting regulatory requirements

(d) repetition of specific conditions adverse to quality and the consequence of recurrence, as well as the relationship or similarity between different adverse conditions and causes

(e) the extent to which the adverse condition or cause may apply to and impact other items or activities beyond the specific occurrence or work in progress

302.2 Conditions adverse to quality identified under para. 301 of this Subpart should be classified according to significance using the established criteria. Examples of conditions that may be significant under certain conditions include

(a) deficiencies in design, manufacturing, construction, testing, or process requiring substantial rework, repair, or replacement

(b) damage to a structure, system, component, or facility requiring substantial rework, repairs, or replacement

(c) a nonconservative error detected in a computer program after it has been released for use that impacts the criteria of paras. 302.1(a) through (d)

(d) the loss of essential data

(e) repeated failures to implement approved procedures, quality program documents, or technical requirements documents

303 Cause Determination

The cause(s) (including apparent, contributing, and root causes based on the significance of the condition) should be identified and used to determine the action(s) necessary to correct and preclude future occurrence of the condition. Causes, corrective action(s), and follow-up action(s) should be documented.

For significant conditions adverse to quality, cognizant management should be notified immediately; cause analysis should be conducted and may include apparent, contributing, and root causes based on the significance of the condition. A root cause analysis should be performed for significant conditions adverse to quality. An extent of condition should be performed, and the impact of such conditions on completed and/or related items and activities should be evaluated. The causes, corrective action(s), and follow-up action(s) should be documented.

At a minimum, methods and measures should be developed for determining the root cause(s) of significant conditions adverse to quality. Typical root cause categories might include

(a) inadequate management or supervision

(b) inadequate human performance capability or skill

(c) procedure inadequacy or error

(d) inadequate training or qualification of personnel performing work

(e) equipment or processing malfunction, inadequacy, or misuse

(f) inappropriate, self-imposed requirements or acceptance criteria

(g) unrealistic schedules that adversely impact safety or quality

(h) worker fatigue

(i) latent organizational or equipment issues

(j) safety culture impacts

304 Corrections

The remedial action(s) should be determined, documented, and promptly implemented. The overall roles and responsibilities for implementation of corrective actions should be identified and documented. For significant conditions adverse to quality, action(s) necessary to eliminate the cause(s) should be implemented to prevent recurrence.

Where corrective or preventive measures have already been completed to address conditions adverse to quality, based on design, nonconformance, or audit program elements, further action is not required unless the conditions are judged to be significant or are determined to be ineffective. The analysis to determine the action(s) to be taken to prevent recurrence of significant conditions adverse to quality may include studies, simulations, investigations, experimentations, trending, and personnel interviews. The analysis and identified actions should be documented and may include

(a) identification of preventive action to be taken

(b) a determination that generic implications have been considered

(c) a determination that action taken will preclude recurrence

Additional guidance for the prevention of recurrence is as follows:

A corrective action process should include documentation of the condition, the actions that have been taken, and, as appropriate, the effectiveness of the implementation. Upon completion of corrective actions, acceptance by the responsible organization, and the verification of implementation by the assigned organization, the corrective action report may be closed or allowed to remain open until effectiveness reviews have been completed in accordance with para. 306.

305 Follow-Up

Corrective action status should be monitored. Corrective action and implementation should be verified as complete only when the actions to correct the condition adverse to quality, including, where appropriate, the actions to prevent recurrence, are complete and documented. When completion of corrective action cannot be promptly verified due to an extended delay from the responsible organization, modification of the original schedule and communication to the affected organization(s) should be made. Compensatory (interim) measures may be identified and implemented to allow for work activities to proceed under controlled conditions.

306 Effectiveness Review

After verification of completion of corrective action for significant conditions adverse to quality, follow-up reviews, surveillance, or supplemental audits should be performed to determine whether actions taken have been and continue to be effective. When corrective actions have not been effective, further analysis should be performed to identify and correct the cause. In addition, the problem should receive escalated management attention.

307 Trend Analysis

Conditions adverse to quality should be reviewed periodically to determine the existence of adverse trends and repeat occurrences. Trends should be evaluated in a manner and at a frequency that ensures that significant adverse trends are identified promptly and evaluated for appropriate corrective action.

The significance of identified trends should be classified in accordance with para. 302 of this Subpart to determine whether further action is necessary.

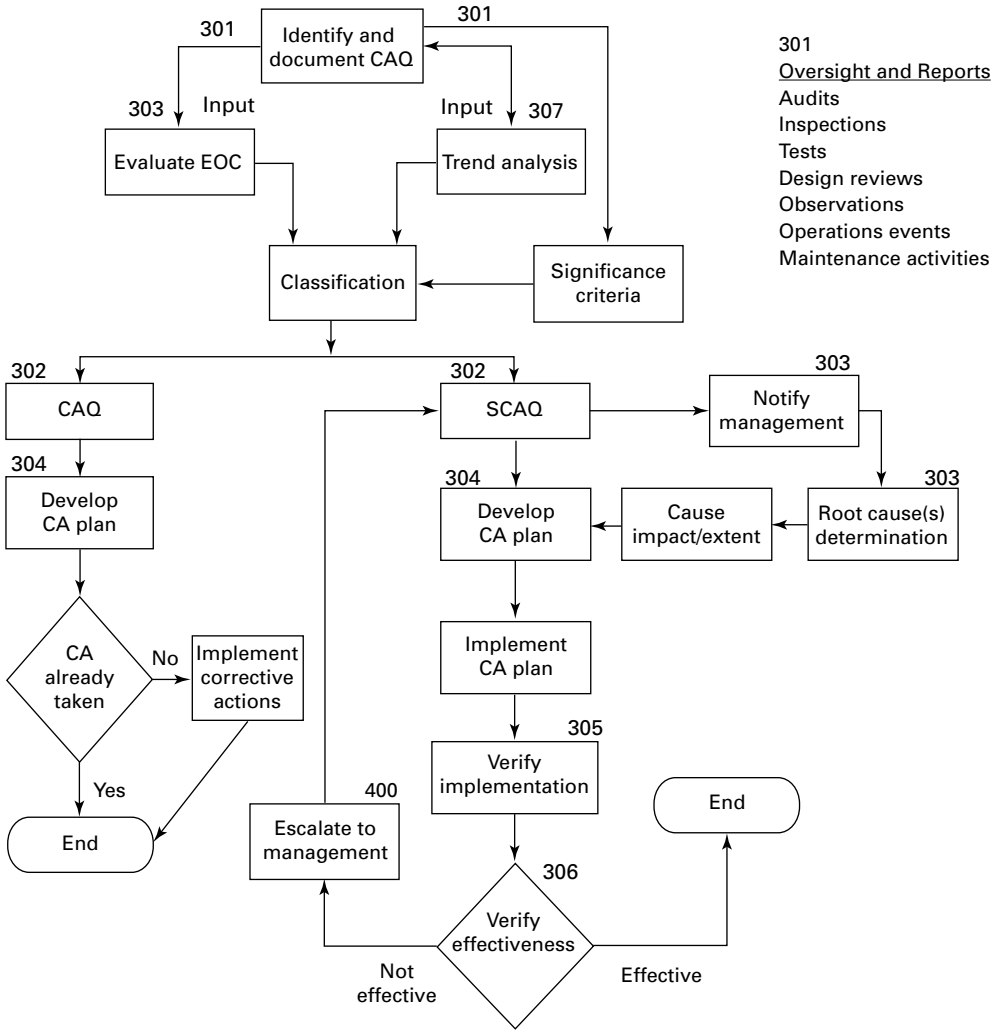
400 MANAGEMENT INVOLVEMENT

Appropriate levels of management should be involved in the corrective action process, and their roles and responsibilities should be documented. In addition, the corrective action activities should provide for cognizant management to be notified immediately when conditions adverse to quality are determined to be significant.

500 PROCESS CHART

Figure 300 depicts the flow of activities through the basic element described in sections 300 and 400 of this Subpart. The logic process illustrates a typical corrective action program and is provided for guidance and illustration only.

Fig. 300 Corrective Action Process Chart



GENERAL NOTE: CA, Corrective Action; CAQ, Condition Adverse to Quality; EOC, Extent of Condition; SCAQ, Significant Condition Adverse to Quality.

SUBPART 3.1-17.1
Implementing Guidance for Part I, Requirement 17: Quality Assurance Records

100 GENERAL

This Subpart provides nonmandatory guidance on records as specified in Requirement 17 of Part I, except for electronic records. Nonmandatory guidance for electronic records is contained in Subpart 3.1-17.2.

101 Generation of Records

Documents that are designated to become records should be legible, accurate, and completed appropriate to the work accomplished so that they can be read and understood and be traceable to the associated items or activities.

102 Authentication of Records

Statements of authenticity, handwritten signatures, electronic signatures, or any other means that ensures traceability to a specific individual or organization of authentication and associated date are acceptable methods of authentication. If initials or codes are used for identification, then a system should be established to ensure traceability to the authenticating individual or organization.

The records system should provide methods for authenticating copies of original records when the original record is contaminated or lost and a copy of the original record is available.

103 Indexing

Indexing can take many forms, including directories or listings. Indices should identify summary information for the records, such as the associated item or activity, title or description, originating individual or organization, retention period (lifetime or nonpermanent), location, and the media used for retention. For nonpermanent records, the period of retention should be defined.

104 Corrected Information in Records

When records are corrected, it is a good practice for such corrections should include the date and identification of the person authorized to issue such corrections.

105 Storage

A written storage procedure should be prepared and responsibility assigned for the implementing procedure. Storage procedures are suggested that include the following:

(a) a description of the storage facility

(b) the filing system to be used

(c) a method for verifying that the records received are in agreement with the transmittal document and that the records are legible

(d) a method of verifying that the records are those designated

(e) the rules governing access to and control of the files

(f) a method for maintaining control of and accountability for records removed from the storage facility

(g) a method for filing supplemental information and disposing of superseded records

106 Preservation and Safekeeping

To help ensure the preservation and safekeeping of records, the following should be considered:

(a) placement of records in binders, folders, or envelopes for storage in steel file cabinets or on shelving

(b) prevention of damage from environmental conditions

(c) manufacturer's recommendations on storage

(d) measures to preclude the entry of unauthorized personnel into the records system or storage area for protection from larceny or vandalism may include access lists, locked entry, attendant security, or a combination of these measures

(e) measures for replacement restoration, or substitution of lost or damaged records

(f) inspections of records to detect deterioration

107 Facilities and Containers

Current industry practices identify the use of two methods of providing storage facilities, single or dual.

(a) Single Facilities and Containers. NFPA-232[1] provides a set of methods that may be used for the storage of records in vaults, file rooms, or records protection containers. Where file rooms are used, an exception to NFPA-232 should be applied to permit forced air circulation system to be used, provided it is dampered in accordance with the room rating.

(b) Dual Facilities. If storage at dual facilities for records is provided, the establishment of sufficiently remote storage facilities depends on the type of hazard, such as earthquakes, fires, tornadoes, etc., and the probability for occurrence of these hazards.

[1] National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02169-9101.

108 Retrieval

A key function of a records system is to ensure that records are retrievable through their life cycle.

Records maintained at a Supplier's facility or other location should be accessible to the Purchaser or a designated alternate.

109 Records Transfer to Owner or Purchaser

Records accumulated at various locations, prior to transfer, should be made accessible to the Owner or Purchaser directly or through the procuring organization. For records transferred to the Owner or Purchaser, it is recommended that the Owner or Purchaser inventory the submittals, and acknowledge receipt.

Prior to transfer of the Supplier's records, the Supplier should consider the following:

(a) ASME Boiler and Pressure Vessel Code requirements are met
(b) regulatory requirements are satisfied
(c) operational requirements are satisfied
(d) warranty consideration is satisfied
(e) Purchaser's requirements are satisfied

200 LIST OF TYPICAL LIFETIME RECORDS

The following is a list of typical lifetime records categories and example record types or titles containing information meeting Part I, Requirement 17. Other records are also listed in Part I sections. The nomenclature of these may vary.

201 Design and Safety Basis Records

(a) Applicable codes and standards used in design
(b) Computer programs or corresponding mathematical model
(c) Design drawings
(d) Design calculations and record of checks
(e) Approved design change requests
(f) Design deviations
(g) Design reports
(h) Design verification data
(i) Design Criteria or Design Input data
(j) Design specifications and amendments
(k) Safety, hazards, and accident analysis reports
(l) Stress reports for code items
(m) Systems descriptions
(n) Systems process and instrumentation diagrams
(o) Technical analysis, evaluations, and reports
(p) Software evaluation reports and acceptance test plans and reports
(q) Software verification and validation data

202 Procurement Records

(a) Procurement specifications
(b) Purchase order and contracts (un-priced) including amendments
(c) Evaluated supplier listing

203 Manufacturing Records

(a) Applicable code data reports
(b) As-built drawings and records
(c) Certificate of Compliance
(d) Inspection and test data
(e) Heat treatment records
(f) Location of weld filler material
(g) Major defect repair records
(h) Nonconformance reports
(i) Performance test procedure and results records
(j) Pipe and fitting location report
(k) Pressure test results (hydrostatic or pneumatic)
(l) NDE final results or review/evaluation results
(m) Welding procedures
(n) Welder qualification reports
(o) Certified Material Test Report

204 Installation Construction Records

204.1 Civil

(a) Check-off sheets for tendon installation
(b) Concrete design mix reports, cylinder test reports, and charts
(c) Concrete placement records
(d) Inspection reports for channel pressure tests
(e) Material property reports
(f) Pile drive log and load test reports
(g) Procedure for containment vessel pressure proof test and leak rate tests and results
(h) Reports for periodic tendon inspection and testing
(i) Subsurface investigation results
(j) Embed as-builts

204.2 Welding

(a) Test results
(b) Heat treatment records
(c) NDE procedures
(d) Material property records
(e) NDE final results or review/evaluation results
(f) Weld location diagrams
(g) Weld procedures
(h) Welding qualification

204.3 Mechanical

(a) Cleaning procedures and results
(b) Code data reports
(c) Installed lifting and handling equipment procedures, inspection, and test data
(d) Lubrication procedures
(e) Material properties records
(f) Pipe and fitting location reports
(g) Pipe hanger and restraint data
(h) Pressure test results (hydrostatic or pneumatic)
(i) Safety valve response test procedures
(j) NDE final results or review/evaluation results

204.4 Electrical and I & C

(a) Cable installation procedures and results; pulling tension data, separation data, splicing procedures, and terminating procedures

(b) Certified cable test reports

(c) Relay test procedures

(d) Voltage breakdown test results on liquid insulation

204.5 General

(a) As-built drawings and records

(b) Final inspection reports and releases

(c) Nonconformance reports, causal analysis, and trending

(d) Specifications and drawings

(e) Construction records

205 Preoperational and Start-Up Test Records

(a) Power source procedures and results

(b) Final system adjustment data

(c) Pressure test results (hydrostatic or pneumatic)

(d) Initial start-up heat procedures and results

(e) Initial reactor/facility loading data, test procedures, and results

(f) Instrument AC system and inverter test procedures and reports

(g) On-site emergency power source energizing procedures and test reports

(h) Facility load ramp change data

(i) Facility load step change data

(j) Power transmission substation test procedures and results

(k) Preoperational test procedures and results

(l) Primary and secondary auxiliary power test procedures and results

(m) Reactor/facility protection system tests and results

(n) Start-up logs

(o) Start-up test procedures and results

(p) Station battery and DC power distribution test procedures and reports

(q) Water chemistry report

206 Operation Records

(a) Records and drawing changes identifying facility design modifications made to systems and equipment described in the Final Safety Analysis Report

(b) New and irradiated fuel/nuclear material inventory, fuel/nuclear material transfers, and assembly fuel/nuclear material-depletion history records

(c) Off-site environmental monitoring survey records

(d) Spent fuel/nuclear material shipment records

(e) Facility radiation and contamination survey results

(f) Radiation exposure records for individuals entering radiation control areas

(g) Records of gaseous and liquid radioactive material released to the environs

(h) Records of transient or operational cycles for those facility components designed for a limited number of transients or cycles

(i) Training and qualification records for current members of the facility-operating staff

(j) In-service inspection records

(k) Records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments

(l) Surveillance activities, inspections, and calibrations required by the technical specifications records

(m) Records of reactor/facility tests and experiments

(n) Changes made to operating procedures

(o) Low-level radioactive waste shipments records

(p) Sealed source leak test results

(q) Records of annual physical inventory of all sealed source material

(r) Logs of facility operation covering time interval at each power level

(s) Records and logs of maintenance activities, inspections, repair, and replacement of principal items of structures, systems, and components

(t) Water chemistry reports

(u) Operational, shift supervisor, and control room logs

(v) Event reports

(w) Fire protection records

(x) Nonconformance/corrective action reports

(y) Facility equipment operations instructions

(z) Emergency plan and procedures

(aa) Quality assurance and quality control manuals

(bb) Applicable records noted in other sections of this Subpart for any modifications or new construction applicable to structures, systems, or components

(cc) Evaluation of results of reportable safety concerns as required by regulations

(dd) Annual environmental operating report

(ee) Annual facility operating plan

(ff) Records to support licensing conditions such as safeguards and special nuclear material accountability

(gg) Results for in-use testing

207 Decommissioning and Destruction

(a) Radiological survey results prior and during destruction

(b) Waste container inspection and test reports

(c) Waste packing inspection results

(d) Nondestructive assay results for processed waste

(e) Nonconformance reports

(f) Waste form documentation and compliance certification

(g) Waste labeling and tracking

(h) Waste management record

SUBPART 3.1-17.2
Implementing Guidance for Part I, Requirement 17: Quality Assurance Records, Electronic Records

100 GENERAL

This Subpart provides nonmandatory guidance on records, as specified in Part I, Requirement 17 that are generated and maintained in an electronic format.

Organizations that generate and maintain quality assurance records in an electronic format should develop controls and associated procedures that address the unique capabilities and requirements of this technology. Electronic record controls should address how electronic records are identified, generated, authenticated, stored, and maintained per the required retention schedule.

200 GENERATION OF RECORDS

Electronic records may be generated using several different methods. These methods may include electronic data (defined in Part IV, Subpart 4.2.2), electronic mail, and records resulting from the conversion from one media type to another.

Electronic data designated to be records should be traceable to the associated items or activities. This can be accomplished by developing a naming scheme for both the electronic data itself and the media (e.g., file folders, CDs) that is used to store the electronic data.

Electronic databases may be used to create and/or maintain electronic records, including electronic data. Controls should be in place to ensure that the database record content, context, and structure is maintained. The database record content may contain, but is not limited to, electronic data (see Part IV, Subpart 4.2.2), an image in a not easily alterable format (e.g., tif, pdf), or an electronic address of the location where the image is stored. The database context is considered to be information about the internal structure of the database tables. The database structure is information about the table relationships.

Electronic mail may be used as a quality record if the controls provided in this Subpart are utilized. Electronic mail should be traceable to the subject of the record, the originator, and the date of origination. The information contained in the electronic mail is acceptable as a record, provided that the electronic mail system prevents unauthorized alterations or changes. Corrections to e-mail should be processed in the same manner as the original.

Conversion of a record from one media type to another should include verification to ensure that content, context, and structure are maintained. The conversion process includes conversion from various media forms including hardcopy, photographic, optical, and magnetic. The conversion process may involve scanning the original hardcopy record to create an image in a not easily altered format (e.g., tif, pdf). Verification should include reviews of the page, paragraph, and individual record configuration to ensure such information adequately represents the original document. This also applies to the situation where an electronic record is the original. When the conversion involves an electronic migration, a statistically valid sample set should be selected for verification purposes. Any recognized sampling standard that provides requirements for inspection and acceptance sample size may be used as a basis for the development of a sample set verification plan. To prevent data corruption or loss during the conversion process, the design authority should approve any changes to the database context or structure.

300 AUTHENTICATION OF RECORDS

Provisions for the authentication of electronic records should provide for the use of automated systems for the identification and signature recognition of the personnel performing the record authentication. An electronic signature is a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to represent the individual's handwritten signature. If electronic codes or user account information (e.g., username and password) is used for identification, controls should be established to ensure traceability to the authenticating individual or organization. Consideration should be given to periodically requiring the establishment of new user passwords. Methods for authenticating electronic records should be reliable and generally equivalent to paper records and handwritten signatures executed on paper.

Electronic signatures that are not based on biometrics should employ at least two distinct verification components such as user identification and password. Electronic signatures based upon biometrics should be controlled to ensure that they cannot be used by anyone other than the legitimate owners.

The integrity of the records in the new system or media should be verified. It is recommended that a not easily alterable format be used to ensure that the content, context, and structure are maintained consistent with the original record copy. If use of a not easily alterable format is not practical, controls should exist to provide an equivalent level of control.

When a record is converted to electronic media, the authentication of that record does not need to be reperformed.

400 INDEXING

Electronic records should be indexed to provide for the timely retrieval of the record. Organizations should develop and document external and/or internal indexing methods for the index system(s).

External indexing includes the labeling of records stored on external off-line media. External labeling should be developed and attached to the media used. For example, magnetic tapes should include the recording density, number of tracks, block size, types of internal labels, and if the tape is part of a multi-reel set.

Internal indexing of electronic records should enable the user to identify and access a specific record by using a table of contents, directory, key word, or other index strategy. In some cases the index may be automatically created by the system, while in other cases the originator may generate it. Where the originator creates the index, provisions should be established to ensure that all indices are identified using a common naming convention.

500 STORAGE

Storage of electronic records requires both media and compatible processing systems. The media containing the electronic records and the compatible processing systems access should translate the records into an appropriate retrievable, legible format. A typical processing system may consist of a computer and an application program.

The types of media utilized for electronic record storage should be identified in the records management program. The selection of the storage media should consider the shelf life of the media and the manufacturer's recommended qualified life.

The degradation of electronic media starts immediately after manufacture. Electronic records should be migrated onto new media before the manufacturer's recommended useful life is exceeded.

Two sets of electronic records should be maintained to ensure timely recovery in the event they are damaged or lost. These sets may be established in processing systems installed on separate servers, stand-alone computer platforms, or in a removable media format (e.g., optical disk, floppy disk).

The level of user access and the security of the compatible processing systems may also impact the required controls for the storage of electronic records.

Controls for remote access, local access, and secure processing systems should be established to prevent the alteration, damage, or loss of electronic records. Remote access systems are systems that store records on a network server, which are accessible to multiple users through a network or Internet hub. Local access systems are systems that store records on a local area network server that is accessible only to local users. Secure processing systems are stand-alone processing systems that are not accessible through a local area network or Internet hub.

Storage procedures for remote and local access systems should include security measures such as user passwords, network firewalls, file encryption, and virus protection. Appropriate environmental controls should be established for each type of electronic media to prevent damage to electronic media from environmental conditions such as light, heat, humidity or electromagnetic fields. Recommendations from the media manufacturer should be considered in establishing environmental controls.

Storage procedures should consider the control of the record media, and only release copies of the electronic records to requestors.

All electronic processing systems should also have power isolation devices to minimize the risk of damage from voltage surges, spikes, and other power-line disturbances.

If temporary storage for electronic records is used, two sets of in-process records should be maintained since the electronic media may be exposed to computer viruses and inadvertent alteration.

600 DISPOSAL

Electronic records designated for disposal should be erased or overwritten since use of the delete key may not actually delete the record but only make it irretrievable for one using the standard access methods. Physical destruction of the storage media or device may be used as an acceptable alternative. Storage media previously used for electronic records containing sensitive or proprietary information should not be reused.

700 MAINTENANCE OF RECORDS

Lifetime electronic records should be reviewed periodically for legibility. This review should also confirm the accessibility and retrievability of the record, thus providing assurance that compatible software and hardware systems are available. Media intended for storage of electronic records should be tested prior to use to ensure that it is free of errors, defects, and corruption.

SUBPART 3.1-18.1
Implementing Guidance for Part I, Requirement 18: Audits

100 GENERAL

This Subpart provides nonmandatory guidance on quality assurance audits as specified in Requirement 18 of Part I.

200 AUDIT ADMINISTRATION

201 Purpose

Quality assurance audits should be performed to

(a) determine the status, adequacy, and implementation effectiveness of the quality assurance program that has been developed and documented

(b) verify by examination and evaluation of objective evidence whether quality assurance program elements, items, processes, work areas, or records, as appropriate, conform to specified requirements

(c) evaluate the effectiveness of the organizational controls and verification activities, as directed by management

(d) evaluate strengths and weaknesses of work processes, process monitoring, and process control systems

(e) determine whether the work processes and control systems are effective in producing a product of desired quality

(f) provide management with an evaluation of the performance of the product to specified requirements

(g) evaluate problems and errors in work process execution that will affect specified product performance

(h) evaluate management effectiveness in responding to independent audit results

(i) report audit results to all levels of management who should be informed and who should take corrective action

(j) verify that corrective action has been planned, initiated, or completed

202 Elements

Elements of audits administration should include the following:

(a) a management policy statement or procedure that establishes organizational independence and authority of the auditors and commits the organization to executing an effective audit system

(b) resources, funding, and facilities to implement the audit system

(c) identification of audit personnel and their qualifications

(d) provision for reasonable and timely access of audit personnel to facilities, documents, and personnel necessary in the planning and performance of the audits

(e) methods for reporting audit results to responsible management of both the audited and auditing organizations

(f) provision of access by the auditor(s) to levels of management of the auditing and audited organizations that have the responsibility and authority to assure corrective action

(g) methods for verification of effective corrective action on a timely basis

203 Frequency of Audits

Auditing should begin as early in the life of the activity as practical and should be continued at intervals consistent with the schedule for accomplishing the activity.

Frequency of regularly scheduled internal and external audits should be commensurate with the status and importance of the associated activities and based upon annual evaluations of all applicable and active elements of the quality assurance program. These evaluations, whether conducted separately or via audits, should include an assessment of the adequacy and effective implementation of the quality assurance program based upon review of such information as the following:

(a) previous audit results and their dispositions

(b) internal and supplier documents and records, such as nonconformance reports, corrective action reports, and their dispositions

(c) independent information (e.g., from external sources such as generic experience of the nuclear industry, ASME, peer organizations, and regulating bodies)

(d) supplier histories for similar products or services

(e) changes in responsibilities, resources, or management

204 Shared External Audits (15)

If more than one Purchaser uses a Supplier, the Purchaser may arrange for an audit of the Supplier on behalf of itself and the other Purchasers to reduce the number of external Supplier audits. The scope of the audit should address the needs of all Purchasers and the report should be distributed to Purchasers for whom the audit was conducted. Each Purchaser relying on the results of such an audit remains individually responsible

for the adequacy of the audit and for its use by their organization.

205 Supplemental Audits

Regularly scheduled audits should be supplemented by additional audits for any of the following conditions:

(a) to determine the capability of a Supplier's quality assurance program prior to awarding a contract or purchase order

(b) when, after award of a contract, sufficient time has elapsed for implementing the Supplier's quality assurance program and it is appropriate to determine that the organization is adequately performing the functions defined in the quality assurance program description, codes, standards, and other contract documents

(c) when significant changes are made in functional areas of the quality assurance program, such as reorganizations, process control changes, mission or work scope changes, or procedure revisions

(d) when it is suspected that the quality of a product is in jeopardy due to deficiencies in the quality assurance program

(e) when a systematic, independent evaluation of program effectiveness is considered desirable

(f) when it is necessary to verify effectiveness of required corrective action

(g) when it is directed by management

206 Audit Equivalents

Audit equivalent activities such as independent assessments and technical surveillances may be used to satisfy part or all of an audit requirement provided

(a) they each meet the requirements for a quality assurance audit as defined in this Standard

(b) they are reviewed and approved for such use by the organization responsible for quality assurance audits

300 PREPARATION FOR AUDITING

301 Team Selection

Prior to assigning personnel to perform audits, management should determine that the individuals have the experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. The recommended practice is to include technical specialists who have directly related experience in the area to be audited as members of an audit team. For example, a design engineer, chemist, operator, etc., from one unit or department may be used to audit the corresponding activity of another unit or department.

In selecting personnel for audit assignments, consideration should be given to special abilities, specialized technical training, prior experience, personal characteristics, and education.

302 Planning the Audit

302.1 Team Familiarization. Prior to commencing the audit, the Lead Auditor should ensure that the audit team is prepared. Pertinent information, including policies, procedures, standards, instructions, codes, regulatory requirements, and prior audit reports, should be made available for review by the auditors. During the planning phase of the audit, particular attention should be directed toward an understanding of internal and external organization contractual interfaces and responsibilities of the organization to be audited.

302.2 Product Selection. In planning for an audit, emphasis should be on the selection of the product to be evaluated and the performance criteria or metrics used to determine the capability and stability of the work processes that produce this product. Risk relative to unavailability and unreliability of product applications should prevail in the product selection. Product selection is usually dependent on the following key factors:

(a) importance of intended function(s) of the product

(b) complexity of product attributes required to perform functions

(c) skill or complexity of work processes that impart these attributes

(d) capability of evaluating or inspecting work processes

302.3 Product Experience. Organization or industry experience with a product's performance should be considered in selecting it for auditing. Information on past performance may be obtained from various sources, such as audit and assessment reports, plant operation and maintenance records, trend data, equipment histories, personal knowledge, and external information, including regulatory agency notices. Nonconformance reports, inspection results, customer complaints, and warranty claims are other sources of input. Product performance information may be useful in determining which technical and quality requirements are most important to achieving satisfactory performance.

302.4 Process Effectiveness. When auditing a process, flowcharts are valuable information sources. The selected processes, item characteristics, and performance criteria should be discussed with those responsible for the technical requirements.

302.5 Audit Plan. The audit plan should identify how the audit will be performed and those key processes and product characteristics that have the greatest influence on item performance. For example, the audit may focus on product manufacturing processes, such as a critical assembly technique. Conversely, if a specific process is routinely inspected and has a stable performance history, the process may not need to be evaluated during the audit.

302.6 Checklists. Checklists should be used for evaluating processes based on defined performance criteria and available work process flowcharts. Checklists should include a brief description of the investigative method necessary to gather information related to the performance criteria. Past and current performance results on items and work processes should be considered in developing audit checklists. Checklists are guidance and may be expanded or condensed during audit performance as circumstances warrant.

303 Audit Notification

Involved organizations should be notified of an audit a reasonable time before the audit is to be performed, except for unannounced audits. This notification should be in writing and include such information as the scope and schedule of the audit and the names of the auditor, audit team leader and team members, if known. For unannounced audits, prior agreements should be reached by the parties involved.

400 AUDIT PERFORMANCE

401 Pre-Audit Conference

A pre-audit conference should be conducted with the management of the organization to be audited. The purpose of the conference should be to confirm the audit scope and planned dates, meet counterparts, discuss the sequence and duration of the audit, set the time for the post-audit conference, and establish channels of communication. During the conference, there should be an agreed-to agenda for the audit.

402 Methods

Audits should be performed in accordance with the audit plan using the following methods:

(a) review of documentation, including procedures and work instructions, for completeness and adequacy

(b) examination in work areas for evidence of implementation of procedures and instructions

(c) observation of processes for evidence of achievement of specified results and evidence that performance criteria are being met

(d) examination of personnel training and qualification records where special skills are required

(e) reexamination of selected work that has been accepted, such as product, design calculations and drawings for conformance with acceptance criteria, and other applicable requirements

(f) examination of process controls, and records to determine conformance with specifications

403 Audit Implementation

403.1 Evaluation. Audit team members or auditor should review and evaluate product and process documentation. Auditors should interview workers and observe the actual work process and evaluate them against requirements and performance criteria. Complete and accurate understanding of the product or process being investigated is best achieved by open and objective interaction with the audited organization representatives. Potential areas for process improvement identified during the audit should be noted and discussed at audit team meetings and reported to management.

403.2 Problems and Errors. When an auditor or team member finds a systemic or technical problem with an item or the outcome of a work process, it is important that the auditor or team member inform the audited organization representatives so they may investigate the facts behind the problem.

404 Post-Audit Conference

At the conclusion of the audit, a post-audit conference should be held by the auditor or audit team with management of the audited organization to present audit results and clarify misunderstandings. It is desirable that agreement be reached on audit results at the post-audit conference.

500 REPORTING

The audit report should be issued within a reasonable time following the audit, usually 30 days. The audit report should include a requested date for a documented response by the audited organization. The audit report should be distributed to responsible management of both the auditing and the audited organizations.

The audit report should express the audit results in terms of how well the audit objectives were satisfied and if the performance requirements were met. In addition to audit findings, audit results should include observed good practices, strengths, and weaknesses.

600 RESPONSE (15)

Management of the audited organization should respond to the report by the requested date. Subpart 3.1-18.2 of this Standard provides guidance for response content.

700 FOLLOW-UP ACTION (15)

Follow-up action by the audit team leader or management of the auditing organization should verify the following:

(a) timely written response to the audit report

(b) adequacy of the response

(c) corrective action accomplished, as scheduled

(d) effectiveness of action taken

Subpart 3.1-18.2 of this Standard provides an example of one acceptable approach for follow-up actions.

SUBPART 3.1-18.2
Implementing Guidance on Classification and Handling Audit Issues

(15)

100 GENERAL

This Subpart provides nonmandatory guidance for classifying and handling issues that are found during the course of an audit as indicated in Requirement 18 of Part I, based upon lessons learned and industry experience.

200 INTRODUCTION

Auditors identify a variety of issues while performing audits. These issues can vary in significance from minor or isolated deviations from established performance standards to significant safety issues or major breakdowns in the QA Program. On the opposite end of the spectrum, the issues may include examples of strong performance.

This guidance provides an acceptable approach to classifying and handling various audit issues and the rationale or logic for applying these different classifications.

Other approaches are equally acceptable, such as identifying conditions adverse to quality (e.g., findings of varying significance levels) or entering the conditions adverse to quality into the company's corrective action system and allowing that system to determine the significance.

Whatever approach is taken by an organization for classifying and handling audit issues, the approach should be documented in implementing procedures.

300 CLASSIFICATION OF ISSUES

The various classifications are discussed in order of significance.

301 Finding

When a condition adverse to quality is identified that represents a failure to develop, document, or implement any element of the approved QA Program that has an actual or high potential impact on nuclear safety or reliability, it should be considered a finding.

The auditing organization should promptly notify affected management of the finding so they can take appropriate prompt action to correct the problem. Additionally, the auditing organization should consider the need to stop work to address any immediate safety concerns.

302 Observation

When an issue is identified that represents a minor procedure violation or deviation in implementation of an approved procedure that does not impact other activities or is an isolated occurrence, it may be considered an observation. Some organizations may refer to these as Concerns, Deviations, or Weaknesses.

303 Opportunity for Improvement

When an issue is identified that is an opportunity for improving performance of a process based on the audit team's experience or known industry best practices, it may be considered an Opportunity for Improvement.

These are not deficiencies. Some organizations may refer to these as Enhancements or Recommendations.

Typically, such items do not require formal corrective action.

304 Strength

When a practice or performance is identified that exceeds requirements, expectations, or industry standards in a beneficial, safe, efficient, and effective manner, it may be considered a strength. Some organizations refer to these as Good Practices.

One way to determine if a process or practice warrants being identified as a Strength is to ask: Would you recommend that other organizations benchmark this practice to improve performance?

400 RESPONSES TO ISSUES

The audited organization is responsible for evaluating all issues identified by the auditing organization and taking corrective actions, as applicable. The audited organization should provide written responses to audit issues, as requested by the auditing organization. Findings and Observations should be entered into the corrective action system to ensure tracking and closure.

Paragraphs 401 through 404 provide guidance on a graded approach for the level of evaluation and response that may be appropriate for the various issues identified.

401 Findings

When the auditing organization issues a finding, they should request a written response, typically within 30 days. This response time allows for a causal investigation and the identification of corrective actions to resolve the problem. An acceptable response identifies the following:

(a) the cause of the issue

(b) corrective actions that have been taken or are planned to correct the issue

(c) corrective actions that have been completed or are planned to address the cause of the issue (corrective actions to prevent recurrence)

(d) a schedule for completing all actions specified in (b) and (c) above

402 Observations

When the auditing organization issues an audit observation, a written response is requested, typically within 30 days, if the condition has not been corrected during the course of the audit. This provides for a timely evaluation of the condition adverse to quality. An acceptable response identifies the following:

(a) corrective actions that have been taken or are planned to correct the issue

(b) a schedule for completing remaining incomplete corrective actions

403 Opportunities for Improvement

When the auditing organization issues an Opportunity for Improvement, they typically do not request a response. However, management should evaluate the merit of the issue identified and determine if the improvements or efficiency gains noted are worth the resources required to implement.

404 Strengths

When the auditing organization identifies a Strength, they do not request a response. However, management of the audited organization should take the opportunity to identify what other organizations or locations under the span of their control may benefit by implementing similar processes or approaches and how to leverage the practice to maximum benefit of the organization.

500 FOLLOW-UP

The auditing organization typically performs the following three types of follow-up activities for Findings and Observations:

(a) Evaluate the written response.

(b) Monitor corrective actions.

(c) Reaudit.

501 Evaluate the Written Response

The auditing organization typically schedules a follow-up to be completed within a week after the response is due. This follow-up evaluates the adequacy of the cause determination (if required), adequacy and timeliness of the proposed actions, and adequacy and timeliness of the actions to prevent recurrence.

If the response is late or does not appear to be adequate, the auditing organization may consider elevating or escalating the issue to senior management for additional support in resolving the issue.

502 Monitor Corrective Actions

Management of the audited organization is responsible for implementing the actions specified in the response to ensure timely and effective corrective actions.

The auditing organization typically schedules follow-up activities that correspond to key milestone dates provided in the response.

Follow-up activities monitor the implementation of the corrective actions to ensure that they are both timely and effective.

When corrective actions begin to deviate from the scheduled corrective actions or appear to be either inadequate or ineffective, the auditing organization may consider elevating or escalating the issue to senior management for additional support in resolving the issue.

503 Reaudit

Findings and Observations are typically focus areas during the next regularly scheduled audit of the area. Some issues may warrant reaudit prior to the next regularly scheduled audit.

When the auditing organization finds recurrence of previously identified issues, they may consider reevaluating the significance of the issue due to the failure of management to correct the previously identified issue.

SUBPART 3.2
Guidance for Implementing Part II Requirements

(Extracted From Former NQA-2.)

The following Subparts provide nonmandatory guidance that may be used in conjunction with the applicable Subparts of Part II.

SUBPART 3.2-2.1
Implementing Guidance for Part II, Requirement 2.1: Cleaning of Fluid Systems

100 GENERAL

This Subpart provides nonmandatory guidance on the management of cleaning and cleanness control for fluid systems and associated components.

200 APPLICABILITY

If the proper attention is given to cleaning and cleanness control during manufacturing, construction, modification, or repair, then only flushing or rinsing should be necessary to render the item ready for service.

Subpart 3.2-2.1 is not intended to be used for items containing liquid metals in liquid metal-cooled nuclear plants, nor is it intended to provide guidance for decontamination of items contaminated by radioactivity, although its requirements may be invoked in such operations if considered appropriate.

300 CLEANING RECOMMENDATIONS AND PRECAUTIONS

(a) The use of halogenated organic solvents is not recommended, except upon crevice-free, open, freely evaporating surfaces. This recommendation is not intended to prohibit the use of such solvents under other conditions, provided adequate removal is assured prior to any subsequent operations.

(b) In the disposal of combustible organic solvents, specific attention should be given to preclude the possibility of fires, explosions, and other related hazards.

400 GUIDELINES FOR ASSIGNING CLEANNESS CLASSIFICATIONS

401 Normal Fluid Systems and Components

Class A cleanness is a very high level, generally applicable to special items whose functions might be impaired by the presence of very small quantities of contaminants. Achievement and maintenance of Class A cleanness is difficult and is generally achieved at the point of final manufacture of the item and maintained by stringent shipping, storage, rework, and installation requirements.

Class B cleanness is a high level, generally applicable to internal surfaces of corrosion-resistant alloys in contact with reactor primary coolant, surfaces in contact with process fluids in fuel manufacturing, and other similar applications. Class B cleanness can also be initially achieved with carbon steel and low alloy steels, but maintenance of this condition is quite difficult.

Class C cleanness is a high level of initial cleanness, generally applicable to carbon steel and low alloy steel surfaces in contact with reactor primary coolant and other fluids where the formation of light corrosion product films in service is expected and can be tolerated. For corrosion-resistant alloys, Class C is a somewhat lower level of cleanness than Class B.

Class D cleanness is a nominal level applicable to both carbon and low alloy steels and the corrosion-resistant alloys in applications where the presence of mill scale or tightly attached heavy corrosion product films on the surfaces in contact with process fluids does not cause concern, or where significant amounts of contamination are anticipated to be present in the process fluids themselves.

NOTE: The cleanness classifications designated in this Subpart are not directly related to component classifications assigned by the ASME Boiler and Pressure Vessel Code for design and inspection or for other purposes.

402 Hydraulic, Instrument Control, and Lubrication Lines and Systems

The criteria listed in Table 304.4 of the main body of Subpart 2.1 may be used as a guide for classifying hydraulic, instrument control, and lubrication system cleanness.

SUBPART 3.2-2.7.1
Implementing Guidance for Part II, Requirement 2.7: Quality Assurance Requirements for Computer Software for Nuclear Facility Applications

(15)

(15)

INTRODUCTION

This Subpart structure is based on the main sections of Subpart 2.7 (e.g., 100, General; 200, General Requirements). Not all sections in Subpart 2.7 (i.e., 600, Standards, Conventions, and Other Work Practices and 800, References) are covered in this Subpart. A review of these sections did not precipitate the need for any discussion of these sections. In most cases, the subsections (e.g., 201, Documentation) contained in Subpart 2.7 are not provided as a one-to-one correspondence in this Subpart.

100 GENERAL

This Subpart has been developed to provide organizations invoking NQA-1 with a discussion of the requirements and how those requirements may apply in various situations where software is used. Guidance pertaining to the linkage between Parts I and II, Subpart 2.7 is provided. Subpart 2.7 is applicable to software when a failure or error in the software could adversely affect the quality of structures, systems, or components of nuclear facilities. Possible exceptions will be detailed in this Subpart. Applicability of Subpart 2.7 is not dependent upon the type of computer equipment (e.g., mainframe, PC, networked workstations) that is installed.

The requirements of both Parts I and II, Subpart 2.7 should be applied in a manner to meet the requirements of ANSI/IEEE Std. 7-4.3.2-1993, IEEE Standard Criteria for Digital Computers and Safety Systems of Nuclear Power Generating Stations. This Subpart provides guidance to support meeting the requirements of that standard.

101 Software Engineering

A variety of software engineering methods may exist within an organization to meet Quality Assurance requirements contained within NQA-1. The extent of application of the software engineering activities should be commensurate with the risk associated with the failure of the software. Factors affecting this risk include the potential impact on safety and/or operation, complexity of computer program design, degree of standardization, the state of the art, and similarity to previously proven computer programs. Subpart 2.7 users should consider establishing a software categorization method that includes

(a) software engineering methods applicable to given categories of software

(b) assurance that the results of the categorization are documented

The software categorization method should consider safety significance and the relative importance of the software.

Paragraphs 101.1 through 101.7 provide additional considerations in developing a categorization method and determining software applicability.

101.1 Simple and easily understood computer programs (e.g., computer programs whose results can be easily confirmed through hand calculations) that are used in the design of plant systems, structures, and components, may be excluded from the controls of Subpart 2.7 if designs using these computer programs are individually verified. Design verification documentation should include design inputs, the computer-program-generated results, and computer-generated evidence of the programmed algorithms or equations (e.g., computer program listings, spreadsheet cell contents). However, frequent use of the software may justify the application of Subpart 2.7 in order to simplify future use of the software.

101.2 Complex computer programs used in the design of structures, systems, and components should be developed and approved for use in accordance with Subpart 2.7 unless software design verification and testing of the computer program (or parts thereof) independent of a specific application is not practical. In these cases each application of the computer program must be design verified and documented in accordance with the requirements of Part I, Requirement 3, section 400.

101.3 Separate software design verification and tests may not be required for computer programs that are design reviewed and tested in conjunction with hardware as a unit, in accordance with other Parts or Subparts (e.g., Measurement and Test Equipment) of this Standard.

101.4 Computer programs that have been software design verified and tested in accordance with other national consensus standards may not require any additional software design verification and tests. However, an evaluation based upon the Subpart 2.7 software design verification and testing requirements should be performed to ensure compliance with Subpart 2.7.

101.5 Exceptions may also be warranted for the Support Software (see Subpart 3.2-2.7, section 600) if this software has a known and acceptable performance history (see IEEE Std. 610.12, Definitions). The basis for accepting the performance history should be documented and approved in conjunction with the development of the software using the Support Software. The resulting system, structures, or components should be submitted for design verification in accordance with Part I, Requirement 3, section 500, or the resulting software (application and the support software) should be developed and approved for use in accordance with Subpart 2.7.

If the Subpart 2.7 user has a software design control program that is compliant with other industry standards, a review should be performed to ensure consistency with the requirements of Subpart 2.7.

101.6 Firmware is dependent on the nature of the software and hardware device. Three possible approaches are described as follows:

(a) If the computer program can be changed after it is embedded, including at run time, all applicable controls of Subpart 2.7 should be applied.

(b) If the computer program cannot be changed after it is embedded, and testing of the completed device is not adequate for full acceptance, Subpart 2.7 software development controls should be applied.

(c) If the embedded computer program functions can be adequately verified by testing the completed unit and the computer program cannot be changed, including at run time, without repeating this verification, controls beyond those used for hardware may not be necessary. This approach is the least desirable because it treats software as hardware and does not recognize the need to apply controls to the computer program.

101.7 Documented evidence (e.g., supplier testing, applicable supplier experience) supporting the acceptance of commercial off-the-shelf software may be used to augment the acceptance requirements of Subpart 2.7, para. 302.

102 Terms and Definitions

Terms may have multiple interpretations even within a standard. Therefore, definitions provided in Subpart 2.7 should be considered in the use of this Subpart. To enhance understanding and ensure consistency in this Subpart, the characteristics of several common software-related terms are discussed.

102.1 Software Characteristics. Software (see IEEE Std. 610.12) can be composed of three elements:

(a) a set of instructions that, when executed, provide a specified function or performance

(b) data structures that enable a computer program to adequately manipulate information

(c) documents that describe the operation and use of the program

Software, therefore, is an all-inclusive term for the nonhardware elements of a computer-based system. A computer program differs from software in that software can include documents that describe the development, operation and maintenance, and retirement of a computer program. Computer programs do not include documents. Computer programs can be written in programming languages (e.g., Pascal or C) or in an assembly language. Although the more common term is "program," for clarity, "computer program" is used throughout the NQA-1 standard.

102.2 Hardware Characteristics. Hardware consists of the physical elements that provide the computing capability and external interface (e.g., CPU, memory, CRTs, printers). Hardware is the physical equipment used to process, store, or transmit computer programs or data (see IEEE Std. 610.12). In contrast, software is characterized as a logical rather than a physical system element.

102.3 Firmware Characteristics. Firmware is the combination of a hardware device, computer programs, and data that reside as read-only software on that device. The firmware (sometimes referred to as embedded software) can perform very limited functions such as keypad controls, or can provide significant function and control capabilities for control rod drives or safety systems. In either case, if firmware is supplied under requirements of Subpart 2.7, the computer program aspect of firmware should be considered in an organization's software engineering method.

200 GENERAL REQUIREMENTS

201 Documentation

The combined requirements of Part I, Requirements 1 through 6, 11, 12, 16, and 17 and Part II Subpart 2.7, establish the need for both documents and records. The applicable software engineering method should define what documentation should be controlled in accordance with these requirements. In general, plans (e.g., project plans, quality assurance plans, configuration management plans), software engineering procedures, and contract documents should be controlled under Requirements 5 and 6.

Records providing evidence of quality-affecting activities include documentation of requirements and design, test plans, test reports, and user documentation. Records

are controlled under Part I Requirement 17 and configuration control.

202 Review

The purpose of software review activities is to provide adequate confidence that the software performs all intended functions, provides correct solutions, and does not perform or cause any adverse unintended functions. The extent of the software review activities should be commensurate with the risk associated with the failure of the software. Factors affecting this risk include the potential impact on safety and/or operation, complexity of computer program design, degree of standardization, state of the art, and similarity with previously proven computer programs.

Reviews performed at the completion of the software development cycle should include assurance that assumptions made during the categorization process and development process are consistent with the intended use of the software.

203 Software Configuration Management

Key attributes of the software engineering method include a determination that all elements of the product baseline, as defined in Subpart 2.7, are accounted for and properly reviewed and approved.

NQA-1, Part I, Requirement 3 requires the establishment of a configuration baseline at the completion of each major phase during development as defined in the software engineering method. Baselining means the assignment of a documented unique identifier to each software configuration item and its associated products. Baselining applies to all identified configuration products used to support the development and/or maintenance of the configuration item. Each configuration product should be identified, controlled, labeled, and documented as constituents of the final product baseline.

Support software (see Subpart 3.2-2.7, section 600) should be identified as part of the final product baseline. A key part of the overall configuration management process should be to identify how support software will remain available to support and, if necessary, rebuild and execute the program. At the completion of software development activities, the final product baseline is the collection of previously baselined configuration products.

In some cases, not all elements of a configuration item need to be changed in order to support a modification to the software. For example, a modification to enhance the execution performance of a program may be invisible to the user and may not require a change to the user documentation. As a result, the most recent revision of a particular configuration product may be part of more than one product baseline.

204 Problem Reporting and Corrective Action

The problem reporting and corrective action requirements of para. 204 of Subpart 2.7 are intended to implement Part I Requirement 16, as these requirements apply to software. Subpart 2.7 users need not develop an independent process to meet these requirements if their existing processes incorporate the requirements of Subpart 2.7, para. 204. Subpart 2.7 users may develop either supplementary procedures for software problem reporting and corrective action, or include software issues in their existing nonconformance and corrective action procedures. The problem-reporting process should be developed into a multitiered system (e.g., a system for dealing with potential improvements requested by software users, the system for documenting problems). The development of this multitiered system may lead to a corrective action prioritization process. The collection and analysis of information from this process can be useful in enhancing the Organization's Subpart 2.7 processes. Among the software considerations that should be made are the following:

(a) How does the error being reported relate to past activities?

(b) How does the corrective action impact past activities?

(c) How does the error being reported relate to the status of the software development process? That is, an error reported during the development process may not require the same level of reporting as one that is reported during testing or use (e.g., report to purchaser).

300 SOFTWARE ACQUISITION

Software developed not using Subpart 2.7 may require full or partial application of Subpart 2.7. The following is guidance to assist in this activity. This application guide serves to recognize the need for a consistent approach to bringing software that has been developed outside the control of Subpart 2.7 under configuration control and into compliance with the Subpart.

301 Procured Software and Software Services

See Part II, Subpart 2.7.

302 Otherwise Acquired Software

See Part II, Subpart 2.7.

400 SOFTWARE ENGINEERING METHOD

The software development or maintenance activities selected for the Software Engineering Method should be defined and discussed in a quality or project planning document (e.g., Software Quality Assurance Plan). Elements or activities of the Software Engineering Method that are omitted should be noted along with the reason for omission.

401 Software Design Requirements

Software Design Requirements should be able to be demonstrated in the acceptance testing activities and should be checked at the conclusion of each element or activity of the software life cycle.

402 Software Design

Design documentation should be completed in a manner that facilitates the Software Design Verification process in accordance with Part I. If any requirements are not met in the design activity, then those requirements should be revised to reflect the final product using the same approval process as the original requirements.

402.1 Software Design Verification. See Part II, Subpart 2.7.

403 Implementation

See Part II, Subpart 2.7.

404 Acceptance Testing

Acceptance testing is a testing activity that is planned during the software development activities. Acceptance testing may be used to fulfill qualification testing requirements (see Part I Requirement 3 for details on qualification testing requirements). Acceptance testing is performed at the end of the software development cycle to provide adequate confidence that the software satisfies the requirements and performs correctly in its operating environment. It is imperative that the acceptance testing be completed before releasing the software for use (i.e., the operation and maintenance activity). Acceptance testing may be started as soon as the software product is completed. This is typically at the end of the implementation activity, but may be conducted over several activities. These tests may range from a single test to a series of tests performed at various stages of the software development. Part I, Requirement 11, Test Control, provides for evaluation of test records. This series of tests would provide assurance of correct translation between states and proper function of individual modules, followed by acceptance tests performed in the operating environment. Acceptance testing may be prepared, performed, and reported by the software developer.

The extent of the acceptance testing activities should be commensurate with the risk associated with the failure of the software. Factors affecting this risk include the potential impact on safety and/or operation, complexity of computer program design, degree of standardization, state of the art, and similarity with previously proven computer programs.

Testing, using documented test plans, cases, procedures, and results, is the primary method of acceptance testing. Acceptance testing may include factory acceptance testing as well as site acceptance testing. Factory acceptance testing performed should be under the control of the purchaser on the version of computer programs to be delivered. These tests should also include exercising the computer program in an environment comparable to the environment in which the computer program will be used. This testing may include testing of associated hardware, and simulation of data inputs or control signals. Site acceptance testing performed by the purchaser should be done to ensure that no damage was incurred during shipment, and confirm proper implementation in the operating environment.

405 Operation

405.1 Use of Software. The software engineering method should provide a means to ensure that the software usage remains consistent with the approved software design and the approved acceptance testing results.

405.2 Access Control. Access control should address both the security of the computer system and the critical data that resides on the system. Both electronic (e.g., firewalls, network security measures) and physical (e.g., console) access should be considered. One method of ensuring system integrity is by employing unique user identifications in combination with a reliable password system. The concept of least privilege can also be implemented, which grants each user access to only the resources for which he has a legitimate need, at the lowest access level (read, execute, write, delete, etc.) required to perform the function. Other methods of physical access control include locks, security badges, or other forms of access to the computer system itself (e.g., using security guards).

406 Maintenance

Changes to software developed and accepted for use are controlled, and the methods for doing so should be identified in the software engineering method. The extent of control necessary for any change to the software should be appropriate to the risk being taken, and should consider criticality of the software, the nature and extent of the change, and the risk of an adverse effect being introduced by the change.

407 Retirement

A process should be established for retired software that defines responsibilities for reporting and managing of identified problems and assessing the problem's impact during the software's previous use.

500 STANDARDS, CONVENTIONS, AND OTHER WORK PRACTICES

See Part II, Subpart 2.7.

600 SUPPORT SOFTWARE

Support software that is critical to the successful development, operation, or maintenance of a software product should be identified and evaluated to determine the extent to which configuration management, acceptance testing, and any other parts of the software engineering method are applied. Based on the role of the support software, the appropriate elements of the software engineering methods should be applied.

A change in compiler options or revision, even without a change in the source code, resulting in a recreation of object or executable files that are part of the baseline, is an example of support software that is key to the successful development and operation of software.

601 Software Tools

See Part II, Subpart 2.7.

602 System Software

See Part II, Subpart 2.7.

(15)

SUBPART 3.2-2.7.2
Implementation Guidance on the Requirements of NQA-1, Parts I and II for Software Used for Nuclear Facility Applications

INTRODUCTION

This Subpart provides nonmandatory guidance on identification, flow, and interdependency of the requirements for software used for nuclear facility applications. The Subpart is based on the NQA-1–2008 Edition with the 2009 Addenda of the Standard, but the information has some application to previous and subsequent editions of the Standard. While the Standard includes requirements for assuring quality of the items and services provided to support the overall organizational objectives, the Standard also includes those requirements for acquiring, developing, testing, verifying, validating, operating, maintaining, and retiring computer programs used in nuclear facility applications. These requirements for software are interspersed within the Standard.

100 GENERAL

This Subpart provides organizations invoking NQA-1 with information to aid the identification, application flow, and interdependency of the requirements for software used for nuclear facility applications. The Subpart discusses the requirements applicable to software within the 18 requirements of Part I, the supplemental requirements of Part II (Subparts 2.7 and 2.14), and the guidance of Part IV, Subpart 4.1 of the Standard.

101 Terms and Definitions

The Subpart introduces no new terms or definitions related to software or computer programs used for nuclear facility applications. The Subpart uses commonly accepted flowchart symbols that were first introduced by Frank Gilbreth to the members of ASME in 1921.[1] The legend associated with the flowchart identifies the symbols used and provides their corresponding meaning.

These diagrams represent the flow of information within the Standard, not the flow of the governed processes. Sometimes the information flow divides into parallel paths, one or more of which may be applied concurrently on an "as applicable" basis. Mandatory paths, processes, and deliverables (notated with solid lines) are always applicable, whereas optional paths, processes, and deliverables (notated with dashed lines) are contingent upon the circumstances.

200 FLOWCHART APPROACH

This Subpart organizes the requirements for software of the Standard into 11 software and NQA-1 related processes that are pictorially illustrated in a series of flowcharts. These 11 processes apply to software and include processes uniquely applicable to computer programs. The processes are

(a) software engineering concepts
(b) software design requirements
(c) software configuration management
(d) support software and tools
(e) problem reporting and corrective action
(f) computer program design
(g) computer program implementation
(h) computer program testing
(i) computer program operation, maintenance, and retirement
(j) software acquisition, including commercial grade dedication
(k) computer program use in design analysis

The flowcharts introduce no new requirements for software. The majority of the requirements presented in the flowcharts are in the exact language of the Standard. In those instances where the language of a requirement is modified, clarified, or interpreted, it is specifically noted. Each process or flowchart presents the initial requirement, illustrates how that requirement flows through the Standard, and finally, identifies any related requirements.

201 Flowcharts

Figures 201-1 through 201-3 provide a pictorial illustration of the Standard's computer program requirements for 3 of the 11 processes described above, their flow through the Standard, related requirements, and any interdependencies between these requirements. The three selected processes for this edition of the Standard

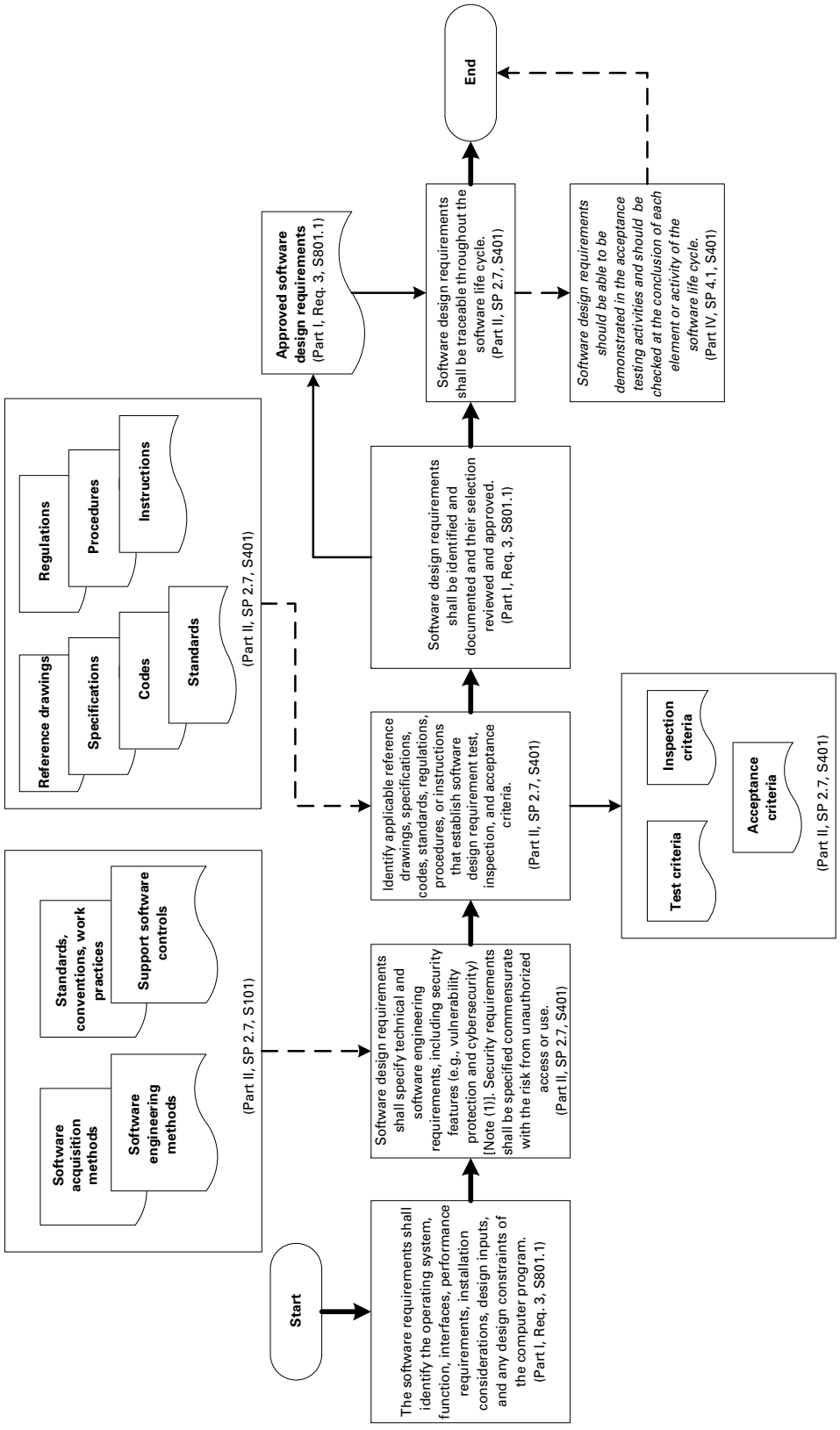
[1] Frank Bunker Gilbreth, Lillian Moller Gilbreth (1921), presentation "Process Charts — First Steps in Finding the One Best Way," ASME.

are software design requirements, computer program testing, and software configuration management. Flowcharts for the remaining processes will be published in subsequent editions of the Standard. These flowcharts are provided for guidance and illustration only and do not necessarily present all considerations that have to be made to ensure compliance with the Standard.

202 Legend

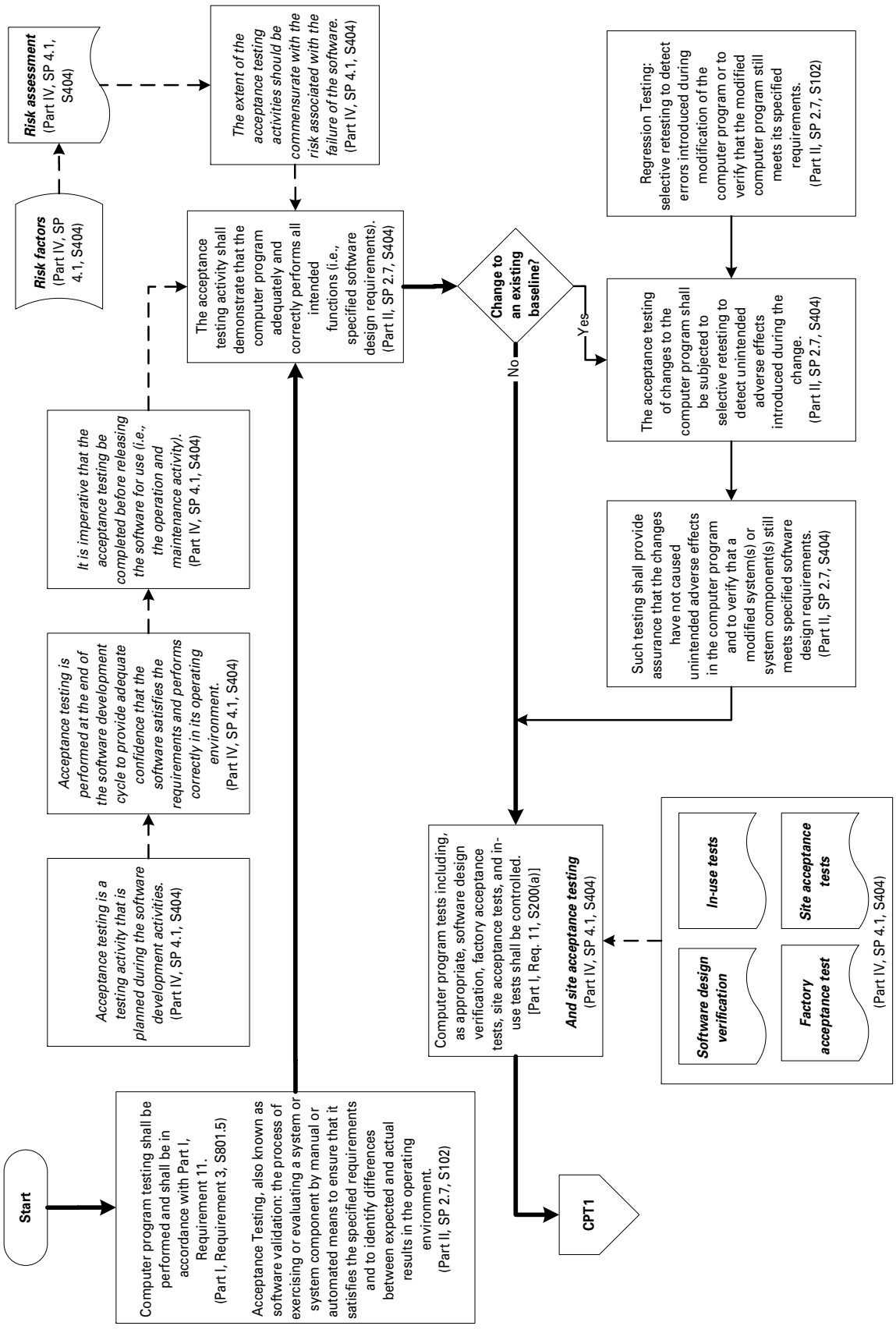
Figure 202-1 provides the legend for the flowcharts described in section 201 of this Subpart.

Fig. 201-1 Software Design Requirements



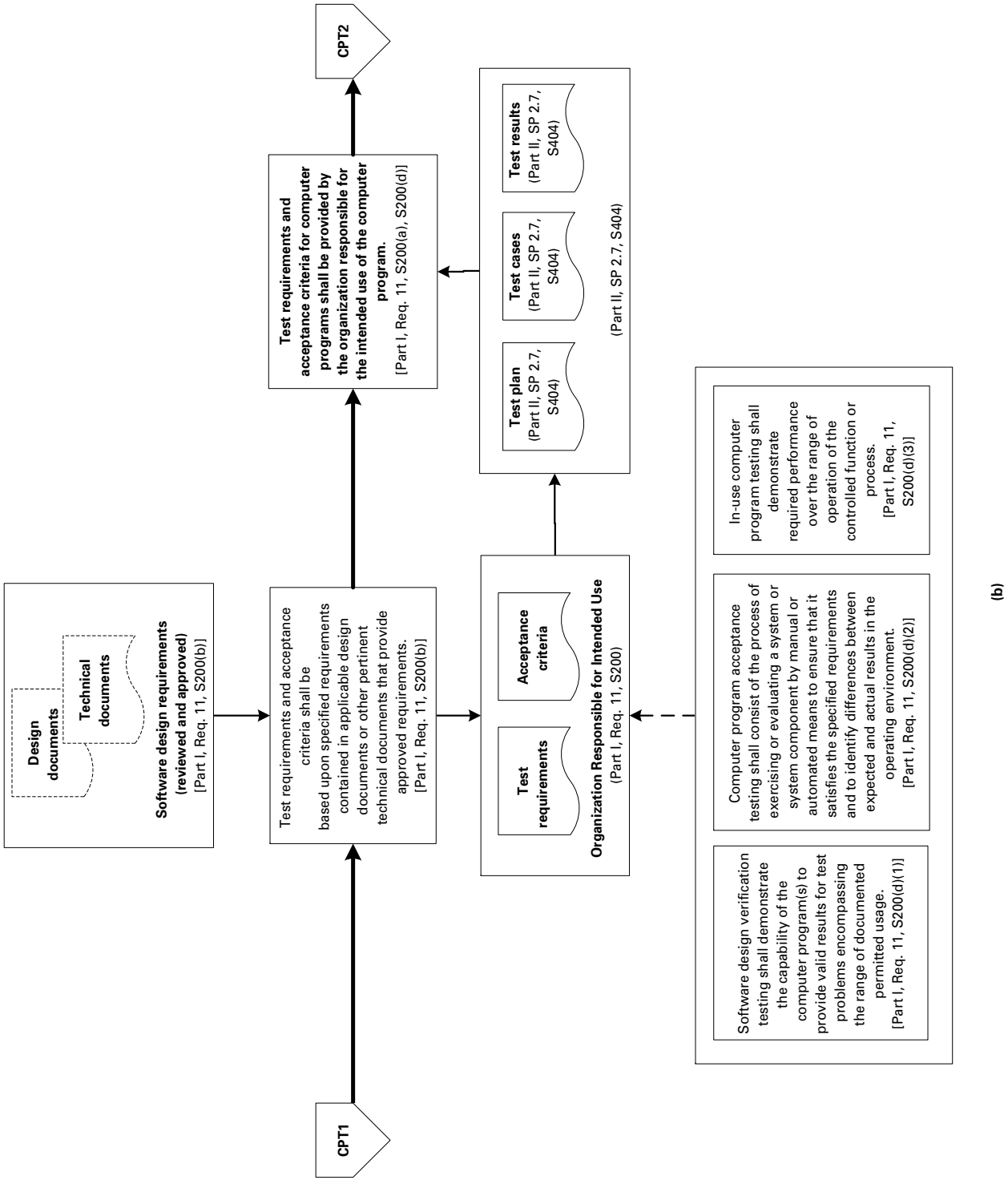
NOTE:
(1) See IEEE Std 7-4.3.2-1993, IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations.

Fig. 201-2 Computer Program Testing



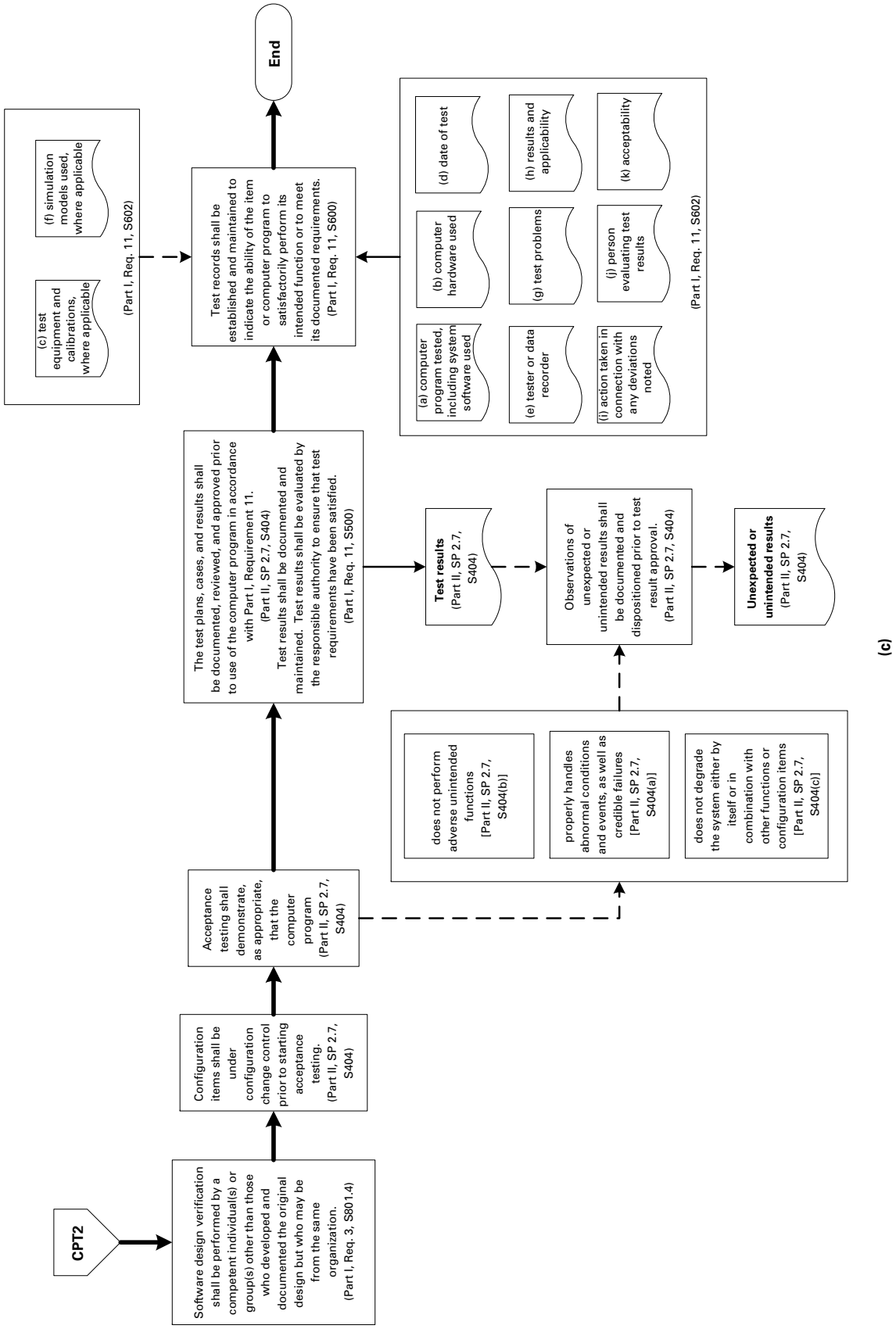
(a)

Fig. 201-2 Computer Program Testing (Cont'd)



(b)

Fig. 201-2 Computer Program Testing (Cont'd)



(c)

Fig. 201-3 Software Configuration Management

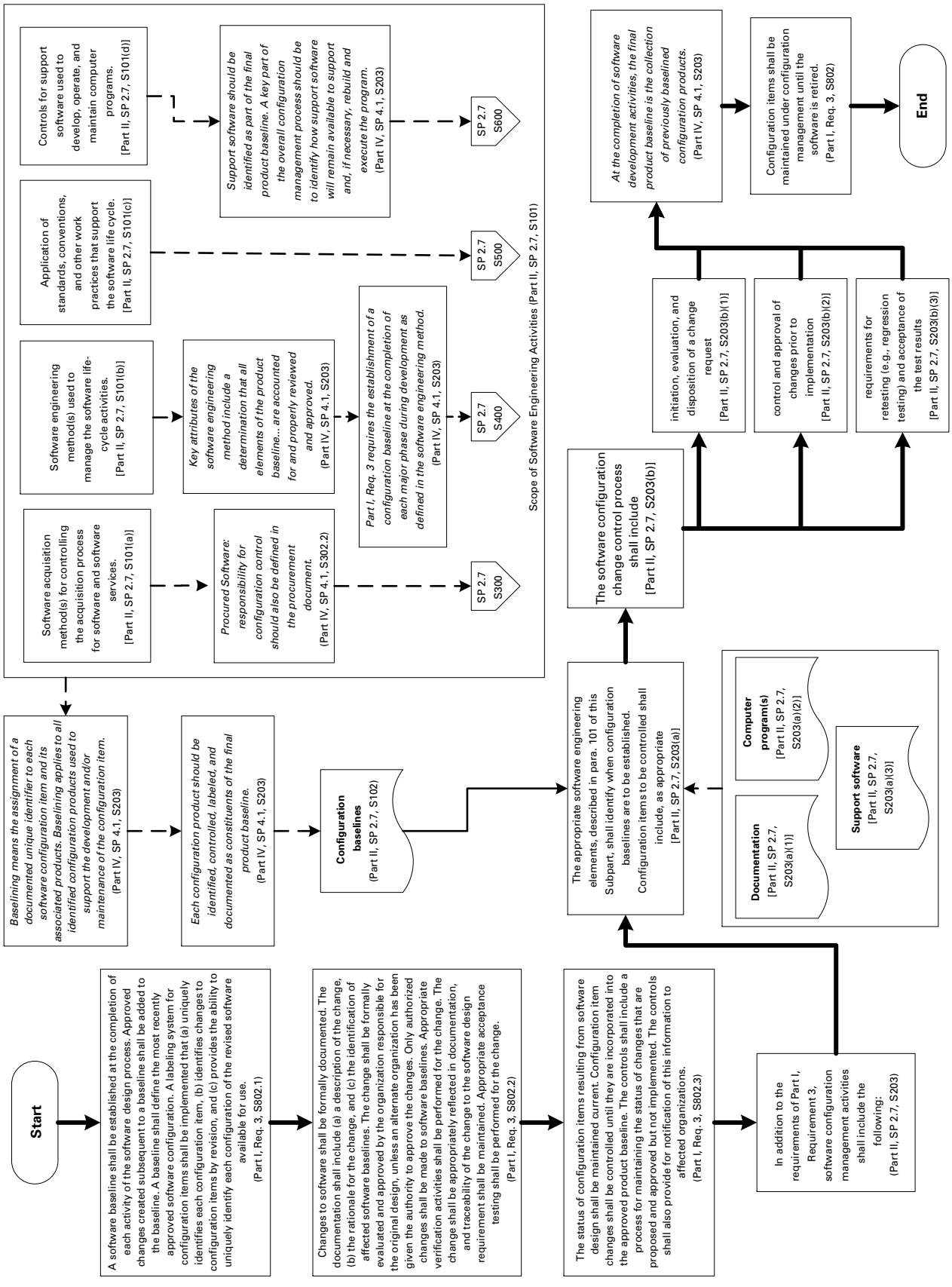
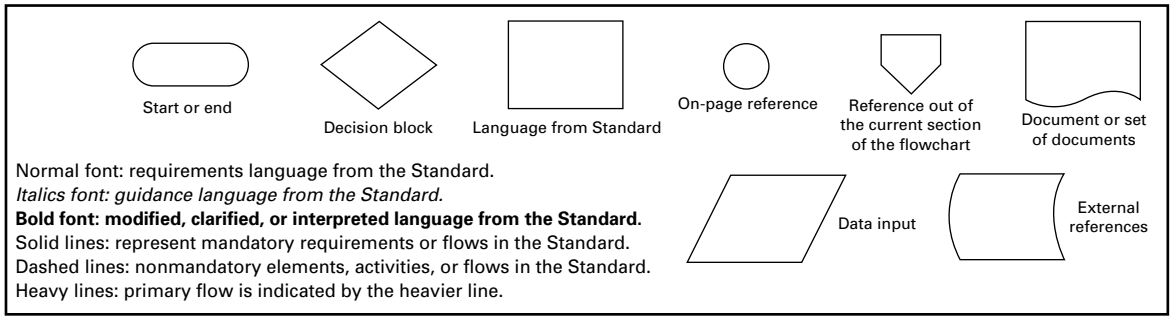


Fig. 202-1 Legend for Flowcharts



SUBPART 3.2-2.14
Implementing Guidance for Part II, Requirement 2.14: Quality Assurance Requirements for Commercial Grade Items and Services, Commercial Grade Computer Programs, and Software Services

100 GENERAL

This Subpart provides nonmandatory guidance on applying Part II, Subpart 2.14 requirements to the dedication of commercial grade computer programs and software services as required by Part II, Subpart 2.7, and para. 302. This Subpart applies to procured and acquired computer programs not installed in physical plant safety systems that support the performance of a safety function and that were not developed or approved under a program consistent with this Standard. The applicability of this Subpart is not dependent upon the type of computer equipment (e.g., mainframe, PC, networked workstations, controllers, or other digital equipment) on which the computer program resides.

As defined in this Standard, computer programs include real-time (e.g., operations or process control) as well as nonreal-time (e.g., design or analysis) computer programs. The application of commercial grade dedication for computer programs included in digital equipment that are installed in physical plant safety systems should be performed as part of the dedication process for that physical plant safety component. For these systems, the requirements of Part II, Subpart 2.14 apply, and existing industry guidance to meet the commercial grade dedication requirements of this Standard includes EPRI TR 106439, Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications, October 1996; IEEE 7-4.3.2-2010, Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations, June 17, 2010; and EPRI TR 107330, Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants, December 1996. This Subpart does not provide guidance for real-time computer programs.

As described in Part II, Subpart 2.7, para. 302, the dedication process includes the following three criteria:

(a) identification of the capabilities and limitations for intended use as critical characteristics.

(b) utilization of test plans and cases as the method of acceptance to demonstrate the capabilities within the limitations.

(c) instructions for use (e.g., a user's manual) within the limits of the dedicated capabilities. The dedication process shall be documented, and the performance of the actions necessary to accept the computer program shall be reviewed and approved. The resulting documentation and associated computer programs(s) shall establish the current baseline.

These criteria can be addressed through implementing the commercial grade dedication process defined by Part II, Subpart 2.14. The identification of the capabilities and limitations for intended use should be addressed during the selection of the set of performance critical characteristics. Test plans and cases required to demonstrate those capabilities within the limitations should be exercised through special tests and surveys. Instructions for use within the limits of the capabilities should be identified through the selection of the physical or performance critical characteristic associated with a user's manual, online help, or other methods to assist the user in the proper operation of the computer program within the limits of the dedication.

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in this Subpart.

commercial grade computer program: a computer program that affects a safety function, which was not designed, developed, or approved in accordance with Parts I and II, Subpart 2.7.

commercial grade computer program service: a service that was not provided in accordance with the requirements of this Standard and that affects the safety function of a computer program or the use of computer programs for design or analysis that supports a safety function.

dependability: a broad concept incorporating various characteristics of computer programs, including reliability, safety, availability, and maintainability (adapted from EPRI TR 106439).

digital equipment: equipment containing one or more computers.

200 DEFINITION APPLICATIONS

One of the concepts of a commercial grade dedication is a determination of whether the item meets the applicable definitions of a commercial grade item or service. Part I states that computer programs that are a physical part of plant systems are included in the term *item*. It is recognized that computer programs that perform a design or analysis function in support of a safety function are not included in the definition of *item*. For this Subpart, the computer program should meet the definition of a commercial grade computer program or service to qualify for dedication. Computer programs that do not meet this definition are subject to the requirements of Part I.

(15) 300 UTILIZATION

Requirement 3, para. 401 provides for two methods of verifying computer programs used in design or analysis of an SSC: preverification and verification of the computer program results after every use. Preverification of computer programs includes applying Part II, Subpart 2.7 in which this Subpart can provide needed guidance. When the results derived from the use of the computer program are independently verified for every use or application, the computer program is not required to be dedicated if the independent verification is performed to the requirement of this Standard. Using this latter method is not a surrogate for commercial grade dedication of the computer program.

To utilize a commercial grade computer program or service, controls should be implemented to provide reasonable assurance that the computer program or service will support an SSC's intended safety function. This Subpart can also be applied to computer programs that control the management or administrative support of safety activities. These controls should include the following:

(a) determination that the computer program or service supports the performance of a safety function

(b) confirmation that the computer program or service meets the applicable commercial grade definitions

(c) identification and documentation of the critical characteristics, including acceptance criteria

(d) selection, performance, acceptance, and documentation of the dedication method(s) for determining compliance with the critical characteristic acceptance criteria

Only computer program or services that support the performance of a safety function and meet the commercial grade definitions should be considered for commercial grade dedication. A dedication plan should be developed for the computer program or service that identifies the critical characteristics, acceptance criteria, and dedication method(s). Dedication plans may be developed for a specific computer program application, a range of application or limits, a specific service, or for a generic group of services. Dedication requirements should be included in applicable procurement and technical documents as necessary to support the dedication.

Computer programs or services that successfully complete the dedication process are subsequently subject to the controls of Parts I and II of the Standard.

400 TECHNICAL EVALUATION

A technical evaluation should be performed to determine the computer program's safety function, applicable requirements of this Standard, computer program and hardware requirements (as applicable), and the level and type of review and testing activities that are appropriate. This evaluation could range from a demonstration that the commercial grade computer program produces accurate and precise results for a predetermined set of verified problems with known solutions to a verification of program requirements, design, testing, and evaluation of test results. Credible failure modes for computer programs should consider the impact of the computer program's failure to produce correct results or an undetected defect within the computer program on the proper operation of the component being designed or the reliability of the analysis being performed.

401 Technical Evaluation Considerations

During the technical evaluation, if available, the following should be considered:

(a) the dedicating entity identifying if the computer program or service can impact a safety-related SSC

(b) conformance with the definitions for commercial grade computer program or service

(c) the mathematical model(s) on which the program is based

(d) the identification of the capabilities and limitations for intended use

(e) establish the class of problems for which the program is intended to be used

(f) confirm whether the computer program's solution methods are appropriate based on state-of-the-art knowledge

(g) determine whether adequate testing has been performed or if additional testing is needed to ensure adequate validation

(h) the acceptance criteria to be used in evaluating the range and validity of program responses

(i) basis for selection of validation cases

(j) the computer hardware and operating system in which the program will be utilized

(k) user interface requirements expected to take place in the use of the computer program

Before the dedicating entity begins the process of evaluating the computer program's adequacy for use, it should be placed in a configuration management process that provides traceability of the computer program's

evaluation and testing activities. To ensure dependability, the dedicating entity should consider data and error reporting associated with the computer program's performance as part of the dedication activities.

402 Technical Evaluation Documentation Review

The dedicating entity should review any available supplier documentation. Examples of supplier documentation supporting the technical evaluation include

(a) statement of problem
(b) requirements specification
(c) design specification
(d) source code
(e) test plan and test results
(f) configuration control

In situations where the above documentation is not available, computer program users' manuals should be reviewed for requirements and design information associated with the scientific, engineering, or mathematical models implemented, the code structure, and interfaces between high-level functions of the computer program. If these documents are not provided by the supplier, a search of publicly available documents should be used to supplement the supplier's documentation. If the supplier documentation cannot be adequately supplemented and the unavailable information is essential to determining reasonable assurance, dedication may not be possible. In the instance where a critical characteristic cannot be verified, the dedicating entity should consider alternate critical characteristics to provide the required reasonable assurance.

Part II, Subpart 2.14, para. 402 should only apply to computer programs if they are reinstalled in the same computer hardware and operating system (including patches), from the same distribution media, developed by the original company, and with the same configuration data. In this scenario, acceptance testing should still be performed to ensure that the computer program performs to the originally established requirements. If a failure has occurred and a backup is used to restore functionality, operational processes should be followed.

Part II, Subpart 2.14, para. 403 should not be used to accept different computer programs in safety-related applications, unless complete equivalency evaluation is possible.

500 CRITICAL CHARACTERISTICS

501 Computer Program Critical Characteristics

Critical characteristics should be identifiable, measurable attributes based on the intended safety function, complexity, application, and performance of the computer program and its data. Based upon the computer program's design and performance basis, a variety of critical characteristics can be identified. However, only a subset of those critical characteristics selected for acceptance (referred to as critical characteristics for acceptance) should be needed to provide the necessary level of reasonable assurance.

Critical characteristics associated with computer programs can be grouped into the following categories:

(a) identification
(b) physical
(c) performance/functional
(d) dependability

The computer program's identification (i.e., version, build date, release name, or part or catalog number) should be considered a critical characteristic if it provides a method for linking the computer program with the manufacturer's product description, user's manual, published data, or product specification. Physical characteristics are associated with the computer program's physical media (e.g., CDs, tapes, downloads, or remote access). Performance/functional characteristic examples include the required functionality of the computer program to perform its safety function and the accuracy of its results. Dependability characteristics are a category of critical characteristics unique to computer programs. The dependability category addresses the critical characteristics evaluated to develop judgment regarding built-in quality of the computer program. Dependability characteristics include both supplier and user attributes, such as a review of the computer program's life-cycle processes and output documentation at the supplier's facilities, review of the user's configuration management activities, supplier and user testing and verification and validation (V&V) activities, and other activities related to the supplier's software development process. Often, supplier dependability characteristics for computer programs cannot be verified through Method 1 [special test(s), inspection(s), and/or analyses; see section 600] alone and are associated with the processes used to produce the computer program.

A prudent approach to achieving the necessary, reasonable assurance for the dedication process is to select multiple critical characteristics from all categories. This approach mitigates limitations of any single critical characteristic and the limitations on acceptance methods for individual characteristics.

Table 501 provides a list of critical characteristics to consider for computer programs. It is not intended to be an all-inclusive list of critical characteristics for acceptance. The table is intended to be used as a guide in selecting critical characteristics for acceptance that are appropriate for the commercial dedication process being performed by the users of this Subpart. This Subpart does not infer that the critical characteristics listed in Table 501 are a minimal set of critical characteristics for acceptance. The users of this Subpart should, consistent with section 400 of this Subpart, determine how the computer program supports the SSC's safety function, consider the critical characteristics in the table,

determine which are appropriate to include for their dedication process, and evaluate whether additional critical characteristics for acceptance not included in Table 501 are needed to provide reasonable assurance that the computer program will adequately support the SSC's safety function.

The specific critical characteristics to be considered for acceptance should be identified through a review of the manufacturer's published software documentation or other technical information documents. For example, the manufacturer's test documentation should also provide important information necessary to define the critical characteristics, consistent with the computer program's application requirements.

502 Computer Program Acceptance Criteria

Each critical characteristic should have associated acceptance criteria to determine whether the computer program adequately meets the identified critical characteristic. Table 501 includes appropriate acceptance criteria for the identified critical characteristic.

The dedicating entity is responsible for determining whether the dedication method and results are adequate to meet the acceptance criteria.

600 METHODS FOR ACCEPTING COMMERCIAL GRADE ITEMS AND SERVICES

601 Dedication

To provide reasonable assurance that a commercial grade computer program will perform its intended safety function, the dedicating entity should verify that the commercial grade computer program meets the acceptance criteria for the identified critical characteristics by using one or more of the following dedication methods specified in Part II, Subpart 2.14:

(a) Method 1: Inspections, tests, or analyses performed after delivery

(b) Method 2: Commercial grade survey of the supplier

(c) Method 3: Source verification of the item or service

(d) Method 4: Acceptable supplier/item performance record

Once critical characteristics are verified, there is reasonable assurance that the computer program produces valid responses when used in the design or analysis of SSCs. At this point, the computer program can be accepted as a safety-related item and will be subject to the controls of Parts I and II of this Standard.

Users of this Subpart should be aware that the method(s) of verification chosen may impact the procurement document content needed for the successful verification of the critical characteristics for acceptance.

Dedication activities will not be considered completed until the computer program is installed and found acceptable by the dedicating entity. Dedication is a safety-related activity, and Part II, Subpart 2.14 requires the dedicating entity to conduct the dedication process under a QA program that meets the requirements of Parts I and II of this Standard.

602 Method 1: Special Test(s), Inspection(s), and/or Analyses

602.1 Special Tests. Tests to verify the adequacy of the commercial grade computer program should be documented in a test plan. Test plan activities that should be considered include the tests to be performed, the test method(s) to be utilized, verification of the identified critical characteristics for acceptance consistent with the acceptance criteria determined in the technical evaluation, demonstration that the mathematical equations are adequate to calculate critical parameters in an SSC, and documentation of test results. The dedicating entity should develop sufficient tests to determine whether the computer program produces valid responses when used in the design or analysis of SSCs.

Tests may be performed by third-party entities if they are documented and the tests are controlled in accordance with the requirements of this Standard. The use of test problems based on codes and standards or established technical references should provide an acceptable approach for some types of design and analysis computer programs. The test plan and results conducted by the dedicating entity or a third-party entity should be retained as part of the dedication documentation. If tests were performed by the supplier, the dedicating entity should verify the adequacy of test coverage consistent with the computer program's application requirements.

The dedicating entity should confirm that a representative testing set of anticipated program applications was carried out by the supplier and that important design features and major logical paths of the computer program were tested consistent with the technical evaluation and critical characteristics for acceptance. Retesting should be required to repeat some of the supplier's tests, and additional testing should also be required if a supplier's test coverage is found to be inadequate. When tests are used to verify acceptance criteria for the critical characteristics, the commercial grade computer program should be kept under configuration control to preclude inadvertent use or changes prior to satisfactory completion of the dedication activities and to prevent unauthorized release.

If the dedicating entity is testing a computer program in-house, test cases should be developed to determine the accuracy of the computer program's predictions based on the identified critical characteristics. In situations where computer program requirements include a clear specification of the range of validity for program responses, an evaluation of test results and documentation that states whether all results fall within the valid range should be acceptable. The range of validity could

be determined based on physical observations, such as experimental benchmarks, by analytic means, or by other validated programs. In some instances, the range of validity is known only in very general terms. The computer program being reviewed is often the only computer program capable of analyzing the problems of interest and providing the needed responses. Physical observations may be available only for simplified, unrepresentative, or distorted problem conditions, and analytic results may be obtainable only for trivialized cases. In such situations, validation becomes a more subjective process dependent on the professional judgment of a professional engineer or other qualified staff of the dedicating entity. In such cases, the dedicating entity should evaluate the test results or conduct analyses to demonstrate that

(a) realistic test cases or test cases representative of the anticipated program used produce physically acceptable results (e.g., no negative temperatures or infinite pressure limits)

(b) simplified test cases produce understandable results when compared with physical observations or analytic predictions

Supplier acceptance tests and purchaser acceptance tests are activities that may be used during dedication. Method 2 should be used along with Method 1 if the dedicating entity wishes to take credit for supplier acceptance testing performed at the commercial supplier's facility.

602.2 Inspections. Inspections should include verification of objective evidence, including product identification and computer program revision date.

Receipt inspections should be included in the dedication plan and performed to accept the computer program. It is important to the process of implementing Method 1 to understand the difference between standard receipt inspections, computer program installation checkouts, and special tests and inspections performed after receipt. This Standard describes the standard receiving inspection in Part I, Requirement 7 as checking the quantity received, damage, general conditions of items, and part number. Computer program receipt inspections are as simple as checking that the computer program media have not been damaged and that the version identifiers are correct. Installation and checkout activities may or may not be part of dedication if it can be proven that these will not affect the computer program's application requirements or prevent the computer program's inadvertent use. Inspections for dedication go beyond the standard receiving inspection activities and installation checkouts to verify that the critical characteristics for acceptance are met. While the computer program version identifiers are attributes of a receipt inspection, they should also be part of the dedication process for the item. Even though receipt inspection and simple computer program installation checkouts are important to the dedication process, they are not adequate on their own for dedication.

602.3 Analyses. Analyses should include a review of the computer program design related to application requirements. As mentioned above, in cases where design specification documentation is not available, the available computer program documentation, such as a user's manual, should be reviewed to identify design specifications and application limits. The review of the applicable computer program life-cycle processes should demonstrate that all computer program requirements associated with the safety function were implemented adequately, ensure traceability to the computer program safety requirements, and clearly describe required functions, inputs, outputs, and options that are not used to potential users or block from use, as necessary.

603 Method 2: Commercial Grade Survey of the Supplier

Commercial grade surveys should be performed in accordance with the survey criteria of Part II, Subpart 2.14, which requires the supplier to have a documented and effective quality assurance program that controls the supplier's specific processes. The survey documentation should provide objective evidence that the life-cycle processes and controls implemented by the computer program's supplier for specified critical characteristics have been observed and evaluated for acceptance. Deficiencies identified in the supplier's process or controls should be corrected if the survey is used for acceptance of the identified critical characteristics.

The survey process should take advantage of available program documentation (such as development process artifacts), as well as user experience. Evidence should exist of software development standards and practices that were in place during the development of the computer program. Existing V&V activities carried out by the developer should be considered, evaluated, and credited as long as it is relevant to the computer program's application. This documentation should be identified and controlled.

Method 2 may be used when the dedicating entity relies on the commercial supplier for analyses, testing, and other activities that are related to the dedication process. Given that the dedicating entity is responsible for verifying critical characteristics, delegation of such activity should come with a thorough assessment of the commercial supplier's process to effectively control critical characteristics.

604 Method 3: Source Verification

Source verification is a method of acceptance conducted at the supplier's facility or other applicable location to verify conformance with one or more identified critical characteristics and acceptance criteria. This

method could be used to witness certain tests or computer program development processes that can only be performed at the supplier's location due to specialized equipment, trained personnel, etc. Source verification is only applicable to the actual activity related to the critical characteristic and acceptance criteria observed during the surveillance. The dedicating entity may establish a frequency in which to witness these activities to ensure that process controls applicable to the critical characteristics be effectively implemented for subsequent computer program revisions. An example of a surveillance would be to send representative(s) to evaluate the execution of the test problems for the new computer program or computer program revision.

This method may have limited application and is not applicable to computer programs that have already been developed since the computer development activities have been completed, for which access to the computer program life-cycle documentation may be restricted due to the proprietary nature of the documentation, or when there is an inability to interact with suppliers.

605 Method 4: Acceptable Supplier Item or Service Performance Record

Acceptable data for historical performance should evaluate the industry-monitored performance of the commercial grade computer program, industry product tests, certification to national codes and standards (nonnuclear-specific), and other industry records or databases. When a computer program has been demonstrated to be reliable based on its historical performance, it should be credited during dedication. Historical performance should be supported by the use of one of the other verification methods listed above.

This acceptance method should have a greater application for the dedication of computer programs used in design or analysis. Computer programs that are commercially available and that have industrywide application may be used successfully hundreds or even hundreds of thousands of times daily. The results of these uses and engineering judgment associated with the acceptance of the computer program should be considered with dedicating the computer program. Errors reported by the users to the supplier and failures associated with structures, systems, and components may be evaluated as part of the failure analysis investigation. This method is most effective when the supplier provides error reports to the purchaser for applicability and significance evaluation and when the users contact the supplier when computer program errors are suspected. A technical support agreement in the procurement documents provides assurance that there is adequate communication between the supplier and users.

700 COMMERCIAL GRADE SOFTWARE SERVICES

Commercial grade software services have a potential impact on the performance of computer programs and their ability to perform specified safety functions. Part II, Subpart 2.14 identifies computer software support as being one example of a service that may be provided as a commercial grade service. Commercial grade software services may include, but are not limited to, installation of computer programs, operating system updates and computer program patches, development or modification of computer programs that perform a safety function, performance of independent V&V activities, or other technical support activities. Alteration of a dedicated computer program's critical characteristics may be considered a commercial grade service. The dedicating entity should have qualified personnel who are knowledgeable of the services being provided in order to dedicate a service. Control of the activities performed by the service provider and the documentation from these activities should be considered critical characteristics to be verified during the dedication of the commercial grade service associated with computer programs.

800 DOCUMENTATION

801 Computer Program Procurement Documents

Depending on the critical characteristics selected and the dedication method, the purchaser's procurement documents for the computer program may need to include the following:

(a) a detailed description of the computer program name, title, release, version, or other descriptive identifiers

(b) technical specification requirements related to the computer program application

(c) the media or process used to provide the computer program to the purchaser

(d) identification of the supplier's QA program applicable to the computer program's development and support

(e) identification of the documentation to be provided with the computer program

(f) special shipping, storage, and handling requirements for media and any precautionary controls related to consideration of temperature, humidity, electromagnetic interference, etc., to be identified by the supplier

(g) right of access for performing surveys or surveillances

(h) need for the supplier to provide error reporting or technical support

802 Dedication Documentation

Documentation of the commercial grade computer program or service dedication process shall be traceable to the computer program or services and should contain the following types of documents, depending on the applicable dedication method:

(a) dedication plans or procedures, including the essential elements of the dedication process

(1) scope and objectives for the dedication process

(2) requirements document for computer program or service dedication

(3) plans for a configuration management process for computer program or service dedication, including planned regression test requirements and expected results

(4) computer program V&V methodology

(b) commercial grade item or service procurement documents

(c) technical evaluations

(1) computer program requirements, summary, and review

(2) documentation referenced during the technical evaluation

(d) critical characteristic identification and acceptance criteria

(e) test plan(s), test specifications, test report(s) or results, inspection reports, and analysis reports

(1) review of test coverage

(2) evaluation of test results — validation

(f) commercial grade survey reports

(g) source verification reports

(h) historical performance information [e.g., availability and use of user experience(s)]

(i) dedication report containing sufficient data to accept the item or service

803 User Documentation

Limitations of the scope of the dedication of a computer program that are based on the critical characteristics should be communicated to the computer program users to ensure usage is within the dedication limits. The configuration control of the computer program can usually be used to control the version of the computer program. When limits on the computer program usage exist that are not blocked by the computer program's process controls, a users' manual with the specified limits should be available to the users.

(15) 900 REFERENCES

ANSI/ANS 10.4, Verification and Validation of Non-Safety-Related Scientific and Engineering Computer Programs for the Nuclear Industry

Publisher: American Nuclear Society (ANS), 555 North Kensington Avenue, LaGrange Park, IL 60526 (www.ans.org)

ANSI/IEEE Std. 7-4.3.2-2010, IEEE Standard Criteria for Digital Computers and Safety Systems of Nuclear Power Generating Stations

ANSI/IEEE Std. 730-2002, IEEE Standard for Software Quality Assurance Plans

ANSI/IEEE Std. 1012-2004, IEEE Standard for Software Verification and Validation

Publisher: Institute of Electrical and Electronics Engineers, Inc. (IEEE), 445 Hoes Lane, Piscataway, NJ 08854 (www.ieee.org)

EPRI Technical Report 106439, Guideline on Evaluations and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications

EPRI Technical Report 107330, Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants

EPRI Technical Report 1025243, Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications

Publisher: Electric Power Research Institute (EPRI), 3420 Hillview Avenue, Palo Alto, CA 94304 (www.epri.com)

ISO 9001:2008, Quality management systems — Requirements

Publisher: International Organization for Standardization (ISO), Central Secretariat, 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Genève 20, Switzerland/Suisse (www.iso.org)

SEI CMMI, CMMI-DEV Version 1.3, November 2010, CMMI for Development

Publisher: Carnegie Mellon University Software Engineering Institute, 4500 Fifth Avenue, Pittsburgh, PA 15213-2612 (www.sei.cmu.edu)

Table 501 Typical Critical Characteristics to Consider for Computer Programs

	No.	CC	Description	Acceptance Criteria	Method of Verification
Typical Identification CC					
	I-1	Host computer operating environment identifiers	The manufacturer, model number, operating system version, service packs, or patch identifiers of the host computer where the computer program is intended to be executed.	The host computer environment identifiers must match the purchase specification.	Verified through one or more of the following: *(a)* inspection of receipt inspection documentation (Method 1) *(b)* inspection of operating system identifiers (Method 1)
	I-2	Computer program name and version identifier	The full name of the computer program and version identifier, including all patches. It should be the same identifier as used for during the procurement/acquisition process.	Computer program name and version identifier must match the product identifier from the supplier catalog or procurement documents. The version identifier can be the build date of the executable. The computer program version identifier includes the computer program name, major functional version, minor functional version, and correct revision.	Verified through one or more of the following: *(a)* inspection of receipt inspection documentation (Method 1) *(b)* inspection of operating system identifiers (Method 1)
	I-3	Support tool name(s) and identifier(s)	The complete name, including version identifier of all support tools that are used during the commercial grade dedication process to assist in performing special tests or other support tools used in the operating environment. These tools, such as database management systems, could impact the correct operation of the safety functions performed by the computer program during special tests or operations.	The support tool name and identifier must match the product identifier from the supplier catalog or specification.	Verified through one or more of the following: *(a)* inspection of receipt inspection documentation (Method 1) *(b)* inspection of operating system identifiers (Method 1)

Table 501 Typical Critical Characteristics to Consider for Computer Programs (Cont'd)

No.	CC	Description	Acceptance Criteria	Method of Verification
Typical Physical CC				
P-1	Life cycle documentation	The documentation that is produced during all phases of the software life cycle. Documentation is evidence of the activities being performed. Documentation from multiple life cycle phases may be combined into one or more physical documents.	Life cycle documentation includes separate or combined documents that include software requirements specification, requirements traceability matrix, design documentation, architecture views, design description document, interface documentation, test plans, test reports, and user documentation.	Verified through the inspection of life cycle documents (Method 1).
P-2	Media	The physical object or distribution media received from the supplier that contains the computer program. This critical characteristic is applicable to all computer programs. Receipt media criteria are expressed as the method in which the computer program is distributed to the dedicating entity (e.g., CD, embedded, or downloadable).	Agreement with published catalogs or as specified in procurement documents.	Verified through the inspection of the received computer program (Method 1).
Typical Performance/Functional CC				
F-1	Accuracy/ precision/ tolerance outputs	For accuracy, the degree to which there is a close correlation with the expected or desired outcome. For precision, the degree of repeatability or degree of measure. For tolerance, the allowable possible error in measurement.	As described in computer program requirements or supplier specification documentation. Criteria may be: accuracy ± 1%; precision ± 0.0001; tolerance ± 0.00001	Verified through a combination of one or more of the following: *(a)* observation and review of design (Method 3) *(b)* inspection and testing (Method 1) *(c)* review of the installed base to determine performance history (Method 4)
F-2	Environmental compatibility: portability	The measure of the effort required to migrate the computer program to a different hardware platform, component, or environment. This critical characteristic may only be important for computer programs that are expected to be executed in a different environment.	As described in computer program requirements or supplier specification documentation. Portability criteria can be expressed as a unit of time (e.g., 16 hr or 15 days).	Verified through performing migration to one or more environments equivalent to the dedicating entities (Method 1).
F-3	Functionality: completeness and correctness	The degree to which the computer program requirements, design, and implementation have satisfied the allocated safety requirements. Formal techniques may be used to mathematically prove that the computer program satisfies its specified requirements. This critical characteristic is important to identify risks of the computer program failing to execute its safety functions.	Completeness and correctness are based upon how many of the computer program's requirements have been verified to be successfully implemented (e.g., 100% of allocated safety requirements are correctly implemented).	Verified through performing a review of the functional requirements traceability to test cases and verification that the test results indicate correct functionality. If requirements traceability is unavailable, the dedicating entity can develop the traceability matrix from the computer program's requirements or procurement specifications and test cases performed (Method 2).

Table 501 Typical Critical Characteristics to Consider for Computer Programs (Cont'd)

No.	CC	Description	Acceptance Criteria	Method of Verification
Typical Performance/Functional CC (Cont'd)				
F-4	Functionality: consistency with appropriate engineering, scientific research, and professional technical approaches	The degree to which the computer program's sample or complete data sets of results correlate with experimental data, expected data results, or professional analyses and to which any erroneous data sets do not correlate with the experimental data or professional analyses. This critical characteristic most likely is important to computer programs used to perform analysis of accident and structural integrity analyses for determining the proper design of safety components.	Consistency with research and professional technical approaches is based upon peer-reviewed published technical papers or industry-accepted computer programs performing a similar function. The output of the computer program can be viewed as how closely the computer program's output matches the technical report or baseline computer program output (e.g., computer program output correlates with experimental data to $\pm 3\sigma$).	Verified through a combination of one or more of the following: *(a)* a comparison of peer-reviewed technical publication detail results against the computer program's output for a similar problem being solved (Method 1). *(b)* a comparison of the baseline computer output against the computer program's output that is being dedicated. The baseline computer program must solve the same or closely similar physical problem as the dedicating computer program (Method 1). *(c)* a review of the computer program's current user base and its applicability to the intended use by the dedicating entity (Method 4).
F-5	Functionality: specific safety functions and algorithms	The critical functions or calculations that are performed. This includes time-dependent functions and functionality to only allow authorized users access to perform the safety functions.	As described in computer program requirements or procurement specification documentation. Functionality criterion may be similar to given source input data, calculate dose exposure at 10 m and 0 receptor height.	Verified through a combination of one or more of the following: *(a)* observation and review of design (Method 3) *(b)* inspection and testing (Method 1) *(c)* review of the installed base to determine performance history (Method 4)
F-6	Interfaces: critical input parameters and valid ranges	The set of input parameters that are used in the critical functions of the computer program and the range of their valid values. This critical characteristic is important to ensure that the computer program will function properly for all possible operational inputs.	As described in computer program requirements or procurement specification documentation. This criteria may be deposition receptor height (e.g., 0 ft to 1 ft), time (dd/mm/yyyy hh:mm:ss), and length (1.00 m to 5.00 m).	Verified through a combination of one or more of the following: *(a)* observation and review of design and/or implementation (Method 3) *(b)* inspection and testing (Method 1) *(c)* inspection of user's manual (Method 1) *(d)* review of the installed base to determine performance history (Method 4)

Table 501 Typical Critical Characteristics to Consider for Computer Programs (Cont'd)

No.	CC	Description	Acceptance Criteria	Method of Verification
Typical Performance/Functional CC (Cont'd)				
F-7	Interfaces: output parameters	The characteristics of the critical output parameters. The characteristics of the critical output parameters include file formats and mathematical notations. This critical characteristic is important to ensure that the computer program output is in the expected format or units of measure.	As described in computer program requirements or procurement specification documentation. This criterion can consist of the output filename (e.g., 28 characters, case-insensitive with a file extension of pdf) or output format specification (e.g., comma-delimited) and units of measure.	Verified through a combination of one or more of the following: *(a)* observation and review of design (Method 3) *(b)* inspection and testing (Method 1) *(c)* inspection of user's manual (Method 1) *(d)* review of the installed base to determine performance history (Method 4)
Typical Dependability CC				
D-1	Built-in quality: adherence to coding practices	The degree to which the computer program complies with the approved coding standards, use of code libraries, or automated configuration management tool. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Coding practice criteria can be a percentage (e.g., 90%) of the supplier coding standards met, and, where appropriate, 100% of possible code library modules are used instead of recoding.	Verified through the review of code inspection reports or other supplier evidence that included reviews of coding practice for the subject code modules. The dedicating entity during a survey may also review the code module's compliance with the supplier's documented coding practices (Method 2).
D-2	Built-in quality: code structure (complexity, conciseness)	The measure to which the computer program is legible, complexity is minimized, and code length is minimized. This critical characteristic can be used to provide an indicator as to the difficulty to verify through reviews and testing that the code will perform as expected.	Code structure criteria can be quantitative, through the use of static analysis tools, or qualitative, through reviews of the documented design or inspection of the code. Code structure criteria may take the form of a number of internal subroutine interfaces, a number of do-loops, numbers of exits from a module, straightforward flow of logic in code module, and code module depth and breadth.	Verified through the review of supplier-documented evidence from the use of a static analysis tool or the dedicating entity performing an inspection and manual analysis of the documented design or computer program code (Method 2).

Table 501 Typical Critical Characteristics to Consider for Computer Programs (Cont'd)

No.	CC	Description	Acceptance Criteria	Method of Verification
Typical Dependability CC (Cont'd)				
D-3	Built-in quality: conformance to national codes, standards, and industry-accepted certifications	The computer program's compliance with applicable national codes and standards or industry-accepted certifications.	Conformance criterion can be a measure of how well the computer program meets industry-accepted practices that provide a qualitative pedigree of the computer program. The criteria can be the degree in which a national code, standard, or third-party certification or recertification programs are achieved (e.g., 90% of achievement of compliance to CMMI SEI maturity level 4 or achieved ISO 9001).	Verified through one or more of the following: *(a)* inspection of supplier-performed assessments of the computer program against the national code or standard (Method 1) *(b)* review of computer program documentation and artifacts against the selected national code or standard (Method 2) *(c)* inspection of the proof of third-party certification (Method 1)
D-4	Built-in quality: existence of QA program	A QA program that includes documented procedures or process controls. QA program generally complies with a recognized standard (e.g., ISO 9001, IEEE 730, and IEEE 1012). This critical characteristic can be used to determine whether the foundation of a QA program exists.	QA program criteria are based upon the supplier's procedural compliance with a recognized standard that addresses development and quality assurance for computer programs. This criterion can be expressed in terms of the number of significant findings from a compliance audit against the chosen recognized standard or achievement of certification for the chosen recognized standard.	Verified through one or more of the following: *(a)* inspection of evidence of any third-party certification (Method 1) *(b)* review of internal or external audit reports (Method 2) *(c)* performance of a survey against the chosen recognized standard (Method 2)
D-5	Built-in quality: internal reviews and verifications	The degree to which static analysis methods (e.g., peer reviews) are performed during the computer program's development to identify errors and noncompliance with supplier procedures and standards.	Criteria for internal reviews and verifications effectiveness are based upon the ratio of errors identified during the review/verification and the number of errors that are discovered in the next life cycle phase (e.g., ratio of the number of requirements errors identified during requirements review and the number of errors detected during the design phase).	Verified through the inspection and analysis of results from reviews or verification activities performed in two or more adjacent life cycle phases (Method 2 and/or Method 3).

Table 501 Typical Critical Characteristics to Consider for Computer Programs (Cont'd)

No.	CC	Description	Acceptance Criteria	Method of Verification
Typical Dependability CC (Cont'd)				
D-6	Built-in quality: testability and thoroughness of testing	A measure of the completeness of the computer program verification, validation, and installation testing to ensure that the computer program is correct and complete. This critical characteristic may be appropriate to use for ensuring that tests were adequate to provide the reasonable assurance that the safety functions can be performed satisfactorily.	Testability criteria are based on the ease or difficulty in conducting verification and validation activities, as well as the breadth and depth of the testing performed. Testability criteria may include the number of hours needed to perform peer reviews, pretest a module, and develop test cases. The thoroughness of computer program testing criteria can be measures that identify the quantity of errors discovered during the various testing activities (e.g., trend analysis of errors per module, comparison of pre and postrelease errors) and traceability of tests performed to the safety requirements for the computer program (e.g., 95% of the requirements were tested).	Verified through one or more of the following: *(a)* inspection of documented review reports and test records that include the time spent to prepare, conduct, and perform postreview or test activities (Method 1). *(b)* review of the objective evidence of the errors identified during the testing processes or traceability of safety requirements to tests completed. If objective evidence is not available, the dedicating entity may be able to create the traceability of the safety requirements to tests performed from the computer program's documented requirements and test reports (Method 2).
D-7	Built-in quality: training, knowledge, and proficiency of personnel performing the work	Staff training, knowledge, and proficiency associated with the design, development, testing, oversight of the computer program, experience in similar projects, and familiarity with specific tools, languages used in design, and implementation. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Staff training, knowledge, and proficiency criteria may include how well the specific staff member satisfies the supplier's qualification requirements for the position held. The criterion can be the percentage of qualification requirements met.	Verified through the review of objective evidence of attendance at courses, staff resumes, and on-the-job training against the supplier qualification requirements to determine how well the staff member satisfies the requirements (Method 2).

Table 501 Typical Critical Characteristics to Consider for Computer Programs (Cont'd)

No.	CC	Description	Acceptance Criteria	Method of Verification
Typical Dependability CC (Cont'd)				
D-8	Problem reporting: notification to customers	Notification by the supplier to customers of potential computer program errors or weaknesses.	This criterion may be the presence and use of a problem reporting system, use of problem reporting metrics, and number of notifications to the users over time.	Verification is performed by reviewing communications of errors with users, any website or other form of communication with the supplier, and a communications log (Method 2).
D-9	Supportability/ maintainability	The ability for the supplier to continue supporting the computer program over the life of its use or the computer program design that provides for ease in performing modifications to the computer program. This critical characteristic may be more appropriate for computer programs whose failure could result in few or no alternatives or those alternatives that are not financially feasible.	Supportability/maintainability criteria can consist of the stability of the supplier based upon business longevity (e.g., 20 yr in business), size of customer base (e.g., 1,000 customers worldwide), planned future product releases (e.g., supplier R&D has updates scheduled for next 3 yr), supplier history of discontinuing products (e.g., cancelled three product lines over past 2 yr), or the time required to change the computer program (mean time to change or fix).	Verified through one or more of the following: *(a)* review of the supplier history for the specific computer program, as well as the history in supporting similar computer programs or products (Method 4) *(b)* review of supplier metrics associated with the length of time to evaluate the change/error correction, make the code change/ correction, test the change/ correction, update all computer program documentation, and release the change (Method 2)

SUBPART 3.2-2.15
Implementing Guidance for Part II, Requirement 2.15: Hoisting, Rigging, and Transportation

100 GENERAL

Subpart 3.2-2.15 provides guidance on the design and use of hoisting, rigging, and transporting equipment to maintain the quality of designated nuclear power plant items that require special handling, from the time these designated items are delivered at the point of receipt for the plant until the operating phase of the plant. The guidelines of Subpart 3.2-2.15 may also be extended to other appropriate parts of nuclear power plants when specified in contract documents.

200 RECOMMENDED DESIGN CRITERIA

This section describes specific design criteria that are appropriate for most applications and that are recommended for general use. If it can be shown that these criteria are not appropriate for a specific application, the engineer responsible shall select compatible criteria and document the justification.

201 Structural

Recommended safety factors for guyed systems are 3 to 1 (breaking strength to working load) for strength of guys, and 2 to 1 based on anchorage pullout.

202 Mechanical

Hydraulic circuits may require design features, such as pressure-operated check valves, to minimize possibilities of unexpected lowering of loads.

300 RECOMMENDED CONTROL OF THE USE OF HANDLING EQUIPMENT

Where applicable, soils tests should be made and the results analyzed by an individual qualified in soils engineering to determine the stability of ground areas in the vicinity of lifting equipment or along the route of transport equipment. Requirements for the use of soil compaction, timber mats, concrete pads, or other methods of reinforcement should be based on these tests and their evaluation. Tests may be waived when a history of previous use with equal or greater weight is available for the same area under similar conditions, including any reinforcement if previously used.

SUBPART 3.2-2.18.1
Implementing Guidance for Part II, Requirement 2.18: Maintenance of Nuclear Facilities, Establishing and Maintaining Equipment Histories

100 GENERAL

This Subpart provides nonmandatory guidance on establishing and maintaining equipment histories as specified by para. 206 of Subpart 2.18.

200 DEVELOPING AN EQUIPMENT HISTORY

A listing should be developed to identify equipment on which historical data will be maintained. This listing should be established for both new and existing equipment as early in the life of the equipment as possible. The procedures for maintaining the historical data should identify the types of data to be collected for each piece of equipment.

300 MAINTAINING HISTORICAL DATA

In general, there are two categories of data for which historical data should be collected: periodic data denoting operating degradation and wear conditions; and abnormal occurrences such as failures.

Several types of documents may be used to collect historical data. These may include, but are not limited to, the following:

(a) work authorization documents
(b) completed maintenance records
(c) modification records
(d) postmaintenance test result records
(e) nonconformance reports
(f) replacement acceptability evaluation records
(g) vendor notices and bulletins
(h) lubrication records
(i) chemistry records
(j) surveillance, inspection, and test reports
(k) calibration reports
(l) reports of industry experience
(m) performance records (e.g., pump baseline curves, vibration monitoring results, thermal monitoring results, acoustics emission monitoring results)
(n) reports from external sources

Historical data do not have to be maintained in a single file or set of files. However, an individual or organization should have responsibility for collecting historical data and ensuring retrievability.

Historical files do not have to contain the actual documents from which the data are collected. The data may be extracted from the documents and used in a manner appropriate to the facility. However, the overall utility of the equipment history will depend upon maintaining adequate identification of the equipment and its traceability to the related data.

400 USING MAINTENANCE HISTORY

Maintenance history files may be used for several purposes, including, but not limited to, the following:

(a) failure analysis
(b) prevent maintenance needs and intervals
(c) outage planning
(d) support for facility life extension
(e) budget planning
(f) root cause analyses
(g) trending
(h) establish and maintain performance indicators
(i) input to the quality assurance grading process
(j) planning for decommissioning
(k) identifying the need for equipment modifications

SUBPART 3.2-2.18.2
Implementing Guidance for Part II, Requirement 2.18: Maintenance of Nuclear Facilities, Engineering Evaluations of Equipment Failures

100 INTRODUCTION

This Subpart provides nonmandatory guidance on performing engineering evaluations of equipment failures that have a serious effect on safety or operability, as specified in para. 403.2 of Subpart 2.18 (Part II).

200 ENGINEERING EVALUATIONS

201 Initiating Engineering Evaluations

Engineering evaluations are initiated whenever equipment or system failures are discovered that could have serious effects on safety and operability, and should also be considered when the potential for such failures is suspected. These actual or potential failures could be identified during normal facility operations. Additionally, they could be identified as a result of accidents; operations or maintenance surveillances; preventive or corrective maintenance actions; predictive maintenance monitoring; reviews of industry experience; and adverse conditions or serious failures of similar equipment in other systems or facilities.

202 Performing Engineering Evaluations

(a) Requirements and procedures for performing, documenting, and applying the results of engineering evaluations should be established and implemented.

(b) The evaluations should be promptly completed. The results should be factored into the bases for continued operation, shutdown, or restart of the equipment or systems affected by the actual or potential failures.

(c) The evaluations should include a systematic determination and analysis of failure causes, including failure symptoms, modes, and mechanisms. Failure Modes and Effects Analysis, Root Cause Analysis, Change Analysis, Barrier Analysis, Fault Tree Analysis, or other appropriate analytical techniques should be employed. Physical and chemical analyses, destructive or nondestructive examinations, and event simulation or reconstruction should be considered and conducted, as appropriate.

(d) The evaluations should be performed by technically competent personnel who are familiar with the design, operation, and maintenance history of the system or equipment involved, and who are skilled and experienced in the use of applicable analytical and investigative techniques.

(e) The evaluations should consider the operating conditions at the time of failure, and relevant contributing factors. Factors to consider may include, among others, the following:

(1) changes in environmental or facility conditions

(2) changes in equipment or system operating modes

(3) interactive effects from other items or events

(4) inadequacies in the original design or subsequent modifications

(5) failure to properly designate/identify critical components

(6) failure to properly factor modifications into the maintenance program

(7) failure to protect environmental or seismic qualifications

(8) operator errors

(9) inadequate predictive, preventive, or corrective maintenance

(10) inadequacies in the performance, application, or bases of previous analyses or assessments

(11) waivers, deferrals, or excessive backlogs of maintenance activities

(12) operation extending beyond equipment or component expected lifetimes

(13) previous operating anomalies that were not understood, followed up, or corrected

(14) changes in vendors or in vendors' processes or specifications for renewal and replacement parts

(f) The evaluations should recommend corrective actions to prevent recurrence of failures. Based on the causes of the failures, these recommendations should consider, as appropriate, the following:

(1) the potential for failure of other items of the same or similar design or service

(2) manufacturer recommendations and industry experience in the use of the item (or similar items), if available

(3) equipment history of the failed item (or similar items) to determine if replacement, repair, or other corrective methods previously used can be expected to restore the reliability of the item

(4) the need for modifications to improve the material, function, configuration, interfaces, location, or orientation of the failed item (or similar items)

(5) the need for improvements in the selection and acceptance criteria for renewal and replacement parts

(6) the need for incorporating redundancies, failure annunciators, or other engineered safety, compensatory, or mitigating features to enhance reliability

(7) the need for improving or increasing equipment or system performance monitoring, data analysis, and predictive maintenance capabilities

(8) the need for modifying preventive maintenance or its frequency

(9) the need for changing operating procedures or facility/environmental conditions

(10) the need for improved training or retraining of maintenance or operating personnel

(11) the need for changing resource allocations and priorities related to the performance of predictive, preventive, and corrective maintenance

203 Using Engineering Evaluation Results

(a) The results of the evaluations should be reviewed for approval by cognizant management to ensure that all applicable facts have been considered and that the recommended corrective actions are pertinent and achievable. Corrective actions should be approved by cognizant management and implemented in a timely manner.

(b) The results of the evaluations, including corrective actions taken, should be entered into the equipment history system. In addition, lessons learned from the evaluations should be disseminated to users of similar types of equipment within the organization and, where practical, to users in other organizations.

SUBPART 3.2-2.20
Implementing Guidance for Part II, Requirement 2.20: Subsurface Investigations for Nuclear Power Plants, Sample Control and Identification

100 GENERAL

This Subpart provides nonmandatory guidance for ensuring quality in the identification and control of samples collected for subsurface investigations.

200 CONTROL OF SUBSURFACE INVESTIGATIONS

The technical adequacy of procedures for conducting subsurface investigations and their implementation should be reviewed and approved by qualified persons other than those who prepared or selected the procedures.

300 IDENTIFICATION OF SAMPLES

Samples should be identified in a manner consistent with their intended use. Identification should be maintained throughout acquisition, handling, testing and analysis, preservation, shipment, transfer, storage, and disposition of samples.

Samples should be identified by placing the identification directly on the samples when possible, or on their container, or on a label or tag attached to the sample or their container. Sample identification should be verified and documented prior to release for testing or analysis. Identification methods should not affect sample characteristics or interface with the intended use.

Identification systems should ensure documented traceability of samples from the initial source, through final disposition. Samples that have lost their identification should not be used for input into the site investigation database.

400 CONTROL OF SAMPLES

Samples should be controlled during handling, acquisition, transfer of custody, shipment, storage, and disposition to preclude damage and loss (including loss of identity or associated documentation) and minimize deterioration. Responsibilities for control of samples should be defined.

Representative archival samples should be maintained from difficult-to-repeat samples collection activities such as principal bore holes.

Consideration should be given to the type of container, time constraints on perishable materials, and other environmental or safety considerations applicable to the sample.

Where multiple organizations are involved, appropriate procedures should describe interface and custody responsibilities. The identification of samples should be verified and maintained when samples are handled, transported, or transferred from one organization's responsibility to another's.

Sample characteristics, integrity, and identification should be maintained or controlled during storage. The controls applied should be consistent with the planned duration and conditions of storage and should describe action to be taken where samples have a maximum life expectancy while in storage. Storage methodology should be developed and implemented to ensure that essential sample characteristics are maintained to protect integrity. Samples should be controlled to preclude mixing of like samples. Samples on which analyses or tests have been performed should be identified and stored or disposed of as required by the procedures.

SUBPART 3.3
Nonmandatory Guidance on Quality Assurance Program Requirements for Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories

(ASME NQA-3)

Refer to ASME NQA-3, specifically Part IV Appendices, for nonmandatory guidance relating to the subject document.

NOTE: It is intended that salient NQA-3 requirements will subsequently be integrated into Part I and/or Part II of ASME NQA-1 document in a future edition.

(15) PART IV: GUIDANCE ON THE APPLICATION AND USE OF NQA-1

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(15) 100 PURPOSE

Part I establishes requirements for the development and implementation of a Quality Assurance Program (QAP) for nuclear facility applications. It is arranged by Requirements 1 through 18. Part II contains additional quality assurance requirements for the planning and conduct of specific work activities under a Quality Assurance Program developed in accordance with Part I. It is arranged by Subparts.

Part III contains guidance for implementing the requirements of Parts I and II. It is arranged by Subparts.

Part IV — this Part — contains guidance for application of NQA-1 and comparisons of NQA-1 with other quality requirements. It is arranged by Subparts. It was developed using lessons learned, proven methods of performance, best practices, and insights of the NQA Committee to provide nonmandatory guidance on approaches and methods to apply Part I and/or Part II requirements to specific applications.

Consistent with its intent to provide nonmandatory guidance, the terms *must*, *require*, and *shall* are not used in statements of action in this Part. As such, alternative approaches and methods may be used to satisfy Parts I and II requirements. The Subparts provided in this Part are intended to be used as inputs and background in the development and implementation of Quality Assurance Programs, policies, protocols, instructions, and procedures. Information contained therein is designed to be of a guidance and explanatory nature and, as such, is not to be considered as requirements unless directly incorporated into an organization's requirement documents.

200 APPLICABILITY

Part IV applications and comparisons of quality requirements from other industry documents and government regulations do not alter or modify Part I or II requirements. Further, the differences identified in such comparisons are not intended to identify deficiencies in either document and relate only to the differences in the defined scope and application of the respective documents.

Part IV does not limit the Standard user from using alternate methods and activities that can be proven to provide results consistent with Parts I and II requirements.

SUBPART 4.1
Guides on Use and Comparison of NQA-1 With Other Quality Requirements

SUBPART 4.1.1
Guidance to Modification of an ISO 9001:2008, Quality Management Systems Standard for Compliance With NQA-1–2008, Part I With the NQA-1a–2009 Addenda

100 INTRODUCTION

This Subpart provides guidance to the ISO 9001:2008 Standard users and interested organizations who may elect to use the ISO 9001:2008, Quality Management Systems Standard as the basis for establishing a Quality Assurance Program that meets the requirements of ASME NQA-1 Standard.

The purposes of this guidance is to compare requirements of ISO 9001:2008 and NQA-1–2008, Part I with the NQA-1a–2009 addenda (NQA-1); to identify the similarities and differences, and to identify where actions may be needed to address the differences. The guidance is intended for all parties involved in the nuclear industry that are currently applying/implementing either NQA-1 or ISO 9001:2008 requirements and are required to comply with both standards.

This Guide can be used to achieve compliance with both sets of requirements simultaneously by providing information on the differences between ISO 9001:2008 and NQA-1, thus allowing organizations to implement controls for the program differences.

This Subpart examines each NQA requirement paragraph from Part I of NQA-1 Standard and identifies the comparable paragraphs of ISO 9001:2008 Standard.

The requirements of both standards have been compared utilizing the 18-criteria format of NQA-1, and guidance for evaluating existing practices or supplementing an ISO 9001:2008 program is summarized below each NQA-1 requirement section. In some cases, the ISO 9001:2008 requirement is stated at a higher level, and the user must determine the need to develop detailed practices for implementation of the NQA-1 requirements. In these cases, it is necessary to compare the implementing practices with the requirements of NQA-1 to determine compliance.

NQA-1 is primarily focused on assuring quality of the design, construction, and operation of a facility in a regulated environment to assure nuclear safety. While it includes requirements for assuring quality of the items and services provided to support the overall objective, it is not primarily directed at the management and continuous improvement processes needed to achieve customer satisfaction. The ISO 9001:2008 Standard seeks to achieve quality by a process that "promotes the adoption of a process approach when developing, implementing, and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements."[1] The ISO 9001:2008 Standard may also be the users' management program framework, which uses NQA-1 for the development and implementation of quality programs.

200 NQA REFERENCE REQUIREMENTS

The guidance following each requirement section (Tables 200-1 through 200-18) contains general topics or areas potentially needing improvement, amplification, and/or clarification. Users of this guidance should recognize that the requirements of NQA-1 are contained in Part I of this Standard. In case of conflict, the requirements of Part I govern.

300 TERMS AND DEFINITIONS

Within the ISO 9001:2008 Standard, there exist terms and usage that are unique, and therefore, differences exist with the terms used within NQA-1. Where these differences exist, care should be taken by the ISO 9001:2008 Standard user to ensure that the requirements of NQA-1, Part I are fully implemented as related to the NQA-1, Part I use of the terms in question.

[1] ISO 9001:2008, Introduction 0.2 Process Approach.

400 APPLICATION OF NQA-1 TO ISO 9001 QMS PROGRAM

For each referenced paragraph of NQA-1, the paragraphs of ISO 9001:2008 containing related requirements are identified. Where potential deficiencies in programs using ISO 9001:2008 may exist, these are identified.

NOTE: The word "shall" is used in this Guide only when quoting or describing a requirement of NQA-1.

Table 200-1 Corresponding NQA Sections (Requirement 1) to ISO Sections

NQA-1 Requirement 1: Organization	ISO 9001:2008
100 General	4.0 Quality Management System 4.1 Quality Management System — General Requirements 5.0 Management Responsibility 5.5.1 Responsibility and Authority
201 General	5.0 Management Responsibility 5.1 Management Commitment 5.5.1 Responsibility and Authority
201 General (Cont'd) "(c) quality achievement is verified by those not directly responsible for performing the work, and (d) those responsible for ensuring that an appropriate quality assurance program has been established and those verifying activities affecting quality."	No corresponding ISO 9001 section to NQA-1 section
202 Delegation of Work	4.1 Quality Management System — General Requirements
300 Interface Control	

RECOMMENDATIONS: There are three areas that need more detail for an ISO 9001 quality program to meet this NQA Requirement. These additional areas are the following:

(a) The Documentation of the Organizational Structure. The organizational structure should be documented to reflect functional responsibilities, levels of authority, and lines of communications for activities affecting quality.

(b) The independency of personnel who perform the verification of quality achievement should meet the requirements of NQA-1. Need to define those individuals who are responsible for verifying quality achievement and that they have sufficient authority, direct access to management, organizational freedom, and access to the work to perform their function. These individuals responsible for quality achievement shall not be directly responsible for performing the work; they are verifying quality achievement.

(c) Interface Control. NQA requires identification of authority of each organization in addition to responsibilities and interfaces. It requires interface control for both internal and external interfaces.

Table 200-2 Corresponding NQA Sections (Requirement 2) to ISO Sections

NQA-1 Requirement 2: Quality Assurance Program	ISO 9001:2008
100 General	4.1 Quality Management System — General Requirements 4.2 Documentation Requirements — General 4.2.2 Quality Manual 4.2.3 5.4.1 Quality Objectives 5.4.2 Quality Management System Planning 5.5.3 Internal Communication 5.6.1 Management Review — General 5.6.2 Review Input 5.6.3 Review Output 6.1 Provision of Resources 6.2.1 Human Resources — General 6.2.2 Competence, Awareness, and Training 6.3 Infrastructure 6.4 Work Environment 7.1 Planning of Product Realization 7.2.1 Determination of Requirements Related to the Product 7.2.2 Review of Requirements Related to the Product 7.2.3 Customer Communication 8.2.1 Monitoring and Measurement Customer Satisfaction 8.2.3 Monitoring and Measurement of Processes 8.4 Analysis of data 8.5.1 Continual improvement
100 General (Cont'd) "The program shall be established at the earliest time consistent with the schedule for accomplishing the activities."	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
200 Indoctrination and Training 201 Indoctrination 202 Training 300 Qualification Requirements 301 Nondestructive Examination (NDE) 302 Inspection and Test	6.2.2 Competence, Awareness, and Training
303 Lead Auditor	No corresponding ISO 9001 section to NQA-1 section. See ISO 19011-2002, Guidelines for Quality and/or Environmental Management Systems Auditing, for guidance.
304 Auditors 305 Technical Specialists 400 Records of Qualification 500 Records	

RECOMMENDATIONS: There are several areas that need more detail for an ISO 9001 quality program to meet this NQA-1 Requirement.

(a) The ISO 9001 documented quality program should

(1) define and include the planning, implementation, and maintenance requirements of NQA-1

(2) include specific recognition, where necessary, of "Controlled Conditions" as it relates to the use of appropriate equipment or processes, suitable environmental conditions, satisfaction of activity prerequisites

(b) Indoctrination and Training

(1) NQA-1 requires documented indoctrination for personnel performing or managing quality-affecting activities to include job responsibilities and authority; general criteria, including applicable codes and standards; regulatory commitments; company procedures; and quality assurance program requirements.

(2) The training requirements of NQA-1 are more explicit and include determining the need for formal training for personnel performing or managing quality-affecting activities. This training may include achieving and maintaining proficiency and/or changes to technology, methods, or job responsibilities.

(c) Qualification Requirements of Designated Personnel. Include explicit qualification requirements for personnel performing activities determined to need qualified personnel. Specific qualification requirements for personnel performing nondestructive examination, inspection, and tests to verify quality and auditing shall be in accordance with NQA-1, Part I, Requirements 2, sections 300 through 500.

Table 200-3 Corresponding NQA Sections (Requirement 3) to ISO Sections

NQA-1 Requirement 3: Design Control	ISO 9001:2008
100 General	7.3.1 Design and Development Planning
200 Design Input	7.3.2 Design and Development Inputs
300 Design Process	7.3.3 Design and Development Outputs
400 Design Analyses 401 Use of Computer Programs 402 Documentation of Design Analyses	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
500 Design Verification 501.1 Design Reviews	7.3.5 Design and Development Verification 7.3.4 Design and Development Review 7.3.6 Design and Development Validation
501.2 Alternate Calculations 501.3 Qualification Tests	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
600 Change Control	7.3.7 Control of Design and Development Changes
600 Change Control (Cont'd) "The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities.	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
"The design organization approving the change shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
"(b) When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate."	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
"(c) Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary."	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
601 Configuration Management of Operating Facilities 700 Interface Control 800 Software Design Control 801 Software Design Process 802 Software Configuration Management 900 Documentation and Records	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.

RECOMMENDATIONS: The scope of the design process is much broader and the requirements more detailed in NQA-1. An ISO 9001:2008 design process must be carefully compared with NQA-1 to establish compliance.

There are several areas that may need more detail for an ISO 9001 quality program organization to meet this NQA Requirement.

(a) Independence of personnel performing design adequacy verification activities needs to meet the criteria of NQA-1.

(b) Design input to be documented in sufficient detail to permit the design process to be carried out in a correct and consistent manner for making design decisions and accomplishing design verification.

Design changes shall have at least the same level of control as applied to the original design and shall be incorporated into the appropriate documents in a timely manner. Those approving design changes shall have demonstrated competence in the specific design area of interest and have adequate understanding of the requirements and intent of the original design.

(c) Formalize and document in detail design analysis, design verification processes, and interface control. The requirements for these design functions are in NQA-1, Part I, Requirement 3, sections 400, 500, and 700. The use of computer programs in design analysis must be defined and documented.

(d) Establish and document the configuration management for the operating facility prior to facility operation. The requirements for the configuration management of the operating facilities are found in NQA-1, Part I, Requirement 3, section 600.

(e) Control computer software design using the requirements found in NQA-1, Part I, Requirement 3, section 800.

(f) Include in documentation and records of the design not only final design documents, such as drawings and specifications, and revisions to those documents but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design.

(g) Commercial Grade Items. ISO 9001:2008 does not address how to treat items not produced to the requirements of nuclear codes and standards. This area needs to be addressed in an ISO program, if use of commercial grade items is anticipated.

Table 200-4 Corresponding NQA Sections (Requirement 4) to ISO Sections

NQA-1 Requirement 4: Procurement Document Control	ISO 9001:2008
100 General	7.4.2 Purchasing Information
200 Content of the Procurement Documents 201 Scope of Work 202 Technical Requirements	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
202 Technical Requirements	7.4.2 Purchasing Information
203 Quality Assurance Program Requirements	7.4.1 Purchasing Process 7.4.2 Purchasing Information
204 Right of Access 205 Documentation Requirements 206 Nonconformances 207 Spare and Replacement Parts	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
300 Procurement Document Review 400 Procurement Document Changes	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.

RECOMMENDATIONS: There are several areas that need more detail to meet this NQA-1 Requirement.

(a) Define the procurement process and procurement documents to ensure the appropriate documents and level of reviews and approvals satisfy the requirements of NQA-1, Part I, Requirement 4, sections 100 through 400.

Some of the key documents are statement of scope of work; technical requirement documents specified; and the appropriate test, inspection, and acceptance criteria.

(b) Define the quality program's controls of sub-tier suppliers, their reporting requirements and quality assurance responsibilities, along with right of access to supplier facilities and supplier reporting of nonconformances.

Table 200-5 Corresponding NQA Sections (Requirement 5) to ISO Sections

NQA-1 Requirement 5: Instructions, Procedures, and Drawings	ISO 9001:2008
100 General	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.

RECOMMENDATIONS: There is one area that needs more detail to meet the NQA-1 Requirement.

The ISO 9001 Quality program standard requires few written procedures to control work in selected areas, whereas the NQA-1, Part I, Requirement 5 requires all "Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings."

Instructions, procedures, and drawings need to be developed and implemented to control all quality affecting work. These instructions, procedures, and drawings shall be of sufficient detail commensurate with the complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).

Table 200-6 Corresponding NQA Sections (Requirement 6) to ISO Sections

NQA-1 Requirement 6: Document Control	ISO 9001:2008
100 General "Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel."	4.2.3 Control of Documents
200 Document Control "The following controls shall be applied to documents and changes thereto:"	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
200 Document Control "(a) the identification of controlled documents	4.2.3 Control of Documents
(b) the specified distribution of controlled documents for use at the appropriate location	
(c) the identification of individuals responsible for the preparation, review, approval, and distribution of controlled documents	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
(d) the review of controlled documents for adequacy, completeness, and approval prior to distribution	
(e) a method to ensure the correct documents are being used."	
300 Document Changes	
301 Major Changes	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
302 Minor Changes	

RECOMMENDATIONS: There are several areas that need more detail to meet this NQA-1 Requirement.

(a) Define in the Document Control program the following:

(1) the identification of controlled documents

(2) the specified distribution of controlled documents for use at the appropriate location

(3) the identification of individuals responsible for the preparation, review, approval, and distribution of controlled documents

(4) the review of controlled documents for completeness and approval prior to distribution

(5) a method to ensure the correct documents are being used

(b) Define in the Document Control program the use of Major and Minor changes allowed by NQA-1, Part I, Requirement 6, section 300.

Table 200-7 Corresponding NQA Sections (Requirement 7) to ISO Sections

NQA-1 Requirement 7: Control of Purchased Items and Services	ISO 9001:2008
100 General	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
200 Supplier Evaluation and Selection 300 Bid Evaluation	7.4.1 Purchasing Process
300 Bid Evaluation "Prior to the award of the contract, the Purchaser shall resolve or obtain commitments to resolve unacceptable technical and quality assurance conditions resulting from the bid evaluation."	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
400 Control of Supplier-Generated Documents 500 Acceptance of Item or Service 501 General 502 Methods of Acceptance 503 Certificate of Conformance 504 Source Verification	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
504 Source Verification "Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points."	7.4.3 Verification of Purchased Product
504 Source Verification "Upon Purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the Purchaser, and to the Supplier."	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
505 Receiving Inspection 506 Postinstallation Testing 507 Acceptance of Services Only 600 Control of Supplier Nonconformances 700 Commercial Grade Items and Services 800 Records	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.

RECOMMENDATIONS: There are several areas that need more detail to meet the NQA-1 Requirement.

(a) Define how potential suppliers are evaluated prior to the award of a contract or during the bid evaluation process, including resolving discrepancy conditions in the technical and/or quality programs. These requirements are found in NQA-1, Part I, Requirement 7, sections 200 and 300.

(b) Define the control of supplier-generated documentation, such as submittal and evaluation of supplier-generated documents.

These controls should also provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria. These requirements are found in NQA-1, Part I, Requirement 7, section 400.

(c) Define in the ISO 9001 Quality Program the Acceptance of Item or Services, Control of Supplier Nonconformances, and Commercial Grade Items. The requirements for these are found in NQA-1, Part I, Requirement 7, sections 500 through 700.

(1) For Acceptance of Item or Services, there are two main parts: the Supplier shall verify that the item or service being furnished complies with the procurement requirements and methods used to accept an item or service from a Supplier shall be a Supplier Certificate of Conformance, source verification, receiving inspection, or postinstallation test at the nuclear facility site or a combination of these methods.

(2) In NQA-1, Part I, Requirement 7, section 500, these methods of acceptance by the Purchaser from the Supplier are clearly defined and need to be a part of the ISO quality program.

(3) To satisfy the Control of Supplier Nonconformances requirement found in NQA-1, Part I, Requirement 7, section 600, the ISO quality program needs to define the methods for control and disposition of Supplier nonconformances for items and services that do not meet procurement documentation requirements.

(4) For Commercial Grade Items, the ISO quality program needs to address the usage of these items where the design utilizes them in accordance with NQA-1, Part I, Requirement 7, section 700.

Table 200-8 Corresponding NQA Sections (Requirement 8) to ISO Sections

NQA-1 Requirement 8: Identification and Control of Items	ISO 9001:2008
100 General	7.5.3 Identification and traceability
200 Identification Methods 201 Item Identification 202 Physical Identification	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
300 Specific Requirements 301 Identification and Traceability of Items 302 Limited Life Items 303 Maintaining Identification of Stored Items	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.

RECOMMENDATIONS: There are several areas that need more detail to meet this NQA-1 Requirement.

Define within the process the identification and traceability requirements found in NQA-1, Part I, Requirement 8, which covers three main areas: basic identification of traceability needs, methods of traceability, and special types of traceability requirements.

Table 200-9 Corresponding NQA Sections (Requirement 9) to ISO Sections

NQA-1 Requirement 9: Control of Special Processes	ISO 9001:2008
100 General "Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements."	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
200 Process Control 201 Special Processes "Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Special process instructions shall include or reference procedure, personnel, and equipment qualification requirements."	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
200 Process Control 201 Special Processes "Conditions necessary for accomplishment of the process shall be included."	7.5.2 Validation of Processes for Production and Service Provision
201 Special Processes "These conditions shall include proper equipment, controlled parameters of the process, specified environment, and calibration requirements."	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
202 Acceptance Criteria 203 Special Requirements	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
300 Responsiblity "It is the responsibility of the organization performing the special process to adhere to the approved procedures and processes."	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
400 Records	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
No corresponding NQA-1 section to ISO 9001 sections below ISO 9001:2008	7.5.1 Control of Production and Service Provision 8.1 Measurement, Analysis and Improvement — General 8.2.4 Monitoring and Measurement of Product

RECOMMENDATIONS: There are several areas that need more detail to meet this NQA-1 Requirement.

Special processes such as welding, heat-treating, and nondestructive examination need to be identified and controlled. These special processes considerations need to be included in the ISO quality program as it relates to welding, heat treating, and nondestructive examination or other processes that are determined to be special processes and the requirement that these processes shall be performed by qualified personnel using qualified procedures in accordance with specified requirements. These processes also need to be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These requirements are found in NQA-1, Part I, Requirement 9.

Table 200-10 Corresponding NQA Sections (Requirement 10) to ISO Sections

NQA-1 Requirement 10: Inspection	ISO 9001:2008
100 General	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
200 Inspection Requirements	
300 Inspection Hold Points	
400 Inspection Planning	
500 In-Process Inspection	
600 Final Inspections	
601 Resolution of Nonconformances	
602 Inspection Requirements	
603 Modifications, Repairs, or Replacements	
604 Acceptance	
700 Inspections During Operations	
800 Records	

RECOMMENDATIONS: There are major additions that need to be included in an existing ISO 9001 quality program to meet this NQA-1 Requirement.

(a) Inspections that verify conformance of an item or activity to specified requirements or continued acceptability of items in service need to be defined in the ISO quality program.

The concept of inspections that verify quality is not given a separate treatment within the ISO 9001 quality standard or the standard ISO 9001 quality program. The key areas are characteristics subject to inspection, inspection methods, and documented inspection results.

(b) Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected. The requirements for inspections are found in NQA-1, Part I, Requirement 10.

Table 200-11 Corresponding NQA Sections (Requirement 11) to ISO Sections

NQA-1 Requirement 11: Test Control	ISO 9001:2008
100 General	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
200 Test Requirements	
300 Test Procedures (Other Than for Computer Programs)	
400 Computer Program Test Procedures	
500 Test Results	
600 Test Records	

RECOMMENDATIONS: There are major additions that need to be included in an existing ISO 9001 quality program to meet this NQA-1 Requirement.

Test required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service is not defined within the ISO 9001 quality standard or the standard ISO 9001 quality program.

There are four key areas within the Test Control Requirement in NQA-1, Part I, Requirement 11 test requirements, test procedures, test results, and test records. The central theme is that characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented, and their conformance with test requirements and acceptance criteria shall be evaluated by a specific organization.

Table 200-12 Corresponding NQA Sections (Requirement 12) to ISO Sections

NQA-1 Requirement 12: Control of Measuring and Test Equipment	ISO 9001:2008
100 General "Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specified periods, adjusted, and maintained to required accuracy limits."	7.5.3 Identification and Traceability
200 Selection "Selection of measuring and test equipment shall be based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements."	7.6 Control of Monitoring and Measuring Devices
300 Calibration and Control	7.6 Control of Monitoring and Measuring Devices
301 Calibration	
302 Reference Standards	
303 Control	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
400 Records	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.

RECOMMENDATIONS: There are several areas that need more detail to meet this NQA-1 Requirement.

(a) The ISO term *measuring devices* is too general to meet NQA requirements found in NQA-1, Part I, Requirement 12.

(1) The ISO 9001 Quality Program definition of *measuring and test equipment* needs to be clarified to include tools. Gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specified periods, adjusted, and maintained to required accuracy limits.

(2) Methods and frequency of checking accuracy should be defined in procedures.

(b) There are also some specific requirements in NQA-1, Part I, Requirement 12, concerning the out-of-calibration controls needed in a quality program that an ISO quality program needs to address. These specific controls concern out-of-calibration devices being tagged or segregated, or both, and not used until they have been recalibrated.

(1) Measuring or test equipment consistently found to be out of calibration should be repaired or replaced. Calibration and control measures are not required for commercial equipment, such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy.

(2) Records to be established and maintained to indicate calibration status and capability of measuring and test equipment.

Table 200-13 Corresponding NQA Section (Requirement 13) to ISO Sections

NQA-1 Requirement 13: Handling, Storage, and Shipping	ISO 9001:2008
100 General 200 Special Requirements 300 Procedures 400 Tools and Equipment 500 Operators 600 Marking or Labeling	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
No corresponding NQA-1 section to ISO 9001 sections below ISO 9001:2008	7.5.4 Customer Property 7.5.5 Preservation of Product

RECOMMENDATIONS: There are several areas that need more detail to meet this NQA-1 Requirement.

(a) Handling, storage, and shipping activities should be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting these activities.

(b) Define specific procedures where critical, sensitive, perishable, or high-value items are involved as determined by the quality program. Where the need for these procedures has been determined the use of special handling tools and equipment, experienced or trained operators shall be determined.

(c) Marking or labeling should be utilized as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls.

Table 200-14 Corresponding NQA Sections (Requirement 14) to ISO Sections

NQA-1 Requirement 14: Inspection, Test, and Operating Status	ISO 9001:2008
100 General	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.

RECOMMENDATIONS: Test and Inspections status is not given a separate treatment within the ISO 9001 Quality standard or the standard ISO 9001 quality program. This is a major addition that needs to be included in an existing ISO quality program to meet the needs of NQA-1, Part I, Requirement 14, Inspection, Test, and Operating Status.

Table 200-15 Corresponding NQA Section (Requirement 15) to ISO Sections

NQA-1 Requirement 15: Control of Nonconforming Items	ISO 9001:2008
100 General "Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use."	8.3 Control of Nonconforming Product
100 General "Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations."	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
200 Identification 300 Segregation 400 Disposition	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.

RECOMMENDATIONS: There are several areas that need more detail to meet this NQA-1 Requirement.

(a) Define the controls for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items and for notification to affected organizations.

(1) The identification of nonconforming items should be specified such as legible marking, tagging, or other methods not detrimental to the item, on the item, the container, or the package containing the item.

(2) The methods of segregation where it is practical placing them in a clearly identified and designated hold area until properly dispositioned or when segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.

(b) The major addition to the ISO quality program is the evaluations and dispositions proposed for the nonconformances as shown is NQA-1, Part I, Requirement 15, section 400.

Table 200-16 Corresponding NQA Sections (Requirement 16) to ISO Sections

NQA-1 Requirement 16: Corrective Action	ISO 9001:2008
100 General "Conditions adverse to quality shall be identified promptly and corrected as soon as practicable."	8.5.2 Corrective Action
100 General "The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management." "Completion of corrective actions shall be verified."	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
No corresponding NQA-1 section to ISO 9001 sections below ISO 9001:2008	8.5.3 Preventive Action

RECOMMENDATIONS: There are several areas that need more detail to meet this NQA-1 Requirement.

Minor clarifications are needed for the following:

(a) The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management.

(b) Completion of corrective actions shall be verified.

Table 200-17 Corresponding NQA Sections (Requirement 17) to ISO Sections

NQA-1 Requirement 17: Quality Assurance Records	ISO 9001:2008
100 General “Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements.”	4.2.4 Control of Records
200 Generation of Records 300 Authentication of Records 400 Classification 500 Receipt Control of Records 600 Storage 700 Retention 800 Maintenance of Records	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.

RECOMMENDATIONS: This is a major addition that needs to be included in an existing ISO 9001 quality program to meet the requirements of NQA-1, Part I, Requirement 17, Quality Assurance Records.

Table 200-18 Corresponding NQA Sections (Requirement 18) to ISO Sections

NQA-1 Requirement 18: Audits	ISO 9001:2008
100 General	8.2.2 Internal Audits
200 Scheduling	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.
300 Preparation 301 Audit Plan 302 Personnel	8.2.2 Internal Audit
303 Selection of Audit Team 400 Performance 500 Reporting 600 Response 700 Follow-Up Action 800 Records	No corresponding ISO 9001 section to NQA-1 section. Implementing program should be evaluated.

RECOMMENDATIONS: This is a major addition that needs to be included in an existing ISO quality program to meet the requirements of NQA-1, Part I, Requirement 18, Audits.

SUBPART 4.1.2
Guidance on the Use of NQA-1–2008/1a–2009 for Compliance With Department of Energy Quality Assurance Requirements 10 CFR 830, Subpart A and DOE O 414.1

100 PURPOSE

This Subpart may be used by organizations intending to adopt NQA-1 as a national consensus Standard for development and implementation of a Quality Assurance Program (QAP) that meets the Department of Energy (DOE) Quality Assurance (QA) requirements. This Subpart describes how NQA-1–2008/1a–2009 addresses the DOE QA requirements and identifies DOE QA requirements that are not addressed by NQA-1.

200 INTRODUCTION

The Department of Energy (DOE) QA requirements for activities that affect, or may affect, quality, nuclear safety, or other site-specified criteria are established by rule, 10 CFR Part 830 Subpart A, dated January 10, 2001 (i.e., Rule). DOE also has requirements for all other federal and contractor activities in QA Order, O 414.1C, dated June 17, 2005 (i.e., Order). The DOE QA requirements and guides are available for review at http://www.directives.doe.gov.

The DOE's objective of the QA Rule and Order is for organizations to establish effective integrated Quality Assurance Programs (i.e., QAPs) to ensure that their products and services meet or exceed DOE's expectations. The objective is accomplished through performance-oriented quality assurance criteria, coupled with appropriate technical standards to manage, perform, and assess work activities. The DOE Rule requires the use of voluntary consensus standards in the development and implementation of the QAP. The NQA-1 Standard is a national voluntary Standard and should be considered for providing the essential implementing methods for a DOE QAP, including details for effective and reliable supporting processes and procedures, as presented in this Subpart. This Subpart does not intend to usurp the sole authority of DOE to issue guidance and interpretations for its rules.

300 DOE RULE AND ORDER GENERAL QAP REQUIREMENTS

The DOE Rule and Order include both administrative and regulatory quality requirements. Those administrative requirements relating to QAP approval authority, change control authority, and compliance should not be considered applicable to the scope of NQA-1. The general DOE QAP quality-related requirements that should be considered within the scope of NQA-1 are addressed in Table 300.

400 DOE RULE AND ORDER QA CRITERIA

The DOE Rule and Order include ten QA criteria that are used to develop and implement a QAP. Table 400 identifies each of the ten DOE Rule and Order QA Critera and how they are addressed by the NQA-1, Part I. Differences in the documents and topics that should be addressed independently of the NQA-1 criteria to meet the DOE criteria are described. In some cases, the nonmandatory guidance in NQA-1 Part III may be appropriate to address the DOE requirements. Where an NQA-1 Part I Requirement addresses the DOE criterion, the associated NQA-1 nonmandatory guidance should also be considered to aid in addressing the DOE general requirement that the QAP describe how the QA criteria will be implemented.

Table 300 10 CFR 830 Subpart A, Dated January 10, 2001 §830.121, Quality Assurance Program; DOE O 414.1C, Dated June 17, 2005

DOE General Requirements (Summarized)	NQA-1 Requirements
Graded Approach (10 CFR 830.7) Where appropriate, a contractor must use a graded approach to implement the requirements of this Part, document the basis of the graded approach used, and submit that documentation to DOE.	**Part I, Introduction, and Requirements 1 and 2** provide for a graded approach to achieving quality by focusing on activities affecting quality and the application of requirements in a manner consistent with the relative importance of the item or activity. **Subpart 3.1-2.1**, Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs, includes guidance on this topic. The cited text does allow for a graded approach; however, a DOE QAP will need to describe how the graded approach is applied and documented to meet the DOE requirement.
QAP Development and Implementation (10 CFR 830) The QAP must describe how the DOE QA criteria are satisfied.	The NQA-1 requirements partially meet the DOE requirement. **Requirement 2** requires that a documented QAP be planned, implemented, and maintained; and requires the QAP provide for the planning and accomplishment of activities affecting quality. **Requirement 5** requires that "Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed results have been satisfactorily accomplished." A DOE QAP will need to describe how the DOE criteria are satisfied.
Integrated Management Systems [DOE O 414.1C 4.2(4)(2)] The QA Program must integrate the QA criteria with the Safety Management System (SMS), or describe how the QA criteria apply to the SMS.	The NQA-1 requirements do not address the DOE requirements for integrated management systems. The QAP must integrate S/CI prevention process, the Corrective Action Management Program, and Software Quality.
Ensuring Subcontractor and Supplier Quality (DOE O 414.1C) The QAP must describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the QA criteria.	**Requirements 1, 2, 4, 7, and 18:** The NQA-1 requirements meet the DOE requirement by the establishment of quality interfaces between organizations, by the inclusion of applicable QA requirements in procurement documents, supplier evaluation activities, and audits of suppliers. A DOE QAP will need to describe how subcontractors/suppliers satisfy the DOE criteria.

Table 400 10 CFR 830 Subpart A, Dated January 10, 2001 §830.122, Quality Assurance Criteria

DOE Quality Assurance Criteria	NQA-1 Requirements
Criterion 1: Management/Program (1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.	**NQA Requirements 1 and 2:** The NQA-1 requirements meet the DOE Criterion, as noted.
Comments: None	
(2) Establish management processes including, planning, scheduling, and providing resources for the work.	NQA-1, Requirement 1, para. 201 (General) and Requirement 2, section 100 (General) meet the DOE Criterion. NQA-1 requires senior management to establish overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result. This implies that adequate resources are provided to obtain desired results.
Comments: A DOE QAP will need to describe the management process for providing resources.	
Criterion 2: Management/Personnel Training and Qualification (1) Train and qualify personnel to be capable of performing their assigned work. (2) Provide continuing training to personnel to maintain their job proficiency.	**NQA Requirement 2:** The NQA-1 requirements meet the DOE Criterion. The NQA-1 requirements satisfy both elements of the DOE Criterion.
Comments: None	
Criterion 3: Management/Quality Improvement (1) Establish and implement processes to detect and prevent quality problems.	**NQA Requirements 2, 4, 7, 15, and 16:** The NQA-1 requirements partially meet the DOE Criterion. NQA requirements 15 and 16 partially meet the DOE Criterion; however, NQA-1 does not address preventing problems before they occur. Appendix 16 A-1 provides additional guidance for corrective action.
Comments: A DOE QA Program will need to extend the requirements of NQA-1 to ALL conditions adverse to quality, not just significant conditions adverse to Quality.	
(2) Identify, control, and correct items, services, and processes that do not meet established requirements.	The NQA-1 requirements 4, 7, 15, and 16 satisfy this element of the DOE Criterion.
Comments: None	
(3) Identify the causes of problems and work to prevent recurrence as part of correcting the problem.	NQA requires actions to prevent recurrence for only significant conditions adverse to quality.
Comments: A DOE QA Program will need to extend the requirements of NQA-1 to ALL conditions adverse to quality, not just significant conditions adverse to Quality.	
(4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvements.	The NQA requirements partially address this element of the DOE Criterion for known deficiencies.
Comments: A DOE QA Program will need to address collection and review of information, beyond deficiencies, to identify items, services, and processes needing improvements.	

Table 400 10 CFR 830 Subpart A, Dated January 10, 2001 §830.122, Quality Assurance Criteria (Cont'd)

DOE Quality Assurance Criteria	NQA-1 Requirements
Criterion 4: Management/Documents and Records	**NQA Requirements 5, 6, and 17:** The NQA-1 requirements meet the DOE Criterion.
(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. (2) Specify, prepare, review, approve, and maintain records.	The NQA-1 requirements satisfy these elements of the DOE Criterion.
Comments: None	
Criterion 5: Performance/Work Processes	**NQA Requirements 5, 8, 9, 12, 13, and 14 and Part I, Introduction:** The NQA-1 requirements meet the DOE Criterion, as noted.
(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.	The NQA requirements address "work" as activities affecting quality.
Comments: A DOE QA Program will need to address "work" as broadly as the DOE Criterion, since the requirements for "work" are derived from multiple sources in the DOE Rule and Order.	
(2) Identify and control items to ensure their proper use.	The NQA-1 requirements satisfy this element of the DOE Criterion.
Comments: None	
(3) Maintain items to prevent their damage, loss, or deterioration.	The NQA-1 requirements satisfy this element of the DOE Criterion.
Comments: None	
(4) Calibrate and maintain equipment used for process monitoring or data collection.	The NQA-1 requirements satisfy this element of the DOE Criterion.
Comments: None	
Criterion 6: Performance/Design	**NQA Requirement 3:** The NQA-1 requirements meet the DOE Criterion.
(1) Design items and processes using sound engineering/scientific principles and appropriate standards. (2) Incorporate applicable requirements and design basis in design work and design changes. (3) Identify and control design interfaces. (4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work. (5) Verify or validate work before approval and implementation of the design.	
Comments: None	

Table 400 10 CFR 830 Subpart A, Dated January 10, 2001 §830.122, Quality Assurance Criteria (Cont'd)

DOE Quality Assurance Criteria	NQA-1 Requirements
Criterion 7: Performance/Procurement (1) Procure items and services that meet established requirements and perform as specified. (2) Evaluate and select prospective suppliers on the basis of specified criteria. (3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.	**NQA Requirements 4 and 7:** The NQA-1 requirements meet the DOE Criterion.
Comments: None	
Criterion 8: Performance/Inspection and Acceptance Testing (1) Inspect and test specified items, services, and processes using established acceptance and performance criteria. (2) Calibrate and maintain equipment used for inspections and tests.	**NQA Requirements 8, 10, 11, and 12:** The NQA-1 requirements meet the DOE Criterion.
Comments: None	
Criterion 9: Assessment/Management Assessment Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.	**NQA Requirements 2 and 18:** The NQA-1 requirements partially meet the DOE Criterion, as noted. While NQA-1, Requirement 2, para. 100(c) (General), requires management to regularly assess the adequacy and effective implementation of the quality assurance program, the DOE Criterion is broader in scope and intent.
Comments: While audits per Requirement 18 of NQA provide an input to this requirement, a DOE QAP will need to meet unique DOE requirements.	
Criterion 10: Assessment/Independent Assessment (1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments. (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.	**NQA Requirements 1, 2, 10, 11, 15, 16, and 18:** The NQA-1 requirements meet the DOE Criterion. DOE defines assessment as a general term that includes a variety of evaluation methods (i.e.; reviewing, evaluating, inspecting, testing, checking, surveillance, auditing or otherwise determining and documenting). As such, several NQA-1 requirements may be necessary to address the various DOE independent assessment methods. These activities when combined with the NQA corrective action requirement have the intent of the DOE Criterion, to "promote improvement."
Comments: Assessment as a DOE activity for a DOE QAP will need to meet unique DOE requirements.	

SUBPART 4.1.3
Guidance on the Use of NQA-1–2000 for Compliance With 10 CFR 71 and/or 10 CFR 72 Requirements

100 PURPOSE

This Subpart may be used by organizations intending to adopt NQA-1 as a national consensus Standard for development and implementation of a Quality Assurance Program that meets 10 CFR 71, "Packaging and Transportation of Radioactive Material, Subpart H, Quality Assurance" and/or 10 CFR 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High Level Radioactive Waste, Subpart G, Quality Assurance" requirements.

This Subpart describes how NQA-1–2000 addresses the 10 CFR 71 and 10 CFR 72 Quality Assurance requirements and identifies additional information an organization intending to adopt NQA-1 for the development and implementation of a Quality Assurance Program that meets the 10 CFR 71 and/or 10 CFR 72 requirements should consider.

200 INTRODUCTION

The Nuclear Regulatory Commission (NRC) establishes "requirements for packaging, preparation for shipment, and transportation of licensed material; and procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for a quantity of other licensed material in excess of a Type A quantity" in 10 CFR 71. Subpart H of 10 CFR 71 describes quality assurance requirements. The 10 CFR 72 regulation states, "establish requirements, procedures, and criteria for the issuance of licenses to receive, transfer, and possess power reactor spent fuel and other radioactive materials associated with spent fuel storage in an independent spent fuel storage installation (ISFSI)." Subpart G of 10 CFR 72 describes quality assurance requirements.

The NRC's approval of an applicant's Quality Assurance Program requires acceptable standards of quality and a description of how the requirements will be met. The NQA-1 Standard is a national consensus Standard and should be considered for providing the essential implementing methods for a Quality Assurance Program including the details for effective and reliable supporting processes and procedures presented in this Subpart.

This Subpart does not usurp the sole authority of the NRC to issue guidance and interpretations for its regulations.

300 SUMMARY RESULTS

In general, the regulations in 10 CFR 71, Subpart H, and 10 CFR 72, Subpart G, are nearly identical and are included within a Quality Assurance Program complying with NQA-1. However, a few differences exist due to the wording or level of detail required by the CFRs.

Table 300 identifies each of the 10 CFR 71 and 10 CFR 72 criteria and how they are addressed by NQA-1. Differences in the documents and topics that should be addressed independently of the NQA-1 criteria to meet 10 CFR 71 and/or 10 CFR 72 criteria are described. Where an NQA-1 Part 1 requirement addresses the 10 CFR 71 and/or 10 CFR 72 criterion, the associated NQA-1 Nonmandatory Guidance should also be considered to aid in addressing the NRC requirement that specifies the Quality Assurance Program should describe how the quality assurance criteria will be implemented.

Overall, the implementer of a program complying with the requirements of NQA-1–2000 may meet the requirements of 10 CFR 71 (1-1-01 Edition) and/or 10 CFR 72 (1-1-01 Edition) with minimal program revisions. The differences cited are of administrative actions and prescriptive details in Parts 71 and 72. Refer to Table 300 for details.

Table 300 10 CFR 71 and 10 CFR 72 Criteria Addressed by NQA-1

10 CFR 71 Regulation	10 CFR 72 Regulation	NQA-1 Requirements
Organization		
71.103, "Quality assurance organization" Describes responsibilities and functions of personnel involved in attaining quality objectives and the quality assurance functions.	*72.142, "Quality assurance organization"* Describes responsibilities and functions of personnel involved in attaining quality objectives and the quality assurance functions.	Basic Requirement 1, "Organization"; Basic Requirement 2, "Quality Assurance Program"; and Subpart 3.1-1.1, Implementing Guidance for Part I, Requirement 1: "Organization," satisfy the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Quality Assurance Program		
71.105, "Quality assurance program" Describes the requirements to establish a quality assurance program, provides controls over activities affecting the quality of materials and components in accordance with their importance to safety, and for the indoctrination and training of personnel performing activities affecting quality.	*71.144, "Quality assurance program"* Describes the requirements to establish a quality assurance program, provides controls over activities affecting the quality of materials and components in accordance with their importance to safety, and for the indoctrination and training of personnel performing activities affecting quality.	Basic Requirement 2, "Quality Assurance Program," and Subpart 3.1-2.1, Implementing Guidance for Part I, Requirement 2: "Quality Assurance Programs," satisfy the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Design Control		
71.107, "Package design control" Describes the requirements of establishing measures to assure applicable regulatory requirements and the package design are correctly translated, establishing measures for the identification and control of design interfaces, and the control of design changes.	*72.146, "Design control"* Describes the requirements of establishing measures to assure applicable regulatory requirements and the design basis are correctly translated, establishing measures for the identification and control of design interfaces, and the control of design changes.	Basic Requirement 3, "Design Control"; Basic Requirement 15, "Control of Nonconforming Items"; and Subpart 3.1-3.1, Implementing Guidance for Part I, Requirement 3: "Design Control," satisfy the majority of the elements of 10 CFR 71 and 10 CFR 72. Minor differences in the requirements should be examined and are detailed below.
Comments: See comments below on specific areas of design control.		
71.107(b) states, "The licensee shall apply any design control measures to items such as the following: criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance and repair, features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests."	72.146 (b) states, "The licensee, applicant for a license, certificate holder, and applicant for a CoC shall apply design control measures to items such as the following: criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance and repair, features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests."	Subpart 3.1-3.1, Implementing Guidance for Part I, Requirement 3: "Design Control"
Comments: In using NQA to satisfy these requirements, additional detail would have to be provided by the user. Subpart 3.1-3.1, Implementing Guidance for Part I, Requirement 3: "Design Control," does cover this area but does not include all the specific items referenced in the CFRs.		

Table 300 10 CFR 71 and 10 CFR 72 Criteria Addressed by NQA-1 (Cont'd)

10 CFR 71 Regulation	10 CFR 72 Regulation	NQA-1 Requirements
71.107(a) states, "These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled."	72.146(a) states, "These measures must include provisions to ensure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled."	Basic Requirement 3, "Design Control," states, "final design shall specify requirements for inspections and tests and shall include or reference appropriate acceptance criteria." This would include provisions to ensure that appropriate quality standards are specified and included in design documents. Also, Basic Requirement 15, "Control of Nonconforming Items," requires items that do not conform to specified requirements shall be controlled to prevent inadvertent installation and use. This includes requirements that deviations from standards be controlled.
Comments: In using NQA-1 to satisfy these requirements, additional detail would have to be provided by the user concerning language on "appropriate quality standards are specified and included in design documents."		
71.107(c) states, "The licensee shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the package approval require NRC approval."	72.146(c) states, "The licensee, applicant for a license, certificate holder, and applicant for a CoC shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval."	Basic Requirement 3, "Design Control," states, "changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities shall be justified and subject to design control measures commensurate with those applied to the original design." Also, Subpart 3.1-3.1, Implementing Guidance for Part I, Requirement 3: "Design Control," states, "Design changes shall be governed by control measures commensurate with those applied to the original design."
Comments: In using NQA-1 to satisfy these requirements, additional details would have to be provided by the user to address the fact that changes in conditions specified require NRC approval.		
71.107(b) states, "These measures must include the establishment of written procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces."	72.146(b) states, "These measures must include the establishment of written procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces."	Basic Requirement 3, "Design Control," and Basic Requirement 6, "Document Control"
Comments: In using NQA-1 to satisfy these requirements, additional detail would have to be provided by the user concerning design interfaces.		
	Procurement Document Control	
71.109, "Procurement Document Control" Describes requirements to assure that adequate quality is required in the documents for procurement of material, equipment, and services.	*71.148, "Procurement Document Control"* Describes requirements to assure that adequate quality is required in the documents for procurement of material, equipment, and services.	Basic Requirement 4, "Procurement Document Control," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		

Table 300 10 CFR 71 and 10 CFR 72 Criteria Addressed by NQA-1 (Cont'd)

10 CFR 71 Regulation	10 CFR 72 Regulation	NQA-1 Requirements
Instructions, Procedures, and Drawings		
71.111, "Instructions, procedures, and drawings" Describes requirements for prescribing activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and for requiring that said documents be followed.	*72.150, "Instructions, procedures, and drawings"* Describes requirements for prescribing activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and for requiring that said documents be followed.	Basic Requirement 5, "Instructions, Procedures, and Drawings," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Document Control		
71.113, "Document control" Describes measures for the control and issuance of documents and to assure that documents, including changes, are reviewed for adequacy, approved for release, and distributed and used at the location where the activity is performed.	*72.152, "Document control"* Describes measures for the control and issuance of documents and to assure that documents, including changes, are reviewed for adequacy, approved for release, and distributed and used at the location where the activity is performed.	Basic Requirement 6, "Document Control," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Control of Purchased Items and Services		
71.115, "Control of purchased material, equipment, and services" Requires measures to be established to assure that purchased material, equipment, and services conform to the procurement documents, measures to assure that material and equipment conform to procurement specifications before installation, and measures to assess the effectiveness of the control of quality at intervals consistent with the importance, complexity, and quantity of the product or service.	*72.154, "Control of purchased material, equipment, and services"* Requires measures to be established to assure that purchased material, equipment, and services conform to the procurement documents, measures to assure that material and equipment conform to procurement specifications before installation, and measures to assess the effectiveness of the control of quality at intervals consistent with the importance, complexity, and quantity of the product or service.	Basic Requirement 7, "Control of Purchased Items and Services," satisfies the elements of 10 CFR 71 and 10 CFR 72. Basic Requirement 18, "Audits," addresses the measures to assess the effectiveness of the Quality Assurance Program.
Comments: NQA-1 utilizes the terminology *Supplier* as "...An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels." Also, NQA-1 allows post-installation, whereas parts 71 and 72 specifically state before installation.		
Identification and Control of Items		
71.117, "Identification and control of materials, parts, and components" Requires the establishment of measures for the identification and control of materials, parts, and components. These measures must be designed to prevent the use of incorrect or defective materials, parts, and components.	*72.156, "Identification and control of materials, parts, and components"* Requires the establishment of measures for the identification and control of materials, parts, and components. These measures must be designed to prevent the use of incorrect or defective materials, parts, and components.	Basic Requirement 8, "Identification and Control of Items," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		

Table 300 10 CFR 71 and 10 CFR 72 Criteria Addressed by NQA-1 (Cont'd)

10 CFR 71 Regulation	10 CFR 72 Regulation	NQA-1 Requirements
Control of Special Processes		
71.119, "Control of special processes" Requires the establishment of measures to assure that special processes are controlled and accomplished by qualified personnel using qualified procedures.	*72.158, "Control of special processes"* Requires the establishment of measures to assure that special processes are controlled and accomplished by qualified personnel using qualified procedures.	Basic Requirement 9, "Control of Special Processes," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Inspection		
71.121, "Internal inspection" Requires the establishment and execution of a program for inspection of activities to verify conformance with the documents for accomplishing the activities.	*72.160, "Licensee Inspection"* Requires the establishment and execution of a program for inspection of activities to verify conformance with the documents for accomplishing the activities.	Basic Requirement 10, "Inspection," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Test Control		
71.123, "Test control" Describes the requirements for establishing a test program to assure that all required testing is identified and performed in accordance with written test procedures.	*72.162, "Test control"* Describes the requirements for establishing a test program to assure that all required testing is identified and performed in accordance with written test procedures.	Basic Requirement 11, "Test Control," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Control of Measuring and Test Equipment		
71.125, "Control of measuring and test equipment" Requires that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy.	*72.164, "Control of measuring and test equipment"* Requires that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy.	Basic Requirement 12, "Control of Measuring and Test Equipment," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Handling, Storage, and Shipping		
71.127, "Handling, storage, and shipping control" Requires the establishment of measures to control the handling, storage, shipping, cleaning, and preservation of materials and equipment to prevent damage or deterioration.	*72.166, "Handling, storage, and shipping control"* Requires the establishment of measures to control the handling, storage, shipping, cleaning, and preservation of materials and equipment to prevent damage or deterioration.	Basic Requirement 13, "Handling, Storage, and Shipping," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		

Table 300 10 CFR 71 and 10 CFR 72 Criteria Addressed by NQA-1 (Cont'd)

10 CFR 71 Regulation	10 CFR 72 Regulation	NQA-1 Requirements
Inspection, Test, and Operating Status		
71.129, "Inspection, test, and operating status" Requires the establishment of measures to indicate the status of inspection and tests and the operating status of components such as tags and valves to prevent inadvertent operation.	*72.168, "Inspection, test, and operating status"* Requires the establishment of measures to indicate the status of inspection and tests and the operating status of components such as tags and valves to prevent inadvertent operation.	Basic Requirement 14, "Inspection, Test and Operating Status," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Control of Nonconforming Items		
71.131, "Nonconforming materials, parts, or components" Requires the establishment of measures to control materials, parts, or components that do not conform to requirements to prevent their inadvertent use or installation.	*72.170, "Nonconforming materials, parts, or components"* Requires the establishment of measures to control materials, parts, or components that do not conform to requirements to prevent their inadvertent use or installation.	Basic Requirement 15, "Control of Nonconforming Items," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Corrective Action		
71.133, "Corrective action" Requires measures be established to assure that conditions adverse to quality are promptly identified and corrected.	*72.172, "Corrective action"* Requires measures be established to assure that conditions adverse to quality are promptly identified and corrected.	Basic Requirement 16, "Corrective Action," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Records		
71.135, "Quality assurance records" Describes the requirements for maintaining sufficient written records to describe the activities affecting quality.	*72.174, "Quality assurance records"* Describes the requirements for maintaining sufficient written records to describe the activities affecting quality.	Basic Requirement 17, "Quality Assurance Records," and Subpart 3.1-17.1, Implementing Guidance for Part I, Requirement 17: "Quality Assurance Records," satisfy the majority of elements of 10 CFR 71 and 10 CFR 72. Minor differences in the requirements should be examined and are detailed below.
Comments: Although not all records specified in part 71 and 72 are included, reference Subpart 3.1-17.1, Implementing Guidance for Part I, Requirement 17: "Quality Assurance Records" as identified in a detailed listing of record types to be retained for the life of a nuclear facility.		
71.135, "Quality assurance records," states, "The records must include the instructions or procedures which establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility."	72.174, "Quality assurance records," states, "The records must include the instructions or procedures which establish a records retention program that is consistent with applicable regulations and	Subpart 3.1-17.1, Implementing Guidance for Part I, Requirement 17: "Quality Assurance Records," covers such areas as duration, location, and assigned responsibility.
Comments: None		

Table 300 10 CFR 71 and 10 CFR 72 Criteria Addressed by NQA-1 (Cont'd)

10 CFR 71 Regulation	10 CFR 72 Regulation	NQA-1 Requirements
71.135 states, "The records must include the instructions, procedures, and drawings required by paragraph 71.111 to prescribe quality assurance activities and must include closely related specifications such as required qualifications of personnel, procedures, and equipment."	72.174 states, "The records must include the following: design records, records of use and the results of reviews, inspections, tests, audits, monitoring of work performance, and material analyses. The records must include closely related data such as qualifications of personnel, procedures, and equipment. Inspections and test records must, at a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the actions taken in connection with any noted deficiencies."	Subpart 3.1-17.1, Implementing Guidance for Part I, Requirement 17: "Quality Assurance Records," covers typical lifetime records. Basic Requirement 10, "Inspection," satisfies the elements of 10 CFR 72.
Comments: None		
71.135 states, "The licensee shall retain these records for years beyond the date when the licensee last engages in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee shall retain the superseded material for 3 yr after it is superseded."	72.174 states, "Records pertaining to the design, fabrication, erection, testing, maintenance, and use of structures, systems, and components important to safety must be maintained by or under the control of the licensee or certificate holder until the NRC terminates the license or CoC."	Subpart 3.1-17.1, Implementing Guidance for Part I, Requirement 17: "Quality Assurance Records," covers typical lifetime records.
Comments: In using NQA to satisfy these requirements, additional detail concerning the retention of superseded procedures or instructions for 3 yr and maintenance of records until NRC termination of license or CoC would have to be provided by the user concerning record control.		
Audits		
71.137, "Audits" Requires a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program, and to determine the effectiveness of the program.	*72.176, "Audits"* Requires a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program, and to determine the effectiveness of the program.	Basic Requirement 18, "Audits," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		

SUBPART 4.1.4
Guidance to Modification of an IAEA GS-R-3 Quality Program to Meet NQA-1a–2009 Requirements and Modification of an NQA-1a–2009 Quality Program to Meet IAEA GS-R-3 Requirements

100 PURPOSE AND SCOPE

The purposes of this Subpart are to compare requirements of IAEA GS-R-3 2006-STI/PUB/1252 and NQA-1–2008, Part I with the NQA-1a–2009 Addenda, to identify the similarities and differences, and to identify where actions may be needed to address the differences. The comparisons are illustrated from the following two perspectives:

(a) how IAEA GS-R-3 requirements address NQA-1 requirements

(b) how NQA-1 requirements address IAEA GS-R-3 requirements

Two tables are included providing a detailed line-by-line comparison from each perspective. These same tables are used in IAEA Safety Report "Management Systems Standards: Comparison of IAEA GS-R-3 and NQA-1–2008 Requirements" to ensure a consistent understanding across the global nuclear community. The term NQA-1 will be used hereafter instead of NQA-1–2008, Part I with the NQA-1a–2009 Addenda. The term GS-R-3 will be used instead of (IAEA) Safety Standard GS-R-3, 2006-STI/PUB/1252.

NOTE: Some relevant parts of NQA-1, contained in Parts II through IV, are indicated in the recommendations, as were guidance documents for IAEA GS-R-3.

200 APPLICABILITY

The guidance is intended for all parties involved in the nuclear industry that are currently applying/implementing either NQA-1 or IAEA GS-R-3 requirements and are required to comply with other requirements.

This Subpart can also be used to achieve compliance with both sets of requirements simultaneously by providing information on the similarities and differences between IAEA GS-R-3 and NQA-1, thus allowing the organization to implement controls for the program differences.

300 BACKGROUND

301 Global Uses of NQA-1 and IAEA GS-R-3

As governments adopt or apply IAEA GS-R-3 requirements through regulations, facility operators and organizations providing nuclear items or products and services around the globe may be compelled to comply with the GS-R-3 management system requirements while maintaining certification or compliance of their activities, items, products, and services to an NQA-1 quality assurance program.

Consequently, many organizations will have to adopt both IAEA GS-R-3 and NQA-1 as the basis of their management system or QA Program. IAEA GS-R-3 requires these requirements to be integrated within one management system. There was therefore a need for guidance to assist organizations to satisfy these requirements.

302 Conceptual Approaches to the Development of NQA-1 and GS-R-3

IAEA GS-R-3 and NQA-1 apply to the life cycle of nuclear facilities and activities, including siting, design, construction, commissioning, operation, and decommissioning. IAEA GS-R-3 and NQA-1 foster the application of requirements in a manner that is consistent with the relative importance of the item or activity. Both IAEA GS-R-3 and NQA-1 can be invoked by contract, adopted voluntarily, or used as the basis for assessing a management system or quality assurance program.

NQA-1 defines requirements for an organization to establish, implement, and assess a Quality Assurance (QA) Program to achieve nuclear safety. NQA-1 reflects industry experience and current understanding of QA requirements for the safe, reliable, and efficient utilization of nuclear energy and management and processing of radioactive materials.

The NQA-1 approach applies quality assurance requirements to activities that could affect the quality of nuclear material applications, structures, systems, and components of nuclear facilities. Quality assurance requirements are used to develop a Quality Assurance Program necessary to achieve safe, reliable, and efficient

utilization of nuclear energy and management and processing of radioactive material.

IAEA GS-R-3 defines requirements for an organization to establish, implement, assess, and continually improve a management system that integrates safety, health, environmental, security, quality, and economic elements to ensure safety is not compromised. It fosters a strong safety culture and improved safety performance in all the activities of the organization.

IAEA GS-R-3 adopts an integrated management system approach to be applied to all work of the organization. IAEA GS-R-3 requires the integration of safety, health, environmental, security, quality, and economic elements of the management system to ensure that safety is properly taken into account in all activities. It specifies requirements designed to achieve and enhance safety, while enhancing the satisfaction of interested parties. A management system based on IAEA GS-R-3 includes safety culture, human performance, a process approach to the achievement of objectives, and continual improvement of the management system and its processes (www-pub.iaea.org/MTCD/publications/download.asp).

400 HOW TO USE THIS GUIDE TO ACHIEVE COMPLIANCE WITH GS-R-3 OR NQA-1

401 Two Perspectives and Two Tables

The requirements of both standards are listed in two tables and have been compared utilizing the 18-criteria format of NQA-1, Part I and the Process Approach of IAEA GS-R-3. Guidance for evaluating existing practices or supplementing each program is summarized below each requirement section. In most cases, the IAEA requirements are stated at a higher process level, and the user must determine the need to develop detailed practices for implementation of the NQA-1 requirements. In these cases, it is necessary to compare the implementing practices with the requirements of NQA-1 to determine compliance. Two examples of the perspectives that must be considered and addressed by the guidance are the following:

(a) a Purchaser considering a Supplier for a nuclear facility that meets one of the programs but also needs to meet the requirements governed by the Purchaser's program

(b) a Supplier wanting to provide items/services to a Purchaser who requires compliance with the program that is not the Supplier's current program

402 How to Use Tables I and II

The first table presents a column of the requirements of NQA-1, Part I on a line-by-line basis for all 18 requirements and each subparagraph of each requirement. Immediately adjacent to the column for the NQA-1 requirement is a second column that contains the corresponding GS-R-3 requirement that specifically addresses the NQA-1 requirement. In cases where GS-R-3 does not specifically meet the NQA-1 requirement, recommendations are provided that describe how best to meet the NQA-1 requirement, within the GS-R-3 program. It should be noted here that the recommendation is for the GS-R-3 user to meet the NQA-1 requirement, as opposed to trying to meet some requirement that may not be considered acceptable.

Likewise, the second table lists all five elements of the GS-R-3 requirements, plus the specific subtier elements of each. In this second table, where a particular NQA-1 requirement meets the specific GS-R-3 requirement, it is so stated. Where there is no corresponding NQA-1 element that meets the GS-R-3 requirement, a recommendation is provided as to how the GS-R-3 requirement should be met.

It should be noted that neither table provides any direction for introductory/informational material from the two documents.

Table I The Extent to Which GS-R-3 Addresses NQA-1 Requirements

Requirement	NQA-1	GS-R-3 and Recommendations
1 Organization		
1-100 General	Key words: responsibilities, organizational structure, functional responsibilities, levels of authority, and lines of communications	GS-R-3 Requirements 2.8, 3.12, and 3.14
1-200 Structure and Responsibility	**201 General** Key words: (a) management expectations (b) quality achieved and maintained by (c) quality achievement is verified by (d) sufficient authority, direct access, organizational freedom, access to work, independence, verification functions **202 Delegation of Work**	GS-R-3 Requirements 2.1, 2.2, 2.4, 3.12, 3.13, 3.14, 5.7, 5.10, and 6.5 *Recommendations*. GS-R-3 users should address organizational freedom, independence of verification activities, and the following verification functions: (a) identifying quality problems (b) initiating, recommending, or providing solutions to quality problems through designated channels (c) verifying implementation of solutions (d) ensuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred
1-300 Interface Control		GS-R-3 Requirements 5.4, 5.5, and 5.10
2 Quality Assurance Program		
2-100 General	Key words: (a) documented planned, implemented, and maintained (c) management assess	GS-R-3 Requirements 2.1, 2.6, 2.7, 3.8, 4.1, 4.2, 4.4, 4.5, and 6 *Recommendations*. GS-R-3 users should establish the programme at the earliest time consistent with the schedule for accomplishing the activities and provide for special controls, required by NQA-1 (see recommendations under 2-200, 2-300, 2-400, and 2-500 for additional details).
2-200 Indoctrination and Training	**201 Indoctrination** **202 Training**	GS-R-3 Requirements 4.3 and 4.4 *Recommendations*. GS-R-3 users should ensure indoctrination to job responsibilities, and authority includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance requirements, required by NQA-1. GS-R-3 users should conduct indoctrination and training commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person consistent with the grading requirements in GS-R-3 2.6 and 2.7.
2-300 Qualification Requirements	Key words: designate activities that require qualification, written procedures **301 Nondestructive Examination (NDE)** **302 Inspection and Test** **303 Lead Auditor** **303.1 Communication Skills** **303.2 Training** **303.3 Audit Participation** **303.4 Examination** **303.5 Maintenance of Proficiency** **303.6 Requalification** **304 Auditors** **305 Technical Specialists**	No corresponding requirement. *Recommendations*. GS-R-3 users should ensure the responsible organization designates those activities that require qualification. The minimum requirements for personnel to verify quality and auditing are specified in paras. 301 through 304 of this Requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.

Table I The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
2-400 Records of Qualification		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
2-500 Records		GS-R-3 Requirement 5.21. *Recommendations*. GS-R-3 users should ensure records of the implementation for indoctrination and training include one or more of (a) through (c) of this requirement. The GS-R-3 users should establish and maintain records for auditor and lead auditor qualification and requalification and inspection and test personnel qualification and requalification.
3 Design Control		
3-100 General	Key words: defined, controlled	No corresponding specific requirement. *Recommendations*. GS-R-3 Requirements 5.1 to 5.10 address process management in general. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-200 Design Input		No corresponding specific requirement. *Recommendations*. GS-R-3 Requirement 5.4 addresses process inputs. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-300 Design Process	Key words: (a) prescribe and document the design activities (b) design methods (c) final design, commercial grade items, and services	No corresponding specific requirement. *Recommendations*. GS-R-3 Requirement 5.14 addresses control of products. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-400 Design Analyses	**401 Use of Computer Programs** **402 Documentation of Design Analyses**	No corresponding specific requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-500 Design Verification	**501 Methods** **501.1 Design Reviews** **501.2 Alternate Calculations** **501.3 Qualification Tests**	No corresponding specific requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-600 Change Control	Key words: (a) changes to design justified, evaluation of effects, approved, approving organization, demonstrated competence (c) incorrect design **601 Configuration Management of Operating Facilities**	No corresponding specific requirement. *Recommendations*. GS-R-3 Requirement 5.13 addresses changes to documents. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.

Table I The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
3-700 Interface Control	Key words: responsibility, procedures, design information	No corresponding specific requirement. *Recommendations*. GS-R-3 Requirement 5.5 addresses the control of interfaces generally. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-800 Software Design Control	**801 Software Design Process** **801.1 Identification of Software Design Requirements** **801.2 Software Design** **801.3 Implementation of the Software Design** **801.4 Software Design Verification** **801.5 Computer Program Testing** **802 Software Configuration Management** **802.1 Configuration Identification** **802.2 Configuration Change Control** **802.3 Configuration Status Control**	No corresponding requirement. *Recommendations*. GS-R-3 Requirements 5.3, 5.9, and 5.10 address process management in general. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-900 Documentation and Records	Key words: sources of design inputs	No corresponding specific requirement. *Recommendations*. GS-R-3 Requirements 5.6 through 5.10 address process management generically. These generic requirements address process documentation and records to demonstrate the achievement of process results. GS-R-3 Requirements 5.12 and 5.13 address document control, and Requirements 5.21 and 5.22 address records. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
4 Procurement Document Control		
4-100 General	Key words: design bases, suppliers, quality assurance programme	GS-R-3 Requirements 5.23 and 5.24 *Recommendations*. GS-R-3 users should ensure design bases are addressed in the documents, if applicable.
4-200 Content of the Procurement Documents	Key words: all tiers of procurement **201 Scope of Work** **202 Technical Requirements** **203 Quality Assurance Program Requirements** **204 Right of Access** **205 Documentation Requirements** **206 Nonconformances** **207 Spare and Replacement Parts**	GS-R-3 Requirements 5.24 and 5.25 *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Procurement documents should include the scope, technical requirements, quality assurance requirements, purchaser right of access, documentation requirements, nonconformance reporting provisions, and spare and replacement parts. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
4-300 Procurement Document Review		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement, including documented changes to procurement documents prior to award to ensure that documents transmitted to a prospective Supplier include the appropriate provisions for ensuring that items or services will meet the specified requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.

Table I The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
4-400 Procurement Document Changes		GS-R-3 Requirements 5.13 and 5.14
5 Instructions, Procedures, and Drawings		
5-100 General	Key words: documented, quantitative or qualitative acceptance criteria, detail commensurate with the complexity	GS-R-3 Requirements 2.6 through 2.10, 4.3, 5.6, 5.7, and 5.9
6 Document Control		
6-100 General		GS-R-3 Requirements 5.12 and 5.13
6-200 Document Control		GS-R-3 Requirements 2.8, 2.9, and 5.12
6-300 Document Changes	**301 Major Changes** **302 Minor Changes**	GS-R-3 Requirement 5.13
7 Control of Purchased Items and Services		
7-100 General		GS-R-3 Requirements 5.15, 5.16, 5.23, 5.24, and 6.3
7-200 Supplier Evaluation and Selection		GS-R-3 Requirements 5.23, 5.24, and 6.3 *Recommendations*. GS-R-3 users should address one or more of the following: Supplier's history, Supplier's current quality records, and Supplier's technical and quality capability.
7-300 Bid Evaluation		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
7-400 Control of Supplier-Generated Documents		No corresponding requirement. *Recommendations*. When Supplier documents are received, GS-R-3 Requirements 5.12, 5.21, and 5.24 provide the necessary controls. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
7-500 Acceptance of Item or Service	**501 General** Key words: Supplier shall verify **502 Methods of Acceptance** **503 Certificate of Conformance** **504 Source Verification** **505 Receiving Inspection** **506 Postinstallation Testing** **507 Acceptance of Services Only**	GS-R-3 Requirements 5.24 and 5.25 *Recommendations*. GS-R-3 users should address paras. 503 through 507.
7-600 Control of Supplier Nonconformances	Key words: (a) evaluation (b) submittal (c) disposition (d) verification (e) records	GS-R-3 Requirements 5.25 and 6.11 through 6.16 *Recommendations*. GS-R-3 users should address paras. 600(a) through (e).
7-700 Commercial Grade Items and Services	**701 General**	No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.

Table I The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
7-800 Records		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
8 Identification and Control of Items		
8-100 General	Key words: correct and accepted items	GS-R-3 Requirements 5.18 and 5.19
8-200 Identification Methods	**201 Item Identification** **202 Physical Identification**	No corresponding requirements. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
8-300 Specific Requirements	**301 Identification and Traceability of Items** **302 Limited Life Items** **303 Maintaining Identification of Stored Items**	No corresponding requirements. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
9 Control of Special Processes		
9-100 General	Key words: welding, heat treating, nondestructive examination, qualified personnel, qualified procedures	No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
9-200 Process Control	**201 Special Processes** **202 Acceptance Criteria** **203 Special Requirements**	No corresponding requirements. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
9-300 Responsibility		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
9-400 Records		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
10 Inspection		
10-100 General		GS-R-3 Requirements 5.7 and 5.15 *Recommendations*. GS-R-3 users should ensure that inspection for acceptance is performed by qualified persons other than those who performed or directly supervised the work.

Table I The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
10-200 Inspection Requirements		GS-R-3 Requirement 5.7 *Recommendations*. When specifying inspection requirements and acceptance criteria, GS-R-3 users should include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.
10-300 Inspection Hold Points		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Specified hold points should be indicated in appropriate documents. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
10-400 Inspection Planning	**401 Planning** **402 Sampling**	No corresponding requirements. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
10-500 In-Process Inspection		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
10-600 Final Inspections	**601 Resolution of Nonconformances** **602 Inspection Requirements** **603 Modifications, Repairs, or Replacements** **604 Acceptance**	No corresponding requirements. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
10-700 Inspections During Operations		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
10-800 Records		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
11 Test Control		
11-100 General	Key words: collect data, verify conformance, demonstrate satisfactory performance	GS-R-3 Requirements 5.7 and 5.15 *Recommendations*. GS-R-3 users should specify characteristics to be tested and test methods to be employed. Test results shall be documented, and their conformance with test requirements and acceptance criteria shall be evaluated.
11-200 Test Requirements		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.

Table I The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
11-300 Test Procedures (Other Than for Computer Programs)	Key words: test configuration, test objectives, prerequisites	No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
11-400 Computer Program Test Procedures		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
11-500 Test Result		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
11-600 Test Records	**601 Test Records** **602 Computer Program Test Records**	No corresponding requirement. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
12 Control of Measuring and Test Equipment		
12-100 General		GS-R-3 Requirement 5.15 *Recommendations*. GS-R-3 users should address control, calibration at specific periods, adjustment, and maintenance of tools, gages, instruments, and other measuring and test equipment.
12-200 Selection		GS-R-3 Requirement 5.15
12-300 Calibration and Control	**301 Calibration** **302 Reference Standards** **303 Control** **303.1 Application** **303.2 Corrective Action** **303.3 Handling and Storage** **303.4 Environmental Controls** **303.5 Precalibration Checks** **303.6 Status Indication** **304 Commercial Devices**	No corresponding requirements. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
12-400 Records	**401 General** Key words: status, capability **402 Reports and Certificates**	No corresponding requirement. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
13 Handling, Storage, and Shipping		
13-100 General		GS-R-3 Requirements 5.9 and 5.20 *Recommendations*. GS-R-3 users should address cleaning and packaging of items.

Table I The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
13-200 Special Requirements	Key words: equipment, protective environment	No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement, as applicable.
13-300 Procedures		GS-R-3 Requirements 2.6, 5.9, and 5.20.
13-400 Tools and Equipment		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
13-500 Operators		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
13-600 Marking or Labeling		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
14 Inspection, Test, and Operating Status		
14-100 General	Key words: identified, maintained through indicators, authority	GS-R-3 Requirements 5.15 and 5.18 *Recommendations*. GS-R-3 users should address inspection, test, and operating status, required by NQA-1.
15 Control of Nonconforming Items		
15-100 General		GS-R-3 Requirements 6.11 and 6.12 *Recommendations*. GS-R-3 users should address notification to affected organizations.
15-200 Identification		GS-R-3 Requirement 6.12 *Recommendations*. GS-R-3 users should address the use of identification methods not detrimental to the item, on the item, the container, or the package.
15-300 Segregation		GS-R-3 Requirement 6.12 *Recommendations*. GS-R-3 users should employ other precautions to preclude inadvertent use of a nonconforming item in cases when segregation is impractical or impossible due to physical conditions, such as size, weight, or access limitations.

Table I The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
15-400 Disposition	**401 Control** **402 Responsibility and Authority** **403 Personnel** **404 Disposition** **405 Reexamination**	GS-R-3 Requirements 6.12 and 6.13 *Recommendations*. GS-R-3 users should address paras. 402 and 403.
16 Corrective Action		
16-100 General	Key words: condition adverse to quality, significant	GS-R-3 Requirements 6.14 and 6.15 *Recommendations*. GS-R-3 users should address verification of completed corrective actions.
17 Quality Assurance Records		
17-100 General		GS-R-3 Requirements 5.6, 5.21, and 5.22 *Recommendations*. GS-R-3 users should address authentication.
17-200 Generation of Records		GS-R-3 Requirements 5.6 and 5.21
17-300 Authentication of Records	Key words: (a) valid (b) electronic	No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
17-400 Classification	**401 Lifetime Records** **402 Nonpermanent Records**	GS-R-S Requirement 5.22 *Recommendations*. GS-R-3 users should address paras. 401 and 402.
17-500 Receipt Control of Records		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
17-600 Storage	**601 General** Key words: (a) location, minimize risk (b) detrimental activities (c) access (d) damage **602 Facility Types** Key words: (602.1) single, (602.2) dual **603 Temporary Storage**	No corresponding requirements. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
17-700 Retention		GS-R-3 Requirement 5.22
17-800 Maintenance of Records	Key words: (a) protected (b) retrievability (c) methods for record changes (d) electronic record media (e) technology changes (f) duplicated	GS-R-3 Requirement 5.22 *Recommendations*. GS-R-3 users should address (b) through (f).
18 Audits		
18-100 General		GS-R-3 Requirements 5.9, 6.3, 6.5, and 6.6.

Table I The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
18-200 Scheduling		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
18-300 Preparation	**301 Audit Plan** **302 Personnel** **303 Selection of Audit Team**	GS-R-3 Requirement 6.4 *Recommendations*. GS-R-3 users should address paras. 301 and 303.
18-400 Performance		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
18-500 Reporting		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
18-600 Response		GS-R-3 Requirements 6.6 and 6.14 *Recommendations*. GS-R-3 users should address evaluation of audit responses by or for the auditing organization.
18-700 Follow-Up Action		GS-R-3 Requirements 5.9 and 6.15
18-800 Records		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.

GENERAL NOTE: Key words are included as appropriate to help the reader identify the nature of the requirements. Users should refer to NQA-1 for the full text of the requirements.

Table II The Extent to Which NQA-1 Addresses GS-R-3 Requirements

Requirement	GS-R-3	NQA-1 and Recommendations
2.1–2.10 Management System General Requirement		
2.1	Key words: management system, goals, managing organization, planned and systematic actions	NQA-1 Requirements 1 and 2 *Recommendations*. NQA-1 users should ensure that health, safety, environmental, security, and economic requirements will be implemented as part of continual improvement of the management system.
2.2	Key words: safety	No corresponding specific requirement, but Part I, Introduction addresses the safe utilization of nuclear energy and nuclear material processing. *Recommendations*. NQA-1 users should address safety to the extent described by GS-R-3 to ensure safety is paramount.
2.3	Key words: management system, identify and integrate, statutory and regulatory requirements, interested parties, IAEA Safety Requirements, relevant codes and standards	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 2.1 through 2.6 and GS-G-3.1 Appendix I for guidance on implementation of this requirement.
2.4	Key words: demonstrate the effective fulfillment	NQA-1 Requirement 2, section 100(c) *Recommendations*. NQA-1 users should address all aspects of management system requirements.
Safety Culture		
2.5	Key words: graded, significance and complexity, hazards, potential impact, consequences	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 2.32 through 2.36 for guidance on implementation of this requirement.
Grading the Application of Management System Requirements		
2.6	Key words: graded, significance and complexity, hazards, potential impact, consequences	NQA-1 Requirement 2, section 100(a) Requirement 5, Part I, Introduction *Recommendations*. NQA-1 users should deploy appropriate resources based on the potential impact associated with the safety, health, environmental, security, and economics on product or activity in the application of the QA program. Also, see Part III, Subpart 3.1-2.1 for additional guidance.

Table II The Extent to Which NQA-1 Addresses GS-R-3 Requirements (Cont'd)

Requirement	GS-R-3	NQA-1 and Recommendations
2.7	Key words: grading of application	NQA-1 Requirement 2, section 100(a) Requirement 5, Part I, Introduction NQA-1 Requirement 3, section 500(d) Requirement 3, para. 801.4(b), Requirement 4, para. 203, Requirement 6, section 300, Requirement 7, para. 501, and Requirement 7, para. 504 are requirements that are examples of a graded approach. *Recommendations*. NQA-1 users should address the potential impact associated with the safety, health, environmental, security, and economics on products and activities of each process in the application of the QA program. Also, see Part III, Subpart 3.1-2.1 for additional guidance.
Documentation of the Management System		
2.8	Key words: documentation, policy statements, description of management system and structure, description of functional responsibilities, accountabilities, levels of authority and interactions, description of processes, and supporting information	NQA-1 Requirements 1 and 2 Additionally, NQA-1 includes responsibilities specific to processes and activities in other requirements. *Recommendations*. NQA-1 users should address in the documentation of the management system all GS-R-3 requirements, e.g., policy statements, safety, health, environmental, security, and economic.
2.9	Key words: developed documentation of management system, readable, readily identifiable, available	NQA-1 Requirements 1, 2, 6, and 17
2.10	Key words: documentation reflects characteristics of organization, complexities of processes, and interactions	NQA-1 Requirement 2, section 100(a) and Part I, Introduction *Recommendations*. NQA-1 users should address in the documentation of the management system the potential impact associated with the safety, health, environmental, security, and economics on product in the processes. Also, see Part III, Subpart 3.1-2.1 for additional guidance. The organization should identify all processes and their interactions.
3.1–3.14 Management Responsibility		
Management Commitment		
3.1	Key words: management, commitment, establishment, implementation, assessment, continual improvement, management system	NQA-1 Requirement 1 addresses commitment to the establishment and implementation of the quality assurance program. Requirement 2, section 100(c), addresses the assessment of the quality assurance program. *Recommendations*. NQA-1 users should address continual improvement, resource allocation, and all other areas of the management system.

Table II The Extent to Which NQA-1 Addresses GS-R-3 Requirements (Cont'd)

Requirement	GS-R-3	NQA-1 and Recommendations
3.2	Key words: senior management, values, behavioral expectations, role models	No corresponding requirement. *Recommendations*. NQA-1, Requirement 1, para. 201(a) addresses "overall management expectations" for the quality assurance program. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 3.1 through 3.7 for guidance on implementation of this requirement.
3.3	Key words: management, communicate, need to adopt, values	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 3.1 through 3.7 for guidance on implementation of this requirement.
3.4	Key words: management, involvement, individuals, implementation, continual improvement, management system	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 3.1 through 3.7 for guidance on implementation of this requirement.
3.5	Key words: senior management, clear when, how, and by whom; decisions; management system	NQA-1 Requirement 1
Satisfaction of Interested Parties		
3.6	Key words: expectations, interested parties, senior management, activities, interactions, processes, enhancing, satisfaction, ensuring safety	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 3.8 for guidance on implementation of this requirement.
Organizational Policies		
3.7	Key words: senior management, develop, policies	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 3.10 through 3.12 for guidance on implementation of this requirement.
Planning		
3.8	Key words: senior management, establish goals, strategies, plans, objectives	NQA-1 Requirement 2, section 100 addresses aspects of Planning. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 3.13 through 3.16 for guidance on implementation of this requirement.
3.9	Key words: senior management, develop, goals, strategies, plans, objectives, integrated manner, impact on safety, understood, managed	NQA-1 Requirement 2, section 100 addresses aspects of Planning. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 3.13 through 3.16 for guidance on implementation of this requirement.

Table II The Extent to Which NQA-1 Addresses GS-R-3 Requirements (Cont'd)

Requirement	GS-R-3	NQA-1 and Recommendations
3.10	Key words: senior management, measurable objectives, implementing, goals, strategies, plans, appropriate processes	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 3.13 through 3.16 for guidance on implementation of this requirement.
3.11	Key words: senior management, implementation, plans, regularly reviewed, actions are taken, deviations	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1 for guidance on implementation of this requirement.
Responsibility, Authority, and Communication		
3.12	Key words: senior management, responsible, management system, ensure, established, implemented, assessed, continually improved	NQA-1 Requirement 1 *Recommendations*. NQA-1 users should address continual improvement.
3.13	Key words: individual, reporting, senior management, specific responsibility, authority, coordinating, development, implementation, assessment, continual improvement, reporting, performance, influence on safety, need for improvement, resolving, potential conflicts	No corresponding requirement. *Recommendations*. NQA-1 users should ensure an individual (singular) reporting directly to senior management has specific responsibility and authority for and continual improvement of the management system. NQA-1 Requirement 1, para. 201 and Requirement 2, para. 100(c) address assessment attributes for the QA program.
3.14	Key words: overall responsibility, management system, external organization, developing	NQA-1 Requirement 1, para. 202
4.1–4.5 Resource Management Provision of Resources		
4.1	Key words: senior management, determine needed resources	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 4.1 through 4.5 for guidance on implementation of this requirement.
4.2	Key words: management of information, knowledge	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 4.1, 4.2, and 4.4 for guidance on implementation of this requirement.
Human Resources		
4.3	Key words: competency requirements, evaluation of effectiveness	NQA-1 Requirement 2
4.4	Key words: safety, consequences, education, training, relationship to objectives	NQA-1 Requirement 2 *Recommendations*. NQA-1 users should provide training that ensures individuals understand the consequences for safety of their activities. NQA-1 users should provide training to ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organization's objectives.

Table II The Extent to Which NQA-1 Addresses GS-R-3 Requirements (Cont'd)

Requirement	GS-R-3	NQA-1 and Recommendations
Infrastructure and the Working Environment		
4.5	Key words: infrastructure and the working environment	NQA-1 Requirement 2
5.1–5.29 Process Implementation Developing Processes		
5.1	Key words: processes (a) planned (b) implemented (c) assessed (d) continually improved	NQA-1 Requirement 2, section 100(a) and Requirement 5, section 100 address the elements of processes. *Recommendations*. NQA-1 users should address the identification of processes needed to achieve the organization's goals and the continual improvement of processes.
5.2	Key words: process (a) sequence (b) interactions	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 5.1 through 5.9 for guidance on implementation of this requirement.
5.3	Key words: process implementation control methods	NQA-1 Requirement 5, section 100
5.4	Key words: process development, requirements, hazards and risks identified, interactions (d) flow (e) output (f) measurement criteria	NQA-1 Requirement 2, section 100(a) and Requirement 5, section 100 address many of the requirements related to processes in GS-R-3 Requirement 5.1. *Recommendations*. NQA-1 users should address the identification of hazards and risks together with any necessary mitigating actions and process measurement. Consult GS-G-3.1, 5.4 for guidance on implementation of this requirement.
5.5	Key words: process interface control, communication, responsibilities	NQA-1 Requirement 1, sections 100 and 300 address functional interfaces. *Recommendations*. NQA-1 users should address interfaces between different individuals or groups involved in a process.
Process Management		
5.6	Key words: designated individual, develop and documenting effective interaction (d) records (e) monitoring reporting performance (f) promoting improvement (g) aligned with goals of the organization	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 5.10 through 5.23 for guidance on implementation of this requirement. The organization should identify a designated individual for each process.
5.7	Key words: inspection, testing, acceptance criteria, responsibilities	NQA-1 Requirement 10
5.8	Key words: (a) evaluated, effectiveness	NQA-1 Requirement 2, section 100(c) *Recommendations*. NQA-1 users should ensure assessment of the adequacy of the QA program includes assessment of the processes.
5.9	Key words: (a) Controlled conditions, approved procedures, results compared, expected values	NQA-1 Requirement 2, section 100(c) and Requirement 5

Table II The Extent to Which NQA-1 Addresses GS-R-3 Requirements (Cont'd)

Requirement	GS-R-3	NQA-1 and Recommendations
5.10	Key words: (a) external organizations identified, retain overall responsibility	NQA-1 Requirement 1, para. 202 and section 300
Generic Management System Process		
5.11	Key words: (a) Generic processes developed	No corresponding requirement. *Recommendations*. NQA-1 users should refer to corresponding requirements and recommendations for GS-R-3 Requirements 5.12 through 5.29.
5.12	Key words: (a) control of documents	NQA-1 Requirement 6
5.13	Key words: (a) changes to documents	NQA-1 Requirement 6, section 300
5.14	Key words: control of products, specifications and requirements, interface identified	NQA-1 Requirements 3, 4, 7, and 8
5.15	Key words: (a) Acceptance inspection testing verification, validation, tools and equipments type, range accuracy	NQA-1 Requirements 8 and 10 through 13, section 400
5.16	Key words: products meet specified requirements, perform in service	NQA-1 Requirements 7, 8, and 10
5.17	Key words: (a) form, verify satisfy requirements	NQA-1 Requirements 7 and 8
5.18	Key words: (a) verification	NQA-1 Requirement 7, section 500, and Requirements 10 and 14
5.19	Key words: (a) products identified (b) traceability (c) unique identification	NQA-1 Requirements 8 and 14
5.20	Key words: (a) stored, maintained, prevent damage, loss, inadvertent use	NQA-1 Requirements 8, section 300, and Requirement 13
5.21	Key words: (a) records controlled (b) readable (c) complete (d) identifiable (e) retrievable	NQA-1 Requirements 6 and 17
5.22	Key words: (a) Retention time	NQA-1 Requirement 17 *Recommendations*. NQA-1 users should ensure records and associated test materials and specimens are consistent with knowledge management.
5.23	Key words: (a) suppliers selected, specified criteria (b) performance evaluated	NQA-1 Requirements 4 and 7, sections 100, 200, and 300
5.24	Key words: (a) purchasing requirements, procurement documents (b) evidence meet requirements	NQA-1 Requirements 4 and 7

Table II The Extent to Which NQA-1 Addresses GS-R-3 Requirements (Cont'd)

Requirement	GS-R-3	NQA-1 and Recommendations
5.25	Key words: (a) resolution of nonconformance	NQA-1 Requirement 4, para. 206 and Requirement 7, sections 600 and 700
5.26	Key words: (a) safety, health, environment, security, quality, and economic goals (b) interested parties	No corresponding requirement. *Recommendations*. NQA-1 users should address requirements for the communication of relevant information on safety, health, environmental, security, quality, and economic goals. Consult GS-G-3.1, 5.52 through 5.55 for guidance on implementation of this requirement.
5.27	Key words: (a) internal communication, various levels	No corresponding requirement. *Recommendations*. NQA-1 users should address requirements for internal communication regarding the implementation and effectiveness of the management system. Consult GS-G-3.1, 5.52 through 5.55 for guidance on implementation of this requirement.
5.28	Key words: (a) evaluated and classified, importance to safety, change justified	No corresponding requirement. *Recommendations*. NQA-1 users should address requirements for the evaluation, classification, and justification of organizational changes. Consult GS-G-3.1, 5.56 through 5.71 for guidance on implementation of this requirement.
5.29	Key words: (a) planned (b) controlled (c) communicated (d) monitored (e) tracked (f) recorded	NQA-1 Requirement 1, section 100 addresses documenting the organization. *Recommendations*. NQA-1 users should address the evaluation, planning, communication, and monitoring of organizational change. Consult GS-G-3.1, 5.56 through 5.71 for guidance on implementation of this requirement.
6.1–6.18 Measurement, Assessment, and Improvement		
Monitoring and Measurement		
6.1	Key words: monitored and measured	NQA-1 Requirement 1, section 200(a) and Requirement 2, section 100(c) for the QA Program *Recommendations*. NQA-1 users should use the results of monitoring activities and management assessment of the adequacy of the QA Program to identify opportunities for improvement.
Self-Assessment		
6.2	Key words: self-assessment	No corresponding requirement. *Recommendations*. NQA-1 users should address the requirement for self-assessment by all levels of management. Consult GS-G-3.1, 6.6 through 6.21 for guidance on implementation of this requirement.
Independent Assessment		
6.3	Key words: evaluate the effectiveness	NQA-1 Requirements 2 and 18 *Recommendations*. NQA-1 users should address the requirements to evaluate safety culture and identify opportunities for improvement.

Table II The Extent to Which NQA-1 Addresses GS-R-3 Requirements (Cont'd)

Requirement	GS-R-3	NQA-1 and Recommendations
6.4	Key words: conducting independent assessments	NQA-1 Requirements 2 and 18
6.5	Key words: independent assessments	NQA-1 Requirement 1, section 200, and Requirement 18
6.6	Key words: senior management necessary actions, record and communicate their decisions	NQA-1 Requirements 16 and 18
Management System Review		
6.7	Key words: management system review	NQA-1 Requirement 2, section 100(c) for QA Program *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 6.45 through 6.49 for guidance on implementation of this requirement.
6.8	Key words: review shall cover assessment outputs, results delivered, nonconformances and corrective and preventive actions, lessons learned, and opportunities for improvement	No corresponding requirement. *Recommendations*. NQA-1 users should ensure that these inputs to management system review are addressed. Consult GS-G-3.1, 6.47 for guidance on implementation of this requirement.
6.9	Key words: weaknesses and obstacles, identified, evaluated, and remedied	No corresponding requirement. *Recommendations*. NQA-1 users should address the requirement to identify, evaluate, and remedy weaknesses and obstacles as part of management system review. Consult GS-G-3.1, 6.49 for guidance on implementation of this requirement.
6.10	Key words: review shall identify	No corresponding requirement. *Recommendations*. NQA-1 users should address the requirement to identify necessary changes or improvements in policies, goals, strategies, plans, objectives, and processes as part of management system review.
Nonconformances and Corrective and Preventive Actions		
6.11	Key words: causes, nonconformances, determined, remedial actions, prevent recurrence	NQA-1 Requirements 15 and 16 *Recommendations*. NQA-1 users should address the determination of causes of nonconformances for all nonconformances, not just those that are for significant conditions adverse to quality.
6.12	Key words: products, processes, specified requirements, identified, segregated, controlled, recorded, reported, level of management, impact of nonconformances, evaluated, accepted, reworked, corrected, rejected, discarded, destroyed, inadvertent use	NQA-1 Requirement 15
6.13	Key words: concessions, acceptance, product, process, authorization, reworked, corrected, inspection, demonstrate, conformity. requirements, expected results	NQA-1 Requirement 7, section 600, and Requirement 15

Table II The Extent to Which NQA-1 Addresses GS-R-3 Requirements (Cont'd)

Requirement	GS-R-3	NQA-1 and Recommendations
6.14	Key words: corrective actions, eliminating, determined, implemented, preventive actions, causes, potential	NQA-1 Requirement 16 *Recommendations*. NQA-1 users should address the determination and taking of preventive actions to eliminate the causes of potential nonconformances.
6.15	Key words: status, effectiveness, corrective, preventive actions, monitored, reported to management	NQA-1 Requirement 16 *Recommendations*. NQA-1 users should address the requirement to monitor and report on the status and effectiveness of all corrective and preventive actions.
6.16	Key words: potential, detract, performance, identified, feedback, internal and external, technical advances and research, knowledge and experience, best practices	No corresponding requirement. *Recommendations*. NQA-1 users should address the requirement to identify potential nonconformances using feedback from other organizations, both internal and external, through the use of technical advances and research, the sharing of knowledge and experience, and the use of techniques that identify best practices. Consult GS-G-3.1, 6.76 and 6.77 for guidance on implementation of this requirement.
Improvement		
6.17	Key words: opportunities, improvement, identified, actions to improve, processes, selected, planned, and recorded	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 6.78 through 6.84 for guidance on implementation of this requirement.
6.18	Key words: improvement, plans, adequate resources, actions, improvement, monitored, completion, effectiveness	No corresponding requirement. *Recommendations*. NQA-1 users should address the requirement to provide adequate resources for improvement activities, monitor improvement actions, and check the effectiveness of improvements. Consult GS-G-3.1, 6.78 through 6.84 for guidance on implementation of this requirement.

GENERAL NOTE: Key words are included as appropriate to help the reader identify the nature of the requirements. Users should refer to GS-R-3 for the full text of the requirements.

(15)

SUBPART 4.1.5
Guidance to Modification of an ANSI/ANS-15.8–1995 (R2005; R2013) Quality Program to Meet NQA-1–2012 Requirements

100 INTRODUCTION

The purpose of this Subpart is to compare the requirements of ANSI/ANS-15.8–1995 (R2005; R2013) (ANSI/ANS-15.8) and NQA-1–2012 (Parts I and II) and to identify where actions may be needed to address the differences.

200 APPLICABILITY

The guidance is intended for all parties involved in the nuclear industry that are currently applying/implementing either NQA-1 or ANSI/ANS-15.8 requirements and are required to comply with both standards. This Subpart can be used to achieve compliance with both sets of requirements simultaneously by providing information on the differences between ANSI/ANS-15.8 and NQA-1, thus allowing organizations to implement controls for the program differences.

This Subpart examines each requirement paragraph from Parts I and II of the NQA-1 Standard and identifies the comparable paragraphs of the ANSI/ANS-15.8 Standard using NQA-1. Guidance for evaluating existing practices or supplementing an ANSI/ANS-15.8 program appears below each NQA requirement section. In some cases, the comparison states the ANSI/ANS-15.8 requirement at a higher level, and the user must determine the need to develop detailed practices for implementation of the NQA-1 requirements. In these cases, it is necessary to compare the implementing practices based on ANSI/ANS 15.8 with the requirements of NQA-1 to determine compliance. In order to complete the examination, the Subpart also identifies requirements of ANSI/ANS-15.8 that have no corresponding requirement in NQA-1 (see Tables 200-1 through 200-21).

300 BACKGROUND

NQA-1 is primarily focused on assuring quality of the design, construction, and operation of a facility in a regulated environment to ensure nuclear safety. While NQA-1 includes requirements for assuring quality of the items and services provided to support the overall objectives, it does not primarily focus on the management and continuous improvement processes needed to achieve customer satisfaction. Part II, Subpart 2.22 of the Standard provides requirements for continuous improvement processes.

The scope of the ANSI/ANS-15.8 Standard "provides criteria for quality assurance in the design, construction, operation, and decommissioning of research reactors." The "Design, Construction, and Modifications" section of the ANSI/ANS-15.8 Standard closely follows the format of requirements of NQA-1, Part I. Other sections of the ANSI/ANS 15.8 Standard do not follow the NQA-1 format, including Section 3, Facility Operations; Section 4, Applications to Existing Facilities; and Section 5, Decommissioning.

400 TERMS AND DEFINITIONS

Within the ANSI/ANS-15.8 Standard, there exist terms and usage that are unique, and, therefore, differences exist with the terms used within the NQA-1 Standard. Where these differences exist, care should be taken by the user of the ANSI/ANS-15.8 Standard to ensure that the requirements of NQA-1 are fully implemented as related to the NQA-1 use of the terms in question.

500 HOW TO USE THE GUIDE TO ACHIEVE COMPLIANCE WITH NQA-1 OR AN ANSI/ANS-15.8 QUALITY PROGRAM

The section headings of both standards are listed in Tables 200-1 through 200-21 below and have been compared utilizing the format of NQA-1, Parts I and II, and the requirements of ANSI/ANS 15.8. Each table also offers recommendations for those topics or areas potentially needing improvement, amplification, and/or clarification. Users of this guidance should recognize that the requirements of NQA-1 are contained in Parts I and II of the Standard. Table 200-20 reflects the instances where NQA-1 has no corresponding requirement or requires additional rigor in a requirement when compared with ANSI/ANS 15.8. Two examples of the perspectives that must be considered and addressed by the guidance are the following:

(a) experimental equipment
(b) ancillary equipment

Table 200-1 Corresponding NQA Sections (Introduction) to ANSI/ANS 15.8

NQA-1, Part I Introduction	ANSI/ANS 15.8
100 Purpose	1.1 Scope
200 Applicability	1.2 Application
300 Responsibilities	No corresponding requirement
400 Terms and Definitions	1.3 Definitions

RECOMMENDATIONS: There are two areas that need more detail for an ANSI/ANS 15.8 quality program to meet this NQA-1 Requirement. These additional areas are the following:

(a) NQA-1 is more prescriptive in applying quality requirements to refueling operations per NQA-1, Part I, Introduction, section 200.

(b) NQA-1 defines requirements for responsibility of organizations invoking and implementing the standard per NQA-1, Part I, Introduction, section 300.

Table 200-2 Corresponding NQA Sections (Requirement 1) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 1: Organization	ANSI/ANS 15.8
100 General	2.1 Organization
200 Structure and Responsibility	No corresponding requirement
201 General	2.1 Organization 3.2 Quality Assurance Program [Note (1)]
202 Delegation of Work	No corresponding requirement
300 Interface Control	No corresponding requirement

NOTE:

(1) ANSI/ANS-15.8 also applies this Requirement to Facility Operations. ANSI/ANS-15.8, para. 3.1 specifies that management provide sufficient personnel and materials to conduct operations.

RECOMMENDATIONS: There are three areas that need more detail for an ANSI/ANS 15.8 quality program to meet this NQA-1 Requirement. These additional areas are the following:

(a) NQA-1 is more prescriptive in requiring senior management to establish overall expectation for effective implementation of the quality assurance program, assign senior management responsibility for obtaining the desired results, and verify corrective actions by NQA-1, Part I, Requirement 1, section 201.

(b) NQA-1 requires a verification function to ensure control of further processing, delivery, installation, or use until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred per NQA-1, Part I, Requirement 1, section 201.

(c) NQA-1 requires the clear definition and documentation of activities, interfaces, and authority of each organization by NQA-1, Part I, Requirement 1, section 300.

Table 200-3 Corresponding NQA Sections (Requirement 2) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 2: Quality Assurance Program	ANSI/ANS 15.8
100 General	2.2 Quality Assurance Program 3.3 Performance Monitoring [Note (1)]
200 Indoctrination and Training	2.2 Quality Assurance Program
201 Indoctrination	No corresponding requirement
202 Training	2.2 Quality Assurance Program 3.4 Operator Experience [Note (1)] 2.10 Inspections [Note (2)]
300 Qualification Requirements	No corresponding requirement
301 Nondestructive Examination	No corresponding requirement
302 Inspection and Test	No corresponding requirement
303 Lead Auditor	No corresponding requirement
303.1 Communication Skills	2.18 Assessments
303.2 Training	2.18 Assessments
303.3 Audit Participation	No corresponding requirement
303.4 Examination	No corresponding requirement
303.5 Maintenance of Proficiency	No corresponding requirement
303.6 Requalification	No corresponding requirement
304 Auditors	No corresponding requirement
305 Technical Specialists	No corresponding requirement
400 Records of Qualification	No corresponding requirement
500 Records	No corresponding requirement

NOTES:
(1) ANSI/ANS-15.8 also applies this Requirement to Facility Operations.
(2) ANSI/ANS 15.8 is more prescriptive in inspection training requirements (see Table 200-11).

RECOMMENDATIONS: There are several areas that need more detail for an ANSI/ANS 15.8 quality program organization to meet this NQA-1 Requirement.

(a) The ANSI/ANS 15.8 documented quality assurance program does not include

(1) The planning, implementation, and maintenance requirements for the documented quality assurance program described in NQA-1, Part I, Requirement 2, section 100.

(2) NQA-1 is more prescriptive in the specific recognition, where necessary, of "Controlled Conditions" as it relates to the use of appropriate equipment or processes, suitable environmental conditions, and satisfaction of activity prerequisites in NQA-1, Part I, Requirement 2, section 100.

(b) NQA-1 is more prescriptive in the requirements of Indoctrination and Training.

(1) It requires documented indoctrination for personnel performing or managing quality-affecting activities to include job responsibilities and authority and general criteria, including applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements by NQA-1, Part I, Requirement 2, sections 201 and 202.

(2) The training requirements of NQA-1 are more explicit and include determining the need for formal training for personnel performing or managing quality-affecting activities. This training may include achieving and maintaining proficiency and/or changes to technology, methods, or job responsibilities by NQA-1, Part I, Requirement 2, section 202.

(c) NQA-1 is more prescriptive in explicit qualification requirements for personnel performing activities determined to need qualified personnel. Specific qualification requirements for personnel performing nondestructive examination, inspection, tests to verify quality and auditing, and qualification records shall be in accordance with NQA-1, Part I, Requirement 2, sections 300 and 400.

(d) The records requirements for training in NQA-1 are more explicit for formal training of personnel performing or managing quality-affecting activities per NQA-1, Part I, Requirement 2, section 500.

Table 200-4 Corresponding NQA Sections (Requirement 3) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 3: Design Control	ANSI/ANS 15.8
100 General	2.3 Design Control
	2.3.1 Design Requirements
	2.3.2 Design Processes
200 Design Input	2.3.1 Design Requirements
300 Design Process	2.3.2 Design Process
	2.3.5 Commercial Grade Items
400 Design Analysis	No corresponding requirement
401 Use of Computer Programs	2.3.2 Design Process
402 Documentation of Design Analysis	No corresponding requirement
500 Design Verification	2.3.3 Design Verification
501 Methods	2.3.3 Design Verification
501.1 Design Reviews	2.3.3 Design Verification
501.2 Alternate Calculations	2.3.3 Design Verification
501.3 Qualification Tests	2.3.3 Design Verification
600 Change Control	3.10 Configuration Control [Note (1)]
601 Configuration Management of Operating Facilities	2.3.6 Change Control
700 Interface Control	2.3.2 Design Process
800 Software Design Control	No corresponding requirement
801 Software Design Process	No corresponding requirement
801.1 Identification of Software Design Requirements	No corresponding requirement
801.2 Software Design	No corresponding requirement
801.3 Implementation of the Software Design	No corresponding requirement
801.4 Software Design Verification	No corresponding requirement
801.5 Computer Program Testing	No corresponding requirement
802 Software Configuration Management	No corresponding requirement
802.1 Configuration Identification	No corresponding requirement
802.2 Configuration Change Control	No corresponding requirement
802.3 Configuration Status Control	No corresponding requirement
900 Documentation and Records	No corresponding requirement

NOTE:

(1) ANSI/ANS-15.8 also applies this Requirement to Facility Operations.

RECOMMENDATIONS: NQA-1 contains substantially more scope and detailed requirements for the design process. An ANSI/ANS 15.8 design process must be carefully compared with NQA-1 to establish compliance.

There are several areas that may need more detail for an ANSI/ANS 15.8 quality program organization to meet this NQA-1 Requirement.

(a) NQA-1 requires sufficient documented detail of design input to perform the design process in a correct and consistent manner for making design decisions and accomplishing design verification. Design changes shall have at least the same level of control as applied to the original design and shall be incorporated into the appropriate documents in a timely manner. Those approving design changes shall have demonstrated competence in the specific design area of interest and have adequate understanding of the requirements and intent of the original design by NQA-1, Part I, Requirement 3, sections 200 and 600.

(b) The design process of NQA-1 requires approval of design inputs, quality standards, and interface control documents. NQA-1 requires the final design to specify required inspections and tests and include or reference appropriate acceptance criteria by NQA-1, Part I, Requirement 3, section 300.

(c) Formalize and document in detail design analysis, design verification processes, and interface control. The requirements for these design functions are in NQA-1, Part I, Requirement 3, sections 400, 500, and 700.

(d) Establish and document the configuration management for the operating facility prior to facility operation. The requirements for the configuration management of the operating facilities are found in NQA-1, Part I, Requirement 3, section 600.

Table 200-4 Corresponding NQA Sections (Requirement 3) to ANSI/ANS 15.8 (Cont'd)

(e) Controls are required for computer software design using the requirements found in NQA-1, Part I, Requirement 3, section 800. NQA-1 is more prescriptive for software design control in specifying the steps of the software design process, acceptance testing, verification activities, and validation of results for the intended purpose. ANSI 15.8 does not distinguish design control requirements between software and hardware except for the added requirement that verification of design-unique computer programs shall include benchmark testing.

(f) Include in documentation and records of the design not only final design documents, such as drawings and specifications, and revisions to those documents but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design by NQA-1, Part I, Requirement 3, section 900.

(g) NQA-1 defines commercial grade dedication (CGD), prescribes the development of critical characteristics and acceptance criteria, and refers the implementer to specific requirements in a separate Part II, Subpart of NQA-1, for CGD requirements by NQA-1, Part I, Requirement 3, section 300.

(h) NQA-1 requires design verification prior to procurement, manufacture, construction, or use, and if this condition cannot be met, then the unverified portion of the design must be identified and controlled by NQA-1, Part I, Requirement 3, section 500.

(i) NQA-1 is more prescriptive for design verification, design reviews, alternate calculations and qualification tests, configuration management of operating facilities, and design documentation and records by NQA-1, Part I, Requirement 3, section 601.

Table 200-5 Corresponding NQA Sections (Requirement 4) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 4: Procurement Document Control	ANSI/ANS 15.8
100 General	2.4 Procurement Document Control [Note (1)]
200 Contents of the Procurement Documents	No corresponding requirement
201 Scope of Work	No corresponding requirement
202 Technical Requirements	2.4 Procurement Document Control
203 Quality Assurance Program Requirements	No corresponding requirement
204 Right of Access	2.4 Procurement Document Control
205 Documentation Requirements	2.4 Procurement Document Control
206 Nonconformances	2.4 Procurement Document Control
207 Spare and Replacement Parts	No corresponding requirement
300 Procurement Document Review	No corresponding requirement
400 Procurement Document Changes	No corresponding requirement

NOTE: ANS 15.8 is more prescriptive in requiring the approval of supplier nonconformances (NQA-1 establishes this Requirement in Part I, Requirement 7; see Table 200-8) and prohibiting substandard and counterfeit parts and materials.

RECOMMENDATIONS: There are several areas that need more detail to meet this NQA-1 Requirement.

(a) NQA-1 requires suppliers to have a quality assurance program consistent with the applicable requirements of the Standard: a statement of the scope of work to be performed by the supplier, the supplier to incorporate appropriate quality assurance program requirements in subtier procurement documents, right of access to facilities and documentation, and suppliers to identify and document spare and replacement parts and their related ordering data by NQA-1, Part I, Requirement 4, sections 201 through 207.

(b) NQA-1 is more prescriptive in defining the technical and quality assurance requirements, flowing these requirements to all levels of procurement documents, and the review and change control of procurement documents by NQA-1, Part I, Requirement 4, sections 300 and 400.

Table 200-6 Corresponding NQA Section (Requirement 5) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 5: Instructions, Procedures, and Drawings	ANSI/ANS 15.8
100 General	2.5 Procedures, Instructions, and Drawings
No corresponding requirement	3.13 Operating Procedures [Note (1)]

NOTE:

(1) ANSI/ANS-15.8 also applies this Requirement to Facility Operations.

RECOMMENDATIONS: One area needs more detail to meet the NQA-1 Requirement, which is the determination of need and level of detail of written procedures to be based on the complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience) by NQA-1, Part I, Requirement 5, section 100.

Table 200-7 Corresponding NQA Sections (Requirement 6) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 6: Document Control	ANSI/ANS 15.8
100 General	2.6 Document Control
200 Document Control	2.6 Document Control
300 Document Changes	No corresponding requirement
301 Major Changes	2.6 Document Control
302 Minor Changes	No corresponding requirement

RECOMMENDATIONS: Several areas need more detail to meet this NQA-1 Requirement.

(a) NQA-1 delineates the review for adequacy and approval for release by authorized personnel by NQA-1, Part I, Requirement 6, section 100.

(b) NQA-1 defines a method to ensure the correct documents are used by NQA-1, Part I, Requirement 6, section 200.

(c) NQA-1 defines the use of major and minor changes allowed by NQA-1, Part I, Requirement 6, section 300.

Table 200-8 Corresponding NQA Sections (Requirement 7) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 7: Control of Purchased Items and Services	ANSI/ANS 15.8
100 General	2.7 Control of Purchased Items and Services
200 Supplier Evaluation and Selection	2.7.1 Supplier Selection
300 Bid Evaluation	No corresponding requirement
400 Control of Supplier-Generated Documents	2.7.3 Verification Activities
500 Acceptance of Item or Service	No corresponding requirement
501 General	2.7.2 Work Control 2.7.3 Verification Activities
502 Methods of Acceptance	2.7.3 Verification Activities 2.7.4 Item or Service Acceptance
503 Certificate of Conformance	2.7.4 Item or Service Acceptance
504 Source Verification	No corresponding requirement
505 Receiving Inspection	2.7.4 Item or Service Acceptance
506 Postinstallation Testing	2.7.4 Item or Service Acceptance
507 Acceptance of Services Only	No corresponding requirement
600 Control of Supplier Nonconformances	2.7.3 Verification Activities [Note (1)]
700 Commercial Grade Items and Services	No corresponding requirement
800 Records	No corresponding requirement

NOTE:
(1) ANS 15.8 explicitly requires the determination of fraudulent and counterfeit parts and materials.

RECOMMENDATIONS: There are several areas that need more detail to meet the NQA-1 Requirement.

(a) NQA-1 defines how potential suppliers are evaluated prior to the award of a contract or during the bid evaluation process, including resolving discrepancy conditions in the technical and/or quality programs prior to contract award. These requirements are found in NQA-1, Part I, Requirement 7, sections 200 and 300.

(b) NQA-1 defines the control of supplier-generated documentation such as submittal and evaluation of supplier-generated documents. These controls should also provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria. These requirements are found in NQA-1, Part I, Requirement 7, section 400.

(c) NQA-1 defines the acceptance of items or services, control of supplier nonconformances, requirements for Commercial Grade Items (CGI), and the records for purchased items and services. The requirements for these are found in NQA-1, Part I, Requirement 7, sections 500 through 800.

(1) In NQA-1, Part I, Requirement 7, section 500, these methods of acceptance by the Purchaser from the Supplier are clearly defined and need to be a part of the ANSI/ANS 15.8 quality program.

(2) To satisfy the Control of Supplier Nonconformances requirement found in NQA-1, Part I, Requirement 7, section 600, the ANSI/ANS 15.8 quality program needs to define the methods for control and disposition of Supplier nonconformances for items and services that do not meet procurement documentation requirements.

(3) For CGI, the ANSI/ANS 15.8 quality program needs to address the process and usage of these items where the design uses them in accordance with NQA-1, Part I, Requirement 7, section 700 and Part II, Subpart 2.14.

(4) For Records, the ANSI/ANS 15.8 quality program needs to address the establishing and maintenance of records on suppler evaluation, selection, and nonconformance in accordance with NQA-1, Part I, Requirement 7, section 800.

Table 200-9 Corresponding NQA Sections (Requirement 8) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 8: Identification and Control of Items	ANSI/ANS 15.8
100 General	2.8 Identification and Control of Items
200 Identification Methods	No corresponding requirement
201 Item Identification	2.8 Identification and Control of Items
202 Physical Identification	2.8 Identification and Control of Items 3.15 Equipment Labeling [Note (1)]
300 Specific Requirements	No corresponding requirement
301 Identification and Traceability of Items	2.8 Identification and Control of Items
302 Limited Life Items	2.8 Identification and Control of Items
303 Maintaining Identification of Stored Items	No corresponding requirement

NOTE:
(1) ANSI/ANS-15.8 also applies this Requirement to Facility Operations.

RECOMMENDATIONS: NQA-1 defines the process for maintaining the identification of stored items as specified in NQA-1, Part I, Requirement 8, section 303.

Table 200-10 Corresponding NQA Sections (Requirement 9) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 9: Control of Special Processes	ANSI/ANS 15.8
100 General	2.9 Control of Special Processes
200 Process Control	No corresponding requirement
201 Special Processes	2.9 Control of Special Processes
202 Acceptance Criteria	2.9 Control of Special Processes
203 Special Requirements	2.9 Control of Special Processes
300 Responsibility	2.9 Control of Special Processes
400 Records	2.9 Control of Special Processes

GENERAL NOTE: ANS 15.8, para. 2.9, explicitly includes an additional requirement for control of other special processes, e.g., "These (special processes) are also those special processes in which the specific quality cannot be readily determined by inspection or nondestructive testing of the product."

RECOMMENDATIONS: None.

Table 200-11 Corresponding NQA Sections (Requirement 10) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 10: Inspection	ANSI/ANS 15.8
100 General	2.10 Inspections 3.12 Test and Inspection [Note (1)]
200 Inspection Requirements	2.10 Inspections [Note (2)] 3.12 Test and Inspection [Note (1)]
300 Inspection Hold Points	No corresponding requirement
400 Inspection Planning	No corresponding requirement
401 Planning	2.10 Inspections 3.12 Test and Inspection [Note (1)]
402 Sampling	No corresponding requirement
500 In-process Inspection	2.10 Inspections
600 Final Inspections	No corresponding requirement
601 Resolution of Nonconformances	2.10 Inspections
602 Inspection Requirements	2.10 Inspections
603 Modifications, Repairs, or Replacements	No corresponding requirement
604 Acceptance	2.10 Inspections
700 Inspections During Operations	3.10 Configuration Control [Note (1)] 3.12 Test and Inspection [Note (1)]
800 Records	2.10 Inspections

NOTES:

(1) ANSI/ANS-15.8 also applies this Requirement to Facility Operations.

(2) ANSI/ANS 15.8, para. 2.10 is more prescriptive in the following activities:

(a) The inspection program shall apply to procurement, construction, modification, maintenance, and experiment fabrication.

(b) Measuring and Test Equipment used to perform inspections shall be identified in inspection documentation for traceability of inspection results.

(c) The need for formal training shall be determined and training activities conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall be included, with emphasis on firsthand experience gained through actual performance of inspections. Records of inspection personnel's qualification shall be established and maintained by the employer.

RECOMMENDATIONS: There are major additions that need to be included in an ANSI/ANS 15.8 quality program to meet this NQA-1 Requirement.

(a) NQA-1 defines the requirement for and the application of hold points, sampling, modifications, and inspections during operations for the inspection process as described in NQA-1, Part I, Requirement 10, sections 300, 402, 603, and 700.

(b) For Records, NQA-1, Requirement 10, section 800 is more prescriptive in defining the technical requirements.

Table 200-12 Corresponding NQA Sections (Requirement 11) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 11: Test Control	ANSI/ANS 15.8
100 General	2.11 Test Control
200 Test Requirements	2.11 Test Control
300 Test Procedures (Other Than for Computer Programs)	No corresponding requirement
400 Computer Program Test Procedures	2.11 Test Control
500 Test Results	2.11 Test Control
600 Test Records	No corresponding requirement
601 Test Records	No corresponding requirement
602 Computer Program Test Records	No corresponding requirement

RECOMMENDATIONS: There are major additions that need to be included in an existing ANSI/ANS 15.8 quality program to meet this NQA-1 Requirement.

(a) NQA-1 is more prescriptive in defining and requiring the use of acceptance criteria, obtaining accurate results, and performing verification and validation activities of computer programs for design, operation, and in-use according to NQA-1, Requirement 11, sections 200 and 400.

(b) NQA-1 is more prescriptive in defining and requiring test procedures for items and services other than computer programs per NQA-1, Requirement 11, sections 300 and 400.

(c) NQA-1 is more prescriptive in test records for items, services, and in-computer programs per NQA-1, Requirement 11, sections 600 through 602.

Table 200-13 Corresponding NQA Sections (Requirement 12) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 12: Control of Measuring and Test Equipment	ANSI/ANS 15.8
100 General	2.12 Control of Measuring and Test Equipment
200 Selection	No corresponding requirement
300 Calibration and Control	No corresponding requirement
301 Calibration	No corresponding requirement
302 Reference Standards	No corresponding requirement
303 Control	2.12 Control of Measuring and Test Equipment 3.10 Configuration Control [Note (1)]
303.1 Application	No corresponding requirement
303.2 Corrective Action	No corresponding requirement
303.3 Handling and Storage	No corresponding requirement
303.4 Environmental Control	No corresponding requirement
303.5 Precalibration Checks	No corresponding requirement
303.6 Status Indication	No corresponding requirement
304 Commercial Devices	2.12 Control of Measuring and Test Equipment
400 Records	No corresponding requirement
401 General	2.12 Control of Measuring and Test Equipment
402 Reports and Certificates	No corresponding requirement

NOTE:

(1) ANSI/ANS-15.8 also applies this Requirement to Facility Operations.

RECOMMENDATIONS: There are major additions that need to be included in an existing ANSI/ANS 15.8 quality program to meet this NQA-1 Requirement.

(a) NQA-1 is more prescriptive in selecting Measuring and Test Equipment (M&TE) according to NQA-1, Requirement 12, section 200.

(b) NQA-1 is more prescriptive in defining and requiring calibration to certified equipment or reference standards per NQA-1, Requirement 12, sections 301 and 302.

(c) NQA-1 is more prescriptive in calibration control procedures per NQA-1, Requirement 12, sections 303.1 through 303.6.

(d) NQA-1 is more prescriptive in the information and data of calibration records to interpret calibration results and verify conformance to requirements per NQA-1, Requirement 12, section 402.

Table 200-14 Corresponding NQA Sections (Requirement 13) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 13: Handling, Storage, and Shipping	ANSI/ANS 15.8
100 General	2.13 Handling, Storage, and Shipping
200 Special Requirements	No corresponding requirement
300 Procedures	2.13 Handling, Storage, and Shipping
400 Tools and Equipment	No corresponding requirement
500 Operators	No corresponding requirement
600 Marking and Labeling	No corresponding requirement

RECOMMENDATIONS: There are several areas that need more detail to meet this NQA-1 Requirement.

(a) NQA-1 defines specific special equipment and verifiable environments per NQA-1, Part I, Requirement 13, section 200.

(b) NQA-1 defines, where required, the use of documented procedures for the preservation of items in accordance with NQA-1, Part I, Requirement 13, section 300.

(c) NQA-1 requires special handling tools, and equipment shall be inspected and tested in accordance with procedures at specified time intervals or prior to use per NQA-1, Part I, Requirement 13, section 400.

(d) NQA-1 requires operators of special handling or lifting equipment shall be experienced or trained in the use of the equipment per NQA-1, Part I, Requirement 13, section 500.

(e) NQA-1 requires the use of marking or labeling as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls per NQA-1, Part I, Requirement 13, section 600.

Table 200-15 Corresponding NQA Section (Requirement 14) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 14: Inspection, Test, and Operating Status	ANSI/ANS 15.8
100 General	2.14 Inspection, Test, and Operating Status 3.11 Lockouts and Tagouts [Note (1)] 3.15 Equipment Labeling [Note (1)]

NOTE:

(1) ANSI/ANS-15.8 also applies this Requirement to Facility Operations.

RECOMMENDATIONS: There are several actions required to meet this NQA-1 Requirement per NQA-1, Part I, Requirement 14, section 100.

(a) NQA-1 requires the maintenance of the status of the inspection, testing, and operating condition by using indicators.

(b) NQA-1 specifies the authority for application or removal of indicators.

(c) NQA-1 requires the use indicators to prevent inadvertent operation.

Table 200-16 Corresponding NQA Sections (Requirement 15) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 15: Control of Nonconforming Items	ANSI/ANS 15.8
100 General	2.15 Control of Nonconforming Items and Services
200 Identification	2.15 Control of Nonconforming Items and Services
300 Segregation	2.15 Control of Nonconforming Items and Services
400 Disposition	No corresponding requirement
401 Control	No corresponding requirement
402 Responsibility and Authority	No corresponding requirement
403 Personnel	No corresponding requirement
404 Disposition	2.15 Control of Nonconforming Items and Services
405 Reexamination	2.15 Control of Nonconforming Items and Services

RECOMMENDATIONS: There are major additions that need to be included in an existing ANSI/ANS 15.8 quality program to meet this NQA-1 Requirement.

(a) NQA-1 is more prescriptive in identifying a nonconforming item according to NQA-1, Requirement 15, section 200.

(b) NQA-1 is more prescriptive in segregating nonconforming items per NQA-1, Requirement 15, section 300.

(c) NQA-1 is more prescriptive in the control of the disposition of nonconforming items per NQA-1, Requirement 15, section 401.

(d) NQA-1 is more prescriptive in the designation of responsibility and authority for the evaluation and disposition of nonconforming items per NQA-1, Requirement 15, section 402.

(e) NQA-1 is more prescriptive in specifying the qualifications of personnel performing evaluations to determine the disposition of nonconforming items per NQA-1, Requirement 15, section 403.

Table 200-17 Corresponding NQA Section (Requirement 16) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 16: Corrective Action	ANSI/ANS 15.8
100 General	2.16 Corrective Actions

RECOMMENDATIONS: There are activities needing more detail to meet this NQA-1 Requirement in that the language of the requirement in ANSI/ANS 15.8 states, "...cause of the condition shall be investigated...," whereas NQA-1, Part I, Requirement 16, section 100 requires, "...cause of the condition shall be determined..." Further, completion of corrective actions shall be verified per NQA-1, Part I, Requirement 16, section 100.

Table 200-18 Corresponding NQA Sections (Requirement 17) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 17: Quality Assurance Records	ANSI/ANS 15.8
100 General	2.17 Quality Records
200 Generation of Records	2.17 Quality Records
300 Authentication of Records	No corresponding requirement
400 Classification	No corresponding requirement
401 Lifetime Records	No corresponding requirement
401.1	2.17 Quality Records [Note (1)]
401.2	2.17 Quality Records
402 Nonpermanent Records	2.17 Quality Records
500 Receipt Control of Records	No corresponding requirement
600 Storage	No corresponding requirement
601 General	2.17 Quality Records
602 Facility Types	No corresponding requirement
602.1	No corresponding requirement
602.2	No corresponding requirement
603 Temporary Storage	No corresponding requirement
700 Retention	2.3.4 Design Documents and Records
800 Maintenance of Records	No corresponding requirement

NOTE:
(1) ANSI/ANS 15.8, para. 2.17 defines the requirement to maintain records "...which would be of value in planning for facility decommissioning."

RECOMMENDATIONS: There are major additions that need to be included in an existing ANSI/ANS 15.8 quality program to meet this NQA-1 Requirement.

(a) NQA-1 is more prescriptive in specifying the requirements for the generation and storage of records according to NQA-1, Requirement 17, sections 200 and 600.

(b) NQA-1 defines the requirements for the authentication, receipt control, retention, and maintenance of quality assurance records per NQA-1, Requirement 17, sections 300, 500, 700, and 800.

(c) NQA-1 defines the requirements for storage facilities for storage of quality assurance records per NQA-1, Requirement 17, sections 602 and 603.

Table 200-19 Corresponding NQA Sections (Requirement 18) to ANSI/ANS 15.8

NQA-1, Part I, Requirement 18: Audits	ANSI/ANS 15.8
100 General	2.18 Assessments
200 Scheduling	No corresponding requirement
300 Preparation	No corresponding requirement
301 Audit Plan	2.18 Assessments
302 Personnel	No corresponding requirement
303 Selection of Audit Team	No corresponding requirement
400 Performance	2.18 Assessments
500 Reporting	No corresponding requirement
600 Response	2.18 Assessments
700 Follow-up Actions	No corresponding requirement
800 Records	2.18 Assessments

RECOMMENDATIONS: There are major additions that need to be included in an existing ANSI/ANS 15.8 quality program to meet this NQA-1 Requirement.

(a) NQA-1 is more prescriptive in specifying the requirements for audit planning and performance according to NQA-1, Requirement 18, sections 301 and 400.

(b) NQA-1 defines the requirements for the scheduling of audits, authority of audit personnel, audit team composition, audit reporting, and follow-up action per NQA-1, Requirement 18, sections 200, 302, 303, 500, and 700.

Table 200-20 Corresponding NQA Sections (Parts I and II) to ANSI/ANS 15.8

NQA-1, Parts I and II	ANSI/ANS 15.8
No corresponding requirement	2.19 Experimental Equipment
No corresponding requirement	3.5 Operating Conditions
No corresponding requirement	3.6 Operational Authority
No corresponding requirement	3.7 Control Area
No corresponding requirement	3.8 Ancillary Duties
No corresponding requirement	3.9 Emergency Communications
No corresponding requirement	3.14 Operator Aid Postings
As applicable	4 Applicability to Existing Facilities
As applicable	5 Decommissioning

GENERAL NOTE: NQA-1 is more prescriptive in specifying the quality assurance requirements for existing nuclear facilities and decommissioning of nuclear facilities in accordance with NQA-1, Parts I and II.

RECOMMENDATIONS: There are additional requirements needed to meet ANSI/ANS 15.8 Requirements.

(a) ANSI/ANS 15.8 defines specify controls over the design, fabrication, installation, and modification of experimental equipment that impact safety-related items, per para. 2.19.

(b) ANSI/ANS 15.8 requires management to provide sufficient resources in personnel and materials to conduct operations per para. 3.1. See Recommendation in Table 200-2.

(c) ANSI/ANS 15.8 requires preoperational checks, equipment diagnostic checks, documentation of operating status, and notification of abnormal situations per para. 3.5.

(d) ANSI/ANS 15.8 establishes a method and checklists for conducting operations, shift responsibilities, prework documentation review, and turnover briefing per para. 3.6.

(e) ANSI/ANS 15.8 defines control room procedures per para. 3.7.

(f) ANSI/ANS 15.8 requires no ancillary duties for operators during operations per para. 3.8.

(g) ANSI/ANS 15.8 enables effective emergency communications per para. 3.9.

(h) ANSI/ANS 15.8 defines requirements for operator aid postings per para. 3.14.

Table 200-21 Corresponding NQA Sections (Part II) to ANSI/ANS 15.8

NQA-1, Part II Subparts	ANSI/ANS 15.8
2.1 Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants	No corresponding requirement
2.2 Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Facilities	No corresponding requirement
2.3 Quality Assurance Requirements for Housekeeping for Nuclear Facilities	No corresponding requirement
2.4 Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities	No corresponding requirement
2.5 Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Facilities	No corresponding requirement
2.7 Quality Assurance Requirements for Computer Software for Nuclear Facility Applications	No corresponding requirement
2.8 Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Items for Nuclear Facilities	No corresponding requirement
2.14 Quality Assurance Requirements for Commercial Grade Items and Services	No corresponding requirement
2.15 Quality Assurance Requirements for Hoisting, Rigging, and Transporting Items for Nuclear Power Plants	No corresponding requirement
2.18 Quality Assurance Requirements for Maintenance of Nuclear Facilities	No corresponding requirement
2.20 Quality Assurance Requirements for Subsurface Investigations for Nuclear Facilities	No corresponding requirement
2.22 Quality Assurance Requirements for Management Assessment and Quality Improvement for Compliance With 10 CFR 830 and Department of Energy (DOE) Order 414.1 for DOE Nuclear Facilities	No corresponding requirement

RECOMMENDATIONS: There are major additions that need to be included in an existing ANSI/ANS 15.8 quality program to meet the additional unique requirements contained in these subparts.

SUBPART 4.2
Guides on Application of NQA-1 to Work Processes and Activities

SUBPART 4.2.1
Guidance on Graded Application of Nuclear Quality Assurance (NQA) Standard for Research and Development

100 INTRODUCTION

101 Research and Development and Conventional NQA Applications

Application of the provisions of the Nuclear Quality Assurance (NQA) Standard to nuclear and non-nuclear research and development (R&D) activities extends the scope of this Standard from nuclear design, production, construction, and operational activities to basic research, applied research, and development work. The NQA Standard can be applied to R&D, based on the nature of the activities. This Subpart provides guidance for use of the NQA Standard for R&D work.

The basic products of R&D are knowledge and technology supported by data, which generally can be validated and replicated. A graded approach based on importance and significance of activities is key to the successful application of the NQA Standard to R&D activities.

The remainder of this Subpart discusses R&D QA through Peer Review (section 200), QA Graded Approach (section 300), QA R&D Applications (section 400), R&D QA Glossary of Terms (section 500), and Application of NQA-1 to R&D Activities (section 600).

102 The Quality and Nature of Research and Development Work

The term *research and development* includes two types of activities. The first type is scientific (i.e., work that results in the advancement of knowledge or development of technology), and the second type of activity is secondary in nature and supports R&D science (e.g., procurement, maintenance, and operation of facilities).

Good practices traditionally have been followed by the R&D community to ensure the quality of its work. Practices to ensure quality of research include peer review and publication of results in refereed journals. Maintenance of records to describe R&D events and ensure their reproducibility includes the use of laboratory notebooks for documentation. Alternate means of data recording and storage, e.g., electronic media, may be used for large volumes of data.

103 Research and Development in the Technology Life Cycle

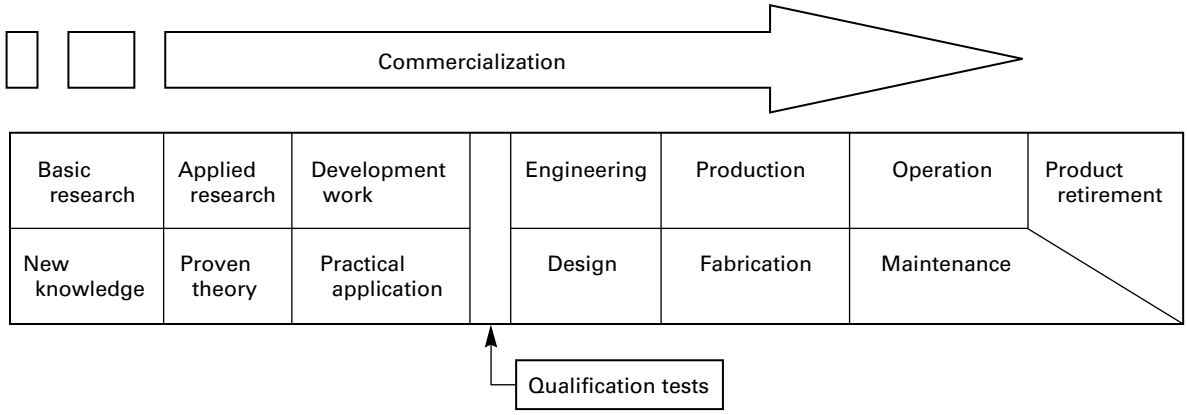
The technology life cycle is depicted in Fig. 103. The figure shows the progression of technology development, commercialization, and retirement in process phases of basic and applied R&D, engineering and production, and operation until process completion. The life cycle is characterized by flexible and informal quality assurance activities in basic research, which becomes more structured and formalized through the applied R&D stages.

103.1 Basic Research. Basic research is conducted to acquire and disseminate new knowledge of a theoretical or experimental nature. It does not always lend itself well to a priori establishment of predetermined results. The timetable for completion of basic research tasks in preparation for the definitive measurement generally cannot be predicted to a high degree of accuracy. By its very nature, the basic research phase of R&D is subject to the highest level of uncertainty, clouding the issue of predetermined results. The results of testing a basic research hypothesis will always be useful, by definition, because they could not be predicted with certainty. Most basic research is predicated on previous work and guided by hypothesis testing, with the hypothesis providing the framework of bounded uncertainty for the activity.

However, QA principles do apply to basic research work. Even in basic research, work is broken down into a series of tasks, with anticipated results and anticipated milestones. A series of assumptions is either confirmed or not. When assumptions are not confirmed, work is redirected through a planning activity.

Basic research is subject to the same success criteria that govern applied R&D work.

Fig. 103 Technology Life Cycle



(a) A hypothesis is defined and tested in a planned way with a statement of qualification conditions.

(b) Variability and uncertainty conditions are identified and accounted for in stating expectations of experimental results.

(c) Methodology and results are documented to describe all elements of inquiry, regardless of the results.

(d) Results are validated through a peer review process.

(e) Results can be reproduced by qualified personnel in the field being investigated.

103.2 Applied Research. Applied research is a process initiated with the intent of solving a specific problem or meeting a practical need. Successful results may be applied to a future development activity. Proof of principle usually occurs in the applied research stage, and with its more explicit objectives, warrants a set of milestones. This leads to the need for a records system that can protect patent rights by ensuring an orderly procedure for maintaining the necessary documentation. Good data and documentation are needed to ensure reproducibility of results, an essential element of good work practice, whether it is basic or applied science or development work.

103.3 Developmental Work. Development activity entails the application of proven theory and experimental results and their extension to its end use, e.g., use in a design environment. Because the developmental objective may be to accomplish goals that have not been achieved previously, a degree of uncertainty exists as to the ultimate success of the effort. A plan that governs a developmental activity leads to a more structured management of the process. Developmental tests define performance boundaries. Qualification tests confirm predicted performance. Tests, with or without acceptance criteria, are prescribed with requirements commensurate with the complexity and scale of the effort, and with the associated risk to the public and workers, to the environment, and to the success of the project.

103.4 Research and Development Support Activities. Support activities are those that are conventional and secondary in nature to the advancement of knowledge or development of technology, but allow the primary purpose of the work to be accomplished in a credible manner. An example of a support activity is the calibration of a measurement instrument.

104 Research and Development Process Interfaces and Continuity

The process interfaces between basic, applied research, and development phases afford an opportunity for technology life-cycle quality problems, analogous to the design interface challenges of a manufacturing operation. By ensuring a consistent application of QA principles to R&D activities, the transition from development to engineering can be accomplished smoothly, and design quality problems can be minimized. Traditionally, research activities are performed as discrete tasks rather than integrated efforts. For basic research, where uncertainty is a significant operational factor, the lack of a life-cycle approach is understandable. However, the development stage of the technology cycle can be treated from an integrated process perspective, anticipating the needs of the engineering phase of the cycle.

200 RESEARCH AND DEVELOPMENT QUALITY ASSURANCE THROUGH PEER REVIEW (15)

The peer review activity can be quantitative or qualitative in nature, depending on the work being evaluated. Peer review is a primary quality assurance mechanism for basic research. Basic research peer review may require intuition on the part of the reviewers to appreciate the creative and innovative characteristics being explored. Applied research peer reviews may rely on quantitative analyses to assess the accuracy of the original results. Developmental peer review may resemble an independent design review in its verification of proof of principle.

Part IV, Subpart 4.2.7 contains additional guidance on peer review.

300 A GRADED APPROACH

Graded approach is the application process for administrative controls. It is a process by which the level of analysis, extent of documentation, and degree of rigor of process control are applied commensurate with their significance, importance to safety, life-cycle state of a facility or work, or programmatic mission.

Broken into a basic format for application, the following evaluations of importance or significance are made for each contemplated activity:

(a) relative significance of accomplishing the proposed R&D work to the prospective customer, the proposing organization, and stakeholders, i.e., the value of the work

(b) relative priority for accomplishing the work to the prospective customer, the organization, and the stakeholders, i.e., the ranking of the activity relative to similar activities

(c) potential consequences to customers, the organization, and stakeholders resulting from doing (or not doing) the work

(d) technological impact of producing invalid data or loss of essential data due to avoidable events

(e) probability of occurrence of postulated consequences

The aggregated results of the above evaluations indicate the relative need to impose controls on activities.

Significance and priority allow categorization of R&D activity. This categorization defines the level of importance of the project, and allows determination of the set of evaluation criteria that needs to be applied to the R&D activity. The evaluation criteria will define the set of control systems needed to ensure success.

The need to meet success criteria is the fundamental consideration in grading the application of control systems. It is not just associated with environment, safety, and health (ES&H) concerns. The graded approach addresses the relative importance to any success factor, including safety, the environment, public health, programmatic mission, and profitability. It provides the quantitative and qualitative expression of possible loss, which considers both the probability of an event occurrence causing harm or loss, and the consequences of the event.

The leader of a research project (i.e., the one responsible for the quality of the research) is responsible for overall quality and for satisfying client expectations. This may include R&D and support work processes that directly affect the quality of the research.

Imposing NQA-1 requirements that are unnecessary or inappropriate can result in excessive expenditure of funds. Not imposing NQA-1 requirements that are applicable can result in discrepant conditions that require rework (or corrective actions) that will generally cost more than doing the job right the first time. Balancing the application of process controls with need (i.e., do the right thing to achieve performance objectives) provides an efficient work process. The primary reason for documenting R&D and support work processes is to provide staff with the basis for exercising good judgement in foreseeable circumstances, and providing them with the means to do so.

The following (paras. 301 through 303) is summary guidance for using the graded approach within each phase of R&D work.

301 Basic Research

In basic research, grading is accomplished at the discretion of the researcher. The graded approach or risk assignment is normally not documented or formalized.

302 Applied Research

During applied research, grading is defined at the project or program level. Grading is minimal and is largely contingent upon the complexity of the research and the ability to duplicate the research if data were lost. The application of quality criteria may be minimal.

303 Development Work and Research and Development Support Activities

Grading in this phase is formalized. Work processes and supporting activities are graded with regard to safety considerations, cost, schedule, and programmatic mission, e.g., importance of data accuracy. The graded approach, methods of implementation, and documentation are formally defined.

400 QUALITY ASSURANCE RESEARCH AND DEVELOPMENT APPLICATIONS

The NQA requirements can be tailored to R&D activities by considering the operational characteristics of the work process as well as examining all of the success factors for a high-quality end product in terms of risk management. The elements of a graded approach should be integrated into the work process, appropriate to the work function and tailored to meet operating needs. Aspects of hazard identification and risk management should be reflected in work process activities to ensure that risks associated with doing business (i.e., project work) are handled effectively. Expression of risk considerations must be contained in policies and procedures that give guidance and direction for R&D activities. Risk is an all-encompassing concern that includes public safety, environmental impact, project cost, and perceived usefulness of data.

Quality assurance will apply in varying degrees to the broad spectrum of R&D both in nuclear and nonnuclear facilities. The degree of application should

depend on user and client mutual agreement. Other source requirement documents (e.g., code of federal regulations, consensus standards) can be used as the basis for a quality assurance program. Commonality of requirements exists in all quality requirement sources documents and can be related to NQA-1 for application.

A graded approach to project risk management should be followed; risk evaluation criteria will be reflected throughout the stages of the technology project life cycle. Risk determinations are made before and during the project design phase, and are re-evaluated during the life of the project when design changes occur or research results indicate the need to do so. To ensure effective risk management, a set of risk evaluation criteria should be established during project design, and carried forward and updated as needed during the life of the project. Risk is a concern that extends beyond ES&H factors; it must be considered in all aspects of work, including business objectives. Supplementary guidance and recommendations for the application of NQA-1 to R&D activities follow the definitions in section 500 of this Subpart.

500 RESEARCH AND DEVELOPMENT QUALITY ASSURANCE GLOSSARY OF TERMS

applied research: a process, the objective of which is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met.

basic research: a process, the objective of which is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward processes or products in mind.

development: systematic use of the knowledge or understanding gained from research, directed toward the creation of useful materials, devices, systems, or methods, including prototypes and processes.

graded approach: the process by which the extent (level of rigor) of application of controls and verification efforts is determined on the basis of the importance and significance of activities, and associated consequences of the activities.

peer review: a critical review of research and development work that is performed by one or more individuals who collectively have scientific expertise at least the equivalent of those who performed the work.

referee process: a peer review performed by an individual(s) independent of the organization doing research and/or development, prior to publication of the results of that research and development in a technical journal.

risk: a quantitative or qualitative measure of the likelihood and unfavorable consequence of an action. Consequences may be related to public or employee safety, the environment, programmatic impact, cost, schedule, or public perception.

support activities: secondary actions associated with R&D work that are conventional in nature and allow the primary purpose of work to be accomplished.

600 APPLICATION OF NQA-1 TO RESEARCH AND DEVELOPMENT ACTIVITIES

In Table 600-1 of this Subpart, it is noted that all requirements of NQA-1 apply to R&D support activities. Guidance is provided on how to apply NQA-1 Part I requirements using a graded approach in paras. 601 through 618 of this Subpart. When considering software within the R&D environment, there are two types of software efforts that can be undertaken: the software effort is a tool supporting the project, and software is a deliverable of the project. Table 600-2 of this Subpart is a subset of Table 600-1 for software and provides the minimum considerations on grading software used within R&D (based on the two types of software efforts).

601 NQA-1, Requirement 1: Organization

601.1 General. An organization should be defined for R&D work to describe roles, responsibilities, and authorities that support achievement of work objectives. Interface responsibilities should be defined between R&D and support functional elements.

601.2 Basic Research. An authoritative relationship should be defined for basic research. It should identify those involved in collaboration and peer review activities to document the credibility of the research process.

601.3 Applied Research. The relationship of those performing specific tasks in applied research should be defined to ensure task objectives are met individually and collectively.

601.4 Development and Support. Roles, responsibilities, and authorities should be defined for development and support activities. They should address those doing the work and those who perform independent verification that work objectives have been met. Interface responsibilities with design and engineering functions should be defined, as appropriate, to ensure that developmental results are useable.

602 NQA-1, Requirement 2: Quality Assurance Program

602.1 General. A graded approach based on importance and significance of activities is key to the successful application of the NQA standard to R&D activities. The R&D quality assurance program should be based on the proven processes that govern the performance of successful scientific research. Highly qualified and

Table 600-1 Applicability to Research and Development Activities

NQA-1, Part I, Requirements	Research and Development Activities			Research and Development Support Activities
	Basic	Applied	Development Work	
1 Organization	Note (1)	Note (1)	Note (1)	Note (1)
2 Quality Assurance Program	Note (1)	Note (1)	Note (1)	Note (1)
3 Design Control	Note (2)	Note (3)	Note (1)	Note (1)
Software	Note (3)	Note (3)	Note (1)	Note (1)
4 Procurement Document Control	Note (1)	Note (1)	Note (1)	Note (1)
5 Instructions, Procedures, and Drawings	Note (3)	Note (3)	Note (3)	Note (1)
6 Document Control	Note (1)	Note (1)	Note (1)	Note (1)
7 Control of Purchased Materials, Items, and Services	Note (1)	Note (1)	Note (1)	Note (1)
8 Identification of Control Items	Note (1)	Note (1)	Note (1)	Note (1)
9 Control of Processes	Note (3)	Note (3)	Note (1)	Note (1)
10 Inspection	Note (2)	Note (2)	Note (3)	Note (1)
11 Test Control	Note (2)	Note (3)	Note (1)	Note (1)
Computer Program	Note (3)	Note (3)	Note (1)	Note (1)
12 Control of Measuring and Test Equipment	Note (3)	Note (3)	Note (1)	Note (1)
13 Handling, Storage, and Shipping	Note (1)	Note (1)	Note (1)	Note (1)
14 Inspection, Test, and Operating Status	Note (3)	Note (3)	Note (1)	Note (1)
15 Control of Nonconforming Items	Note (2)	Note (2)	Note (2)	Note (1)
16 Corrective Action	Note (3)	Note (3)	Note (1)	Note (1)
17 Quality Assurance Records	Note (1)	Note (1)	Note (1)	Note (1)
18 Audits	Note (3)	Note (3)	Note (1)	Note (1)

NOTES:
(1) Applicable.
(2) No applicability for R&D activity.
(3) Graded applicability with explanation.

Table 600-2 Software Within Research and Development

	Tool	Deliverable
Basic	Define the software and use, configuration management, peer review	Software is not a deliverable at this stage of development
Applied	Req. 3 (401), defining the software and configuration management (e.g., 801.2 and 802 of Req. 3)	Req. 3 (800), Req. 11 (software req./para.)
Development and support	Software requirements within Parts I and II (consider guidance material, such as Sp. 3.2-2.7)	Software requirements within Parts I and II (consider guidance material, such as Sp. 3.2-2.7)

motivated people who are engaged in selective investigation activities, that are carefully reviewed by independent competent peers, will turn out documented results that are verifiable and able to withstand scrutiny by reviewers, potential users, and the entire research community.

602.2 Basic Research. Basic research is that phase of the research and development process that is subject to the greatest uncertainties; therefore, it does not lend itself to predetermination of results. Accomplishing the tasks necessary to perform proposed measurements often means breaking new ground in instrumentation or in computational techniques. The timetable for completion of these tasks in preparation for the ultimate measurements generally cannot be predicted because of the obstacles or uncertainties that are frequently encountered. Notebooks of investigators and other collected data assume great importance as evidence of what was done and the methods that were employed. Often, the methods are innovative and cannot be identified with standard procedures; therefore, laboratory notebooks become an important component of the research documentation. The ultimate judgement of the quality of a basic research effort is rendered through peer reviews. Prior awareness of these procedures prompts researchers to ensure research quality.

602.3 Applied Research. The goal of applied research is to solve a specific problem or meet a practical need. In general, applied research is more amenable to the predetermination of results than is basic research. Applied research should be accompanied by more documentation than basic research; research plans, testing, record keeping, and periodic reports commensurate with the scope of a given project may all be present. The peer review process can augment the application of these elements; this, too, will depend upon the magnitude and complexity of the project.

602.4 Development and Support. Development activity entails the application of a proven theory and its extension to a practical situation. The plan that governs a developmental activity leads to a more structured management of the entire process. For example, progress is measured against a predetermined set of results that appear to be appropriate at the outset. However, there are sufficient technical uncertainties in a development project to warrant some flexibility. This is frequently taken into account in the formality associated with the preparation and revision of design and process documentation, and by including in the milestones a plan for evaluating performance at various key junctures during the project. Tests are prescribed with requirements commensurate with the complexity and scale of the work, and with the associated risk to the public, workers, and environment and the future success of the project.

603 NQA-1, Requirement 3: Design Control

603.1 General. The NQA-1 design criterion applies to engineering design definition, verification, and change control in all phases of R&D using a graded approach. Software Design Control (section 800) as an element of Requirement 3 provides for special considerations for software design in order to provide a traceable product that can be reviewed (e.g., peer review). Design control does not apply to design of experiments or experimental plans for basic and applied research; design of experiments and experimental plans should be addressed under Requirement 2.

603.2 Basic Research. Design control does not apply to research for expanding fundamental knowledge.

603.2.1 Software Design Control. The nature of software efforts, whether as a tool supporting research and development or software as the deliverable itself, benefits from the documentation of the software development process. As such, it is important to provide documentation of the development process in order to provide a traceable process to aid in peer review. Additionally, procurement and corrective action should be applied as appropriate to the effort.

603.3 Applied Research. As the applied research matures, design control including software design control, commensurate with that activity (using a graded approach), should be used to support subsequent development work.

603.4 Development and Support. For development and support activities, the level of design control should be applied to support the input needs of the design process. (For software design control, Subpart 2.7 should also be considered.) In some cases, considerable importance is placed on R&D results to demonstrate the acceptability of innovative design.

604 NQA-1, Requirement 4: Procurement Document Control

604.1 General. This element is applicable to R&D activities. The application approach should be to anticipate the needs of the next phase of the R&D life cycle.

604.2 Basic Research. The graded application of this requirement to basic research should be consistent with the maturity of the research. For example, if final results of the work are expected in the next stage of the work, and if the pedigree of materials being used could influence the usefulness of the results of the work during applied research, procurement document specifications should be controlled appropriately.

604.3 Applied Research. As the applied research matures toward an expected completion point, procurement document control should be applied to support the anticipated needs of future development work.

604.4 Development and Support. For development and support activities, the level of procurement document control should be applied to support a commercial design basis, i.e., engineering design system criteria.

605 NQA-1, Requirement 5: Instructions, Procedures, and Drawings

605.1 General. Activities should be planned to the extent possible. R&D work does not always lend itself to preplanned instructions and procedures; however, sufficient documentation should be developed to ensure replication of the work. The researcher/developer should document work methods and results in a complete and accurate manner.

605.2 Basic Research. When appropriate, basic research should be documented in proposals, conceptual drawings, sketches, and notebooks. The level of documentation should be sufficient to withstand a successful peer review. Protocols on generation and safeguarding of data and process development from basic research should be developed if needed for consistency of R&D work.

605.3 Applied Research. The work proposal for applied research should describe the methods of reaching the objectives of the applied research. As work progresses, the researcher should document the work in instruction, procedures, and drawings. These instructions, procedures, and drawings will serve as guidance for subsequent development work.

605.4 Development and Support. Activities should be performed in accordance with documented instructions, procedures, or drawings, as directed by the researcher/developer.

606 NQA-1, Requirement 6: Document Control

This element is applicable to R&D activities. As a minimum, laboratory notebooks should be subject to document control procedures. Also, the process for development of intellectual property documentation should be subject to document control.

607 NQA-1, Requirement 7: Control of Purchased Materials, Items, and Services

This element is applicable to R&D activities. The degree of application should support the desired results of the work, within the specified performance boundaries. The need to ensure conformance with specified requirements depends on the objectives of the work. If the quality of work results depends on the pedigree of materials, items, or services, the work should be planned to include this Requirement.

608 NQA-1, Requirement 8: Identification of Control Items

This element is applicable to R&D activities. The degree of application should support the desired results of the work, within the specified performance boundaries. If the quality of work results depends on the pedigree of materials or items (e.g., analytical chemistry), this Requirement applies.

609 NQA-1, Requirement 9: Control of Processes

609.1 General. The control of processes varies considerably as one advances from basic research through development.

609.2 Basic Research. In basic research, control of processes is left to the researcher to define. Process control is normally recorded in a laboratory notebook.

609.3 Applied Research. During applied research, process control is defined as the process is better understood. Process control is minimal and is largely contingent upon the complexity of the research and the ability to duplicate the research if data were lost. Process control instructions may be defined in laboratory notebooks or operating logs.

609.4 Development and Support. Process control during this phase is formalized. Formalization occurs at the project or program level. Work processes and supporting activities are defined, and work and operating procedures are developed and implemented with respect to safety considerations, quality, cost, schedule, and programmatic mission. Methods of implementation and training requirements are formally defined.

610 NQA-1, Requirement 10: Inspection

610.1 General. Basic and applied research activities are not amenable to inspection. Consideration may be given to performing inspection-like activities on basic and applied research to establish process or product control limits.

610.2 Basic Research. This criterion does not apply to basic research because it requires work to be inspected to predetermined acceptance criteria.

610.3 Applied Research. This criterion does not apply to applied research because it requires work to be inspected to predetermined acceptance criteria.

610.4 Development and Support. The researcher/developer should anticipate the need and plan for inspection criteria for advanced development work to interface with design process needs.

611 NQA-1, Requirement 11: Test Control

611.1 General. Within the Standard, this Requirement encompasses testing activities, testing to collect data, and computer program testing. Computer program testing is an activity where documentation, such as to aid review (peer review), should be specified and documented. For testing to collect data, when

deemed applicable, test methods and characteristics shall be documented and the approaches and procedures recorded. Test control does not apply to basic and applied research activities in which hypotheses are being evaluated. It does apply to support activities associated with the conduct of research.

611.2 Basic Research. Test methods are not well defined and are usually determined by the researcher as work progresses.

611.2.1 Computer Program. The nature of software efforts, whether as a part (or tool) of the effort being undertaken or the effort itself, benefits from the documentation of testing efforts. As such, it is important to provide documentation of the testing activities in order to provide a traceable process to aid in peer review.

611.3 Applied Research. Test control can be specified to the degree that scientific knowledge is understood. These test procedures will serve as guidance for subsequent development work.

611.4 Development and Support. Characteristics to be tested and test methods should be specified. The test results should be documented and their conformance to acceptance criteria evaluated. Tests required should be planned, executed, documented, and evaluated. Testing as part of computer program testing should consider Subpart 2.7.

612 NQA-1, Requirement 12: Control of Measuring and Test Equipment

612.1 General. The researcher should specify the requirements of accuracy, precision, and repeatability of measuring and test equipment (M&TE). These requirements have different implications for basic, applied, and development work.

612.2 Basic Research. In basic research, calibration might not be necessary during the initial (or scope-setting) stages of an activity.

612.3 Applied Research. Depending upon the need for accuracy, precision, and repeatability of M&TE used in research, standard M&TE procedures should be followed. Where standard M&TE procedures are not used, effects of the instrument's performance on the uncertainty of the measurements and tests should be considered in the research.

612.4 Development and Support. During the process development stage and for all R&D support activities, M&TE should be controlled. The degree of control should be dependent on the application of the measurement.

613 NQA-1, Requirement 13: Handling, Storage, and Shipping

This element is applicable to R&D activities. Good laboratory practices may be defined as instructions used for conducting the activity.

614 NQA-1, Requirement 14: Inspection, Test, and Operating Status

614.1 General. This criterion has limited applicability for R&D activities.

614.2 Basic Research. Inspection, test, and operational status of equipment or systems that support research are controlled at the discretion of the researcher.

614.3 Applied Research. The status of items and processes that have inspection and test requirements specified by the researcher should be identified by indicators such as tags, markings, or other suitable means.

614.4 Development and Support. The status of items and processes for which inspections and tests are specified, should be identified by tags, markings, inspection and test records, or other suitable means. The authority for application and removal of inspection and test identification should be specified.

615 NQA-1, Requirement 15: Control of Nonconforming Items

This Requirement should apply only to R&D support activities. The results of R&D activities are not expected to meet predetermined requirements; therefore, obtaining unexpected results does not constitute a nonconforming condition. The point at which a nonconformance can be identified is the point at which development work has transitioned into design or production of engineered items.

616 NQA-1, Requirement 16: Corrective Action

616.1 General. Conditions adverse to quality can be identified for R&D activities, depending on the certainty of operating assumptions and expected results. The documentation, reporting, and tracking of conditions adverse to quality is done at the discretion of the researcher.

616.2 Basic Research. The use or formality corrective action identification and tracking systems is defined by the researcher(s), depending on the need to transmit information to peers.

616.3 Applied Research. The formality of corrective action identification and tracking systems to be used is defined by the researcher(s), depending on the need to transmit information to peers.

616.4 Development and Support. Responsibility should be defined for the identification, cause, and corrective action for significant conditions adverse to quality; these should be documented and reported to

appropriate levels of management. Follow-up actions should be taken to verify implementation and effectiveness of corrective action.

617 NQA-1, Requirement 17: Quality Assurance Records

This element is applicable to R&D activities. In many cases, the notebook or journal of the researcher is the QA record. Controls are needed for these documents, e.g., maintain copies of critical pages or access-controlled filing when not in use to preserve process repeatability and the QA record. Electronic media may be used to record data and should be subject to appropriate administrative controls for handling and storage of data.

618 NQA-1, Requirement 18: Audits

618.1 General. Planned requirements are not always defined for R&D work; therefore, audits should be conducted in a graded manner. R&D audit activities include normally accepted assessment practices, peer reviews, or both.

618.2 Basic Research. For basic research, the objectives of the audit process may be achieved as a part of peer review activities if the peer review process is sufficiently comprehensive.

618.3 Applied Research. As knowledge gained by basic research matures through applied research, audits should be used in conjunction with peer reviews to support subsequent development work.

618.4 Development and Support. Responsibility should be defined for audits and the results of these audits should be documented and reported to appropriate levels of management. Follow-up actions should be taken to verify implementation and effectiveness of corrective action.

700 TECHNOLOGY LIFE CYCLE (SUBPART 4.2.1) AND TECHNOLOGY READINESS LEVELS

This Subpart considers the technology life cycle in terms of basic and applied R&D, development, and engineering work. Other groups (who might use this Subpart) use other technology life-cycle terminology. One such technology life cycle is known as Technology Readiness Levels (TRLs). TRLs are an approach used by major companies and agencies around the world and some U.S. government agencies (e.g., National Aeronautics and Space Administration, Department of Defense) to assess the maturity of evolving technologies (materials, components, devices, etc.) prior to incorporating technology into a system or subsystem. Table 700 provides the relationship of the technology life cycle contained in this Subpart with TRLs, allowing a user of the Subpart to apply the guidance to other more common terminology.

Table 700 Comparison of Subpart 4.2.1 Technology Life Cycle and Technology Readiness Levels

NQA-1 Subpart 4.2.1 Guidance	Technology Readiness Levels Used by Others
Basic research	*TRL 1 Basic Technology Research*. Basic principles observed and reported. Lowest level of technology readiness. Scientific research begins to be translated into applied research and development.
Basic research	*TRL 2 Research to Prove Feasibility*. Technology concept and/or application formulated. Invention begins. Applications are speculative, and there may be no proof or detail analysis to support assumptions.
Applied research	*TRL 3 Research to Prove Feasibility*. Analytical and experimental critical function and/or characteristic proof of concept. Active research and development is initiated. Analytical and laboratory studies to physically validate analytical predictions.
Applied research	*TRL 4 Technology Demonstration*. Component and/or system validation in laboratory environment. Integrate basic technological components to establish low fidelity integration.
Developmental work	*TRL 5 Technology Demonstration*. Laboratory scale, similar system validation in relevant environment. Fidelity of technology increases. Integrate basic technological components with reasonably realistic supporting elements, and test in simulated environment.
Developmental work	*TRL 6 Technology Demonstration*. Engineering/pilot-scale, similar (prototypical) system validation in relevant environment. Develop a representative model or prototype system, and test in a relevant environment.
Developmental work	*TRL 7 Technology Demonstration*. Full-scale, similar (prototypical) system demonstrated in relevant or operational environment.
NQA-1 (i.e., outside Subpart 4.2.1 and into a graded application of NQA-1)	*TRL 8 System Commissioning*. Actual system completed and qualified through test and demonstration.
NQA-1 (i.e., outside Subpart 4.2.1 and into a graded application of NQA-1)	*TRL 9 System Operations*. Actual system operated over the full range of expected conditions.

GENERAL NOTE: This Table used the following references:

(a) DOE/EM Technology Readiness Assessment (TRA)/Technology Maturation Plan (TMP) Process Guide, March 2008 (Tech Readiness Levels taken from DoD).

(b) Technology Readiness Levels, A White Paper, dated April 6, 1995.

(c) Policy, information, and guidance on the Technology Management aspects of UK MOD Defence Acquisition version 1.0.2, December 2009.

(d) DoD 500.1-R, Mandatory Procedures for Major Defense Acquisition Programs and Major Automated Information Systems Acquisition Programs, April 5, 2002.

SUBPART 4.2.2
Guidance for Managing Electronic Information

100 INTRODUCTION

Information management, traditionally referred to as records management and document control, has historically focused on controlling the transmittal, retention, storage, retrieval, and disposition of records and documents. These records and documents have existed in media capable of meeting existing regulatory and standards requirements for permanent storage or archival (e.g., microform, paper).

While improving many business processes (including supply management, engineering design, and plant maintenance and operations), the use of digital technology has resulted in new mediums for records. As a result, the need to apply NQA-1 criteria and the process requirements to meet the criteria, historically applicable to paper and microform, to the records requirements of electronic information was addressed in a revision of Part I Requirement 17, Quality Assurance Records.

This Subpart provides guidance for applying the requirements of NQA-1 Part I to managing electronic information, including data base data, electronic files, and electronic images.

The Introduction to NQA-1 Part I provides definitions for document, electronic document, and quality assurance record; no clarifying definition is required for data. It should be understood that data, in a defined aggregate, can constitute a body of information equal to the definition of a document, electronic document, or quality assurance record. For example, individual data elements entered into an electronic surveillance checklist may be equated to a quality assurance record.

200 ELECTRONIC DOCUMENTS

Part I, Requirement 6, Document Control, provides requirements applicable to documents, which include electronic documents. Examples of electronic documents that may exist in the following electronic formats are

(a) scanned images

(b) native file formats (e.g., word processing files, spreadsheet files)

(c) information captured in a format that might be found in devices such as a Personal Digital Assistants (PDAs), or

(d) nonalterable format (e.g., PDF conversion)

When the Requirement 6 criteria can be met without the development of computer programs, there should be no need to apply Part II Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Application. For example, when commercially available computer programs are used for viewing electronic documents (e.g., Adobe Acrobat), there should be no need to apply Part II Subpart 2.7 to these computer programs.

When the Requirement 6 criteria are to be met through the development of computer program(s), a Part II Subpart 2.7 applicability review should be performed and appropriate requirements invoked. For example, if a computer program will be the only source of the document index, Part II Subpart 2.7 may be applicable. If a computer program will control the document review and approval process with no manual tracking, Part II Subpart 2.7 may be applicable. Part II Subpart 2.7 guidance can be found in Subpart 3.2-2.7, Implementing Guidance for Part II, Requirement 2.7: Quality Assurance Requirements for Computer Software for Nuclear Facility Applications.

Guidance for managing electronic documents can be found in the Nuclear Regulatory Issue Summary, Guidance on Managing Quality Assurance Records in Electronic Media (RIS 2000-18, dated October 23, 2000), and other industry publications related to electronic document management (e.g., NIRMA Technical Guidelines[1]).

300 ELECTRONIC RECORDS

Part I, Introduction, links the definition of *electronic document* to *document* and then to *quality assurance record*. By extension, the definition of quality assurance record should also be applicable to electronic quality assurance records. Hence, Part I Requirement 17 is applicable to electronic records.

When the Part I Requirement 17 criteria can be met without the development of computer programs, there should be no need to apply Part II Subpart 2.7. For

[1] TG11, Authentication of Records and Media; TG15, Management of Electronic Records; TG16, Software Configuration Management and Quality Assurance; and TG21, Electronic Records Protection and Restoration.

example, when commercially available computer programs are used for viewing electronic documents (e.g., Adobe Acrobat), there should be no need to apply Part II Subpart 2.7 to these computer programs.

When Part I Requirement 17 criteria are to be met with the development of computer program(s), a Part II Subpart 2.7 applicability review should be performed and appropriate requirements invoked. For example, computer programs that are developed and implemented to control the approval process of an electronic quality assurance record may require the application of Part II, Subpart 2.7. Guidance for Part II, Subpart 2.7 can be found in Subpart 3.2-2.7.

Guidance for managing electronic records can be found in the Nuclear Regulatory Issue Summary, Guidance on Managing Quality Assurance Records in Electronic Media (RIS 2000-18, dated October 23, 2000), and other industry publications related to electronic document management (e.g., NIRMA Technical Guidelines[1]).

400 ELECTRONIC DATA

Dictionaries generally define data as factual information (e.g., measurements, reference sources, or statistics) used as a basis for reasoning, discussion, or calculation.

By extension, the definition of data can be applied to electronic data. Types of electronic data that can result from activities delineated in NQA-1 include, but are not limited to, the following:

(a) scientific, and site assessment investigation activities, including information extracted from reference sources, and performance assessment analysis

(b) environmental or engineering information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature

(c) engineering designs and design activity

(d) calibration of M&TE and instrument calibrations

(e) operational and maintenance activities

(f) information manually or electronically created but maintained electronically for engineering design inputs/outputs, contracts, and purchase orders

Since electronic management of data is considered an element of electronic information management (hence within the scope of the definition for document, electronic document, and quality assurance record), Part I Requirements 6 and 17 should be considered for applicability to electronic data. As with other forms of quality records, a determination of the need to maintain data as permanent or nonpermanent quality records should be made. The intended use of the electronic data should be considered during this retention determination process. Hence, Part I Requirement 17 should be considered applicable to electronic documents and electronic data that will become an electronic quality assurance record.

Computer programs are usually associated with the electronic management of data. A Part II Subpart 2.7 applicability review should be performed and appropriate requirements invoked. Part II Subpart 2.7 guidance can be found in Subpart 3.2-2.7.

Part I requirements applicable to electronic data should be applied to ensure data accuracy, validity, integrity (over time), and maintainability. Other industry publications pertaining to electronic data (e.g., NRC RIS 2000-18, NIRMA Technical Guidelines[1]) provide guidance for development of computer programs that facilitate meeting those requirements.

SUBPART 4.2.3
Guidance on Qualification of Existing Data

100 GENERAL

This Subpart provides nonmandatory guidance on the qualification of existing data, including data of indeterminate quality, for use in activities specified in Part I. The data qualification process includes data qualification planning, a controlled process for evaluating and establishing data quality, and documentation of the results of this process.

Existing data is defined as data determined to be necessary for activities specified in Part I, but developed prior to the implementation or outside of Part I; or data published in scientific publications. Existing data does not include information that is accepted by the scientific and engineering community as an established fact (e.g., engineering handbooks, density tables, gravitational laws, etc.).

200 SELECTING DATA SETS FOR QUALIFICATION

The identification of data sets to be recommended for qualification should be based on its end use and a consideration of the potential impact on risk, safety, or mission.

300 DATA QUALIFICATION PROCESS

301 Data Qualification Planning

Data qualification planning includes

(a) the reason(s) for qualifying the data

(b) the selected qualification method(s)

(c) the rationale for selecting the methods

(d) the evaluation criteria planned for use in qualifying the data set including specific information such as size of sample to be tested, statistical method to be used, and identification of computer codes to be used

(e) a description of the required technical disciplines and subject matter discipline experts pertaining to the data

(f) the identification of individuals performing the data qualification effort and their requisite qualifications

(g) a schedule for completing the work

302 Data Qualification Preparation

Before initiating a data qualification effort, background information on the subject data set should be collected, including pertinent records concerning any available procedures or documentation of data acquisition or development methodology, and prior reviews of data.

303 Data Qualification Attributes

Attributes to consider in the qualification process include

(a) the technical adequacy of equipment and procedures used to collect and analyze the data

(b) the extent to which the data demonstrate the properties and ranges of interest (e.g., physical, chemical, geological, mechanical)

(c) the environmental conditions under which the data were obtained (if germane to the quality of the data)

(d) the quality and reliability of the measurement control program under which the data were generated

(e) the extent to which conditions under which the data were generated may generally meet the requirements and guidance of NQA-1

(f) prior range of uses of the data and associated verification processes

(g) prior peer or other professional reviews of the data and their results

(h) extent and reliability of the documentation associated with the data

(i) extent and quality of corroborating data or confirmatory test results

(j) the degree to which independent audits of the process that generated the data were conducted

400 QUALIFICATION METHODS

One or more of the following methods should be used to qualify data:

(a) Quality Assurance Program Equivalency

(b) Data Corroboration

(c) Confirmatory Testing

(d) Peer Review

401 Quality Assurance Program Equivalency Method

The Quality Assurance Program Equivalency method may be used to determine if the acquisition, development, or processing of data have been performed in accordance with sound technical, administrative practices or procedures that can be demonstrated to generally meet the applicable requirements and guidance of NQA-1. The employed practices or procedures must demonstrate industry-acceptable scientific, engineering,

or administrative practices or processes with appropriate compliance documentation as defined in data qualification planning. Examples of conditions for which the Quality Assurance Program Equivalency method may be useful include the following:

(a) data acquisition, collection, or development records, including equipment calibration documentation, and personnel qualification records are available

(b) documentation of the technical or administrative practices or procedures used to process the data are available

402 Data Corroboration Method

The Data Corroboration method may be used in order to determine if subject matter data comparisons can be shown to substantiate or confirm parameter values. This method may include comparisons of the data to both other sources of qualified data, as well as to sources of other existing data, as defined in data qualification planning. Examples of conditions for which the Data Corroboration method may be useful include the following:

(a) a sufficient quantity of corroborating data are available to permit valid statistical comparison with the unqualified data set(s)

(b) inferences drawn to corroborate the existing data can be clearly identified, justified, and documented

403 Confirmatory Testing Method

The Confirmatory Testing method may be used when tests can be designed and performed to establish the quality of existing or indeterminate data. Confirmatory Testing also may be used when previous test results are not verifiable as a result of questionable testing methodology or a lack of applicable documentation. Confirmatory test results should demonstrate direct correlation to previous test results, if feasible. However, data extrapolation is acceptable within the limits defined in data qualification planning. Examples of conditions for which the Confirmatory Testing method may be useful include the following:

(a) similar test conditions are prescribed

(b) test result correlation or extrapolations are applicable

(15) 404 Peer Review Method

The Peer Review Method is used to independently evaluate data to determine if the employed methodology is acceptable; confidence is warranted in the data acquisition or developmental results; or the data have been used in a similar range of applications. Use of the Peer Review method for this purpose should include an evaluation of the data acquisition and development approach, including test plans, to determine the acceptability of the uncertainties associated with the employed data acquisition or development methodology, the adequacy and appropriateness of the interpretations derived from the data, and the extent to which the uncertainties affect the interpretations, conclusions, and overall validity of the data. If the evaluation indicates the uncertainties are unacceptable or the data interpretations are inappropriate, this result should be fully documented. A report documenting the peer review activity should be prepared as defined during data qualification planning and provide for the inclusion of any dissenting conclusions and comments by individual peer reviewers.

Part IV, Subpart 4.2.7 contains additional guidance on peer review.

500 DOCUMENTATION OF RESULTS

Results of the data qualification task should be documented in a report that includes

(a) the scope of the task

(b) the data set(s) for qualification

(c) the expertise of the individuals performing the data qualification effort

(d) the method(s) of qualification and rationale for the selected option(s)

(e) the rationale for abandoning any of the qualification methods, if appropriate

(f) evaluation criteria

(g) qualification criteria

(h) data generated by the evaluation (if applicable)

(i) the results of the evaluation

(j) a recommendation for/against changing the qualification status of the data

Management should evaluate the recommendation and disposition of the data appropriately; i.e., if the data set(s) is determined to be "qualified," update the data qualification status from "existing" to "qualified"; or if the data set(s) is determined to be "not qualified," a decision should be made and documented regarding the need to collect more data.

SUBPART 4.2.4
Guidance on the Control of Scientific Investigations

100 GENERAL

This Subpart provides nonmandatory guidance for planning and performing scientific investigations for the collection and evaluation of data related to nuclear facility applications. This guidance should be used in conjunction with NQA-1, Part I requirements and Subpart 4.2.3, Guidance on Qualification of Existing Data, in performance of the subject activities.

101 Definitions

existing data: data determined to be necessary for activities specified in Part I, but developed prior to the implementation or outside of Part I; or data published in scientific publications. Existing data does not include information, which is accepted by the scientific and engineering community as established fact (e.g., engineering handbooks, density tables, and gravitational laws).

sample: a physical part of the whole whose properties are studied to gain information about the whole.

scientific investigation: any observation, identification, description, experimental study, or analysis and explanation of natural phenomena, material, or substance for the purpose of achieving requisite information.

scientific notebook: a record of the methodology and results of scientific investigations that is used when the work involves a high degree of professional judgment or trial and error methods or both.

200 PLANNING AND PERFORMING SCIENTIFIC INVESTIGATIONS

201 Scientific Investigation Planning

Scientific investigation should be planned and coordinated with organizations providing input to or using the results of the investigation. Planning should include provisions for determining the accuracy, precision, and representativeness of results.

202 Performing Scientific Investigations

Scientific investigations should be performed using procedures sufficient to ensure that these activities are adequately controlled and documented. When the use of procedures is not feasible for the particular activity (i.e., a high degree of professional judgement or trial and error methods are required), results of the activity should be documented in scientific notebooks or equivalent.

(a) Scientific notebooks, when used, should contain the following:

(1) statement of objective and description of the work to be performed, or reference to a document that describes the work

(2) methods to be used

(3) identification of any samples or measuring and test equipment used

(4) description of the work as it was performed and results obtained, names of individuals performing the work, and dated initials or signatures, as appropriate, of individuals making the entries

(5) description of changes made to methods used, as appropriate.

(6) identification of any prerequisites, special controls (such as radiological protection), environmental conditions (such as temperature and humidity), or special skills

(7) identification of computer software used

(b) Scientific notebooks should be reviewed by a competent individual(s) or group(s) other than those who created the notebook, but who may be from the same organization, to verify there is sufficient detail to

(1) retrace the investigation and confirm the results

(2) repeat the investigation and achieve comparable results

300 TECHNICAL DATA

301 Data Identification

Data should be identified to provide traceability, indicate usability, and document validation[1] status. Identification and traceability should be maintained throughout the lifetime of the data. Data reduction methods should be described to permit independent reproducibility by another competent individual.

[1] The Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM), NUREG-1575, Rev. 1; EPA 402-R-97-016, Rev. 1; DOE/EH-0624, Rev. 1, provides a nationally consistent consensus approach to conducting radiation surveys and investigations at potentially contaminated sites. It provides the following definitions of data validation and verification that are considered appropriate for use in this Subpart. Data validation involves confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use have been fulfilled. In design and development, verification concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity. Note that NQA-1 uses the term "verification" to include both verification and validation as used in this Subpart.

302 Data Validation, Verification, and Qualification

To the extent appropriate, data collected under Part I requirements should be reviewed to determine suitability for its intended use. The results of the data review should be documented. The reviewer should be independent from the collector (i.e., not directly involved in or responsible for the data collection activity). Validation and verification should not be required for data considered as established fact by the scientific and engineering community.

Data that was not collected under a quality assurance program, including data of indeterminate quality, should be qualified using Subpart 4.2.3, Guidance on Qualification of Existing Data.

303 Data Usage

The selection of data and determination of suitability for use in individual applications should be documented. Data reduction and transfer should be controlled to permit independent reproducibility by another qualified individual.

304 Model Validation

Model usage and model validation documentation should provide adequate justification for the intended use. A model in this context is a representation, often mathematical, of a system, process, or phenomenon, along with any associated hypotheses. Model validation should be accomplished by comparing model analysis results with data acquired from laboratory or field experiments or observations. When data are not available from these sources, alternative approaches (such as peer review or comparisons with data from open literature) should be documented and used for model validation.

400 SAMPLE CONTROL

The following guidance should be considered for the control of samples:

(a) Controls should include identification of sample orientation relative to the location that was sampled, as appropriate.

(b) Sample identification methods should ensure that traceability is established and maintained from the samples to applicable procedures or other specifying documents.

(c) Sample chain of custody should be tracked and documented from the time of collection until final disposition.

(d) Physical markings, when used, should

(1) be applied using materials and methods that provide a clear and legible identification

(2) not detrimentally affect the sample content or form

(3) be transferred to each identified sample part when the sample is subdivided

(4) not be obliterated or hidden by surface treatments or sample preparations unless other means of identification are substituted

(e) Sample control methods should address the following guidance:

(1) If samples have limited use or storage life, methods should be established that preclude using the sample beyond its intended use or storage life. Use of samples beyond their storage life may be permitted when obtaining additional samples is not possible or data resulting from sample analysis will not be affected by exceeding the storage life. Justification for use of samples beyond their storage life should be documented.

(2) If sample storage is required, methods should be established for the control of sample identification that are commensurate with the planned duration and conditions of storage. These methods should provide for

(a) maintenance or replacement of markings and identification tags damaged during handling or aging

(b) protection of identification markings subject to excessive deterioration resulting from environmental exposure

(c) updating related documentation to reflect future intended use

(f) Archiving Samples. Implementing documents should specify the representative samples to be archived.

(g) Handling, Storage, and Shipping. Part I, Requirement 13 should be applied to handling, storage, and shipping of samples.

(h) Disposition of Nonconforming Samples. For samples that do not meet requirements specified in work controlling documents or if the results of sample analysis do not meet desired objectives, it should be identified, documented, evaluated, and the sample should be segregated.

The disposition for nonconforming samples should be identified and documented and should be limited to "use-as-is," "limited use," or "discard."

500 PEER REVIEW

501 General Guidance for Peer Review (15)

Peer reviews should be conducted when the adequacy of information or the suitability of implementing documents and information and methods essential to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards and practice.

Part IV, Subpart 4.2.7 contains additional guidance on peer review.

SUBPART 4.2.5
Guidance on the Transition From Construction to Operation for Nuclear Facilities

100 GENERAL

This Subpart provides nonmandatory guidance on managing the transition from construction to operation for nuclear facilities.

200 APPLICABILITY

The recommendations of this Subpart apply to any organization or individual participating in work related to activities commencing with turnover from construction to testing, continuing through turnover to operations, and ending with the completion of the startup test program. Proper transition is attained by controlling the following activities:

(a) turnover from construction to testing
(b) testing of plant systems and components
(c) turnover to operations
(d) preparation for operation
(e) startup test program

201 Regulatory

In addition, regulatory commitments made during the transition process should be integrated into turnover and testing activities on an ongoing basis. Specific attention should be given to Safety Analysis Report and technical specification reviews including licensee's responses to NRC questions, regulatory and nonregulatory agency requirements, local and state government interfaces, and final certification of readiness for operation. Commitments should be tracked using the licensee's commitment tracking system.

300 TRANSITION RECOMMENDATIONS

301 Turnover From Construction to Testing

Responsibility for components, systems, and areas should be transferred from the construction organization to the testing organization in a controlled manner. Controls should provide for establishing the status of construction phase completion, identifying construction phase testing activities, establishing boundaries and identities, developing interface responsibilities, developing open item and deficiency tracking system(s), maintaining configuration control, establishing rework and turn-back procedures, and evaluating readiness for turnover.

301.1 Construction Phase Testing and Service Activities. The status of construction phase testing and vendor/contractor service activities should be identified and reviewed for completeness. These activities include, but are not limited to

(a) hydrostatic testing
(b) pneumatic testing
(c) flushing and cleaning
(d) calibration, alignment, and testing of mechanical, electrical, and instrumentation and control equipment and systems
(e) initial component/equipment operation
(f) crane/hoist load testing
(g) nondestructive testing
(h) vendor equipment testing
(i) review of systems to support testing, such as hangars, snubbers, supports, insulation, etc.
(j) maintenance activities
(k) preservice inspection

301.2 Boundary Identification. When transferring responsibility, boundaries should be clearly identified and delineated. Particular attention should be given to personnel and equipment protection and safety programs, test status, testability, operability, shared system or facility interfaces, custody identification, and access control.

301.3 Interface. Organizations should clearly understand the transition process in order to ensure that interfaces are coordinated and controlled. Activities to be considered should include, but not be limited to, the following:

(a) maintenance of equipment/components
(b) operation of components and systems
(c) physical identification and jurisdictional controls
(d) plant chemistry
(e) vendor services
(f) testing
(g) system walkdowns
(h) spare and replacement parts procurement and storage

Responsibilities for these activities should be clearly defined and maintained throughout the turnover from construction to testing. When interfaces change during the transition, new interfaces should be established and

understood with the effective time of transition communicated and documented. Particular attention should be given to the interaction of systems and components that are common to multiple facilities. Controls should be established to document and track open items and deficiencies throughout the transition. Deficiencies should be identified and the responsibility for corrective action clearly defined and assigned.

301.4 Configuration Control. The management of configuration control is an ongoing process. During the turnover process, configuration status should be reviewed to ensure that the configuration is maintained and controlled during the testing phase. Specific areas of concern during the testing phase include, but are not limited to

(a) document control
(b) design changes
(c) as-built condition
(d) as-built test documentation
(e) temporary modifications and alterations

301.5 Turnback/Rework/Repair Activities. During the testing phase turnback for rework/repair of components, systems and areas by the responsible work organization should be controlled. Elements of this control include

(a) delineation of organizational responsibilities
(b) identification of system boundaries and system interfaces
(c) development of a work plan that provides for reentry control, cleanliness and chemistry controls, and detailed work controls
(d) requirements for retest, evaluation, and approval
(e) inspection, documentation control, and review

301.6 Readiness for System/Area Turnover. The status of system/area readiness for turnover should be evaluated at designated intervals prior to turnover for test. Walkdowns as performed by knowledgeable personnel in the areas of design, construction, test, operations, and maintenance are an important element in determining readiness. In addition to planned inspections, walkdowns support the test schedule and determine the completeness and acceptability of a system or area.

302 Testing of Plant Systems and Components

An organization(s) with clearly defined responsibilities and organizational interfaces should be established to control testing activities. Specifically, this organization should ensure the adequacy of training and qualification requirements, test program requirements, preparation of test procedures, and the conduct of testing.

302.1 Training and Qualification. Personnel performing testing activities should receive training in the following areas, as applicable:

(a) test program elements as defined in para. 302.2 of this Subpart
(b) modification and temporary alteration process
(c) procedures for handling nonconformances, deficiencies, and engineering evaluation requests
(d) plant tagging system
(e) control and use of test and measuring equipment
(f) document control
(g) set-point requirements
(h) maintenance procedures
(i) work control procedures
(j) environmental controls
(k) chemistry control procedures
(l) vendor services control
(m) regulatory requirements
(n) Safety Analysis Report
(o) plant technical specifications
(p) state and local regulations
(q) regulatory and industry standards
(r) vendor technical manuals
(s) special test requirements
(t) component and integrated system requirements

302.2 Test Program. A test program should be developed that delineates the following requirements:

(a) test scope
(b) form and content of test procedures
(c) review and approval methods
(d) conduct of test
(e) evaluation and verification methods

The test program should utilize plant personnel to the degree practical to enhance their knowledge and plant experience.

302.3 Test Procedure. Test procedures and test documents should be prepared in accordance with industry standards and the plant administrative and operating requirements. Further guidance regarding procedural requirements is contained in ANSI/ANS 3.2 (1988), Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants.

302.4 Conduct of Testing. Testing should be conducted by qualified test personnel in accordance with approved test procedures.

303 Turnover to Operations

Turnover of components, systems, and areas to operations should be accomplished in a controlled manner. This activity should define organizational interfaces, identify turnover package items, track open items and deficiencies, and define jurisdictional controls.

303.1 Organizational Interfaces. Organizational interfaces should be clearly defined and documented to afford an orderly turnover of components, systems, and areas from construction to operations.

303.2 Turnover Package. The scope and status of those items that are to be contained in the turnover

package should be identified. These items include, but are not limited to

(a) documentation of component and system tests, the test results, and the status of testing completeness

(b) system cleanness and chemistry controls that are in effect

(c) an open items list (punch-list that identifies open work, commitments, and incomplete documentation)

(d) outstanding deficiencies

(e) equipment maintenance history records (including preventive maintenance)

(f) available vendor-provided spare parts

(g) special tools and test equipment

A document review should be completed on the turnover package prior to turnover acceptance. Additionally, vendor and contractor services provided by existing contracts should be identified to the operations personnel.

303.3 Tracking Systems. Open items, deficiencies, commitments, and work items identified in the turnover package should be tracked for resolution and completion.

303.4 Jurisdictional Controls. During the turnover process, the jurisdictional responsibility for components, systems, and areas should be clearly defined. The organization with jurisdictional responsibility should ensure use of existing procedures and programs to maintain configuration management, to ensure that access controls are identified and defined, to set forth organizational relationships, to document equipment status and operability requirements, to ensure that personnel safety measures are in place, and to provide work controls so as to provide an accurate knowledge of the status of those portions of the plant under its jurisdiction. If not previously in place, additional procedures governing these controls should be written.

304 Preparation for Operation

In parallel with the turnover of components, systems, and areas, preparation should be made for plant operation. These efforts include, but are not limited to, plant procedure preparation, staffing, training, and qualification requirements.

304.1 Plant Procedures. Plant procedures should be prepared, reviewed, and approved. Procedure content should incorporate industry operating experience feedback, implementation of a lessons-learned program, and corrective action recommendations.

304.2 Staffing, Training, and Qualification. Staffing, training, and qualification requirements should be determined and adequate time allocated to train and qualify personnel for plant positions. The following measures should be considered:

(a) Identify organizational roles, responsibilities, and qualification requirements.

(b) Determine organization composition and develop job descriptions, taking into account previous operating experience, including information contained in regulatory guides, industry standards, and regulatory commitments.

(c) Establish formal training programs for licensed and nonlicensed personnel. Training programs should include provisions for initial and continuing training, as well as qualification and requalification training.

305 Start-Up Test Program

The start-up test program should encompass those functions necessary to load fuel, attain initial criticality, power ascension, and full power operation. The program should be conducted with adherence to licenses, standards, and plant procedures. The start-up test program should delineate

(a) organization responsibilities

(b) organizational interfaces

(c) regulatory and nonregulatory commitments

(d) testing/system interfaces

(e) test review and approval

(f) schedule and tracking systems

(g) test execution, review, and approval

(h) retest execution, review, and approval

(i) resolution of component and system open items and deficiencies

(j) start-up test report submission

The start-up test program should be conducted in accordance with regulatory commitments and guidance, industry standards, the plant policies, directives, and procedures.

Test coordination, communication, documentation, corrective actions, and system interfaces should be controlled to prevent an adverse effect on start-up testing activities. For example, the collective impact caused by preoperational test completion, system surveillance testing requirements, and plant maintenance activities including postmaintenance testing should be coordinated to assure a managed interface.

400 RECORDS

Record copies of procedures, reports, personnel qualification records, training records, test documentation records, construction test records, administrative records, turnover package records, configuration management records, and licenses should be prepared. These records should be retained with other project records as required by code, standard, specification, or project procedures.

SUBPART 4.2.6
Guidance on Quality Assurance for Decommissioning of Nuclear Facilities

100 GENERAL

Subpart 4.2.6 provides quality assurance guidance for decommissioning of nuclear facilities to permit unrestricted release of the facility or site. Decommissioning consists of decontamination, dismantlement, or a combination of both. Safe storage and entombment are not addressed in this Subpart because neither will lead to the release of a facility or site for unrestricted use.

Subpart 4.2.6 supplements Part I and should be used in conjunction with its applicable sections when, and to the extent, specified by the organization invoking this Subpart.

Guidance in this Subpart is intended to assist the user in developing and implementing a quality assurance program for use in the decommissioning of a nuclear facility or site. Unique terms applicable to this Subpart are defined; activities are listed that should be checked before specific tasks are started; checks that should be performed before, during, and after each task are identified; and records that should be developed and retained are discussed.

Quality assurance guidance specified in this Subpart includes

(a) support equipment used in decommissioning
(b) decommissioning

101 Definitions

The following definitions are provided to ensure uniform understanding of terms as used in this Subpart.

byproduct material: any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

checks: the tests, measurements, verifications, or controls placed on an item or activity by means of investigations, inspections, comparisons, or examinations to determine satisfactory condition, accuracy, safety, or performance.

decommission: to remove a nuclear facility or site safely from service and reduce residual radioactivity to levels that permit release of the facility or site for unrestricted use and termination of any applicable license.

decontamination: the reduction or removal of radioactive contamination from a structure, area, object, or person.

dismantlement: those actions required to disassemble and remove sufficient radioactive material from a facility or site to permit release of the facility or site for unrestricted use.

release criteria: the maximum radiation dose rate level and radioactive contamination level that are acceptable following decommissioning for unrestricted release of the facility or site being decommissioned.

200 PREREQUISITES

The following conditions should be confirmed as having been met before the remainder of this document is applied:

(a) Nuclear fuel and byproduct material have been removed from active use and safely stored on site or moved off site.

(b) A physical and radiological characterization of the facility has been performed and documented in accordance with ASTM E1281, Standard Guide for Nuclear Facility Decommissioning Plans.

(c) An assessment of appropriate radiological environmental issues has been performed to satisfy federal, state, and local requirements.

(d) To substantiate para. 200(c) of this Subpart, the following documents should be available for review:

(1) a listing of all applicable federal, state, and local radiological environmental requirements

(2) records to demonstrate compliance with all listed radiological environmental requirements

(e) A decommissioning project plan has been prepared in accordance with applicable ASTM E1281 guidelines.

(f) To substantiate para. 200(e) of this Subpart, the following documents relating to decommissioning should be available for review:

(1) the approved decommissioning project plan

(2) evidence that the decommissioning project plan and changes thereto have been documented, reviewed, and approved

(3) the latest applicable as-built facility drawings

(4) records of applicable physical and radiological characterization of the facility

(g) Quality requirements have been identified and quality assurance activities have been planned to ensure that activity and documentation requirements are met

throughout the predecommissioning, decommissioning, and postdecommissioning phases of the work.

(h) Project, task, staffing, and equipment loading schedules have been prepared to ensure that time and resources have been considered to accomplish the work in accordance with technical, cost, and schedule requirements.

(i) An as low as reasonably achievable (ALARA) program has been prepared to ensure that worker radiation exposure will be minimized.

300 PREDECOMMISSIONING CHECKS

301 General

Before the start of decommissioning, checks should be completed to verify that decommissioning planning and preparations conform to the requirements specified in the decommissioning project plan, implementing plans, and procedures for a specific project.

The quality requirements and quality assurance actions that are necessary during decommissioning should be planned and reviewed. Performance of this review should not be limited to quality assurance personnel.

302 Plans, Specifications, and Procedures

302.1 Decommissioning Project Plan. The decommissioning project plan should be reviewed to verify that the plan meets federal, state, and local requirements and includes, as appropriate, standard industry guidance such as ASTM E1281. The review should also verify that the decommissioning project plan states the project objectives, specifies the major tasks that are to be performed, and identifies the implementation plans for major tasks.

302.2 Implementation Plans. Implementation plans should be reviewed to verify that they provide guidance to accomplish decommissioning in a safe manner and to comply with the approved decommissioning project plan and federal, state, and local requirements. Where implementation plans are required by the decommissioning project plan, they should be reviewed using the guidelines associated with each implementation plan listed below.

(a) Waste Management Plan. Review to confirm that the following activities, as applicable, are addressed:

(1) liquid radwaste processing, packaging, transportation, and disposal

(2) solid radwaste handling, packaging, transportation, and disposal

(b) Quality Assurance Plan. Review to confirm that it complies with applicable requirements of Part I, this Subpart of Part IV, applicable government quality assurance requirements, and decommissioning requirements applicable to each facility or site as specified in the decommissioning project plan.

(c) Training Plan. Review to verify that a worker training program has been developed to ensure performance of tasks specified in the decommissioning plan, implementation plans, procedures, and work instructions. This review should also verify that radiological safety training was included. In addition, documentation of individual training and qualifications in compliance with federal, state, and local requirements should be verified.

(d) When additional implementation plans such as work plans, security plans, emergency plans and environmental, safety, and health plans are required by the decommissioning project plan, these additional implementation plans should be reviewed to verify that they comply with the decommissioning project plan and federal, state, and local requirements.

302.3 Specifications. A review of the facility, structure, system, and component specifications should be performed to verify that decommissioning activities can be accomplished as described in the decommissioning project plan.

302.4 Design and Qualification. Checks should be performed to verify that systems, components, and equipment required to initiate decommissioning have been designed and qualified in accordance with applicable codes, standards, and specifications. Examples of systems, components, and equipment required for decommissioning are decontamination, ventilation, and waste processing systems. Other examples are hoisting, rigging, and remotely operated cutting equipment.

302.5 Procedures. Consistent with the implementation plans, checks should be performed to verify that procedures are ready when needed during the applicable phase of decommissioning. These checks should verify the following:

(a) Engineering and operational limitations and requirements, as applicable, have been incorporated in the procedures and instructions for the systems, components, and equipment required to initiate decommissioning. These limitations and requirements should include, as appropriate, storage and handling, installation, testing (functional and periodic), maintenance, and on-site processes such as cleaning, welding, nondestructive examination, and parameters such as pressure, flow, speed, load limits (static and dynamic), travel limits, physical clearances, control and alarm settings, and environmental and thermal limits, which are included in design specifications, manufacturer's data sheets, instruction and maintenance manuals, and design reports.

(b) Procedures and instructions have been prepared and approved for each identified task and comply with applicable federal, state, and local requirements.

(c) Methods are provided to ensure that procedures and instructions will be revised as necessary to maintain

current procedures and instructions that represent the status of the facility as the work progresses and provide guidance for safe and orderly work.

(d) Procedures and instructions address the following topics:

(1) precautions and limitations to minimize radioactive material release to the environment

(2) component and equipment protection requirements

(3) prerequisites, including facility conditions, data, sequence of procedure execution, and related systems status

(4) test and inspection equipment, radiation instrumentation, and other equipment have been calibrated and maintained in accordance with requirements for each equipment item

(5) sequence of activities to be followed and steps within each activity

(6) qualification of personnel, including required training

(7) reporting requirements

(8) hold points for technical or quality verifications

(9) approval and signature requirements

(10) data and report forms

(11) interface requirements

(e) Approved procedures and work instructions for performing decommissioning activities, as specified by the decommissioning project plan, have been prepared in accordance with applicable codes, standards, and other requirements.

(f) Approved procedures, drawings, manuals, or other work instructions have been provided to appropriate workers at their work locations.

(g) Special instructions and checklists required to install and operate systems, components, and equipment required for decommissioning are available at the appropriate area or attached to the system, component, and equipment.

(h) Approved procedures and instructions for tasks to be performed during decommissioning reflect latest facility radiological characterization, control of contamination spread, and adherence to ALARA principles.

(i) Approved procedures and instructions for special processes such as coating, cutting, remotely controlled processes, and decontamination are available at the appropriate location.

(j) Qualification of individuals, organizations, equipment, and procedures has been completed in accordance with applicable requirements.

(k) Where applicable, personnel, procedures, and instructions should have been qualified through the preparation of workmanship standards, samples, or mockups that simulate actual job conditions (except radiation fields). This is especially applicable for timed operations or processes such as decommissioning activities conducted in radiation fields and remotely controlled processes or operations.

(l) Systems, components, and equipment required for decommissioning are available at the work location and comply with specified requirements.

(m) Warnings and safety notices, appropriate to the task being performed, are posted.

(n) Approved inspection and test procedures for ensuring that systems, components, and equipment required for decommissioning perform in accordance with their intended design requirements. Procedures shall include provisions for change control, revision, approval, and acceptance.

303 Identification

Checks should be made to verify that the identity of systems, components, and equipment required for decommissioning has been maintained and is in accordance with the latest approved-for-construction drawings, equipment lists, specifications, and established procedures. If these checks disclose an apparent loss of identification, the identity should be reaffirmed before release of systems, components, and equipment for use. Otherwise they shall be removed from service.

Checks should be made to verify that a control system has been established for maintaining identification of systems, components, and equipment required for decommissioning through the applicable phase of decommissioning, including provisions for control of substitution or exchange of systems, components, and equipment. The procedures for identification control should provide traceability to drawings, specifications, or other records when identification or markings are destroyed, hidden, or removed from an item.

304 Physical Condition

Checks, as appropriate, should be performed to verify that systems, components, and equipment required for decommissioning meet specified requirements and that quality has been maintained. In addition, checks should be made to verify that the facility being decommissioned meets specified requirements. These checks should verify the following:

(a) Materials have been selected and systems, components, and equipment required to initiate decommissioning have been fabricated and assembled in accordance with their design specifications and applicable published codes and standards. Conformance to requirements should have been demonstrated by the responsible organization by using appropriate documents from the following list:

(1) design specifications

(2) latest approved drawings

(3) system, component, or equipment specifications

(4) manufacturer's installation instructions

(5) installation procedures

(6) evidence of compliance by manufacturer with purchase requirements, including quality assurance requirements

(7) evidence that engineering and design changes are documented and approved before installation

(8) records of inspections and tests during on-site receiving, storage, and handling of systems, components, and equipment required for decommissioning

(9) release of systems, components, and equipment for installation or use

(10) records of functional testing completed before placing systems, components, and equipment required for decommissioning into service

(11) evidence that nonconformances have been satisfactorily resolved or controlled if unresolved

(12) records of required calibration, testing, and maintenance of systems, components, and equipment required for decommissioning

(b) Protective measures and physical integrity during storage have been maintained in conformance with specified requirements.

(c) Items required for decommissioning have been cleaned/decontaminated in accordance with specified requirements.

(d) When possible, items required for decommissioning have been protected against possible contamination in accordance with specified requirements.

(e) Installation of systems, components, and equipment required for decommissioning will not adversely affect the subsequent installation or operation of other systems, components, and equipment; repair or rework on any nonconforming items can be performed satisfactorily.

(f) Approved temporary supports and mountings that will interface with the system, component, and equipment required during decommissioning have been properly installed.

(g) Servicing and maintenance of systems, components, and equipment have been performed.

(h) Deactivation of all active systems (i.e., gas, electrical, air, and water) that are being dismantled has been performed.

305 System Protection

Checks, as appropriate, should be performed to verify that conditions at the nuclear facility conform to specified requirements, and that predecommissioning tasks have been performed to prevent conditions that would adversely affect the quality of systems, components, and equipment required to support decommissioning. These checks should verify the following:

(a) protection of specific areas from adjacent decommissioning activities. This protection should include implementation of appropriate radiation exclusion zones and area cleanliness requirements.

(b) protection from inclement weather and other ambient conditions adverse to quality.

(c) control of materials or conditions that may be deleterious to the systems, components, and equipment required during decommissioning.

400 CONTROL DURING DECOMMISSIONING

401 General

Actions should be planned and executed to ensure conformance of decommissioning activities to requirements specified in the decommissioning project plan, implementation plans, and work procedures.

In addition, checks of testing activities should be performed during the installation and operation of systems, components, and equipment required for decommissioning to verify that the required quality is being achieved in accordance with prescribed procedures. Checks should be performed in a systematic manner throughout the decommissioning process. The coordination and sequencing of checks should be identified in the work procedures including hold points. When the work procedures are properly executed, they will ensure conformance of completed work to specified requirements and containment of radioactive materials during decommissioning as well as other requirements specified in plans and procedures.

A method should be provided to ensure that engineering design and design changes implemented during decommissioning are documented and controlled.

402 Processes and Procedures Control

Checks should be made to verify that a system of controls has been established and is being maintained at the decommissioning site to ensure that

(a) applicable revisions of approved procedures, drawings, and instructions are being used

(b) qualified personnel are performing the work

(c) qualified and approved processes, materials, tools, and other equipment are being used

(d) status of decommissioning activities is clearly indicated or identified in appropriate documents

(e) specified sequence of decommissioning activities is being followed and documented

(f) nonconforming items are identified, appropriately segregated, and dispositioned before use

(g) as-built information for systems, components, and equipment required for decommissioning is being processed and documented

(h) inspection and test reports for systems, components, and equipment required for decommissioning are current, accurate, and complete

(i) inspection reports for special decommissioning processes, such as remote operations or timed activities in radiation fields, are current, accurate, and complete

(j) procedures for radiological sampling and analyses are followed and adequately address the need for radiological environmental monitoring

(k) procedures for decommissioning activities performed in radiological conditions are followed and ensure ALARA exposures to personnel

403 Checks of Systems, Components, and Equipment Required for Decommissioning

Checks of systems, components, and equipment required for decommissioning should be performed to verify the items will be located, installed, assembled, or connected in compliance with the latest approved-for-construction drawings, manufacturer's instructions, and procedures. Checks should be performed to verify that systems, components, and equipment have been correctly installed and will function properly.

404 Checks During Decommissioning

Checks should be performed to verify that decommissioning activities are being performed in compliance with the latest approved procedures and work instructions. Checks should be performed, as appropriate, for the following decommissioning activities:

(a) decontamination operations

(b) liquid radwaste processing and disposal

(c) removal of radioactively contaminated components and equipment

(d) hoisting and rigging operations

(e) solid radwaste handling, segregation, packaging, transportation, and disposal

(f) timed operations in high-radiation fields to include adequate personnel protective measures

(g) removal, handling, and disposal of major systems or components

(h) removal, handling, and disposal of activated/contaminated concrete

(i) removal, handling, and disposal of nonradioactive equipment and components

(j) demolition, removal, and disposal of structures

(k) excavation, removal, and disposal of contaminated soil to satisfy release criteria

(l) ongoing radiological environmental monitoring to assess effectiveness of contamination control

500 POSTDECOMMISSIONING CHECKS

Following the completion of decommissioning activities, checks should be made on the results of the final facility or site characterization to verify that the final condition conforms to the specified release criteria as stated in the decommissioning project plan. Controls should be provided for the identification, documentation, and resolution of identified nonconformances.

600 RECORDS

Record copies should be prepared and collected of the decommissioning plan; procedures; reports; and personnel qualification, radiological site characterization, dismantlement, inspection, surveillance, audit, and assessment records. These records should be retained with other project records as required by code, standard, specification, or project procedures.

(15)

SUBPART 4.2.7
Guidance on Peer Review

100 GENERAL

This Subpart provides guidance on the performance of peer reviews in support of the independent review activities identified in Part IV[1] of this Standard. This guidance provides additional detail on how peer review can be applied to these as well as other applications.

200 TERMS AND DEFINITIONS

highly influential scientific information:[2] scientific information that could have an impact on nuclear safety or radiation exposure at existing or planned nuclear facilities in either the public or private sector or that the dissemination is novel, controversial, precedent-setting, or has significant interagency interest.

influential scientific information:[2] scientific information that an organization can reasonably determine will have or does have a clear and substantial impact on important public policies or private sector decisions that affect nuclear safety or radiation exposure regulations or policies. Information dissemination can have a significant economic impact even if it is not part of rule making or decision making.

peer review: a documented, in-depth critique of documented work by an individual or group of peers who are independent from the work being reviewed. A peer review critiques assumptions, calculations, extrapolations, alternative interpretations, methodologies, acceptance criteria employed, and conclusions drawn by the original work.

peer reviewer: a person having verifiable technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work.

peer review panel: an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed and could vary in size based on the subject matter and influence of the subject matter.

peer review plan: documents the approach, purpose, scope, and selection of reviewers of a peer review.

peer review report: a report providing documentation of the proceedings and findings of a peer review.

peer review sponsor: the organization responsible for the use or disposition of the information being subjected to peer review.

scientific information: factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as engineering or physical sciences. Other disciplines are also considered but are not part of the specific mission.

300 PERFORMANCE

301 General

Peer review is an important method used to ensure that the quality of information used in nuclear applications meets the standards of the regulatory, scientific, and technical community. Peer review involves the review of information for acceptability by specialists in the field who were not involved in producing the information, and it may take a variety of forms, depending upon the nature and importance of the information. For example, peer reviews are typically conducted when the adequacy of information or the suitability of implementing documents or methods essential to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards and practices. Peer review may also be used to determine that highly influential scientific information or influential scientific information was developed under a system of controls providing quality assurance sufficient to permit use of the information in nuclear applications. The following conditions are examples of situations for which a peer review should be considered:

(a) Influential or highly influential scientific information will be disseminated.

(b) Critical interpretations or decisions are necessary in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.

(c) Decisions or interpretations have significant impact on performance assessment.

(d) Novel or beyond state-of-the-art testing, plans and procedures, or analyses will be utilized.

[1] ASME/ANS RA-Sa–2009 provides requirements for peer review of probabilistic risk assessments for nuclear power plants.

[2] These definitions were developed based on guidance from the Office of Management and Budget Bulletin dated December 16, 2004, Final Information Quality Bulletin for Peer Review and modified to be placed in a nuclear safety context.

(e) Detailed technical criteria, technical/scientific bases, or standard industry procedures are not available.

(f) Results of tests are not reproducible or repeatable in a timely manner because of cost or schedule requirements.

(g) Data or interpretations are ambiguous, conflicting, or lack scientific consensus.

(h) Data adequacy is questionable (e.g., the data may not have been collected in conformance with an established quality assurance program).

302 Planning

Planning the method of peer review establishes key elements to the successful performance of the peer review.

Uncertainty is inherent in science, and in many cases, individual studies do not produce conclusive evidence. Specialists attempt to reach a consensus by weighing the accumulated evidence. Peer reviewers can make an import contribution by distinguishing scientific facts from professional judgments.

302.1 Management Responsibilities. Peer review sponsors (typically management) are provided broad discretion in determining what type of peer review is appropriate and what procedures should be employed to select appropriate reviewers. The sponsor is expected to choose a peer review mechanism that is adequate for determining the acceptability of the information for its intended use, giving due consideration to the novelty and complexity of the information to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review.

The intensity of peer review should be commensurate with the significance of the information to be disseminated and the likely implications for its effect on nuclear safety or policy decisions. A more rigorous peer review, including a larger panel, more thorough examination of the controls placed upon development of the information, and more formal documentation process, would be expected for information based on novel methods or that presents complex challenges for interpretation. Furthermore, the need for rigorous peer review would be greater when the information contains precedent-setting methods or models, presents conclusions that are likely to change prevailing practices, or is likely to affect policy decisions that have a significant impact. While it will not always be easy for the sponsor to quantify the benefits and costs of peer review, they are encouraged to approach peer review from a cost-benefit perspective.

302.2 Review Planning. Peer review is most effective when the charge is specific and directs reviewers to specific technical questions while also allowing reviews to offer a broad evaluation of the overall product. The peer review plan should

(a) contain the instructions to the peer reviewers regarding the objective of the peer review.

(b) contain information on the specifics being sought.

(c) request reviewers provide advice on the reasonableness of judgments made from the scientific evidence.

(d) request reviewers to evaluate the qualifications of personnel who collected or produced the data.

(e) ask that peer reviewers ensure that scientific uncertainties are clearly identified and characterized. Since not all uncertainties have an equal effect on the conclusions drawn, reviewers should be asked to ensure that the potential implications of any uncertainties associated with the technical conclusions drawn are clear.

(f) define the expected time period for the peer review. Whenever possible, the peer review sponsor should examine other peer reviews of similar size and scope in order to ensure peer reviewers have sufficient time to thoroughly examine the information and make judgments regarding its quality for the intended use.

(g) define the process for submitting and resolving reviewer comments.

302.3 Planning Documentation. Initiation of the peer review process should include a peer review plan that

(a) specifies the work and source documents to be reviewed.

(b) identifies the number of reviewers and primary disciplines or expertise needed to support the review. It also describes the expected method (through a panel or individual letters) and reporting schedule.

(c) identifies the required degree of independence from the information being reviewed for the peer review panel members.

(d) establishes the charter for the peer review panel, when applicable.

(e) specifies the chairperson for the peer review panel, when applicable.

(f) specifies whether there will be opportunities for the sponsor, third parties, or the public to comment on the work product to be peer reviewed and, if so, how and when these opportunities will be provided.

(g) specifies whether the organization will provide significant and relevant public comments to the peer reviewers before they conduct their review.

(h) determines whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers.

(i) establishes review criteria that address, as appropriate

(1) validity of the assumptions and unverified assumptions

(2) alternate interpretations

(3) adequacy of requirements and criteria

(4) appropriateness and limitations of the methods and implementing documents used to complete the work under review

(5) adequacy of application

(6) accuracy of calculations

(7) uncertainty of results and impact if wrong

303 Methods

There are three peer review methods commonly used: individual, panel, and a combination of both. The number of peers comprising a peer group should vary with the complexity of the work to be reviewed, its importance to establishing that performance goals are met, the number of technical disciplines involved, the degree to which uncertainties in the data or technical approach exist, and the extent to which differing viewpoints are held concerning the issues under review.

303.1 Individual Peer Review. Letter reviews by several experts generally will be more expeditious than convening a panel of experts. Individual letter reviews are more appropriate when a draft document covers only one discipline or when premature disclosure of a sensitive report to a stakeholder could cause harm to government or private interests.

303.2 Peer Review Panel. When time and resources warrant, panels are preferable, as they tend to be more deliberative than individual letter reviews.

303.3 Individual and Panel Peer Review. A combination of the two approaches to peer review can be particularly valuable for highly complex, multidisciplinary, and more important documents.

400 REVIEWER SELECTION

Reviewer selection is critical to the success of a peer review. Selection of peer reviewers should be based on competence or technical expertise, independence or potential conflict of interest, and balance of reviewer selection.

401 Competence/Technical Expertise

The peer review sponsor must ensure that the selected reviewers have the knowledge, experience, competence, and skills necessary to perform the review. The nature of some reviews may be better suited to having multiple reviewers, in order to span the areas of technical expertise. For instance, expertise in applied mathematics and statistics is essential in the review of models.

Collective technical expertise and qualifications of the peer reviewers should span the technical issues and areas involved in the information to be reviewed, including differing bodies of scientific thought. Technical qualifications in the review area should be at least equivalent to that needed for developing the information under review. Peer reviews are best performed by individuals that have technical credentials that are recognized and verifiable.

402 Independence/Conflict of Interest

Independence poses a complex set of questions to be considered when peer reviewers are selected. Peer reviewers should be independent from the material requiring the peer review. Commensurate with the significance of the information to be reviewed, potential peer reviewers should be external to the organization requesting the peer review or the peer review sponsor, in order to increase the level of independence.

Peer review sponsors should make every effort to examine the perceived or actual conflicts of each prospective reviewer. The level of effort to examine prospective reviewers' potential conflicts should be commensurate with the significance of the information to be reviewed and the likely implications on existing and future policy decisions.

In those cases where total independence cannot be met, the rationale as to why someone of equivalent technical qualification and greater independence was not selected is to be documented as part of the peer review report.

403 Balance

While expertise is the primary consideration, reviewers should also be selected to represent a diversity of scientific perspectives to the subject. On most controversial issues, there exists a range of respected scientific viewpoints regarding interpretation of available literature or existing data. Consideration should be given to selecting reviewers with strong opinions to test the scientific strength and balance of their reports.

404 Training

The peer review sponsor should ensure that all peer reviewers have received training on the peer review process being employed and adequate orientation for performing the assigned work. Orientation may take the form of reading assignments, briefings, classroom training, or a combination. Training and orientation should be documented as to content and scope.

500 COMMENT RESOLUTION

Peer reviewers should supply any comments regarding the information being reviewed to the peer review sponsor or panel chairperson. All reviewer comments should be given consideration and incorporated into the final peer review report where relevant and valid. A peer review is considered completed once the peer review sponsor or panel chairperson has addressed all reviewers' comments.

600 PEER REVIEW REPORT

A written report documenting the results of the peer review should be issued. The report should clearly state the work or issue that was peer reviewed and the conclusions reached by the peer review process. The report should include individual statements by peer review group members reflecting dissenting views or additional comments, as appropriate.

A peer review panel report is usually prepared under the direction of the chairperson of the peer review panel and signed by each member or contains information detailing which peer reviewers have chosen not to sign and why. The report should include individual statements by the peer reviewers reflecting dissenting views or additional comments, as appropriate. The peer review group should work to resolve dissenting views if possible before issuing the report. In cases where there is a public panel, the sponsoring organization should plan publication of the peer review report(s) and the organization's response to peer review comments.

The credibility of the final scientific report is likely to be enhanced if the sponsoring organization addresses concerns raised by the peer reviewers. As such, the sponsor should consider preparing a written response to the peer review report explaining the organization's agreement or disagreement, actions the organization has undertaken or will undertake in response to the report, and (if applicable) the reasons the sponsor organization considers those actions to satisfy any key concerns or recommendations in the report.

700 RECORDS

Peer review records should include the following documents, as applicable:

(a) peer review plans
(b) rationale for selection of peer reviewers
(c) training and qualification records
(d) review comments and resolutions
(e) peer review report

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ASME NQA-1 INTERPRETATIONS

Replies to Technical Inquiries
November 2012 Through November 2013

FOREWORD

General Information

This publication includes all of the written replies issued between the indicated dates by the Secretarial Staff, speaking for the ASME Committee on Nuclear Quality Assurance, to inquiries concerning interpretations of technical aspects of ASME NQA-1, Quality Assurance Requirements for Nuclear Facility Applications.

These replies are taken verbatim from the original letters except for a few typographical corrections and some minor editorial corrections made for the purpose of improved clarity. In some instances, a review of the interpretation revealed a need for corrections of a technical nature; in these cases a corrected interpretation follows immediately after the original reply.

These interpretations were prepared in accordance with the accredited ASME procedures. ASME procedures provide for reconsideration of these interpretations when or if additional information is available which the inquirer believes might affect the interpretation. Further, persons aggrieved by this interpretation may appeal to the cognizant ASME committee or subcommittee. ASME does not "approve," "certify," "rate," or "endorse" any item, construction, proprietary device, or activity.

An interpretation applies to the Edition and Addenda stated in the interpretation itself or, if none is stated, to the latest published Edition at the time it is issued. Subsequent revisions to the rules may have superseded the reply.

For detailed instructions on the preparation of technical inquiries, refer to the Preparation of Technical Inquiries to the Nuclear Quality Assurance Committee (p. vi of ASME NQA-1).

Subject and Numerical Indexes

Subject and numerical indexes have been prepared to assist the user in locating interpretations by subject matter or location in this Standard. These indexes, which are the compilation of former NQA-1 and NQA-2 interpretations indexes, will be updated with each Edition.

Interpretation: QA15-001

Subject: NQA-1–2008 Edition, Audit Independence

Date Issued: November 15, 2012

File: 10-1768

Question: Can an organization use one or more of the following measures, as applicable, to audit the quality assurance organization without violating the "personnel who do not have direct responsibility for performing activities being audited" and "sufficient authority and organizational freedom" requirements in sections 100 and 302 of Requirement 18 of NQA-1–2008?

(a) use an internal group to audit the quality assurance organization provided use of personnel in one section or function of the quality assurance organization to audit other sections or functions

(b) use of appropriately qualified personnel from nonquality assurance organizations to audit the quality assurance organization

(c) use a Lead Auditor from other company units (e.g., sister divisions) outside the Lead Auditor in the company to audit the quality assurance organization

(d) use a Lead Auditor from corporate headquarters quality organization to audit the quality assurance organization of a subordinate company unit, which reports to the headquarters quality organization management

Reply: Yes.

Interpretation: QA15-002

Subject: NQA-1–2008 Edition With the 2009 Addenda, Design Criteria for Commercial Grade Items

Date Issued: December 11, 2012

File: 12-1323

Question: If the design criteria for a commercial grade item are known by the dedicating entity, and the item is to be dedicated to these criteria in lieu of defining a specific safety function, is a technical evaluation still required to be performed in accordance with NQA-1a–2009, Subpart 2.14, section 401?

Reply: Yes.

Interpretation: QA15-003

Subject: NQA-1, Part I, Requirement 3, Vendor Evaluation Design Control

Date Issued: December 11, 2012

File: 12-1888

Question (1): When procuring from a vendor providing items under a QA Program that meets the requirements of NQA-1, and the vendor is responsible for the design, must the preaward evaluation of the vendor include Requirement 3?

Reply (1): Yes. Refer to Interpretation QA12-007 (File No. 10-1365).

Question (2): For the items described in Question (1), is it necessary to evaluate the supplier for Parts 200, Design Input; 300, Design Process; 400, Design Analysis; and 500, Design Verification, etc.?

Reply (2): Yes. Refer to the Reply to Question (1).

Interpretation: QA15-004

Subject: NQA-1–2008 Through NQA-1b–2011, Lead Auditor Qualification

Date Issued: January 8, 2013

File: 11-1319

Question (1): If an individual was qualified as a Lead Auditor several years ago (20–25 yr in this case) and has failed to maintain this qualification, may he be requalified based on retraining in accordance with para. 303.2 and reexamination in accordance with para. 303.4 and participation as an Auditor on one nuclear quality assurance audit?

Reply (1): Yes.

Question (2): May a company qualify a prospective Lead Auditor based on audits that the individual participated in as an auditee?

Reply (2): No.

Interpretation: QA15-005

Subject: NQA-1–2008 Edition With the 2009 Addenda, Commercial Grade Items and Software

Date Issued: May 28, 2013

File: 12-138

Question: In NQA-1a–2009, Part II, Subpart 2.14, section 101, the first definition for *Commercial Grade Items (CGI)* states, "Commercial grade items do not include items where the design and manufacturing process requires in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected." When a Technical Evaluation is performed as part of the application of Subpart 2.14 to otherwise acquired software as described in Subpart 2.7, section 302, and the evaluation identifies a design and implementation process that can only be verified in-process, does the otherwise acquired software meet the exception portion of the first definition of commercial grade item in Subpart 2.14, section 101?

Reply: Yes. The Standard excludes otherwise acquired software that requires in-process verification as a result of the technical evaluation from the first definition of commercial grade item in Part II, Subpart 2.14, section 101. However, as indicated in Footnote 1 of Subpart 2.14, "Regulation 10 CFR Part 21, Reporting of Defects and Noncompliance, establishes criteria for commercial grade item definition and dedication activities. . . . It is the responsibility of the U.S. facility management to determine the applicability of this Subpart to meet the U.S. facility regulatory requirements, including all pertinent definitions."

Interpretation: QA15-006

Subject: NQA-1–2008 Edition, Quality Assurance Program Structure

Date Issued: September 4, 2013

File: 13-37

Question (1): Does NQA-1 Requirement 2 require that the "documented quality assurance program" be in a specific format or structure (e.g., manual and procedures, three-tier documentation, etc.)?

Reply (1): No.

Question (2): Does NQA-1 Requirement 5 have any specific requirements for how "documented instructions, procedures, or drawings" may be prescribed within the quality assurance program for activities affecting quality and services?

Reply (2): No.

Question (3): Does Requirement 5 prohibit referencing selected sections of a QA program description in QA procedures, instructions, or drawings?

Reply (3): No.

Interpretation: QA15-007

Subject: NQA-1–2008 With the 2009 Addenda, Design Output Documentations and Design Analysis Documentation

Date Issued: October 14, 2013

File: 13-57

Question (1): In accordance with NQA-1–2008 and the 2009 Addenda, Part I, Requirement 3, section 300, does a design output document (e.g., design drawing) require that associated design inputs be explicitly referenced or otherwise explicitly identified in the design output document for the purpose of design verification?

Reply (1): No.

Question (2): In accordance with NQA-1–2008 and the 2009 Addenda, Part I, Requirement 3, para. 402(d), must the documentation of design analyses also identify those assumptions that must be verified later (as the design proceeds)?

Reply (2): Yes.

Question (3): Are the statements made about assumptions in NQA-1–2008 and the 2009 Addenda, Part I, Requirement 3, para. 501.1(b) under the heading of Design Reviews as a method of design verification (i.e., assumptions necessary to perform the design activity are adequately described and reasonable and, where necessary, assumptions requiring subsequent reverification are identified for reverification when the detailed design activities are complete) considered to be requirements for assumptions included in documents other than design analysis?

Reply (3): No. Assumptions must be included in the documentation of design analysis, per Requirement 3, para. 402(d).

Question (4): For assumptions that are to be verified as design proceeds, per Requirement 3, para. 402(d), must the assumptions be identified as unverified portions of the design and controlled in accordance with Requirement 3, para. 500(b)?

Reply (4): Yes.

Interpretation: QA15-008

Subject: NQA-1–2008 Edition, Applicability of Part II Requirements

Date Issued: November 1, 2013

File: 12-360

Question: Would an organization's QA program be in compliance with NQA-1 (any edition with Parts) if it only addressed the requirements in Part I and not the requirements of Part II (or vice versa)?

Reply: No. Parts I and II are designated as requirements. An organization must address the requirements of Parts I and II that are applicable to an organization's work activities affecting quality, as either internally identified or externally invoked upon the organization. NQA-1 is in the process of considering a revision to the Introductions to Parts I and II to further clarify this issue.

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