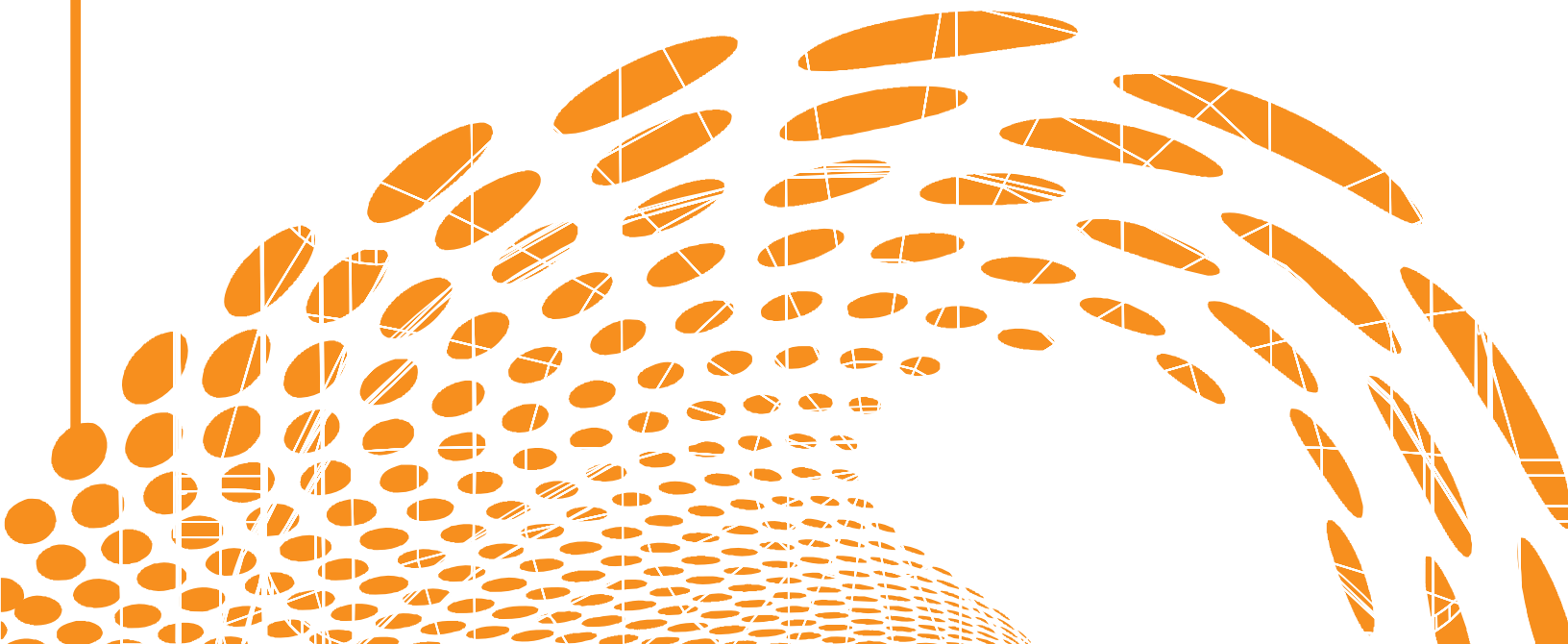
ASME STANDARDS TECHNOLOGY, LLC

STP-NU-062-1

Comprehensive Comparison of International Quality Standards



STP-NU-062-1

COMPREHENSIVE COMPARISON OF INTERNATIONAL QUALITY STANDARDS

Prepared by:

William K. Sowder, PH.D.
Quality Management Services Co., LLC

ASME STANDARDS TECHNOLOGY, LLC

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Summary of Changes
June 2015

STP-NU-062-1

COMPREHENSIVE COMPARISON OF INTERNATIONAL QUALITY STANDARDS

The following changes have been made to the first revision of STP-NU-062.

Page	*Location*	*Change*
All	--	Document number on all pages changed from "STP-NU-062" to STP-NU-062-1
All	--	General change to all pages, NQA-1 title from NQA-2008 to NQA-2012
All	--	General change to all 18 NQA sections lead pages, from "100 Basic " to "100 General"
ii	2nd Page	Date changed to June 2015
vi	Foreword	ASME NQA-1 "Quality Assurance Requirements for Nuclear Facility Application-Edition 2008", changed to ASME NQA-1 "Quality Assurance Requirements for Nuclear Facility Application-Edition 2012",
2	Section 2	ASME NQA-1 "Quality Assurance Requirements for Nuclear Facility Application-Edition 2008" changed to ASME NQA-1 "Quality Assurance Requirements for Nuclear Facility Application-Edition 2012"
17	Appendix A, Requirement 1	Requirement 1, 201 General, add (c) quality achievement is verified by those not directly responsible for performing the work
19-35	Appendix A, Requirement 2	Requirement 2, 100 General, deletion of "The program shall identify the activities and items to which it applies."
45	Appendix A, Requirement 3	Requirement 3, revise first paragraph "The design shall be defined, controlled, and verified."
52-53	Appendix A, Requirement 3	Requirement 3, 500 Design Verification, revise and add to (a) paragraph "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."
109	Appendix A, Requirement 12	Requirement 12, 303 Control, delete paragraph "Methods and frequency of checking accuracy shall be defined in procedures."
123	Appendix A, Requirement 17	Requirement 17, Sub-Section 100 General delete 4th paragraph "The term records, used throughout this section, is to be interpreted as quality assurance records."
6	References	Updated NQA titles as shown here: ASME NQA-1 Part IV, 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 ASME NQA-1 Part IV, 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

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FOREWORD

This technical report was developed to comprehensively evaluate the following international quality standards: ASME NQA-1 "Quality Assurance Requirements for Nuclear Facility Application-Edition 2012" [1], NQSA NSQ-100 "Nuclear Safety and Quality Management System Requirements" [2], IAEA GS-R-3: 2006 "The Management System for Facilities and Activities" [3], and ISO 9001:2008 "Quality Management Systems Requirements" [4]. The report discusses the competitive strengths and weaknesses of these documents.

Established in 1880, the American Society of Mechanical Engineers (ASME) is a professional not-for-profit organization with more than 135,000 members and volunteers promoting the art, science and practice of mechanical and multidisciplinary engineering and allied sciences. ASME develops codes and standards that enhance public safety, and provides lifelong learning and technical exchange opportunities benefiting the engineering and technology community. Visit www.asme.org for more information.

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The author wishes to acknowledge, with deep appreciation, the activities of ASME staff and volunteers who have provided valuable technical input, advice and assistance with review of, commenting on, and editing of, this document.

ABBREVIATIONS AND ACRONYMS

ASME	American Society of Mechanical Engineers
ASME ST-LLC	ASME Standards Technology, LLC
Bureau Veritas	Multinational Company providing conformity assessment, certification and services to industry, government and individuals
DOE	US Department of Energy
IAEA	International Atomic Energy Agency
ISO	International Organization for Standardization
NQSA	Nuclear Quality Standard Association
NRC	US Nuclear Regulatory Commission
QA	Quality Assurance
QSC	Quality Systems Certificate
TAG	Technical Advisory Group
TC	Technical Committee

1 PURPOSE AND SCOPE

This report was developed to evaluate and assess the various international quality and management documents that are in use today for new nuclear construction. A number of concerns were voiced in the USA, Europe and Asia, about how these documents are being used by construction and engineering companies, regulators, standard developing organizations, vendors and suppliers. There is also a question of the compatibility with existing standards that were the basis of a large majority of new nuclear construction and existing nuclear plant replacements, globally. The comparison provided herein, offers a comprehensive look at these issues.

2 SELECTION OF STANDARDS

This technical report compares the requirements contained in ASME NQA-1 "Quality Assurance Requirements for Nuclear Facility Application Edition 2012" Part 1, NSQ-100 "Nuclear Safety and Quality Management System Requirements", IAEA GS-R-3: 2006 "The Management System for Facilities and Activities", and ISO 9001:2008 "Quality Management Systems-Requirements". These standards were selected on the basis of their relevance to the nuclear industry.

The ASME NQA-1 document 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.

The International Atomic Energy Agency (IAEA)-IAEA Safety Standards Series No. GS-R-3, "The Management System for Facilities and Activities (IAEA GS-R-3)", defines the requirements for establishing, implementing, assessing and continually improving a management system. A management system designed to fulfill these requirements integrates safety, health, environmental, security, quality and economic elements. IAEA GS-R-3, together with its supporting Safety Guides, supersedes Safety Series No. 50-C/SG-Q, Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations. This document was issued in 2006 by the IAEA in their IAEA Safety Standards Series. This series covers nuclear safety, radiation safety, transport safety and waste safety.

The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The ISO 9001:2008 was prepared by Technical Committee ISO/TC 176 of this organization. The ISO is designed to promote the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, and to enhance customer satisfaction by meeting customer requirements. This Standard specifies requirements for a quality management system where an organization a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

The NSQ 100 document was issued as a draft document in June 2011 and a Revision 0 in December 2011 by the Nuclear Quality Standard Association (NQSA) organization. The NQSA organization is a joint venture of AREVA, SAS and Bureau Veritas and the purpose of its development is as stated on the NQSA organization's web site, "A new environment generates new needs and calls for a new standard. In 2011, the NQSA (Nuclear Quality Standard Association) – open to all major nuclear utilities, nuclear engineers and manufacturers – responded to the nuclear supply chain challenges in terms of quality and safety by creating and promoting a new standard: NSQ-100". The newest member of the NQSA organization is Société Générale de Surveillance (SGS), which is a leading inspection, verification, testing, and certification company based in Geneva, Switzerland with global offices as well.

3 DIFFERENCES BETWEEN STANDARDS DEVELOPMENT

The primary difference between the development of the NSQ 100, IAEA GS-R-3 and ISO 9001 Standards and Documents and the corresponding ASME NQA-1 Standard is that they are developed from different viewpoints.

The ASME is not subsidized by, reporting to or a part of any U.S. Government Agency. The ASME organization standards development function is a total volunteer-based effort. ASME 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 management and continuous improvement processes needed to achieve customer satisfaction.

The NSQ 100 document was developed within the membership of the NQSA organization and is comprised of three companies previously mentioned. This document was issued in December 2011 with very little history of use.

The IAEA Standard represents a consensus view of the IAEA's Member States. The IAEA GS-R-3 Management System Standard uses an integrated management system approach and 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.

The ISO 9001 was prepared by Technical Committee ISO/TC 176 of ISO and voted on for approval by the members of the TC176 Technical Committee with each member country allowed one vote. The ISO 9001:2008 Standard is a Quality Management System Standard, and used by companies to manage the quality of their product from inception of marketing idea through reaching the market place and gauging customer satisfaction. This standard is also a business model for many corporations to provide a disciplined approach to the development of their product.

ASME's standards development process is unique in that it uses a consensus process with participation from a balanced and international base of expertise and experience. This expertise comes from industrial companies, manufacturing and construction companies, regulators, engineering and inspection organizations and private consultants. The ASME meetings are open to public involvement and active participation. There are over 500 standards developed by ASME, which are being used in over 100 countries, and ASME also administers over 40 U.S. Technical Advisory Groups (TAGs) for ISO.

4 IMPORTANT DIFFERENCE IN FOCUS OF REVIEWED DOCUMENTS

The ASME NQA-1 approach applies Quality Assurance requirements to activities (narrow focus) that could affect the quality of nuclear material applications and of 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.

The other three documents reviewed use a process approach (broad focus) to achieve their objectives, and continual improvement of the management system and its processes to preclude a negative impact on safety.

Quality managers continually debate the strengths and weaknesses of these approaches.

5 SUMMARY OF EVALUATION RESULTS

The comparison was developed and the detailed results are shown in Appendix A. ASME NQA-1 was used as the baseline against which the other standards were evaluated. In reviewing the four documents it was apparent that the authors of the ASME NQA-1 and the IAEA GS-R-3 documents were looking at their respective view points as the only appropriate methods to be used to accomplish their intended end result of maintaining a safe nuclear operating facility.

In the case of the ISO 9001 document, it is primarily used for manufacturing quality management and was not designed for nuclear safety or the nuclear regulatory environment. Therefore, its authors were focused on repetitive manufacturing type of processes with product to market and customer satisfaction. This is not the primary concern for the nuclear industry or its supplier base, where the primary focus is on nuclear regulations, certifications and nuclear safety.

The authors of the NSQ 100 document were more concerned with using the ISO 9001 Standard as its base document and added content from the other existing standards that the authors felt was missing. It appears that the authors performed a "cut and paste" activity using the various documents. There did not seem to be any regard for out-of-sequence paragraph numbering or consistency with paragraph content. This lifting of content is very apparent when scanning through the NSQ 100 document.

The IAEA GS-R-3 and ASME NQA-1 Standards apply to the lifecycle of nuclear facilities and activities, including siting, design, construction, commissioning, operation, and decommissioning. IAEA GS-R-3 and ASME 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 ASME NQA-1 can be invoked by contract, adopted voluntarily, or used as the basis for assessing a management system or a quality assurance program.

ASME NQA-1 defines requirements for an organization to establish, implement and assess a quality assurance (QA) program to achieve nuclear safety. The ASME 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. IAEA GS-R-3 adopts an integrated management system approach to be applied to all work of the organization.

The use of ISO 9001:2008, IAEA GS-R-3: 2006 and NQA-1:2012 standards for nuclear regulated activities have been reviewed by several standard development organizations such as ASME, IAEA and several nuclear agencies and regulators such as the U.S. Nuclear Regulatory Commission (NRC) and the IAEA. Several documents have been issued by these organizations to document the suggested limited use of ISO 9001:2008 or IAEA GS-R-3 to meet the nuclear safety needs of these regulators and these limited uses were suggested unless additional requirements were implemented; see references [5]-**Error! Reference source not found.**.

REFERENCES

[1] NQA-1: 2012 "Quality Assurance Requirements for Nuclear Facility Application Edition 2012".
[2] NSQ 100 document "Nuclear Safety and Quality Management System Requirements" Rev. 2011.
[3] IAEA GS-R-3: 2006 Safety Standard "The Management System for Facilities and Activities".
[4] ISO 9001: 2008 "Quality Management Systems-Requirements".
[5] IAEA Safety Reports Series No.70 "Management System Standards: Comparison between IAEA GS-R-3 and ASME NQA-1-2008 and NQA-1a-2009 Addenda".
[6] IAEA Safety Reports Series No. 69 "Management System Standards: Comparison between IAEA GS-R-3 and ISO 9001:2008".
[7] ASME NQA-1 Part IV, 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
[8] ASME NQA-1 Part IV, 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
[9] U.S. NRC SECY-03-0117 "Approaches for Adopting More Widely Accepted International Quality Standards".

Appendix A—International Quality Standards Comparison

NQA-2012	IAEA GS-R-3	ISO 9001/2008	NSQ-100
REQUIREMENT 1 Organization	**Management System**	**Quality Management System**	**1 Scope**
100 General	**2.1 General**	**4.1 General Requirements**	**1.1 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.	A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by: —Bringing together in a coherent manner all the requirements for managing the organization; —Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied; —Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.	The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.	This document is intended for any organization which supplies product or services within nuclear industry. It is emphasized that the requirements specified in this document are complementary (not alternative) to contractual and applicable statutory and regulatory requirements. Should there be a conflict between the requirements of this document and applicable statutory or regulatory requirements, the latter shall take precedence.
		4.1 Quality Management System General Requirements	
		The organization shall a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2),	

NQA-2012	IAEA GS-R-3	ISO 9001/2008	NSQ-100
REQUIREMENT 1 Organization	**Management System**	**Quality Management System**	**1 Scope**
		b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure (where applicable), and analyze these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes.	
		4.1 Quality management System General Requirements	
		Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system. **NOTE 1**: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization and measurement, analysis and improvement. **NOTE 2**: An outsourced process is identified as one needed for the	

NQA-2012	IAEA GS-R-3	ISO 9001/2008	NSQ-100
REQUIREMENT 1 Organization	**Management System**	**Quality Management System**	**1 Scope**
		organization's quality management system but chosen to be performed by a party external to the organization. **NOTE 3**: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements, b) the degree to which the control for the process is shared, c) the capability of achieving the necessary control through the application of 7.4.	
	2.2		
	Safety shall be paramount within the management system, overriding all other demands.		
	5.26		
	Information relevant to safety, health, environmental, security, quality and economic goals shall be communicated to individuals in the organization and, where necessary, to other interested parties.		
	2.3		
	The management system shall identify and integrate with the		

NQA-2012	IAEA GS-R-3	ISO 9001/2008	NSQ-100
REQUIREMENT 1 Organization	**Management System**	**Quality Management System**	**1 Scope**
	requirements contained within this publication: —The statutory and regulatory requirements of the Member State; —Any requirements formally agreed with interested parties (also known as stakeholders); —All other relevant IAEA Safety Requirements publications, such as those on emergency preparedness and response and safety assessment —Requirements from other relevant codes and standards adopted for use by the organization.		
	2.4		
	The organization shall be able to demonstrate the effective fulfillment of its management system requirements.		
	5.27		
	Internal communication concerning the implementation and effectiveness of the management system shall take place between the various levels and functions of the organization.		
	SAFETY CULTURE		
	2.5		**4.1.1 Nuclear safety culture**
	The management system shall be used to promote and support a strong safety culture by: —Ensuring a common understanding of the key aspects of safety culture within the organization;		The organization shall promote and support a strong safety culture by: —ensuring a common understanding of the key aspects of safety culture within the organization, —providing the means by which the organization supports individuals

NQA-2012	IAEA GS-R-3	ISO 9001/2008	NSQ-100
REQUIREMENT 1 Organization	**Management System**	**Quality Management System**	**1 Scope**
	—Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization; —Reinforcing a learning and questioning attitude at all levels of the organization; —Providing the means by which the organization continually seeks to develop and improve its safety culture.		and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization, —reinforcing a learning and questioning attitude at all levels of the organization, -providing the means by which the organization continually seeks to develop and improve its safety culture.
200 STRUCTURE AND RESPONSIBILITY	**GRADING THE APPLICATION OF MANAGEMENT SYSTEM REQUIREMENTS**		
201 General	**2.6**		**4.1.2 Classification of product**
The organizational structure and responsibility assignments shall be such that:	The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of: —The significance and complexity of each product or activity; —The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or activity; —The possible consequences if a product fails or an activity is carried out incorrectly		The organization shall break down the product classification in order to identify items or activities important for safety or important for the final quality of the product. Classification of items or activities important for safety shall be based on analysis of consequences of their potential failure or malfunction on the nuclear safety function of the product. The classification shall be submitted to the customer for acceptance. The classification procedure shall be documented and records related to an item or activity shall be maintained.

NQA-2012	IAEA GS-R-3	ISO 9001/2008	NSQ-100
REQUIREMENT 1 Organization	**Management System**	**Quality Management System**	**1 Scope**
	2.7		**4.1.3 Grading the application of quality requirements**
	Grading of the application of management system requirements shall be applied to the products and activities of each process.		For classified items or activities, the associated quality management level, surveillance level and documentation requirements shall be graded in accordance with the classification of the item or activity. The organization shall justify and document the method used to define the above relevant requirements.
	DOCUMENTATION OF THE MANAGEMENT SYSTEM		
	2.8		**4.2 Documentation requirements**
	The documentation of the management system shall include the following: —The policy statements of the organization; —A description of the management system; —A description of the structure of the organization; —A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work; —A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.		
	2.9		**4.2.1 General**
	The documentation of the		The organization shall ensure that

NQA-2012	IAEA GS-R-3	ISO 9001/2008	NSQ-100
REQUIREMENT 1 Organization	**Management System**	**Quality Management System**	**1 Scope**
	management system shall be developed to be understandable to those who use it. Documents shall be readable, readily identifiable and available at the point of use.		personnel have access to, and are aware of, relevant quality management system documentation and changes. Documentation shall be provided to the personnel in an appropriate language for its understanding.
	2.10		
	The documentation of the management system shall reflect: —The characteristics of the organization and its activities; —The complexities of processes and their interactions.		
	3 MANAGEMENT RESPONSIBILITY		**5 MANAGEMENT RESPONSIBILITY**
	Management Commitment	**Management Commitment**	**Management commitment**
	3.1	**5.1**	**5.1**
(a) senior management establishes overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result;	Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities.	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources.	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by: f) ensuring a common understanding of the key aspects of safety culture within the organization, g) providing the means by which the organization continually seeks to develop and improve its safety culture.
		5.5.1 Responsibility and authority	

NQA-2012	IAEA GS-R-3	ISO 9001/2008	NSQ-100
REQUIREMENT 1 Organization	**Management System**	**Quality Management System**	**1 Scope**
(b) quality is achieved and maintained by those assigned responsibility for performing work;		Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.	
	3.2		**5.2 Customer focus**
	Senior management shall develop individual values, institutional values and behavioral expectations for the organization to support the implementation of the management system and shall act as role models in the promulgation of these values and expectations.		Top management shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken, if planned results are not, or will not be, achieved, while, at the same time, ensuring that safety is not compromised.
	3.3		
	Management at all levels shall communicate to individuals the need to adopt these individual values, institutional values and behavioral expectations as well as to comply with the requirements of the management system.		
	3.4		
	Management at all levels shall foster the involvement of all individuals in the implementation and continual improvement of the management system.		
	3.5		
	Senior management shall ensure that it is clear when, how and by whom decisions are to be made within the management system		
	SATISFACTION OF INTERESTED PARTIES		

NQA-2012	IAEA GS-R-3	ISO 9001/2008	NSQ-100
REQUIREMENT 1 Organization	**Management System**	**Quality Management System**	**1 Scope**
	3.6		
	The expectations of interested parties shall be considered by senior management in the activities and interactions in the processes of the management system, with the aim of enhancing the satisfaction of interested parties while at the same time ensuring that safety is not compromised.		
	ORGANIZATIONAL POLICIES		
	3.7	**5.3 Quality policy**	
	Senior management shall develop the policies of the organization. The policies shall be appropriate to the activities and facilities of the organization.	Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	
	5.28		
	Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified.		
	5.29		
	The implementation of such		

NQA-2012	IAEA GS-R-3	ISO 9001/2008	NSQ-100
REQUIREMENT 1 Organization	**Management System**	**Quality Management System**	**1 Scope**
	changes shall be planned, controlled, communicated, monitored, tracked and recorded to ensure that safety is not compromised.		
	RESPONSIBILITY AND AUTHORITY FOR THE MANAGEMENT SYSTEM		
	3.12		
	Senior management shall be ultimately responsible for the management system and shall ensure that it is established, implemented, assessed and continually improved.		
	3.13	**5.5.2 Management Representative**	**5.5.2 Management Representative**
	An individual reporting directly to senior management shall have specific responsibility and authority for: —Coordinating the development and implementation of the management system, and its assessment and continual improvement;	Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained,	Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes: b) reporting directly to top management on the performance of the quality management system and any need for improvement,
	—Reporting on the performance of the management system, including its influence on safety and safety culture, and any need for improvement; —Resolving any potential conflicts between requirements and within the processes of the management system.	b) reporting to top management on the performance of the quality management system and any need for improvement, and c) ensuring the promotion of awareness of customer requirements throughout the organization.	

NQA-2012	IAEA GS-R-3	ISO 9001/2008	NSQ-100
REQUIREMENT 1 Organization	**Management System**	**Quality Management System**	**1 Scope**
(c) quality achievement is verified by those not directly responsible for performing the work			d) the organizational independence to resolve quality management issues.
(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; and (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	**3.14**	**NOTE**	
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 therefore.	The organization shall retain overall responsibility for the management system when an external organization is involved in the work of developing all or part of the management system.	The responsibility of a management representative can include liaising with external parties on matters relating to the quality management system.	

NQA-2012	IAEA GS-R-3	ISO 9001/2008	NSQ-100
REQUIREMENT 1 Organization	**Management System**	**Quality Management System**	**1 Scope**
300 INTERFACE CONTROL			**5.5 Responsibility, authority and communication**
	5.5		**5.5.1 Responsibility and authority**
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 activities of and interfaces between different individuals or groups involved in a single process shall be planned, controlled and managed in a manner that ensures effective communication and the clear assignment of responsibilities.		The organization shall retain overall responsibility for the management system when an external organization is involved in the work of developing all or part of the management system.
The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.			**5.5.4 Communication with Regulatory Bodies**
			With regards to the safety related product issues, the organization shall ensure that appropriate processes are defined in liaison with the customer to address any communication from nuclear safety Regulatory Bodies.

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100 General	**2.8**	**4.2.1 Documentation requirements** **General**	
(a) A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Part (Part I), or portions thereof.	The documentation of the management system shall include the following: —The policy statements of the organization; —A description of the management system; —A description of the structure of the organization; —A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work; —A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.	The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures and records required by this International Standard, and d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes. **NOTE 1**: Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document. **NOTE 2**: The extent of the quality management system documentation can differ from one organization to another due to a) the size of the organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel.	

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		NOTE 3: The documentation can be in any form or type of medium.	
	2.10		
	The documentation of the management system shall reflect: —The characteristics of the organization and its activities; —The complexities of processes and their interactions.		
		4.2.2 Quality manual	**4.2.2 Quality manual**
		The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of, and justification for, any exclusions, b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system.	The organization shall specify in a controlled document (quality manual, quality assurance program or a plan) the organizational, documentary and technical provisions to meet the requirements of this document and to address the nuclear safety aspects. If not covered by this document, the quality assurance program or plan shall consider additional quality requirements coming from the contract, the applicable regulations, codes and standards.
The program shall provide control over activities affecting quality to an extent consistent with their			

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importance.			
	2.9		
	The documentation of the management system shall be developed to be understandable to those who use it. Documents shall be readable, readily identifiable and available at the point of use.		
		5.4.1 Quality objectives	**5.3. Quality policy**
		Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization.	Top management shall ensure that the quality policy: f) is appropriate to safety aspects related to the product.
	3.10		
	Senior management shall ensure that measurable objectives for implementing the goals, strategies and plans are established through appropriate processes at various levels in the organization.	The quality objectives shall be measurable and consistent with the quality policy.	
	6.1		
	The effectiveness of the management system shall be monitored and measured to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement.		
	3.11	**8.2.1 Monitoring and measurement Customer satisfaction**	**8.2.1 Customer satisfaction**

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The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily.	Senior management shall ensure that the implementation of the plans is regularly reviewed against these objectives and that actions are taken to address deviations from the plans where necessary.	As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined. **NOTE 1**: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports. The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate. **NOTE 2**: When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements	Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product conformity, on-time delivery performance, customer complaints, corrective action requests and implementation of safety culture The organization shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

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		and on the effectiveness of the quality management system. **8.4 Analysis of data** The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. **8.4 Analysis of data** The analysis of data shall provide information relating to a) customer satisfaction, b) conformity to product requirements, c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers.	
The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.			
	PLANNING		**5.4 Planning**
	3.8	**5.4.2 Quality management system planning**	**5.4.2 Quality management system planning**

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The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions.	Senior management shall establish goals, strategies, plans and objectives that are consistent with the policies of the organization.	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	**NOTE**: Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified. The implementation of such changes should be planned, controlled, communicated, monitored and recorded to ensure that nuclear safety is not compromised.
	3.9		
	Senior management shall develop the goals, strategies, plans and objectives of the organization in an integrated manner so that their collective impact on safety is understood and managed.		
	4. RESOURCE MANAGEMENT		
	PROVISION OF RESOURCES		
	4.1		
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.	Senior management shall determine the amount of resources necessary and shall provide the resources to carry out the activities of the organization and to establish, implement, assess and continually improve the management system.		
	4.2		
	The information and knowledge of the organization shall be managed as a resource.		
	INFRASTRUCTURE AND THE		

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	WORKING ENVIRONMENT		
	4.5		
	Senior management shall determine, provide, maintain and re-evaluate the infrastructure and the working environment necessary for work to be carried out in a safe manner and for requirements to be met.		
	HUMAN RESOURCES		
	4.3		
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.	Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained.		
	6.17	**8.5.1 Continual Improvement**	
The organization shall establish and implement processes to detect and correct quality problems.	Opportunities for the improvement of the management system shall be identified and actions to improve the processes shall be selected, planned and recorded.	The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	
	6.18		
	Improvement plans shall include plans for the provision of adequate resources. Actions for improvement		

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	shall be monitored through to their completion and the effectiveness of the improvement shall be checked.		
	4.4		
(b) The program shall provide for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to assure that suitable proficiency is achieved and maintained.	Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall 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.		
	6.7	**5.6.1 Management review** **General**	**5.6.2 Review input**
(c) Management shall regularly assess the adequacy and effective implementation of the quality assurance program.	A management system review shall be conducted at planned intervals to ensure the continuing suitability and effectiveness of the management system and its ability to enable the objectives set for the organization to be accomplished. **6.2**. Senior management and	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy	Lessons learned from other organizations shall be also taken into account.

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	management at all other levels in the organization shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture. **6.8.** The review shall cover but shall not be limited to: —Outputs from all forms of assessment; —Results delivered and objectives achieved by the organization and its processes; —Non-conformances and corrective and preventive actions; —Lessons learned from other organizations; —Opportunities for improvement. **6.9.** Weaknesses and obstacles shall be identified, evaluated and remedied in a timely manner. **6.10.** Reviews shall identify if there is a need to change policies, plans, objectives and processes.	and quality objectives. Records from management reviews shall be maintained. **5.6.2 Review input** The input to management review shall include information on a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement. **5.6.3 Review output** The output from the management review shall include any decisions and actions related to a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.	
		5.5.3 Internal communication Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place	

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		regarding the effectiveness of the quality management system.	
	4.1 PROVISION OF RESOURCES Senior management shall determine the amount of resources necessary and shall provide the resources to carry out the activities of the organization and to establish, implement, assess and continually improve the management system.	**6.1 Provision of resources** The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.	**6.1 Provision of resources** **NOTE**: Information and knowledge of the organization shall be managed as a resource.
	4.2 PROVISION OF RESOURCES The information and knowledge of the organization shall be managed as a resource.	**6.2.1 Human resources General** Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience. **NOTE**: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.	**6.2.1 General** Personnel involved in the realization of the product shall be trained on the importance of their tasks and of the eventual consequences on the nuclear safety of any malfunction or error in their activities.
	4.3 HUMAN RESOURCES Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained.		**6.2.2 Competence, qualification, training and awareness** The organization shall: b) where applicable, provide training or take other actions, as maintenance of proficiency, to achieve the necessary competence, f) assess the adequacy of the personnel with the expected or required competence.

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	4.4 HUMAN RESOURCES Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall 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.		
	4.5 INFRASTRUCTURE AND WORK ENVIRONMENT	**6.3 Infrastructure**	
	Senior management shall determine, provide, maintain and re-evaluate the infrastructure and the working environment necessary for work to be carried out in a safe manner and for requirements to be met.	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable, a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport, communication or information systems).	
	5.2	**6.4 Work environment**	**6.4 Work environment**

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	The sequence and interaction of the processes shall be determined.	The organization shall determine and manage the work environment needed to achieve conformity to product requirements. **NOTE**: The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).	**NOTE**: The term "work environment" refers to working conditions including radiation safety.
	5.3		
	The methods necessary to ensure the effectiveness of both the implementation and the control of the processes shall be determined and implemented.		
	5.1	**7.1**	**7.1 Planning of product realization**
	The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved.	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents, and to provide resources specific to the product;	The organization shall determine, as appropriate: a) quality objectives and requirements for the product, which may include aspects such as: —product performances, —nuclear safety, —reliability, availability and maintainability, —producibility and inspectability during and after manufacture, —health and safety aspects during set-up, operating and maintenance phases, —when contractually required,

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		c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements. The output of this planning shall be in a form suitable for the organization's method of operations. **NOTE 1**: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan. **NOTE 2**: The organization can also apply the requirements given in 7.3 to the development of product realization processes.	environmental aspects of parts and materials used in the product, and —when contractually required, safety and environmental aspects during retrieval. e) management of product change, f) commissioning program, if applicable, and g) when contractually required, resources to support the operating and maintenance of the product. **NOTE 1**: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a project quality plan. **NOTE 2**: Product change means any product change or any modification in production processes which may affect its quality or performances.
			7.1.1 Project management
			As appropriate to the organization and the product, the organization shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints, complemented, if applicable, with health and safety, environmental, security and

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			economic considerations.
			7.1.2 Risk management
			The organization shall develop a project risk management, related to the achievement of applicable requirements. This includes, as appropriate to the organization and the product: a) definition of risk criteria (e.g. likelihood, consequences, risk acceptance), b) identification, assessment and communication of risks throughout product realization including supply chain, c) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria.
	5.4	**7.2.1 Determination of requirements related to the product**	**7.2.2 Review of requirements related to the product**
	The development of each process shall ensure that the following are achieved: —Process requirements, such as applicable regulatory, statutory, legal, safety, health, environmental, security, quality and economic requirements, are specified and addressed. —Hazards and risks are identified, together with any necessary	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements applicable to the product, and	The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that: d) manufacturing feasibility has been investigated and confirmed,

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	mitigatory actions. —Interactions with interfacing processes are identified. —Process inputs are identified. —The process flow is described. —Process outputs (products) are identified. —Process measurement criteria are established.	d) any additional requirements considered necessary by the organization. **NOTE**: Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.	e) all risks are considered for: —the respect of all safety functions of the product (including mechanical, electrical, instrumentation and command aspects), —manufacturing, erection, testing and commissioning of the product.
		7.2.2 Review of requirements related to the product The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, and c) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained. Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before	

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		acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. **NOTE** In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.	
		7.2.3 Customer communication The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.	**7.2.3 Customer communication** The organization shall determine and implement effective arrangements for communicating with customers in relation to: a) product information, including nuclear safety aspects, b) when required, management of communication with nuclear Regulatory Bodies. The organization shall be able to communicate necessary information, in particular, and compulsorily, those related to nuclear safety issues, including data, in a customer-specified language and format (e.g. computer aided design data, electronic data exchange).
200 INDOCTRINATION AND TRAINING			
Indoctrination and training shall be commensurate with scope,			

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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	**4.3**		
The need for a formal training program for personnel performing or managing activities affecting quality shall be determined.	Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained.		
	4.4		
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	Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have		The organization shall designate activities that require qualification of personnel and the minimum requirements for such personnel. Provisions shall be taken to define competent personnel able to

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applications or experience is needed to achieve and maintain proficiency.	received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall 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.		elaborate, verify and approve documents issued in foreign languages. A list of these personnel shall be established and maintained. A documented procedure shall be defined for qualification of such personnel.
		6.2.2 Competence, awareness and training The organization shall a) determine the necessary competence for personnel performing work affecting conformity to product requirements, b) where applicable, provide training or take other actions to achieve the necessary competence, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience.	
300 QUALIFICATION REQUIREMENTS			

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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)			
This section 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			

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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 years.			
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.			

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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 303.6 of this Requirement prior to being designated a Lead Auditor.			
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.			

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(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 years 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			

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(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 which 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			

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Lead Auditors who fail to maintain their proficiency for a period of 2 years 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			

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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.			
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) basis of qualification			
(a) education, experience, indoctrination, and training (b) test results, where applicable (c) capability demonstration results;			

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	DOCUMENTATION OF THE MANAGEMENT SYSTEM		
(5) results of periodic evaluation;			
(6) results of physical examinations, when required;			
(7) signature of employer's designated representative who is responsible for such certification;			
(8) date of certification or recertification and certification expiration.			
(b) The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.			
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 below.			

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	DOCUMENTATION OF THE MANAGEMENT SYSTEM		
500 RECORDS			
Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records.			
Records of indoctrination and training shall include one or more of the following: (a) attendance sheets (b) training logs, or (c) personnel training records.			
The employer shall establish and maintain records for indoctrination and training; Auditor and Lead Auditor qualification and re-qualification; and inspection and test personnel qualification and re-qualification.			

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REQUIREMENT 3 Design Control			
100 General	**5.14**	**7.3.1 Design and development planning**	**7.3.1 Design and development planning**
The design shall be defined, controlled, and verified.	Specifications and requirements for products, including any subsequent changes, shall be in accordance with established standards and shall incorporate applicable requirements. Products that interface or interact with each other	The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages,	During the design and development planning, the organization shall determine and document: d) the design interfaces. Where appropriate, the organization shall divide the design and development effort into distinct activities and, for

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	shall be identified and controlled.	b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development.	each activity, define the tasks, necessary resources, responsibilities, design content, input and output data and planning constraints. The different design and development tasks to be carried out shall be based on the nuclear safety and functional objectives of the product in accordance with customer, legal, statutory and regulatory requirements. Design and development planning shall consider the ability to produce, inspect, install, test and maintain the product.
Design inputs shall be specified on a timely basis and translated into design documents.			
		7.3.1 Design and development planning	
Design interfaces shall be identified and controlled.		The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.	
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.	**5.13** Changes to documents shall be reviewed and recorded and shall be subject to the same level of approval as the documents themselves.		
		Planning output shall be updated, as	

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		appropriate, as the design and development progresses. **NOTE** Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.	
200 DESIGN INPUT	**5.14**	**7.3.2 Design and development inputs**	**7.3.2 Design and development inputs**
Applicable design inputs shall be identified and documented, and their selection reviewed and approved.	Specifications and requirements for products, including any subsequent changes, shall be in accordance with established standards and shall incorporate applicable requirements. Products that interface or interact with each other shall be identified and controlled.	Inputs relating to product requirements shall be determined and records maintained. These inputs shall include a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development.	Inputs relating to product requirements shall be determined, translated into design documents and records maintained (see 4.2.5). These inputs shall include: a) functional and performance requirements including nuclear safety requirements e) risk identified for the product Design and Development inputs shall include a description of hardware and the specifications addressing interfaces between hardware and software.
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.		The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.	

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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.			
		7.3.3 Design and development outputs The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use. **NOTE**: Information for production and service provision can include details for the preservation of product.	Design and development outputs shall: d) specify the characteristics of the product that are essential for its safe and proper use (to be included in Instructions of use), and e) specify, for IFS items or activities, any critical characteristics translated into technical specifications. **NOTE 1**: Information for production and service provision shall at least include details for the manufacture, test, installation, operating, maintenance and preservation of product. **NOTE 2**: Configuration management shall identify and document characteristics of the software and ensure that consistency is maintained.

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(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:			The organization shall define the data required to allow the product to be identified, manufactured, inspected, used and maintained, including at least: —the software configuration management.
(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; and			
(3) identify assemblies and/or components that are part of the item being designed.			—the drawings, part lists and specifications necessary to define the configuration and the design features of the product, —the material, process, manufacturing and assembly data needed to ensure conformity of the product, and
When such an assembly or component part is a commercial grade item, the characteristics of the item to be verified for acceptance and the			

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acceptance criteria for those characteristics shall meet the requirements of Part II, Sub-Part 2.14, Quality Assurance Requirements for Commercial Grade Items and Services.			
Characteristics to be verified are those which 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			**7.3.1 Design and development planning**
To the extent required in para. 401(a) and (b) of this Requirement, computer program acceptability shall be pre-verified or the results verified with the design analysis for each application.			In case of computation or computerized models, the organization shall demonstrate that those are verified within their scope and validated. Individuals using the above shall be competent-Methods

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			and means used for design verification and their combinations shall be defined prior to design and development realization. The software design and development stages shall be organized throughout the life cycle including the main four following processes: —Specification, —General and detail design, —Coding, —Integration and tests. If tests are used for any design & development purposes, provisions of 7.3.8 shall be respected
Pre-verified computer programs shall be controlled in accordance with the requirements of this Standard.			
(a) The computer program shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.			
(b) The encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.			
402 Documentation of Design Analysis			
Documentation of design analyses shall include the following:			
(a) the objective of the analyses;			
(b) design inputs and their sources;			

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(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; and			
(f) review and approval.			
500 DESIGN VERIFICATION		**7.3.5 Design and development verification**	**7.3.5 Design and development verification**
(a) The responsible design organization shall identify and document the particular design verification method(s) used.		Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.	The methods used for design verification shall be identified and documented. Design verification shall be performed by any competent person or group, clearly indicated and other than those who performed the original design of the product or participated to related design activities.
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.			

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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 for 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,			

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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		**7.3.4 Design and development review**	**7.3.4. Design and development review**
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.		At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements a) to evaluate the ability of the results	At suitable stages, systematic reviews of design and development shall be performed in accordance with Planned arrangements:

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		of design and development to meet requirements, and b) to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.	c) to authorize progress to the next stage. Reviews shall be documented and detailed in such a manner that no ambiguity or misunderstanding may occur.
(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 re-verifications 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			

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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			**7.3.8. Design and development verification and validation testing**
Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions.			Where tests are necessary for verification and validation of the design, these tests shall be planned, controlled, reviewed and documented to ensure and prove the following: a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria, b) test procedures describe the method of operation, the performance of the test and the recording of the results, c) the correct configuration of the product is submitted for the test, d) the requirements of the test plan and the test procedures are observed, and e) the acceptance criteria are met. For software, testing methods to be implemented are:

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			—unit testing, to check software compliance with detailed design inputs, —integration testing, to check software compliance with general design inputs, —system testing, to check that overall software complies with specifications. Any requirement of the software specification shall be validated by a test and testing conditions shall include normal and downgraded 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.			**7.3.6 Design and development validation** **NOTE**: If required, the design and development validation may involve inspections or reviews from independent parties. Such demonstration shall be recorded.
		7.3.6 Design and development validation	

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		Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained	
600 CHANGE CONTROL		**7.3.7 Control of design and development changes**	**7.3.7 Control of design and development changes**
(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.		Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation.	Design and development changes shall be identified, justified, records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on classification, constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained. The personnel or group approving the design and development changes must be authorized, competent in the field of concern and have knowledge of the requirements and the intent of the original design.

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These measures shall include evaluation of effects of those changes on the overall design and on any analyses upon which the design is based.		**7.3.7 Control of design and development changes** The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained**.**	
			7.3.8 Design and development verification and validation documentation At the completion of design and/or development, the organization shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions. Records of related documents shall be kept
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 which reviewed and approved the original design documents. When the organization originally responsible for review and approval of the original design documents is no longer responsible, then the owner or his designee shall have responsibility or			

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designate a new responsible design 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			**7.1.3 Configuration Management**
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			When applicable, the organization shall establish, implement and

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ensure changes that may affect the approved configuration are recognized and processed.			maintain a configuration management process that includes, as appropriate to the product: a) configuration management planning, b) configuration identification, c) change control, d) configuration status accounting, & e) configuration audit
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 assure that proposed changes to the configuration			

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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 utilized 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 which require further evaluation, review, or approval.			

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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			
The requirements of Section 800 apply to computer software design control and shall be used instead of sections 200, Design Input; 300, Design Process; 500, Design Verification; and 600, Change Control.			
Part II, Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications, provides work practice requirements to implement the requirements of this paragraph. 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.			
801 Software Design Process			
The software design process shall be documented, approved by the responsible design organization, and controlled.			

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REQUIREMENT 3 Design Control			
This process shall include the activities described in paras. 801.1 through 801.5 of this Requirement.			
801.1 Identification of Software Design Requirements			
Software design requirements shall be identified and documented and their selection reviewed and approved.			
The software requirements shall identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.			
801.2 Software Design			
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.			

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801.3 Implementation of the Software Design			
The software design shall be translated into computer program(s) using the programming organization's or design organization's programming standards and conventions.			
801.4 Software Design Verification			
Software design verification shall be performed by 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.			

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The extent of verification and the methods chosen are a function of:			
(a) the complexity of the software;			
(b) the degree of standardization;			
(c) the similarity with previously proved software; and			
(d) the importance to safety.			
801.5 Computer Program Testing. Computer program testing shall be performed and shall be in accordance with Requirement 11.			
802 Software Configuration Management			**7.3.7 Control of design and development changes**
Software configuration management includes, but is not limited to, configuration identification, change control, and status control.			
Configuration items shall be maintained under configuration management until the software is retired.			Software changes management shall ensure the integrity, i.e. only validated changes are incorporated. Software changes verification shall include regression testing.
802.1 Configuration Identification			
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.			
A labeling system for configuration items shall be implemented that:			

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(a) uniquely identifies each configuration item;			
(b) identifies changes to configuration items by revision; and			
(c) provides the ability to uniquely identify each configuration of the revised software available for use.			
802.2 Configuration Change Control			
Changes to software shall be formally documented.			
The documentation shall include:			
(a) a description of the change;			
(b) the rationale for the change; and			
(c) 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.			
802.3 Configuration Status Control			

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

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REQUIREMENT 4 Procurement Document Control			
100 General		**7.4.2 Purchasing information**	
Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services.		The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.	

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REQUIREMENT 4 **Procurement Document Control**			
To the extent necessary, procurement documents shall require Suppliers to have a quality assurance program consistent with the applicable requirements of this Standard.			
	5.17	**7.4.1 Purchasing process**	
	Products shall be provided in such a form that it can be verified that they satisfy the requirements.	The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.	
200 CONTENT OF THE PROCUREMENT DOCUMENTS	**5.24**		
Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the Purchaser.	Purchasing requirements shall be developed and specified in procurement documents. Evidence that products meet these requirements shall be available to the organization before the product is used.		

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REQUIREMENT 4 Procurement Document Control			
201 Scope of Work			**7.4.2.1 Content of the procurement documents**
Procurement documents shall include a statement of the scope of the work to be performed by the Supplier.			Purchasing information shall describe the product to be purchased and its corresponding scope of work, including, where appropriate: —flow down to the supply chain the relevant requirements including customer requirements, i) records retention requirements,
202 Technical Requirements			**7.4.2.1 Content of the procurement documents**
Technical requirements shall be specified in the procurement documents.			d) technical requirements : identification, revision and, if appropriate, status of specifications, drawings, codes, standards, regulations, process requirements, and other relevant technical data
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.			
	5.16	**7.4.2**	**7.4.2.1 Content of the procurement documents**
The procurement documents shall identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.	The organization shall confirm that products meet the specified requirements and shall ensure that products perform satisfactorily in service.	Purchasing information Purchasing information shall describe the product to be purchased, including, where appropriate, a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of	e) requirements for design, test, inspection and surveillance (including instructions and acceptance criteria) for determining acceptance of the product and, as applicable, critical characteristics,

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REQUIREMENT 4 **Procurement Document Control**			
		personnel,	
	5.24. Purchasing requirements shall be developed and specified in procurement documents. Evidence that products meet these requirements shall be available to the organization before the product is used.		
203 Quality Assurance Program Requirements			**7.4.2.1 Content of the procurement documents**
Quality assurance program requirements shall be specified in the procurement documents.		c) quality management system requirements.	c) quality management system requirements consistent with nuclear safety classification and/or impact on final quality of the product,
These requirements shall be consistent with importance and/or complexity of the item or service being procured.		**7.4.1 Purchasing process** The organization shall ensure that purchased product conforms to specified purchase requirements.	
The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in subtier procurement documents.		**7.4.1 Purchasing process** The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.	
204 Right of Access			**7.4.2.1 Content of the procurement documents**
The procurement documents shall provide for access to the Supplier's and sub-tier Supplier's facilities and records for surveillance, inspection, or audit by the Purchaser, its designated representative, and others authorized by the Purchaser.			j) right of access by the organization, their customers, third party organizations, Regulatory Bodies, and/ or their respective representatives, to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

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REQUIREMENT 4 Procurement Document Control			
205 Documentation Requirements			**7.4.2.1 Content of the procurement documents**
The procurement documents shall identify the documentation required to be submitted for information, review, or approval by the Purchaser.			f) identification of the documentation that the supplier has to submit for information, review or approval,
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	**5.25**		**7.4.2.1 Content of the procurement documents**
The procurement documents shall specify the Purchaser's requirements for the Supplier's reporting of nonconformances.	Requirements for the reporting and resolution of non-conformances shall be specified in procurement documents.		h) requirements regarding the need for the supplier to: —notify the organization of nonconforming product, —obtain organization approval for nonconforming product disposition
207 Spare and Replacement Parts			**7.4.2.1 Content of the procurement documents**
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.			g) requirements to identify spare parts and the related data required for ordering these spare parts,
300 Procurement Document Review			**7.4.2.2 Procurement document review**
A review of the procurement documents, and changes thereto, shall be made and documented prior to award to assure that documents			The organization shall ensure by a review of the procurement document, the adequacy of specified purchase requirements prior to their

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REQUIREMENT 4 Procurement Document Control			
transmitted to prospective Supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements.			communication to the supplier. Procurement document review shall be performed by competent personnel, other than those who issued the procurement document, and recorded.
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.			h) requirements regarding the need for the supplier to: —notify the organization of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and, where required, obtain organization approval.
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			**7.4.2.3 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.			Procurement document changes affecting the technical or quality requirements shall be subject to the same process and control as utilized in the preparation of the original documents.

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REQUIREMENT 5 Instructions, Procedures, and Drawings			

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100 General	**5.9**		
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 work performed in each process shall be carried out under controlled conditions, by using approved current procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness. Results shall be compared with expected values.		
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).	**5.9** The work performed in each process shall be carried out under controlled conditions, by using approved current procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness. Results shall be compared with expected values.		

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REQUIREMENT 6 Document Control			
100 General	**5.12**	**4.2.3 Control of documents**	**4.2.3 Control of documents**
The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be	Documents shall be controlled. All individuals involved in preparing, revising, reviewing or approving documents shall be specifically assigned this work, shall be	Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled	The preparation, issue, and change of documents that specify product quality requirements or prescribe activities affecting product quality such as instructions, procedures, and

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REQUIREMENT 6 Document Control			
controlled to assure that correct documents are being employed.	competent to carry it out and shall be given access to appropriate information on which to base their input or decisions. It shall be ensured that document users are aware of and use appropriate and correct documents.	according to the requirements given in 4.2.4.	drawings shall be verified and approved for release by authorized personnel.
	5.10 The control of processes contracted to external organizations shall be identified within the management system. The organization shall retain overall responsibility when contracting any processes.		
Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.			Changes to documents shall be reviewed, recorded and shall be subject to the same level of approval as the documents themselves.
200 DOCUMENT CONTROL		**4.2.3 Control of documents**	
The following controls shall be applied to documents and changes thereto:		A documented procedure shall be established to define the controls needed a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin determined by the organization	

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REQUIREMENT 6 Document Control			
		to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.	
(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;			The individual who performs the verification must be other than those who have prepared, issued or changed the document.
(d) the review of controlled documents for adequacy, completeness, and approval prior to distribution; and			
(e) a method to ensure the correct documents are being used.			
300 DOCUMENT CHANGES			
301 Major Changes	**5.13**		
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.	Changes to documents shall be reviewed and recorded and shall be subject to the same level of approval as the documents themselves.		
The reviewing organization shall have access to pertinent background data or			

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REQUIREMENT 6 Document Control			
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.			

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REQUIREMENT 7 Control of Purchased Items and Services			
100 General			
The procurement of items and services shall be controlled to assure 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.			

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REQUIREMENT 7 Control of Purchased Items and Services			
200 SUPPLIER EVALUATION AND SELECTION	**5.23**		**7.4.1 Purchasing process**
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.	Suppliers of products shall be selected on the basis of specified criteria and their performance shall be evaluated.		The organization shall be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer. Anyone involved in the supply chain shall take the required measures in the purchasing data to ensure that the customer's requirements are transmitted to the suppliers. Furthermore, the supplier at every level of the supply chain has to verify that requirements have been taken into account and implemented in order to ensure the product acceptance.
Supplier evaluation and selection and the results therefrom shall be documented and shall include one or more of the following:			The organization shall evaluate and select suppliers, based on their ability to supply product in accordance with the organization's requirements (at least, taking into account technical, quality and safety aspects), and: a) define the process, responsibilities and authority for: —the approval status decision, —the change of the approval status. b) define the necessary actions to implement in case of selection of commercial grade item supplier. c) periodically review supplier performance; the results of these reviews shall be used as a basis for

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REQUIREMENT 7 **Control of Purchased Items and Services**			
			establishing the monitoring level to be implemented, and d) maintain a register of approved suppliers. When a supplier does not meet applicable requirements of this document, partial or complete substitution by the organization quality system to the supplier's one shall be ensured. Information of this substitution shall be made available up to the Contractor.
(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	**5.23**	**7.4.1**	
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.	Suppliers of products shall be selected on the basis of specified criteria and their performance shall be evaluated.	**Purchasing process** The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established.	

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		Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.	
			7.4.1.2 Important For Safety product, item or activity In case of subcontracted product, item or activity identified as IFS, any supplier involved in the supply chain has to comply with the relevant requirements of this document, according to graded approach results
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 assure 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			

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REQUIREMENT 7 Control of Purchased Items and Services			
501 General	**5.24**		**7.4.3 Verification of purchased product**
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.	Purchasing requirements shall be developed and specified in procurement documents. Evidence that products meet these requirements shall be available to the organization before the product is used.		Any verification activity shall be planned, documented and recorded. **NOTE**: Customer verification activities performed at any level of the supply chain should not be used by the organization or the supplier as evidence of effective monitoring of quality and does not absolve the organization or the supplier of their responsibility to provide acceptable product compliant with all requirements. Organization, customer, licensee, third party organizations, Regulatory Bodies, and/or their respective representatives, may reserve the right to verify throughout the supply chain that products and quality management system comply with specified purchasing requirements.
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	**5.24**		
Purchaser methods used to accept an item or service from a Supplier shall be a Supplier Certificate of Conformance, source verification, receiving inspection, or post-installation test at the nuclear facility	Purchasing requirements shall be developed and specified in procurement documents. Evidence that products meet these requirements shall		

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site, or a combination of these methods.	be available to the organization before the product is used.		
		7.4.3 Verification of purchased product The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.	
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.			

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

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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.		**7.4.3 Verification of purchased product** Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.	
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; and (e) cleanliness.			

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REQUIREMENT 7 Control of Purchased Items and Services			
Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.			
506 Post-installation Testing			
When post-installation testing is used, post-installation 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	**5.25**		
Methods for control and disposition of Supplier nonconformances for items and services that do not meet procurement documentation	Requirements for the reporting and resolution of non-conformances shall be specified in procurement documents.		

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REQUIREMENT 7 Control of Purchased Items and Services			
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;			

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REQUIREMENT 7 Control of Purchased Items and Services			
(c) Purchaser disposition of Supplier recommendation;			
(d) verification of the implementation of the disposition; and			
(e) maintenance of records of Supplier-submitted nonconformances.			
700 COMMERCIAL GRADE ITEMS			
701 General			
When commercial grade items or services are utilized, the requirements of Part II Sub-Part 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			

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REQUIREMENT 8 **Identification and Control of Items**			
100 General		**7.5.3 Identification and traceability**	**7.5.3 Identification and traceability**
Controls shall be established to assure that only correct and accepted items are used or installed.		Where appropriate, the organization shall identify the product by suitable means throughout product realization.	IFS items or activities are subject to an identification. The associated documentation shall be clearly identified and linked to the products without ambiguity. When acceptance authority media are used (e.g. stamps, electronic signatures, passwords), the organization shall establish appropriate controls for the media.
		The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.	
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.	**5.19** Products shall be identified to ensure their proper use. Where traceability is a requirement, the organization shall control and record the unique identification of the product.	Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records	
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			

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REQUIREMENT 8 Identification and Control of Items			
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			

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REQUIREMENT 8 Identification and Control of Items			
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.			

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REQUIREMENT 9 Control of Special Processes	**Process Management**		
100 General	**5.6**	**7.5.1 Control of production and service provision**	**7.5.1 Control of production and service provision**
	For each process a designated individual shall be given the authority and responsibility for: —Developing and documenting the process and maintaining the necessary supporting documentation;	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product,	The organization shall plan and carry out production and service provision under controlled conditions.

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REQUIREMENT 9 **Control of Special Processes**	**Process Management**		
	—Ensuring that there is effective interaction between interfacing processes; —Ensuring that process documentation is consistent with any existing documents; —Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation; —Monitoring and reporting on the performance of the process; —Promoting improvement in the process; —Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the organization.	b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring equipment, e) the implementation of monitoring and measurement, and f) the implementation of product release, delivery and post-delivery activities.	
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.			Controlled conditions shall include, as applicable: c) the use of suitable equipment, **NOTE**: Suitable equipment can include product specific tools (e.g., jigs, fixtures, molds) and computer program. g) evidence that all production, inspection and/or surveillance operations have been completed as planned, or as otherwise documented and authorized. Planning shall consider, as appropriate: —establishing, implementing and

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REQUIREMENT 9 **Control of Special Processes**	**Process Management**		
			maintaining appropriate processes to manage IFS items or activities, including process monitoring where critical characteristics have been identified, —identifying in-process inspection points when adequate verification of conformance cannot be performed at later stages of realization, and —special processes
			7.5.1.1 Control of production process changes Personnel authorized to approve changes to production processes shall be identified. The organization shall control and document changes affecting processes, production equipment, tools or computer programs. The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.
			7.5.2 Validation of processes for production and service provision The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. **NOTE:** These processes are often referred to as special processes.

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REQUIREMENT 9 **Control of Special Processes**	**Process Management**		
	5.8	**7.5.2 Validation of processes for production and service provision**	**7.2 Customer-related processes**
	Each process shall be evaluated to ensure that it remains effective.	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. **8.1 Measurement, analysis and improvement General** The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity to product requirements, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system This shall include determination of applicable methods, including statistical techniques, and the extent of their use.	**7.2.1 Determination of requirements related to the product** The organization shall determine: c) statutory and regulatory requirements, including nuclear safety aspects, applicable to the product. The supplier has to establish a documented list of items and activities classified as IFS or important for the final quality of the product, and determine the associated quality management level, surveillance level and documentation requirements. **NOTE 2**: Nuclear safety aspects concern the safety culture, the graded approach, IFS items and activities, and the implementation of applicable construction codes and standards.
200 Process Control			
201 Special Processes	**5.9**		
Special processes shall be controlled by instructions, procedures, drawings,	The work performed in each process shall be carried out under controlled conditions, by using		

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REQUIREMENT 9 **Control of Special Processes**	**Process Management**		
checklists, travelers, or other appropriate means.	approved current procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness. Results shall be compared with expected values.		
	5.7		
Special process instructions shall include or reference procedure, personnel, and equipment qualification requirements.	For each process, any activities for inspection, testing, verification and validation, their acceptance criteria and the responsibilities for carrying out these activities shall be specified. For each process, it shall be specified if and when these activities are to be performed by designated individuals or groups other than those who originally performed the work.		
		7.5.2 Validation of processes for production and service provision	
Conditions necessary for accomplishment of the process shall be included.		The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.	
These conditions shall include proper equipment, controlled parameters of			**7.5.1.2 Control of production equipment, tools and computer**

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REQUIREMENT 9 **Control of Special Processes**	**Process Management**		
the process, specified environment, and calibration requirements.			**programs** Production equipment, tools and computer programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and shall be maintained. Storage requirements, including periodic preservation/condition checks, shall be defined for production equipment or tooling in storage.
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.			
	5.10		
	The control of processes contracted		

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REQUIREMENT 9 **Control of Special Processes**	**Process Management**		
	to external organizations shall be identified within the management system. The organization shall retain overall responsibility when contracting any processes.		
	5.16	**8.2.4 Monitoring and measurement of product**	
	The organization shall confirm that products meet the specified requirements and shall ensure that products perform satisfactorily in service.	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product for delivery to the customer.	
	5.17		
	Products shall be provided in such a form that it can be verified that they satisfy the requirements.		
		8.2.4 Monitoring and measurement of product The release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.	**8.2.3 Monitoring and measurement of processes** In the event of process nonconformity, the organization shall: a) take appropriate action to correct the nonconforming process, b) evaluate whether the process nonconformity has resulted in product nonconformity, c) determine if the process nonconformity is limited to a

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REQUIREMENT 9 **Control of Special Processes**	**Process Management**		
			specific case or whether it could have affected other processes or products, and d) identify and control any nonconforming product
			8.2.4 Monitoring and measurement of product Measurement requirements for product acceptance shall be documented and shall include: a) criteria for acceptance and/or rejection, b) where, in the sequence measurement and testing, operations are to be performed, c) required records of the measurement results (as a minimum, indication of acceptance or rejection), and d) any specific measurement instruments required and any specific instructions associated with their use. When IFS items or activities have been identified, the organization shall ensure that these items or activities are inspected by any clearly indicated competent personnel other than those who performed the activity. The organization shall ensure that all documents required to accompany the product are present at delivery.
400 RECORDS			
Records shall be maintained as appropriate for the currently qualified			

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REQUIREMENT 9 Control of Special Processes	**Process Management**		
personnel, processes, and equipment of each special process.			

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REQUIREMENT 10 Inspection	**Control of Product**		
100 General	**5.7**		**7.5.1.3 Inspection and surveillance activities**
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.	For each process, any activities for inspection, testing, verification and validation, their acceptance criteria and the responsibilities for carrying out these activities shall be specified. For each process, it shall be specified if and when these activities are to be performed by designated individuals or groups other than those who originally performed the work.		The organization shall ensure the provisions for inspection and surveillance activities have been taken into account.
Characteristics subject to inspection and inspection methods shall be specified.			The methods used for inspection and surveillance shall be defined.
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			

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REQUIREMENT 10 Inspection	**Control of Product**		
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.			These activities shall be planned and performed by competent personnel other than those who carried out the work.
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.			These activities shall be planned and performed by competent personnel other than those who carried out the work.
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.			

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REQUIREMENT 10 Inspection	**Control of Product**		
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 re-inspection or retest, as appropriate, to verify acceptability.			
604 Acceptance			
The acceptance of the item shall be approved by authorized personnel.			

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REQUIREMENT 10 Inspection	**Control of Product**		
700 Inspections During Operations			
Periodic inspections (e.g., in-service inspections) or surveillances of structures, systems, or components shall be planned and executed to assure the continued performance of their required functions.			
800 RECORDS			**7.5.1.3 Inspection and surveillance activities**
Appropriate records shall be established, maintained, and, as a minimum, identify the following:			Appropriate records shall be established, maintained and, as a minimum, identify the following:
(a) item inspected;			—item inspected,
(b) date of inspection;			—date of inspection or surveillance
(c) inspector;			—identification of personnel who performs the inspection or surveillance
(d) type of observation;			—activity surveyed, —statements' details,
(e) results or acceptability; and			—results or acceptability,
(f) reference to information on action taken in connection with nonconformances.			—if necessary, follow up actions.

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REQUIREMENT 11 Test Control			
100 General	**5.7**		
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	For each process, any activities for inspection, testing, verification and validation, their acceptance criteria and the responsibilities for carrying out these activities shall be		

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REQUIREMENT 11 Test Control			
performance for service shall be planned and executed.	specified. For each process, it shall be specified if and when these activities are to be performed by designated individuals or groups other than those who originally performed the work.		
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.			
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			

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data with sufficient accuracy for evaluation and acceptance.			
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.			
(d) 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. (1) 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. (2) 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			

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REQUIREMENT 11 Test Control			
expected and actual results in the operating environment. (3) In-use computer programs testing shall demonstrate required performance over the range of operation of the controlled function or process.			
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,			

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REQUIREMENT 11 Test Control			
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			
The requirements of section 400 of Requirement 11 apply, instead of section 300, Test Procedures, to testing of computer programs, and as appropriate, the computer hardware and operating system.			
(a) 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 assuring 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			

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REQUIREMENT 11 Test Control			
empirical data and information from technical literature.			
(b) 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 in-use 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.			
(c) Test procedures or plans shall specify the following, as applicable: (1) required tests and test sequence (2) required ranges of input parameters (3) identification of the stages at which testing is required (4) criteria for establishing test cases (5) requirements for testing logic branches (6) requirements for hardware integration (7) anticipated output values (8) acceptance criteria (9) reports, records, standard formatting, and conventions			

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REQUIREMENT 11 **Test Control**			
500 TEST RESULTS			
Test results shall be documented and maintained. Test results shall be evaluated by a 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 paragraph 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			
602 Computer Program Test Records (a) computer program tested including system software used (b) computer hardware used (c) test equipment and calibrations, where applicable			

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REQUIREMENT 11 Test Control			
(d) date of test (e) tester or data recorder (f) simulation models used, where applicable (g) test problems (8) results and acceptability (h) action taken in connection with any deviations noted (i) person evaluating test results (k) acceptability			

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REQUIREMENT 12 Control of Measuring and Test Equipment			
100 General	**5.15**	**7.5.3 Identification and traceability**	**7.6 Control of monitoring and measuring equipment**
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.	Activities for inspection, testing, verification and validation shall be completed before the acceptance, implementation or operational use of products. The tools and equipment used for these activities shall be of the proper range, type, accuracy and precision.	The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.	The organization shall maintain a register of the monitoring and measuring equipment and define the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.
		7.6 Control of monitoring and measuring devices The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.	

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REQUIREMENT 12 Control of Measuring and Test Equipment			
200 SELECTION		**7.6 Control of monitoring and measuring devices**	**7.6 Control of monitoring and measuring equipment**
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.		The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.	Selection of measuring and test equipment shall be based at least on their measuring range and measurement accuracy having regard to the tolerance specified.
300 CALIBRATION AND CONTROL			**7.6 Control of monitoring and measuring equipment**
301 Calibration			
Measuring and test equipment shall be calibrated at prescribed time periods or usage and whenever the accuracy of the 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 and verified to corresponding nationally recognized standards.			Calibration /verification method shall be based against standards. Where no such standard exists the basis for calibration/verification shall be defined.
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			

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REQUIREMENT 12 Control of Measuring and Test Equipment			
allowable calibration tolerance. Where this 4: 1 ratio can-not be maintained, the basis for selection of the standard in question shall be technically justified.			
303 Control		**7.6 Control of monitoring and measuring devices**	**7.6 Control of monitoring and measuring equipment**
Calibration procedures shall identify or reference required accuracy and shall define methods and frequency of checking accuracy.		Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4); b) be adjusted or re-adjusted as necessary; c) have identification in order to determine its calibration status; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage.	The organization shall maintain a register of the monitoring and measuring equipment and define the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.
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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.			

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REQUIREMENT 12 **Control of Measuring and Test Equipment**			
		7.6 Control of monitoring and measuring devices When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary. **NOTE**: Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.	
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.			In order to avoid use of monitoring and measuring equipment, which are non-conform or requiring calibration/verification, the organization shall: —Implement and maintain a process for the recall of such equipment —Identify and/or segregate or remove from service such equipment.
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		**7.6 Control of monitoring and measuring devices**	

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REQUIREMENT 12 Control of Measuring and Test Equipment			
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.		In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.	
303.3 Handling and Storage			
Measuring and test equipment shall be properly handled and stored to maintain accuracy.			
303.4 Environmental Controls			**7.6 Control of monitoring and measuring equipment**
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.			The organization shall ensure that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out.
303.5 Pre-calibration 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			

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REQUIREMENT 12 Control of Measuring and Test Equipment			
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			
Records shall be established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform their 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.			

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REQUIREMENT 13 **Handling, Storage, and Shipping**			
100 BASIC	**5.20**		**7.5.5 Preservation of product**
Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.	Products shall be handled, transported, stored, maintained and operated as specified, to prevent their damage, loss, deterioration or inadvertent use.		Preservation of product shall also include, where applicable, in accordance with product specifications and applicable statutory and regulatory requirements, provisions for: a) limiting the access to the product to avoid undue intervention, b) cleaning, c) prevention, detection and removal of foreign objects, d) special handling for sensitive products or hazardous materials, and e) marking and labeling including safety warnings.
			7.5.6 Post-delivery support As applicable, post-delivery support shall be provided for: a) collection and analysis of in-service data, b) actions to be taken, including investigation and reporting, when problems are detected after delivery, c) control and updating of technical documentation, d) approval, control and use of repair schemes, and e) inspection required for off-site work (e.g., organization's work undertaken at the customer's facilities).
		7.5.4 Customer property The organization shall exercise care with customer property while it is under the organization's control or	

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REQUIREMENT 13 **Handling, Storage, and Shipping**			
		being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records. **NOTE**: Customer property can include intellectual property and personal data.	
		7.5.5 Preservation of product The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.	
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			

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REQUIREMENT 13 Handling, Storage, and Shipping			
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 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.			

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REQUIREMENT 14 Inspection, Test, and Operating Status			
100 General	**5.15**		
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 which have not passed the required inspections and tests are not inadvertently installed, used, or operated	Activities for inspection, testing, verification and validation shall be completed before the acceptance, implementation or operational use of products. The tools and equipment used for these activities shall be of the proper range, type, accuracy and precision.		
	5.18		
Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means.	Controls shall be used to ensure that products do not bypass the required verification activities.		
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.			

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REQUIREMENT 15 **Control of Nonconforming Items**			
100 General	**6.12**	**8.3 Control of nonconforming product**	**8.3 Control of nonconforming product**
Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use	Products and processes that do not conform to the specified requirements shall be identified, segregated, controlled, recorded and reported to an appropriate level of management within the organization. The impact of nonconformances shall be evaluated and non-conforming products or processes shall be either: —Accepted; —Reworked or corrected within a specified time period; or —Rejected and discarded or destroyed to prevent their inadvertent use.	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.	**NOTE**: The term "nonconforming product" includes nonconforming product returned by a customer. The following way may be used by the organization to deal with nonconforming product: e) by taking actions necessary to contain the effect of the nonconformity on other processes or products. When the characteristics of the product along the supply chain are not conforming with specified requirements, a nonconformity shall be reported.
	6.16		
	Potential nonconformances that could detract from the organization's performance shall be identified. This shall be done: by using feedback from other organizations, both internal and external; through the use of technical advances and research; through the sharing of knowledge and experience; and through the use of techniques that identify best practices.		
Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of	**6.11** The causes of non-conformances shall be determined and remedial actions shall be taken to prevent their recurrence.	**8.3 Control of nonconforming product** Where applicable, the organization shall deal with nonconforming	Products and processes that do not conform to the specified requirements shall be timely identified, segregated, controlled,

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REQUIREMENT 15 **Control of Nonconforming Items**			
nonconforming items, and for notification to affected organizations.		product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application; d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.	recorded and reported to an appropriate level of management within the organization. Nonconformity shall be timely reported in compliance with the customer requirements.
	6.13 Concessions granted to allow acceptance of a non-conforming product or process shall be subject to authorization. When non-conforming products or processes are reworked or corrected, they shall be subject to inspection to demonstrate their conformity with requirements or expected results.	**8.3 Control of nonconforming product** Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.	
		8.3 Control of nonconforming product When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.	
200 IDENTIFICATION			
Nonconforming items shall be identified by legible marking, tagging, or other methods not detrimental to the item, on either the item, the			

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REQUIREMENT 15 Control of Nonconforming Items			
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			

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REQUIREMENT 15 **Control of Nonconforming Items**			
(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.			Where applicable, justifications of use-as-is or provisions for repair shall be submitted to customer for approval. Product intended for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.
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 unless the disposition has established alternate acceptance criteria.			
Repaired items shall be reexamined in accordance with applicable procedures			

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REQUIREMENT 15 **Control of Nonconforming Items**			
and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.			

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REQUIREMENT 16 **Corrective Action**			
100 General	**6.14**	**8.5.2 Corrective action**	**8.5.2 Corrective action**
Conditions adverse to quality shall be identified promptly and corrected as soon as practicable.	Corrective actions for eliminating non-conformances shall be determined and implemented. Preventive actions to eliminate the causes of potential nonconformances shall be determined and taken.	The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	A documented procedure shall be established to define requirements for: g) flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity, h) determining specific actions, where timely and/or effective corrective actions are not achieved, i) determining if additional nonconforming product exists, based on the causes of the nonconformity and taking further action when required. Records shall be maintained to demonstrate the completion of any stage of corrective action procedure.
		8.5.2 Corrective action A documented procedure shall be established to define requirements for: a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities,	

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		c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken, and f) reviewing the effectiveness of the corrective action taken.	
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.			
	6.15		
The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management.	The status and effectiveness of all corrective and preventive actions shall be monitored and reported to management at an appropriate level in the organization.		
Completion of corrective actions shall be verified.			
		8.5.3 Preventive action The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.	**8.5.3 Preventive action** A documented procedure shall be established to define requirements for: f) providing provisions of adequate resources for improvement plans. The potential nonconformities shall be determined using also: —feedback from other organizations, —through the use of technical advance and research, —sharing of knowledge and

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REQUIREMENT 16 Corrective Action			
			experience, —through the use of techniques that identify best practices.
		8.5.3 Preventive action A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing the effectiveness of the preventive action taken.	

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REQUIREMENT 17 Quality Assurance Records	**Control of Records**		
100 General	**5.21**		**4.2.4 Control of records**
			The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.
The control of quality assurance records shall be established consistent with the schedule for accomplishing work activity. Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements.	Records shall be specified in the process documentation and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable.	**4.2.4 Control of records** Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.	

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REQUIREMENT 17 **Quality Assurance Records**	**Control of Records**		
Quality assurance records shall be identified, generated, authenticated, and maintained, and their final disposition specified.		**4.2.4 Control of records** Records shall remain legible, readily identifiable and retrievable**.**	
Record control requirements and responsibilities for these activities shall be documented.		**4.2.4 Control of records** The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.	
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.			

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REQUIREMENT 17 Quality Assurance Records	**Control of Records**		
(b) Electronic documents shall be authenticated with comparable information as in para. 300(a) of this Requirement, 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 by the Owner, or his agent when authorized, 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 which would be of significant value in demonstrating capability for safe operation;			
(b) those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item;			
(c) those which would be of significant value in determining the cause of an accident or malfunction of an item; and			
(d) those which provide required baseline data for in-service inspections.			
	5.22		

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REQUIREMENT 17 Quality Assurance Records	**Control of Records**		
401.2 Lifetime records are required to be maintained by or for the plant Owner for the life of the particular item while it is installed in the plant or stored for future use.	Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and knowledge management obligations of the organization. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record.		
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.			
	5.22		
Nonpermanent records shall be maintained for the identified retention period.	Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and knowledge management obligations of the organization. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record.		
500 Receipt Control of Records			
Each organization responsible for the receipt of records shall designate a			

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REQUIREMENT 17 Quality Assurance Records	**Control of Records**		
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			
(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, and			
(4) dust or other 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			

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REQUIREMENT 17 Quality Assurance Records	**Control of Records**		
conditions, (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media utilized for record storage.			
(c) If records are electronic documents maintained in active read/write format, provisions for dual storage in separate locations shall be provided and maintained.			
(1) Provisions shall be made for electronic documents and specially processed records 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.			
(2) Maintenance activities for media (e.g., containing electronic documents) that can degrade during the retention period shall be performed as appropriate.			
(d) When temporary storage of records (such as for processing, review, or use) is required, procedural controls shall establish the storage conditions and the maximum allowable time for temporary storage.			
Storage conditions not meeting the criteria specified in paras. 600(a) through (c)(2) of this Requirement shall be based on probabilistic risk of damage or loss.			

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REQUIREMENT 17 Quality Assurance Records	**Control of Records**		
602 Facility Types There are two equally satisfactory methods of providing storage facilities, 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	**5.22**		
Containers, or 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 above, but shall meet the requirements of para. 601.	Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and knowledge management obligations of the organization. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record.		
700 MAINTENANCE OF RECORDS			
(a) Lifetime records are required to be maintained by or for the Owner for the life of the particular item while it is installed in the plant or stored for future use.			
(b) Retention periods for nonpermanent records shall be			

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REQUIREMENT 17 Quality Assurance Records	**Control of Records**		
established and documented, and those records shall be maintained for their identified retention period.			
701 Retrieval	**5.22**		
(a) Record retention periods shall be documented.	Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and knowledge management obligations of the organization. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record.		
	5.22		
(b) Records shall be maintained for their retention periods.	Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and knowledge management obligations of the organization. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record.		
702 Change Control			
(a) The methods for record changes shall be documented.			
(b) Only authorized changes shall be made to records.			

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REQUIREMENT 17 Quality Assurance Records	**Control of Records**		
703 Access Control			
Quality records are maintained to support quality activities that require access to the records.			
Access to quality records shall be controlled to:			
(a) limit access to authorized personnel; and			
(b) for temporary record storage, identify and account for the location, responsibility, and timely return of records.			
704 Record Duplication or Media Transfer			
Records that are duplicated to the same medium or to a different medium shall be controlled to assure that:			
(a) duplication is appropriately authorized;			
(b) the record content is transferred accurately;			
(c) legibility and readability is maintained;			
(d) retrievability is maintained.			
800 MAINTENANCE 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.			Retention time must be in accordance with legal or customer requirements.
(c) The methods for record changes shall be documented.			

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REQUIREMENT 17 Quality Assurance Records	**Control of Records**		
(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			

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REQUIREMENT 18 Audits	**6. Measurement, Assessment and Improvement**		
	Independent Assessment		
100 General	**6.3**	**8.2.2 Internal audit**	**8.2.2 Internal audit**
Audits shall be performed to verify compliance to quality assurance program requirements, verify that performance criteria are met and to determine the effectiveness of the program.	Independent assessments shall be conducted regularly on behalf of senior management: —To evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives; —To determine the adequacy of work performance and leadership;	The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements	Planned arrangements for internal audit shall include specific quality assurance programs or plans.

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REQUIREMENT 18 **Audits**	**6. Measurement, Assessment and Improvement**		
	Independent Assessment		
	—To evaluate the organization's safety culture; —To monitor product quality; —To identify opportunities for improvement.	established by the organization, and b) is effectively implemented and maintained.	
	6.4	**8.2.2 Internal audit**	
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.	An organizational unit shall be established with the responsibility for conducting independent assessments. This unit shall have sufficient authority to discharge its responsibilities.	A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.	
	6.5		
	Individuals conducting independent assessments shall not assess their own work.		
	6.6		
	Senior management shall evaluate the results of the independent assessments, shall take any necessary actions, and shall record and communicate their decisions and the reasons for them.		
Audit results shall be documented and reported to and reviewed by responsible management		**8.2.2 Internal Audits** The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.	
Follow-up action shall be taken where indicated.		**8.2.2 Internal Audits** Follow-up activities shall include the verification of the actions taken and the reporting of verification results.	

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REQUIREMENT 18 Audits	**6. Measurement, Assessment and Improvement**		
	Independent Assessment		
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.			Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities including safety culture.
Scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.			
300 PREPARATION			
301 Audit Plan		**8.2.2 Internal audit**	
The auditing organization shall develop an audit plan for each audit.		An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits.	
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.		The audit criteria, scope, frequency and methods shall be defined.	
302 Personnel			
Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.		This selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.	Auditors shall not audit their own work and shall be appointed by personnel independent of the audited activity.
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			

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REQUIREMENT 18 Audits	**6. Measurement, Assessment and Improvement**		
	Independent Assessment		
audit. The audit team shall have experience or training commensurate with the scope, 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; and			
(d) describe each reported adverse audit finding.			
600 RESPONSE			
Management of the audited organization or activity shall investigate adverse audit findings,			

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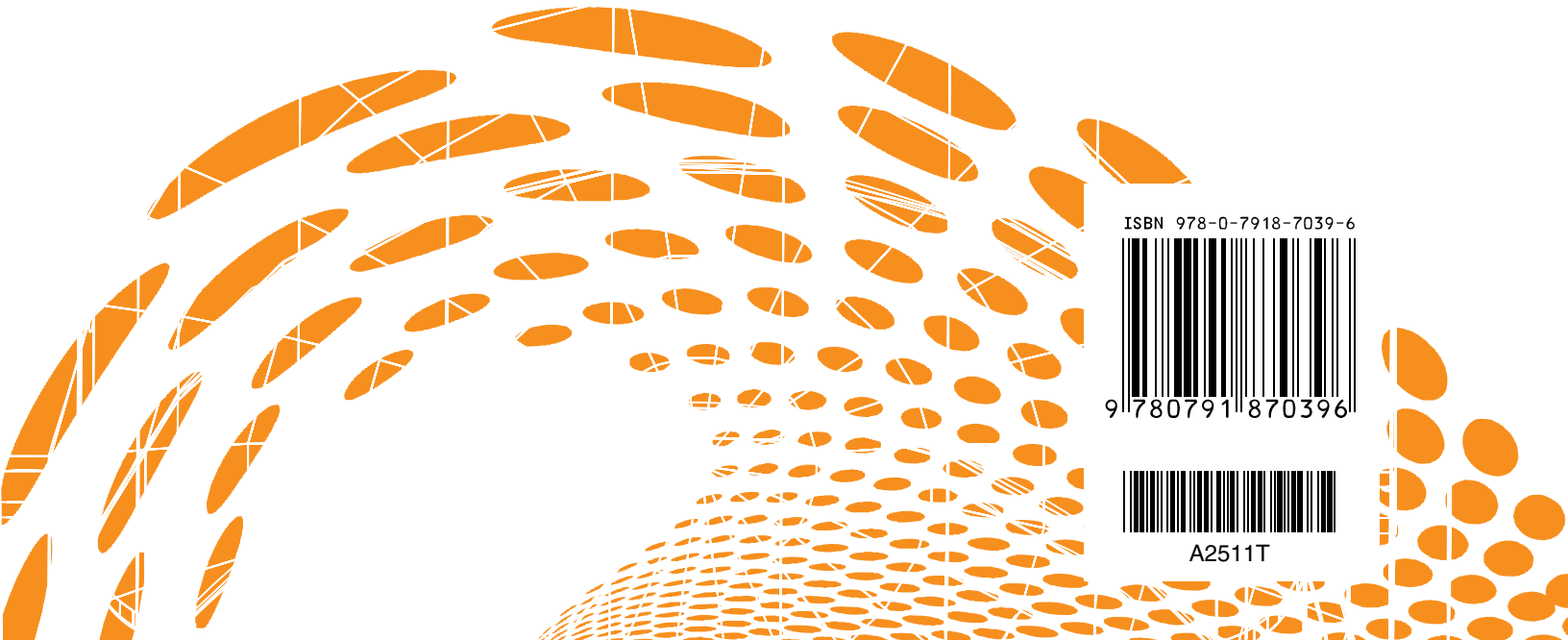
REQUIREMENT 18 Audits	**6. Measurement, Assessment and Improvement**		
	Independent Assessment		
schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of action taken or planned.			
Audit responses 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.			



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