Designation: E1212 – 17

Standard Practice for Establishing Quality Management Systems for Nondestructive Testing Agencies [1]

This standard is issued under the fixed designation E1212; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope*

1.1 This practice covers general requirements for the establishment and maintenance of a quality management system for agencies engaged in nondestructive testing (NDT).

1.2 This practice utilizes criteria contained in Practice E543.

1.3 This practice utilizes criteria contained in American National Standard ANSI/ISO/ASQ Q9001–2008, Quality management systems—Requirements.

1.4 This practice recognizes the importance of establishing minimum safety criteria.

1.5 The use of SI or inch-pound units, or combinations thereof, will be the responsibility of the technical committee whose standards are referred to in this standard.

1.6 *This practice does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this practice to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E543 Specification for Agencies Performing Nondestructive Testing

E1359 Guide for Auditing and Evaluating Capabilities of Nondestructive Testing Agencies

2.2 *ASNT/ANSI Standards:*[3]

ASNT Recommended Practice No. SNT-TC-1A Personnel Qualification and Certification in Nondestructive Testing

ANSI/ASNT CP 189 Qualification and Certification of Nondestructive Testing Personnel

2.3 *ANSI/ASQ Standards:*

A8402 Management and Quality Assurance-Vocabulary[4]

Q9000 Series of Quality Management and Quality Assurance (Q9000 through Q9004 inclusive) Standards (These are exact equivalents to the ISO 9000 through ISO 9004 series)

2.4 *AIA Standard:*

NAS 410 NAS Certification and Qualification of Nondestructive Testing Personnel[5]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *agency, n*—the public, independent, or in-house nondestructive testing organization selected by the authority to perform the examination(s) required by the purchase order or specification.

3.1.2 *authority, n*—the owner, prime contractor, engineer, architect, or purchasing agent in responsible charge of the work, or duly recognized or designated representative.

3.1.3 *continual quality improvement, n*— an ongoing quality improvement activity for achieving results. Improvement may be directed at individual processes, finished products, or administrative processes. The continual quality improvement program utilizes statistical methods, team projects, and other tools as appropriate to obtain and sustain improvements.

3.1.4 *customer, n*—customer is used with the same meaning as "authority."

3.1.5 *process capability, n*—the degree to which a process can produce the same results without variation, that is, reproducibility.

[1] This practice is under the jurisdiction of ASTM Committee E07 on Nondestructive Testing and is the direct responsibility of Subcommittee E07.09 on Nondestructive Testing Agencies.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American Society for Nondestructive Testing (ASNT), P.O. Box 28518, 1711 Arlingate Ln., Columbus, OH 43228-0518, http://www.asnt.org.

[4] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

[5] Available from Aerospace Industries Association of America, Inc. (AIA), 1000 Wilson Blvd., Suite 1700, Arlington, VA 22209-3928, http://www.aia-aerospace.org.

*A Summary of Changes section appears at the end of this standard

3.1.6 *process control, n*—managing a process to ensure that it is performing to its designed capability.

3.1.7 *quality management system, n*—the organizational structure, responsibilities, practices, procedures, processes, and resources for implementing and maintaining the quality program.

3.1.8 *quality manual, n*—a comprehensive document stating the quality policy and specifying organizational structure, practices, and procedures necessary to empower the quality policy and quality management system.

3.1.9 *quality objectives, n*—specific obtainable improvement goals supporting the quality program.

3.1.10 *quality policy, n*—the overall intentions and direction of an organization regarding quality as formally expressed by top management.

3.1.11 *quality records, n*—formal documentation of examination results or data supporting the quality management system.

3.1.11.1 *Discussion*—Examples are: audit reports, calibration data, NDT records, process qualification results, qualification data, and test data.

4. Significance and Use

4.1 This practice covers procedures for establishing and maintaining a quality system for nondestructive testing agencies.

4.2 Controlling the quality of service rendered is a continuing process. This practice provides guidelines for establishing a quality management system that provides for: calibration, standardization, reference samples, examination plans, and procedures.

4.3 The basic requirements for a quality management system encompass the following areas, all of which shall be documented.

4.3.1 Quality policy statement, planning, and administration,

4.3.2 Organization,

4.3.3 Human resources,

4.3.4 Physical resources, and

4.3.5 Quality management.

5. Quality Policy Statement, Planning, and Administration

5.1 *Policy Statement*—A policy statement shall describe management's specific intention and policy with respect to quality. The policy statement should specify an organized approach for carrying out those intentions and should address itself to all major quality parameters. It should be approved by the chief executive officer for company-wide policies or by subordinate officers for specialized policies. Periodic audits should be required to ensure adherence to quality policies.

5.2 *Quality Objectives*—Objectives should be established for appropriate key elements of performance such as safety requirements, internal performance levels, vendor performance, training, and qualification of personnel.

5.3 *Quality Management System*—A quality management system shall be established that will carry out the stated policies and objectives.

5.4 *Quality Planning*—Planning for each new or modified process or test method should define those characteristics to be controlled. Quality planning also includes providing for administrative processes needed to implement compliance with this practice.

5.5 *Quality Manual*—The quality policy and system shall be documented and be in accessible form, such as a quality manual or series of manuals. Key elements should include, as necessary:

5.5.1 The general quality statement,

5.5.2 A description of the quality system,

5.5.3 A general description of quality planning requirements with specifics for each product category where appropriate,

5.5.4 The requirements of Practice E543 pertaining to the laboratory procedure manual, and

5.5.5 Typically used examination procedures.

5.6 *Administration*—Clear lines of authority shall be established to administer the quality management system.

5.6.1 *Quality Responsibility*—The quality responsibility of each unit within the organization shall be approved by the chief operation officer of each unit.

5.6.2 *Quality Performance Reporting*—Responsibility for reporting performance against stated quality objectives to higher management should rest with functions independent of those responsible for the attainment of those objectives. Procedures for documentation and record retention should be established.

5.6.3 *Quality System Audits*—To provide assurance, a periodic audit of the quality management system should be made by an organizational element independent of the unit being audited or by a qualified third party to monitor the effectiveness of various quality management system processes. It may include, as appropriate:

5.6.3.1 Management audits to determine how well quality policy and objectives are being met,

5.6.3.2 System audits, including examination process audits to determine how well quality planning has been implemented and to identify areas where changes would be beneficial to the quality services performed, and

5.6.3.3 Records documenting findings and corrective and preventive actions taken.

6. Organization

6.1 The following information concerning the organization of the agency shall be documented.

6.1.1 A description of the organization including:

6.1.1.1 The complete legal name and address of the main office,

6.1.1.2 The names and positions of the principal officers and directors,

6.1.1.3 The agency's ownership, managerial structure, and principal members,

6.1.1.4 The functional description of the agency's organizational structure, operational departments, and support departments and services. This may be demonstrated in the form of charts that depict all the divisions, departments, sections and units, and their relationships,

6.1.1.5 All relevant organizational affiliates of the agency and principal officers of affiliates and directors of affiliates where applicable,

6.1.1.6 External organizations and organizational components and their functions that are utilized for significant technical support services, and

6.1.1.7 A brief history of the agency including its relationship with its organizational component affiliations and other supporting information.

6.1.2 A listing of the relevant technical services offered.

6.1.3 A list giving applicable dates of qualifications and accreditations.

7. Human Resources

7.1 *General*—Those aspects of the quality system where the work of the employees will affect the quality of products shall be identified, and specific action taken to control them.

7.2 *Management Responsibilities*—The quality-related requirements, duties, and responsibilities of all personnel shall be identified. Job criteria that are quality-related should be specified in job descriptions to permit proper employee selection.

7.3 *Employee Selection and Training*—Employees shall be selected on the basis of capability and experience or the potential to fully qualify for the job. A training program shall be maintained to ensure employees develop and retain skill competence. Nondestructive testing (NDT) personnel shall be qualified in accordance with a nationally recognized NDT personnel qualification practice or standard such as ANSI/ASNT-CP-189, ASNT/SNT-TC-1A, AIA/NAS 410, or a similar document. The practice or standard used and the applicable revision shall be specified in the contractual agreement between the using parties.

7.4 The agency shall provide the following documentation:

7.4.1 A written outline or chart giving operational personnel positions and their lines of responsibility and authority, and

7.4.2 A summary job description for each professional, scientific, supervisory, and technical position category including the required education, training and experience, certification, or professional licenses.

7.5 The agency shall provide a description of its methods of maintaining personnel records to document the qualifications, work experience, and training history of each person in the positions described in 7.4.2. The agency shall also provide a description of its means of ensuring confidence in its human resources including the maintenance of records.

8. Physical Resources

8.1 The agency shall provide an inventory of its relevant physical resources including:

8.1.1 A general description of the agency's facilities for NDT related activities.

8.1.2 An inventory of equipment used to perform NDT including the following for each item of equipment:

8.1.2.1 Type of equipment and use,

8.1.2.2 Name of manufacturer,

8.1.2.3 The equipment model and serial number,

8.1.2.4 Properties of the equipment subject to standardization or calibration,

8.1.2.5 The range of operation and range of calibration,

8.1.2.6 Reference to a recognized calibration procedure,

8.1.2.7 Frequency of calibration, and

8.1.2.8 Allowable tolerances or maximum sensitivity.

8.1.3 A system of written procedures for each NDT service performed by the agency. The procedures shall include a description of the methods used for NDT and the methods used for data recording, data processing, data reporting, and for certification of the results. When required, customer approval shall be obtained.

8.1.4 An inventory of reference material including a library of standards, applicable technical publications, and pertinent specifications and amendments.

9. Quality Management

9.1 *Purchased NDT Equipment, Materials, and Services:*

9.1.1 *General*—The quality management system shall include procedures to ensure effective supplier quality management for all purchased materials and services. Controls shall be provided for materials, equipment, and any subcontracted services.

9.1.2 *Supplier Quality Program and Selection Methods*—Procedures shall be established for the selection and qualification of suppliers, such as supplier surveys, past quality history, and industry history. Each supplier's quality capability shall be periodically evaluated, including audit visits where appropriate, based upon performance. The requirements for quality management shall be established in the purchase agreement. The purchase agreement should include the elements of the quality management system that are to be performed by the supplier in assuring quality.

9.1.3 *Receiving Inspection*—For those purchased items where inspection upon receipt is acceptable, inspection of submitted items shall be performed to the degree and extent needed to determine acceptability. Receiving inspection shall include well-maintained records so that past supplier performance is available. Adequate facilities and procedures for storage, handling, protection, and controlled release of purchased materials shall be established. Materials inspected, tested, and approved shall be separated from withheld or rejected materials.

9.1.4 *Nonconforming Material Control*—Control of nonconforming purchased supplies or equipment shall be maintained to ensure that such items are not used.

9.1.5 *Subcontracted Services*—When the agency utilizes the services of another agency to perform all or part of its services, provisions shall be made to ensure that the activities are performed in accordance with the purchaser's requirements. Actions to be taken shall be included in the agency's quality assurance manual. The requirements of Guide E1359 shall be

used as a guide in evaluating the quality system of the subcontracted agency.

9.2 *Measuring and Test Equipment:*

9.2.1 Measuring and test equipment shall be of the type, range, accuracy, precision, stability, and resolution appropriate for its intended use.

9.2.2 Measuring and test equipment shall be calibrated and controlled to ensure accuracy of measurement of product and processes to specified requirements. A calibration system shall be established to ensure that measuring and test equipment are maintained by periodic calibration against certified equipment traceable to nationally recognized standards and serviced so that equipment will function properly and are within their prescribed limits.

9.2.3 The calibration system shall be an integral part of the quality management system that will ensure the quality of the product or services provided. The calibration system shall be documented and shall require that the appropriate records be maintained to substantiate conformance with specified requirements.

9.3 *Document Control*—All examinations shall be performed in accordance with instructions, procedures, or other documents appropriate to the circumstances. All such work instructions, procedures, specifications, and drawings shall be controlled by the quality management system. Documents shall be reviewed for correctness and adequacy prior to release to the appropriate work station. The system shall ensure that correct revisions of applicable documents are available for use at the locations where the activities affecting quality are performed. The system shall also provide for the timely recall of obsolete documents.

9.4 *Handling, Storage, and Shipping:*

9.4.1 Factors potentially affecting the quality of items being examined as they move within the activity or on their way to the customer shall include handling damage, corrosion or infestation, degradation, loss from vandalism, and loss or obliteration of identifying markings. Methods for ensuring quality during handling, storage, and shipping include:

9.4.1.1 *Control of Handling Methods*—Use of established methods to prevent handling damage, such as special containers, environments, or vehicles,

9.4.1.2 *Item Audit*—Periodic audits of stored items to ensure against deterioration or expiration of shelf life,

9.4.1.3 *Control of Shipping Methods*—Monitoring shipping procedures to ensure that transit requirements are met and that required shipping documents are used, and

9.4.1.4 *Environment Control*—Review of procedures maintaining special protective environments, such as temperature, moisture, or gas pressure.

9.5 *Records:*

9.5.1 *Types of Quality Records*—Basic information for an effective quality system shall include, where appropriate:

9.5.1.1 Product identification to allow traceability of what has been examined, which materials and equipment were used, and by what operation, and on what date.

9.5.1.2 Examination and quality management system procedures, with applicable standards, checks, and tests. These are the working instructions of the quality management system.

9.5.1.3 Records as evidence that the prescribed examinations have been performed and results thereof.

9.5.1.4 Identification and recording of rejected product with assurance that it had been properly reported to the customer.

9.5.2 *Content and Use of Records*—All quality records shall:

9.5.2.1 Be current, complete, accurate, legible, and pertinent, showing (where required) information such as identification and quality of product examined, date, examination procedures followed, and examination results,

9.5.2.2 Contain the date of origination of the records,

9.5.2.3 Be traceable to product, process, or production period,

9.5.2.4 Where required, be identifiable as to individuals responsible for their preparation,

9.5.2.5 Where required, show quantity, type, and severity of discrepancies found, and

9.5.2.6 Be retained in accordance with a stated record retention policy, so as to be available for periodic independent reviews as may be needed to comply with the customer's contractual requirements. Protection from fire, theft, pilferage, and water damage shall be considered.

9.5.2.7 The methods to be used for management of records shall be documented in the agency's quality manual or procedures.

9.6 *Process Control:*

9.6.1 *Control of Operations*—The quality management system shall ensure that all required operations are performed in the specified manner and sequence. Operations should be defined to the maximum practical extent by documented work instructions. Exceptions made to provide for details of common practice should be limited.

9.6.2 *Receipt of Items*—Items shall be inspected upon receipt to ensure they are the items specified in the customer's order. Records shall be maintained of this inspection, traceability data (such as lot, batch, heat, or other identification), shall be recorded.

9.6.3 *Special Process Control*—Processes having parameters that affect results require special controls. To ensure adequate control of these processes, the following procedures shall be considered:

9.6.3.1 Periodic verification of accuracy and variability of the equipment used in examination of the product, for example, standardization of ultrasonic testing (UT) equipment.

9.6.3.2 Periodic verification of the continuing capabilities of operators to meet specific process quality requirements.

9.6.3.3 Periodic verification of special environments, times, temperatures, or other factors affecting product quality; for example, solution control for radiographic testing (RT) film processors.

9.6.4 *Control of Item Status*—The quality management system shall clearly identify the status of material and assemblies. Such identification may take the form of stamps, tags, or notations on travelers or records that accompany the items.

9.7 *Control of Nonconforming Material:*

9.7.1 Measures shall be established to identify and control nonconforming material. Controls shall apply to items that do not comply with acceptance criteria and to nonconforming equipment or material. Nonconforming items shall be as follows:

9.7.1.1 Identified with a clear mark, such as using a "HOLD" tag or stamp,

9.7.1.2 Segregated in a designated holding area, where practical, with access restricted to those authorized to make disposition, and

9.7.1.3 Reviewed by a clearly defined authority designated by management and customer requirements.

9.8 *Corrective Action*—The agency shall have a system to ensure that repetitive conditions adverse to the quality of the agency's work are identified and corrected. The method to be used shall be documented in the agency's quality manual or procedures. The corrective action program should be extended to suppliers as appropriate.

9.9 *Continual Quality Improvement:*

9.9.1 Continual quality improvement should be used to continually improve the effectiveness of the quality management system processes as well as to maintain satisfactory performance levels, as defined by the customer's requirements. In some instances, improvement action might be maintaining or returning to previous levels of performance. In other instances, the data analysis may support a "breakthrough" and allow achieving improved performance. Examples would include the following:

9.9.1.1 Analysis of calibration data to obtain the optimum calibration cycle.

9.9.1.2 Analysis of data to identify inconsistent performance. Note that inconsistent performance does not always mean unacceptable performance.

9.9.1.3 Analysis of data to identify opportunities to improve a process.

9.9.2 *Preventive Action*—Corrective action (see 9.8) may not be enough to identify and prevent a loss of control or change in a process. Through use of data analysis (statistical techniques) it may be possible to identify and eliminate root causes of potential problems. The method to be used shall be documented in the agency's quality manual or procedures.

9.9.3 A procedure shall be developed to focus on the quality improvement effort, so that it is used to maximum benefit.

9.10 *Interface with Other Quality Management Systems:*

9.10.1 When the agency is part of a larger operation, the quality management system supporting nondestructive testing may be integrated as a sub-system of the larger (parent) system. Though the parent system may be supporting separate quality specifications, those specifications usually provide for the nondestructive testing agency to operate as a separate agency.

9.10.2 Data collected by the nondestructive testing agency may serve as a primary source for data analysis by the customer. Whether the customer is internal or external, provision needs to be made to support the customers requirements for data analysis.

10. Customer Satisfaction

10.1 Establishing clear customer requirements prior to the start of work, and communicating the importance of meeting customer requirements to employees of the agency is necessary to have a meaningful purchase order. Customer satisfaction is ensured when customers experience that requirements have been met and that there is active communication and discussion of any issues that concern either party.

11. Keywords

11.1 nondestructive testing agency; process control; quality control program; quality management system; quality manual; quality objectives; quality policy; quality records

SUMMARY OF CHANGES

Committee E07 has identified the location of selected changes to this standard since the last issue (E1212–12) that may impact the use of this standard.

(1) Title revised.

(2) Scope revised by addition of Section 1.7.