

The American Society of Mechanical Engineers

NQA-1 QUALITY ASSURANCE MANUAL CHECKLIST

INTRODUCTION

The NQA-1 Quality Assurance Manual Checklist is required to be completed by the Applicant, and is prepared to assist the ASME Survey Teams. This Checklist is not intended to replace or interpret the requirements of the ASME NQA-1 Standard. The Checklist does not list all of the applicable requirements of the NQA-1 Standard, but rather lists the highlights that the Applicant is required to include in their Quality Assurance Program. The “Applicant” is defined as the organization seeking to obtain or renew its ASME NQA-1 Quality Program Certificate

In addition to assisting the ASME Survey Team, this Checklist is provided to Applicants for their use in verifying and identifying the paragraph(s) where their QA Manual is to be compared for compliance with the NQA-1 Standard. The QA Manual must contain the controls for implementing the Quality Assurance Program, but it is not required to contain all the detailed programmatic requirements which will be found in working documents, such as, but not limited to, procedures and working instructions. The QA Manual is not a reiteration of the requirements specified in the NQA-1 Standard but rather an auditable Manual which identifies who, what, when, where & how the Quality Assurance Program meets the current requirements of the NQA-1 Standard.

This Checklist is based on the ASME NQA-1 Standard (2022 Edition) and is subject to revisions based on changes made to the Standard.

Each survey shall cover the review of the Applicant's QA Manual and its implementation. It is recognized that the Quality Assurance Program will vary from Applicant to Applicant and not all aspects identified on this Checklist may apply for the scope of activity to be identified on the Applicant's NQA-1 Quality Program Certificate. The QA Manual shall identify and describe those activities to be performed under the scope of the Certificate. The ASME Survey Teams are advised that:

- All aspects of this Checklist may not apply to every Applicant's Quality Assurance Program;
- This Checklist may not outline all possible aspects of each Applicant's Quality Assurance Program; and
- The Applicant's QA Manual need not follow the format of this Checklist.

The Applicant is encouraged to complete the Checklist using Adobe Reader and to provide a copy of the PDF file to the ASME Survey Team Leader.

Questions of possible need for an interpretation of the NQA-1 Standard raised by ASME Survey Teams or the Applicant shall be submitted to the Secretary, NQA Standards Committee.

Suggestions for revisions or clarification to this Checklist should be directed to the ASME Director, Conformity Assessment.

HOW TO USE THIS CHECKLIST

The Applicant is to provide the information requested in the title block and then review each item under the column heading "Quality Assurance Manual Requirements", and where appropriate, complete the three columns under the main column heading "Completed By Applicant – QA Program References". In the space provided:

- 1) under the column heading "QA Manual Para(s)." **the paragraph number within the QA Manual that covers the subject addressed is to be identified.** Items which are not applicable to the Applicant's Quality Assurance Program are to be marked "NA" to indicate "Not Applicable".
- 2) under the column heading "NQA Part II Subparts", if certain work activities are being amplified by a subpart under Part II of the NQA-1 Standard, identify the subpart number being invoked by the program, when appropriate. Also list the para(s). number(s) under the subpart which are not applicable; the listing is to be preceded by the acronym "NA:".
- 3) under the column heading "Implementing Documents (Procedures, Work Instructions, etc.)", identify the document number which contain the detail instructions to complete the controlled activity, when appropriate.

The three columns under the main heading "For Auditor's Use Only" are not to be completed by the Applicant; they are reserved for use by the ASME Survey Team during the Survey.

On the first day of the survey, the ASME Survey Team is to be provided with:

- the original completed Checklist (and PDF file) along with sufficient copies for use during the Survey for each individual on the Survey Team;
- a current controlled and approved copy of the QA Manual along with sufficient copies for use during the Survey for each individual on the Survey Team;
- sufficient copies of the exhibits (forms) shown in the QA Manual completed, if the exhibits (forms) shown in the QA Manual are blank copies; and
- at least one (1) copy of implementing procedures.

IMPLEMENTATION OF THE QUALITY ASSURANCE PROGRAM

If not noted on the application form, Applicants applying for initial issue or renewal of an ASME NQA-1 Quality Program Certificate should be aware that the ASME survey will require that all elements of the Quality Assurance Program be implemented/demonstrated to the Survey Team. The Applicant shall provide examples, of items/services appropriate to the scope of the work to be certified for evaluation by the Survey Team. Such items/services may be either work-in-process, completed work, or a mock-up that is processed under controls of the program.

The ASME survey will be conducted in five phases or segments as follows:

1. **Manual Review:** Shall be performed by the Survey Team and observers authorized by ASME only, on the first day of the survey. This review will normally be performed remote from the Applicant's facility; at the hotel where the Survey Team has made its sleeping room reservation. In some rare instances and under certain circumstances it may be performed at the Applicant's facility, and will only be done with the concurrence of the Survey Team Leader.
2. **Entrance Meeting/Facility Tour:** Will be held on the second day. The entrance meeting will provide the Applicant and the Survey Team an opportunity to: introduce themselves, review the Certificate and scope of activity applied for, and to establish the survey agenda. ASME fully encourages executive/senior management to attend the entrance meeting. During this meeting the Applicant may, if they wish, give a presentation of the company, products, personnel, etc.
3. **Implementation:** The Applicant is expected to demonstrate the implementation of the entire Quality Assurance Program. If any deficiencies are discovered during the survey, they will be immediately identified to the Applicant, in order to provide them an opportunity to correct them prior to the conclusion of the survey.
4. **Team Closed Meeting:** This meeting will be held at the Applicant's facility prior to the exit meeting. This meeting will be attended only by the Survey Team members and observers authorized by ASME. During this meeting the Survey Team will review the results of the survey and vote on the recommendation that the team will present to ASME.
5. **Exit Meeting:** This meeting will be held with the Applicant's management and will review the results of the survey. ASME fully encourages executive/senior management to attend the exit meeting. If there were any deficiencies issued they will be reviewed and the Applicant advised of their status. The Survey Team's recommendation to ASME will be made known. The Applicant will be allowed to ask any questions relative or pertinent to the survey. At the conclusion of the exit meeting the survey is officially ended and there will be no more discussion of the survey.



QUALITY ASSURANCE MANUAL CHECKLIST

QA
Manual
Edition
No.:

Company Name:

Contact Name:

Title:

Revision
Level:

Date:

QUALITY ASSURANCE MANUAL REQUIREMENTS	For Auditor's Use Only			Completed By Applicant – QA Program References		
	A	SR	NA	QA Manual Para(s).	NQA Part II Subparts	Implementing Documents (Procedures, Work Instructions, etc.)
REQUIREMENT 1, ORGANIZATION						
The program includes measures established to:						
A. Define responsibilities for the establishment and implementation of the Quality Assurance Program, and document the organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality.						
B. Ensure that senior management establishes overall expectations for effective implementation of the Quality Assurance Program and is responsible for obtaining the desired end result.						
C. Ensure that quality is achieved and maintained by those assigned responsibility for performing work, and that quality achievement is verified by persons or organizations not directly responsible for performing the work.						
D. Ensure that those responsible for assuring that an appropriate Quality Assurance Program has been established, and those verifying activities affecting quality, have: (1) sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work; (2) sufficient independence from cost and schedule when opposed to safety function considerations; and (3) the responsibility and organizational freedom to: (a) identify quality problems, (b) initiate, recommend, or provide solutions to quality problems through designated channels, (c) verify implementation of solutions, and (d) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.						

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E. Ensure that individuals or organizations responsible for establishing and executing the Quality Assurance Program may delegate any or all of the work to others but retain responsibility thereof.						
F. Where more than one organization is involved, clearly define and document the responsibilities, interfaces, and authority of each organization, and document the external interfaces between organizations and the internal interfaces between organizational units, and changes thereto.						
REQUIREMENT 2, QUALITY ASSURANCE PROGRAM						
The program includes measures established to:						
A. Provide a Quality Assurance Manual which documents in detail the Quality Assurance Program and includes a statement of policy and authority by management indicating management support. <i>† ASME NQA-1 certification-program requirement (certificate terms); not an NQA-1-2022 Part I requirement.</i>						
B. Ensure management participation in and support of the program. <i>† ASME NQA-1 certification-program requirement (certificate terms); not an NQA-1-2022 Part I requirement.</i>						
C. Provide for obtaining ASME's acceptance of proposed changes to the Quality Assurance Program. <i>† ASME NQA-1 certification-program requirement (certificate terms); not an NQA-1-2022 Part I requirement.</i>						
D. Ensure that a documented Quality Assurance Program is planned, implemented, and maintained in accordance with Part I of NQA-1 (or portions thereof), and established at the earliest time consistent with the schedule for accomplishing the activities.						
E. Identify the activities and items to which the Quality Assurance Program applies, and provide control over activities affecting quality to an extent consistent with their importance.						
F. Include monitoring of activities against acceptance criteria sufficient to provide assurance that activities affecting quality are performed satisfactorily.						

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G. Provide for the planning and accomplishment of activities affecting quality under controlled conditions, which include: (1) use of appropriate equipment, (2) suitable environmental conditions, and (3) assurance that prerequisites for the activity have been satisfied.						
H. Provide for any special controls, processes, test equipment, tools, and skills necessary to attain and verify the required quality of activities and items.						
I. Establish and implement processes to detect and correct quality problems.						
J. Provide for regular assessment by management of the adequacy and effective implementation of the Quality Assurance Program.						
K. Provide for indoctrination and training, as necessary, of personnel performing or managing activities affecting quality, commensurate with the scope, complexity, and importance of the activities and the education, experience, and proficiency of the person, including: (1) indoctrination in job responsibilities and authority (general criteria, technical objectives, applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements); (2) determination of the need for a formal training program and provision of training, where needed, to achieve and maintain proficiency and to adapt to changes in technology, methods, or job responsibilities; and (3) on-the-job training where direct hands-on application or experience is needed.						
L. Designate those activities that require qualification of personnel and the minimum requirements for such personnel, and establish written procedures for qualification so that only qualified personnel perform these activities.						
M. Ensure that personnel performing nondestructive examination (NDE) are qualified and certified in accordance with the applicable codes, standards, or design criteria.						

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N. Ensure that personnel performing designated inspection and test activities are qualified and certified, with initial capability determined by evaluation of education, experience, training, and either test results or capability demonstration; job performance reevaluated at intervals not to exceed 3 years; and reevaluation required after 1 year without performing the activity.						
O. Provide for removal of personnel from an activity when it is determined that the individual's capabilities are not in accordance with the specified qualification requirements, until the required capability is demonstrated.						
P. Ensure that Auditors are qualified and that Lead Auditors are qualified and certified.						
Q. Ensure that Lead Auditors are designated based upon: (1) communication skills, (2) training, including knowledge and understanding of this Standard and other nuclear-related codes, standards, regulations, and regulatory guides (as applicable). The general structure of quality assurance programs and applicable elements as defined in this Standard. The auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings. The planning audits of activities affecting quality and the on-the-job training to include applicable elements of the audit program (3) audit participation (a minimum of five quality assurance audits within a period not to exceed 3 years prior to qualification, one of which is a nuclear quality assurance audit within the year prior to qualification; up to four of the five may be satisfied by qualifying independent assessments), (4) examination, (5) maintenance of proficiency, and (6) requalification when proficiency is not maintained for 2 years or more.						
R. Establish the qualifications and requirements for the use of technical specialists to accomplish the auditing of quality assurance programs.						

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S. Ensure that records of qualification are certified in writing and maintained, including: (1) for inspection, test, and Lead Auditor personnel: the employer's name, identification of the person being certified, the activities certified, and the signature of the employer's designated representative; (2) for inspection and test personnel: education, work experience, training, demonstration of capabilities, date of certification/recertification, any special physical requirements, and certification expiration; and (3) for Lead Auditor personnel: education, work experience, training, audit participation, examination results, date of certification/recertification, and annual assessment of proficiency maintenance.						
T. Establish and maintain records of indoctrination and training (such as attendance sheets, training logs, or personnel training records).						
REQUIREMENT 3, DESIGN CONTROL						
The program includes measures established to:						
A. Provide a controlled design process that defines, controls, and verifies the design; specifies design inputs on a timely basis and translates them into design documents; identifies and controls design interfaces; verifies design adequacy by individuals other than those who designed the item or computer program; and governs design changes by control measures commensurate with those applied to the original design.						
B. Identify and document applicable design inputs, and review and approve their selection, specified to the level of detail necessary to permit the design activities to be carried out correctly and to provide a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.						

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C. Prescribe and document the design activities (design process) to the level of detail necessary to permit the design to be carried out correctly and verified, including: (1) identification and documentation of appropriate quality standards, with their selection reviewed and approved; (2) selection and review for suitability of the design methods, materials, parts, equipment, and processes essential to the function of the item, with applicable experience information made available to cognizant design personnel; and (3) a final design that is relatable to the design input by documentation sufficient to permit verification, specifies or references required inspections and tests and their acceptance criteria, and identifies assemblies and/or components that are part of the item being designed.						
D. Provide for design analyses that are sufficiently detailed such that a technically qualified person can review, understand, and verify the adequacy of the results without recourse to the originator, including: (1) acceptance and control of each computer program used for design analysis in accordance with the applicable requirements of Parts I and II prior to use, or independent verification of the program's results with the design analysis for each application, demonstrating correct solutions for the applied mathematical model and a valid solution to the physical problem; and (2) documentation of the analysis, including the objective; design inputs and their sources; results of literature searches or other background data; assumptions and identification of those that must be verified as the design proceeds; identification of any computer calculation (computer type, program name and revision, inputs, outputs, and evidence of or reference to program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem); and review and approval.						

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E. Provide for design verification that: (1) identifies and documents the particular verification method(s) used, with results documented and the verifier clearly identified; (2) is performed by any competent individual(s) or group(s) other than those who performed the original design (which may include the originator's supervisor only under the conditions permitted by NQA-1, and not by cursory supervisory review); (3) is completed prior to release for procurement, manufacture, construction, or use, with any unverified portion identified and controlled, and completed before relying on the item or computer program to perform its function; (4) reverifies the design when it is modified to resolve verification findings; (5) establishes the extent of verification as a function of importance to safety, complexity of the design, degree of standardization, state of the art, and similarity with previously proven designs, with the applicability of standardized or previously proven designs to the pertinent design inputs verified for each application, known problems affecting such designs and their effects on other features considered, and the original design and associated verification documentation referenced in the records of subsequent application of the design.						

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F. Perform design verification using acceptable methods, as applicable, including: (1) design reviews that provide assurance the final design is correct and satisfactory by addressing, where applicable: (a) whether the design inputs were correctly selected; (b) whether the assumptions necessary to perform the design activity are adequately described and reasonable and, where necessary, are identified for subsequent reverification when the detailed design activities are completed; (c) whether appropriate design methods and computer programs were used; (d) whether the design inputs were correctly incorporated into the design; (e) whether the design output is reasonable compared to the design inputs; (f) whether the necessary design inputs for interfacing organizations are specified in the design documents or in supporting procedures or instructions; and (g) whether suitable materials, parts, processes, and inspection and testing criteria have been specified; (2) alternate calculations that use alternate methods to verify the correctness of the original calculations or analyses, including review of the appropriateness of assumptions, input data used, and the computer program (and its associated computer hardware and system software) or other calculation method used; and (3) qualification tests that demonstrate adequacy of performance under conditions that simulate the most adverse design conditions (with operating modes and environmental conditions considered in determining the most adverse conditions), verify other design features by other means where the test is intended to verify only specific features, establish and verify scaling laws when tests are performed on models or mockups, and subject the results of model test work to error analysis, where applicable, prior to use in the final design.						

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G. Establish measures to ensure that changes to design inputs, final designs, field changes, and temporary or permanent modifications to operating facilities are justified and subject to design control measures commensurate with those applied to the original design, including evaluation of the effects of the changes (with the evaluation including the facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities), approval by the same affected groups or organizations (or a designated responsible organization) that have demonstrated competence in the specific design area of interest and an adequate understanding of the requirements and intent of the original design, incorporation of the change into the affected documents, and review and modification of the design process and verification procedure where a significant design change results from an incorrect design.						

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H. Establish and document procedures for configuration management of operating facilities that: (1) define the responsibilities and authority of the organizations whose functions affect the configuration of the facility; (2) ensure that changes that may affect the approved configuration are recognized and processed; (3) establish and approve the configuration at the earliest practical time prior to initial operation and maintain it for the life of the facility; (4) 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; (5) include interface controls that integrate the activities of organizations that can affect the approved configuration; (6) document the design bases and the approved configuration for the approved modes of operation; (7) evaluate proposed changes for conformance to the design bases and review the implementation sequence for approved changes; (8) obtain approval from the design authority prior to implementing a change to the design bases; and (9) document the configuration in drawings, specifications, procedures, and other documents that reflect the operational status of the facility, and control the current revision and issuance of these documents taking into account the use of the document and the need for revision in support of operation.						
I. Identify and control design interfaces, including assignment of responsibility and establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces, and documentation of design information transmitted across interfaces (including the status of the information and identification of incomplete items, with oral or informal transmittals promptly confirmed by controlled document).						

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J. Control computer software design in accordance with Part II, Subpart 2.7, which applies to computer software design control and is used in place of the design input, design process, design verification, and change control provisions of this Requirement for computer software.						
K. Ensure that design documentation and records include not only final design documents (such as drawings and specifications) and revisions to those documents but also documentation that identifies the important steps in the design process, including the sources of design inputs that support the final design.						

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REQUIREMENT 4, PROCUREMENT DOCUMENT CONTROL						
The program includes measures established to:						
A. Ensure that procurement documents for items and services include or reference applicable design bases and other requirements necessary to assure adequate quality and, to the extent necessary, require Suppliers to have a quality assurance program consistent with the applicable requirements of NQA-1, including provisions for: (1) a statement of the scope of the work to be performed by the Supplier; (2) technical requirements, specified as appropriate by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions (including revisions), and identification of appropriate test, inspection, and acceptance criteria; (3) quality assurance program requirements consistent with the importance and complexity of the item or service, and a requirement that the Supplier incorporate appropriate quality assurance program requirements in subtier procurement documents; (4) access to the Supplier's and subtier Suppliers' facilities and records for surveillance, inspection, or audit by the Purchaser, its designated representative, and others authorized by the Purchaser; (5) identification of documentation to be submitted for information, review, or approval, the time of submittal, and, when required, record retention times and disposition requirements; (6) the Purchaser's requirements for the Supplier's reporting of nonconformances; and (7) the Supplier's requirements to identify spare and replacement parts or assemblies and the related data required for ordering these parts or assemblies.						
B. Ensure that procurement documents, and changes thereto, are reviewed and documented prior to award to assure that they include appropriate provisions for items or services to meet the specified requirements, and that technical or quality assurance program changes resulting from bid evaluations or negotiations are incorporated prior to issuance to the Supplier.						

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C. Ensure that procurement document reviews are performed by personnel who have access to pertinent information and an adequate understanding of the requirements and intent of the procurement documents.						
D. Ensure that procurement document changes affecting the technical or quality assurance program requirements are subject to the same degree of control as utilized in the preparation of the original documents.						
REQUIREMENT 5, INSTRUCTIONS, PROCEDURES, AND DRAWINGS						
The program includes measures established to:						
A. Prescribe and perform activities affecting quality and services in accordance with documented instructions, procedures, or drawings.						
B. Ensure that instructions, procedures, and drawings include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished, and are described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results.						
C. Determine the need for, and level of detail in, written procedures or instructions based upon the complexity of the task, the significance of the item or activity, the work environment, and worker proficiency and capability (education, training, experience).						
REQUIREMENT 6, DOCUMENT CONTROL						
The program includes measures established to:						
A. Control the preparation, issuance, and change of documents that specify quality requirements or prescribe activities affecting quality (such as instructions, procedures, and drawings) to ensure that correct documents are employed, with such documents and changes reviewed for adequacy by a cognizant individual other than the originator and approved for release by authorized personnel.						
B. Provide for the unique identification of controlled documents, including a revision control identifier.						
C. Specify the distribution of controlled documents for use at the appropriate location where the prescribed activity is performed.						
D. Identify the individual roles responsible for the preparation, review, approval, and distribution of controlled documents.						

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E. Review controlled documents for adequacy and completeness prior to approval, distribution, or processing.						
F. Provide a method to ensure that the correct document and revision is being used.						
G. Ensure that major changes to controlled documents are reviewed and approved by the same organizations that performed the original review and approval (unless other organizations are specifically designated), with the reviewing organization having access to pertinent background data or information.						
H. Define minor changes as those that do not change the applicability, meaning, intent, or technical content of a document (such as editorial corrections) and that do not require the revised documents to receive the same review and approval as the original documents, and specify the types of changes to be considered minor.						
REQUIREMENT 7, CONTROL OF PURCHASED ITEMS AND SERVICES						
Section 7.1 — Control of Purchased Items and Services						
The program includes measures for the purchase of items and services to:						
A. Ensure and document conformance of purchased items and services to specified requirements by using the following methods, as appropriate: (1) source evaluation and selection, (2) evaluation of objective evidence of quality furnished by the Supplier, (3) source inspection, (4) audit, and (5) examination of items or services upon delivery or completion.						

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B. Evaluate and document, prior to award of a contract, the Supplier's capability to provide items or services in accordance with the procurement documents, including one or more of the following: (1) the Supplier's history of providing an identical or similar product that performs satisfactorily in actual use, reflecting current capability; (2) the Supplier's current quality records supported by documented qualitative and quantitative information (which may include current third-party certificates recognizing the Supplier's quality assurance program or other technical certifications); and (3) the Supplier's technical and quality capability as determined by a direct evaluation of its facilities, personnel, and the implementation of its quality assurance program.						
C. When bids are solicited, include in the bid evaluation a determination of the Supplier's capability to conform to the technical and quality assurance requirements, and resolve (or obtain commitments to resolve) unacceptable technical and quality assurance conditions prior to award of the contract.						
D. Control the submittal and evaluation of Supplier-generated documents and changes in accordance with the procurement document requirements, providing for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria.						
E. Require the Supplier to verify, prior to offering an item or service for acceptance, that it complies with the procurement requirements, with the extent of Purchaser verification a function of the relative importance, complexity, and quantity of the item or service and the Supplier's quality performance, and, where required, documentary evidence available at the nuclear facility site prior to installation or use.						

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F. Control the acceptance of an item or service by one or a combination of the following methods: (1) Supplier Certificate of Conformance (meeting the minimum certificate criteria, with means to verify the validity of certificates and the effectiveness of the certification system); (2) source verification (performed at predetermined points, with documented evidence of acceptance furnished to the receiving destination, the Purchaser, and the Supplier); (3) receiving inspection (verifying by objective evidence such features as configuration, identification, dimensional/physical/other characteristics, freedom from shipping damage, and cleanliness, coordinated with review of required Supplier documentation); and (4) postinstallation testing (with test requirements and acceptance documentation mutually established by the Purchaser and Supplier).						
G. Accept services only (such as third-party inspection; engineering and consulting; auditing; and installation, repair, overhaul, or maintenance) by any or all of the following: technical verification of data produced, surveillance and/or audit of the activity, and review of objective evidence for conformance to the procurement document requirements.						
H. Provide methods for the control and disposition of Supplier nonconformances for items and services that do not meet procurement document requirements, including evaluation of nonconforming items; submittal of a nonconformance notice to the Purchaser (with Supplier-recommended disposition and technical justification) for dispositions requiring Purchaser approval; Purchaser disposition of the Supplier recommendation; verification of implementation of the disposition; and maintenance of records of Supplier-submitted nonconformances.						
I. Establish and maintain records to indicate the performance of Supplier evaluation and selection, acceptance of items or services, and Supplier nonconformances to procurement document requirements, including their evaluation and disposition.						

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Section 7.2 — Commercial Grade Items and Services						
When dedication is used to accept commercial grade items or services, amplify the controls by establishing plans, procedures, and work instructions in accordance with NQA-1, Part II, Subpart 2.14, to:						
A. Define or reference the applicable terms in accordance with NQA-1, Part II, Subpart 2.14, Section 101, Definitions.						
B. Identify the dedicating entity (which may be the manufacturer, a third-party dedicating entity, the Purchaser, or the nuclear facility organization).						
C. Ensure that a dedication plan is developed and documented for the item or service, identifying the critical characteristics and dedication methods (including acceptance criteria), with dedication requirements included in the applicable procurement and technical documents as necessary to support the dedication.						
D. Perform a technical evaluation that identifies the item or service safety function, design requirements, and critical characteristics with acceptance criteria, and that provides correct technical and quality requirements which are translated and specified in the procurement documents (including provisions for like-for-like and equivalent item determinations).						
E. Verify that the commercial grade item or service meets the acceptance criteria for the identified critical characteristics by one or more of the following dedication methods: (1) Method 1: inspections, tests, or analyses performed after delivery; (2) Method 2: commercial grade survey of the supplier; (3) Method 3: source verification of the item or service; and (4) Method 4: acceptable supplier/item performance record.						
F. Ensure that qualified personnel are used to perform Method 2 (commercial grade survey of the supplier) and Method 3 (source verification).						
G. Ensure at receiving inspection that damage was not sustained during shipment, that the item or service satisfies the specified acceptance criteria for the identified critical characteristics, and that specified documentation was received and is acceptable.						
H. Control supplier-generated documents, including changes thereto, in accordance with procurement document control requirements.						

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I. Provide for correction of supplier deficiencies identified by the acceptance method(s) that affect the acceptance criteria for critical characteristics, with corrective actions evaluated for acceptability by the dedicating entity (uncorrected deficiencies may result in selection of another dedication method).						
J. Establish and maintain documentation of the dedication process traceable to the item, group of items, or services, including dedication plans or procedures, commercial grade item or service procurement documents, technical evaluations, critical characteristic identification and acceptance criteria, test reports or results, inspection reports, and analysis reports, commercial grade survey reports, source verification reports, historical performance information, and a dedication report containing sufficient data to accept the item or service.						
REQUIREMENT 8, IDENTIFICATION AND CONTROL OF ITEMS						
The program includes measures established to:						
A. Establish controls to ensure that only correct and accepted items are used or installed.						
B. Maintain identification on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained.						
C. Identify items of production (batch, lot, component, part) from initial receipt and fabrication through installation and use, relating each item to an applicable design or other pertinent specifying document.						
D. Use physical identification to the maximum extent possible (such as written markings, etching, stickers with bar or quick response (QR) codes, stamping, and tags), and, where physical identification on the item is impractical or insufficient, employ physical separation, procedural control, or other appropriate means.						
E. Apply identification markings using materials and methods that provide clear and legible identification and do not degrade the function or service life of the item; transfer markings to each part of a subdivided item; and ensure that markings are not obliterated or hidden by surface treatment or coating unless other means of identification are substituted.						

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F. Provide identification and traceability control when codes, standards, or specifications include specific identification or traceability requirements (such as identification of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records).						
G. Identify and control items having limited calendar or operating life or cycles to preclude use of items whose shelf life or operating life has expired.						
H. Make provisions for the control of item identification consistent with the planned duration and conditions of storage, including: (1) maintenance or replacement of markings and identification records due to damage during handling or aging, (2) protection of identifications on items subject to excessive deterioration due to environmental exposure, and (3) updating of existing plant records.						
REQUIREMENT 9, CONTROL OF SPECIAL PROCESSES						
The program includes measures established to:						
A. Ensure that special processes that control or verify quality (such as those used in welding, heat treating, and nondestructive examination) are performed by qualified personnel using qualified procedures in accordance with specified requirements.						
B. Control special processes by instructions, procedures, drawings, checklists, travelers, or other appropriate means.						
C. Ensure that special process instructions include or reference: (1) procedure, personnel, and equipment qualification requirements; (2) the conditions necessary to accomplish the process, including proper equipment, controlled process parameters, specified environment, and calibration requirements; and (3) the requirements of applicable codes and standards, including acceptance criteria for the process.						
D. Specify or reference the necessary requirements for qualification of personnel, procedures, or equipment for special processes not covered by existing codes and standards, or where specified quality requirements exceed those of existing codes or standards.						

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E. Ensure that the organization performing the special process adheres to the approved procedures and processes.						
F. Maintain records, as appropriate, for the currently qualified personnel, processes, and equipment of each special process.						
REQUIREMENT 10, INSPECTION						
The program includes measures established to:						
A. Plan and execute inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service, specifying the characteristics subject to inspection and the inspection methods, and documenting inspection results.						
B. Ensure that inspection for acceptance is performed by qualified persons other than those who performed or directly supervised the work being inspected.						
C. Ensure that inspection requirements and acceptance criteria include the specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.						
D. Indicate mandatory inspection hold points, beyond which work shall not proceed without the specific consent of the designated representative, in appropriate documents, and record consent to waive specified hold points prior to continuation of work beyond the designated hold point.						
E. Identify the characteristics to be inspected, the methods of inspection, and the acceptance criteria during the inspection planning process, and base any sampling procedures on standard statistical methods with engineering approval.						
F. Perform in-process inspection or monitoring, as necessary, to verify quality; where inspection of processed items is impossible or disadvantageous, provide indirect control by monitoring processing methods, equipment, and personnel by qualified personnel independent from those performing the process (or by qualified automated means), and provide both inspection and process monitoring when quality verification is inadequate without both.						

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G. Provide for final inspections that include: (1) a records review of the results and resolution of nonconformances identified by prior inspections; (2) inspection of completed items 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; (3) reinspection or retest, as appropriate, of any modifications, repairs, or replacements performed subsequent to final inspection; and (4) acceptance of the item approved by authorized personnel.						
H. Plan and execute periodic inspections (e.g., in-service inspections) or surveillances of structures, systems, or components to ensure the continued performance of their required functions.						
I. Establish and maintain appropriate inspection records that, as a minimum, identify the item inspected, date of inspection, inspector, type of observation, results or acceptability, and reference to information on action taken in connection with nonconformances.						
REQUIREMENT 11, TEST CONTROL						
The program includes measures established to:						
A. Plan and execute tests required to collect data (such as for siting or design input), to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service, specifying the characteristics to be tested and the test methods, and documenting and evaluating test results against test requirements and acceptance criteria.						
B. Ensure that test requirements and acceptance criteria are provided or approved by the responsible design organization and are based upon specified requirements contained in applicable design documents or other pertinent technical documents, and that required tests (other than for Computer Programs) including, as appropriate, prototype qualification, production, proof, construction, preoperational, and operational tests are controlled under appropriate environmental conditions using the tools and equipment necessary to obtain the required data with sufficient accuracy for evaluation and acceptance.						

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C. Obtain approval by the design authority prior to testing when temporary changes to the approved configuration of a facility are required for testing purposes.						
D. Ensure that test procedures (other than for computer programs) include or reference the test configuration and test objectives and 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, with prerequisites including, as applicable: (1) calibrated instrumentation, (2) appropriate equipment, (3) trained personnel, (4) condition of the test equipment and the item to be tested, (5) suitable environmental conditions, and (6) provisions for data acquisition.						
E. Alternatively, use appropriate sections of related documents (such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria), supplemented with appropriate criteria to assure that adequate test procedures are used.						
F. Control computer program test procedures and computer program test records in accordance with Part II, Subpart 2.7.						
G. Ensure that test results are documented, maintained, and evaluated by the responsible authority to ensure that test requirements have been satisfied.						
H. Establish and maintain test records that indicate the ability of the item or computer program to satisfactorily perform its intended function, containing as a minimum the item tested, date of test, tester or data recorder, type of observation, results and acceptability, action taken in connection with any deviations, and the person evaluating the test results.						

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Requirements for computer program test records shall include: The computer program tested including system software used. The computer hardware used. The test equipment and calibrations, where applicable. The date of test. The name of the tester or data recorder. The simulation models used, where applicable. The test problems and traceability to requirements. The results. The action taken in connection with any deviations noted. The name of the person evaluating test results and the acceptability						
REQUIREMENT 12, CONTROL OF MEASURING AND TEST EQUIPMENT						
The program includes measures established to:						
A. Ensure that tools, gauges, instruments, and other measuring and test equipment used for activities affecting quality are controlled, calibrated at specified periods, adjusted, and maintained to required accuracy limits (calibration and control measures are not required for commercial equipment such as rulers, tape measures, and levels if such equipment provides the required accuracy).						
B. Select measuring and test equipment based on the type, range, and accuracy needed to accomplish the required measurements for determining conformance to specified requirements.						
C. Calibrate measuring and test equipment at prescribed times or intervals and whenever the accuracy of the results is suspect, against and traceable to certified equipment or reference standards having known valid relationships to nationally recognized standards (or international standards known to be equivalent), and, where no such standards exist, define the basis for calibration.						
D. Ensure that reference standards have a minimum accuracy four times greater than that of the equipment being calibrated, and, where this 4:1 ratio cannot be maintained, technically justify the basis for selection of the standard.						

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E. Ensure that calibration procedures identify or reference the required accuracy and define the methods and frequency of checking accuracy, with the calibration method and interval based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting performance.						
F. Ensure that measuring and test equipment overdue for calibration or found to be out-of-calibration is tagged and/or segregated or removed from service and not used until it has been recalibrated, and that equipment consistently found out-of-calibration is repaired or replaced.						
G. When measuring and test equipment is lost, damaged, or found to be out-of-calibration, evaluate and document the validity of previous measurement, inspection, or test results and the acceptability of items previously inspected or tested, from at least the last acceptable calibration, with the evaluation and resulting actions commensurate with the significance of the condition.						
H. Ensure that measuring and test equipment is: (1) traceable to its application and use; (2) properly handled and stored to maintain accuracy; (3) used and calibrated in environments controlled to the extent necessary to ensure that the required accuracy and precision are maintained; (4) checked, with the results recorded, before any required adjustments or repairs are made; and (5) suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records.						
I. Establish and maintain records that indicate calibration status and the capability of measuring and test equipment to perform its intended function, with calibration reports and certificates including the information and data necessary for interpretation of the results and verification of conformance to applicable requirements, including as-found calibration data when calibrated items are found to be out of tolerance.						

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REQUIREMENT 13, HANDLING, STORAGE, AND SHIPPING						
The program includes measures established to:						
A. Ensure that handling, storage, cleaning, packaging, shipping, and preservation of items are controlled to prevent damage or loss and to minimize deterioration, and are conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use.						
B. Specify, provide, and verify the existence of special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmospheres, specific moisture content levels, and temperature levels) when required.						
C. Use specific procedures for handling, storage, packaging, shipping, and preservation when required for critical, sensitive, perishable, or high-value items.						
D. Ensure that special handling tools and equipment are utilized and controlled where necessary to ensure safe and adequate handling, and are inspected and tested in accordance with procedures at specified time intervals or prior to use.						
E. Ensure that operators of special handling and lifting equipment are experienced or trained in the use of the equipment.						
F. Utilize marking or labeling as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls.						
REQUIREMENT 14, INSPECTION, TEST, AND OPERATING STATUS						
The program includes measures established to:						
A. Identify the status of inspection and test activities either on the items or in documents traceable to the items, to ensure that required inspections and tests are performed and that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.						
B. Identify the operating status of nuclear facility structures, systems, and components to prevent inadvertent operation.						
C. Specify the authority for the application and removal of status indicators.						

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D. Maintain status indication through physical means such as tags, markings, labels, stamps, or other suitable methods to prevent inadvertent installation, use, or operation.						
REQUIREMENT 15, CONTROL OF NONCONFORMING ITEMS						
The program includes measures established to:						
A. Ensure that items that do not conform to specified requirements are controlled to prevent inadvertent installation or use, with controls providing for identification, documentation, evaluation, segregation when practical, disposition, and notification to affected organizations.						
B. Identify nonconforming items by legible marking, tagging, or other methods (such as identifying and controlling the item as nonconforming in an electronic system), and, where identification of each item is not practical, identify the container or package; the identification method shall not be detrimental to the item.						
C. Segregate nonconforming items, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned, and, where segregation is impractical or impossible, employ other precautions to prevent inadvertent use.						
D. Evaluate nonconforming items and propose recommended dispositions, and control further processing, delivery, installation, or use pending the evaluation and an approved disposition by authorized personnel.						
E. Define the responsibility and authority for the evaluation and disposition of nonconforming items, and designate in writing the responsibility for the control of further processing, delivery, installation, or use.						
F. Ensure that personnel performing evaluations to determine a disposition have: (1) demonstrated competence in the specific area they are evaluating, (2) an adequate understanding of the requirements, and (3) access to pertinent background information.						

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G. Make and document a disposition (such as use-as-is, reject, repair, or rework), document the technical justification for the acceptability of items dispositioned as repair or use-as-is, subject nonconformances to design requirements dispositioned as use-as-is or repair to design control measures commensurate with those applied to the original design, and reflect the use-as-is or repair condition in required as-built records.						
H. Reexamine reworked items in accordance with applicable procedures and the original acceptance criteria, and reexamine repaired items in accordance with applicable procedures and the original acceptance criteria unless the disposition has established alternate acceptance criteria.						
REQUIREMENT 16, CORRECTIVE ACTION						
The program includes measures established to:						
A. Identify conditions adverse to quality promptly and correct them as soon as practicable.						
B. Ensure that in the case of a significant condition adverse to quality: (1) the cause of the condition is determined, (2) corrective action is taken to preclude recurrence, (3) the identification, cause, and corrective action are documented and reported to appropriate levels of management, and (4) completion of the corrective action is verified.						
REQUIREMENT 17, QUALITY ASSURANCE RECORDS						
The program includes measures established to:						
A. Establish the control of quality assurance records consistent with the schedule for accomplishing work activities, so that records furnish documentary evidence that items or activities meet specified quality requirements, and document the record control requirements and responsibilities.						
B. Ensure that quality assurance records are identified, generated, authenticated, and maintained, and their final disposition specified.						

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C. Ensure that records are legible, traceable to associated items and activities, and accurately reflect the work accomplished or information required, and specify the records to be generated, supplied, or maintained in applicable documents (such as design specifications, procurement documents, test procedures, and operational procedures).						
D. Authenticate records so that documents are considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated, with corrections reviewed and approved by the responsible individual from the originating or authorized organization, and authenticate electronic documents with comparable information (with identification on the media or authentication information contained within or linked to the document).						
E. Classify records as lifetime or nonpermanent in accordance with the specified criteria and consistent with applicable regulatory requirements, and establish documented retention periods.						
F. Provide a receipt control system in which each responsible organization designates a person or organization to receive records and to implement receipt controls, providing a method for identifying the records received, receipt and inspection of incoming records, and submittal of records to storage.						

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G. Provide storage that: (1) locates records at predetermined location(s) in facilities, containers, or a combination, constructed and maintained to minimize the risk of loss, damage, or destruction from natural disasters, adverse environmental conditions, infestation, and dust or airborne particles; (2) prohibits activities detrimental to the records in the storage area and limits access to the processing, storage, and retrieval of records to authorized personnel, and makes provisions to prevent damage from harmful conditions (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media used for record storage; (3) uses single storage (a facility, vault, room, or container with a minimum two-hour fire rating, reviewed for adequacy by a person competent in fire protection or certified/rated by an accredited organization) or dual storage (at locations sufficiently remote from each other to eliminate the chance of simultaneous exposure to a hazard, with dual-storage facilities meeting the general storage requirements even though they need not satisfy the single-storage fire-rating requirement); and (4) provides a one-hour fire rating for temporary storage, unless the dual storage requirements are met.						
H. Document record retention periods and maintain records for their retention periods.						
I. Maintain records so that they are protected from damage or loss; provide for retrievability within planned retrieval times; document the methods for record changes; prevent unacceptable degradation of electronic record media during the retention period; ensure that records remain retrievable after hardware, software, or technology changes; and ensure that any duplication or transfer of records is appropriately authorized and maintains record content, legibility, and retrievability.						
REQUIREMENT 18, AUDITS						
The program includes measures established to:						
A. Perform audits to verify compliance with quality assurance program requirements, verify that performance criteria are met, and determine the effectiveness of the program, in accordance with written procedures or checklists.						

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B. Ensure that audit results are documented and reported to and reviewed by responsible management.						
C. Schedule audits to provide coverage and coordination with ongoing activities based on the status and importance of the activity, supplement scheduled audits with additional audits of specific subjects when necessary to provide adequate coverage, and apply a grace period of up to 90 days as permitted; if an audit is performed early, the next scheduled date is based on the date it was actually performed.						
D. Ensure that internal and external audit frequencies meet the specified intervals, including: (1) internal audits of all applicable quality assurance program elements at the intervals specified for nuclear facilities before and after operation and for suppliers and other nuclear support organizations, with extensions based on annual evaluation and objective evidence of satisfactory performance and not exceeding the specified maximums; and (2) external audits (e.g., Supplier audits) performed on a triennial basis, supplemented by annual evaluations of the Supplier's performance (or a continuous or ongoing evaluation) to determine whether the audit frequency should be maintained, decreased, or other corrective action is required.						
E. Develop a documented audit plan for each audit that identifies the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.						
F. Ensure that audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective, and that audits are performed by personnel who do not have direct responsibility for performing the activities being audited.						
G. Identify an audit team prior to the beginning of each audit, containing one or more Auditors with one designated as Lead Auditor who organizes and directs the audit, and having experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.						

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H. Evaluate the elements selected for audit against specified requirements, examine objective evidence to the depth necessary to determine effective implementation, and report conditions requiring prompt corrective action immediately to the management of the audited organization.						
I. Ensure that each audit report is signed or otherwise endorsed by the Lead Auditor, issued to the audited organization, and includes: (1) a description of the audit scope, (2) identification of the Auditors and persons contacted, (3) a summary of the audit results, including a statement on the effectiveness of the elements audited, and (4) a description of each audit finding.						
J. Ensure that management of the audited organization investigates audit findings, schedules corrective action (including measures to prevent recurrence of significant conditions adverse to quality), and notifies the appropriate organization in writing of action taken or planned, and that audit responses are evaluated by or for the auditing organization.						
K. Take follow-up action to verify that corrective action is accomplished as scheduled.						
L. Ensure that audit records include audit plans, audit reports, written replies, and the record of completion of corrective action.						