EPRI NUCLEAR QUALITY ASSURANCE MANUAL

REVISION 23

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☐ This is a minor revision allowed by QAP 5.1.
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SUMMARY OF CHANGES

Section	Description	Type of Change
	Revision 23 changes are below	
Revision Number and Summary of Changes Table	Modified Revision Number and Summary of Changes table to accommodate Editorial changes. Added link to prior QAP revisions.	Editorial
Sections 9.0, 10.0, 11.0	Replaced Project Quality Plan with PQP/QMP-2 Project Plan	Editorial

Prior revisions of this Manual are available here: https://ecm.epri.com/otcs/cs.exe/open/1754087

POLICY STATEMENT

For certain products and activities, U.S. nuclear regulations require that special quality assurance (QA) processes be invoked to ensure the quality of those products and services. The EPRI Nuclear Quality Assurance Program applies when EPRI members or customers request that EPRI provide products and services in accordance with a nuclear Safety Related Nuclear Quality Assurance program or when EPRI technical management determines that the product or service will be used in nuclear Safety Related applications.

The EPRI Nuclear Quality Assurance Program meets the following requirements:

- Title 10 Part 50 Appendix B and Title 10 Part 21 of the Code of Federal Regulations – United States (US) federal QA requirements for nuclear safety applications
- NQA-1-2015 - QA program standards endorsed by the US Nuclear Regulatory Commission as acceptable methods for meeting the requirements of 10CFR50 Appendix B

The EPRI Nuclear Quality Assurance Program is defined in the EPRI Nuclear Quality Assurance Manual and associated QA procedures (QAPs) and forms (QAFs). These documents are available on the EPRI internal intranet, for use by EPRI staff. The EPRI Nuclear Quality Assurance Manual is also available on the EPRI website.

This policy governs the activities of EPRI Nuclear Sector personnel and other EPRI staff supporting Nuclear Sector activities, as defined in the EPRI Nuclear Quality Assurance Manual, and supporting procedures.

BACKGROUND

EPRI provides products, services, and research that may be utilized by the nuclear industry to support nuclear facility design, construction, maintenance, operation, and decommissioning. The EPRI Vice President Nuclear Sector and Chief Nuclear Officer is committed to achieving excellence in the quality of products and services EPRI provides.

The EPRI Nuclear Quality Assurance Manual is the top-level policy document that establishes the manner in which EPRI is to achieve the quality of its nuclear Safety Related products and services. The EPRI Nuclear Quality Assurance Manual focuses employee attention on regulatory requirements and management expectations and requires identification of concerns and non-conforming conditions. In addition, implementing QAPs and project-specific quality documents have been developed and are maintained that define, in detail, how key activities are to be performed while achieving EPRI Nuclear Quality Assurance Program commitments.

Each employee involved in providing Safety Related products and services is responsible for the quality of their work and is required to be knowledgeable of and to adhere to the requirements of the EPRI Nuclear Quality Assurance Program.

IMPLEMENTATION of NQA-1-2015

The EPRI Nuclear Quality Assurance Manual and Program are intended to comply with 10CFR50 Appendix B and NQA-1-2015.

1.0 ORGANIZATION

Organizational Structure

EPRI documents and maintains the organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality in implementing procedures.

The organization structure and responsibility assignments are such that:

1. Senior management establishes overall expectations for effective implementation of the EPRI Nuclear Quality Assurance Program and is responsible for obtaining the desired end result.
2. Quality is achieved and maintained by those who have been assigned responsibility for performing work; and
3. Quality achievement is verified by persons or organizations not directly responsible for performing the work.
4. Those responsible for verifying quality achievement have sufficient authority, direct access to management, organizational freedom, and access to work to perform their function.

Interface Control

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

Delegation of Work

Functions may be performed by a superior or may be delegated to another qualified individual within the organization. If work is delegated, the individual(s) or organization(s) responsible for establishing and executing the EPRI Nuclear Quality Assurance Program retain ultimate responsibility.

Independence of Persons Performing EPRI Nuclear Quality Assurance Functions

The Nuclear Quality Assurance Manager reports directly to the Vice President - Nuclear for EPRI Nuclear Quality Assurance-related matters, including 10 CFR Part 21 reporting matters. This reporting relationship ensures that the Nuclear Quality Assurance Manager and NQA staff are sufficiently independent from cost and schedule, when opposed to quality, and that the EPRI Nuclear Quality Assurance Department has sufficient authority, access to work areas, and organizational freedom to:

A. Detect and identify quality problems;

B. Initiate, recommend, or provide solutions to quality problems through designated channels;

C. Verify implementation of solutions; and

D. Ensure that further processing, delivery, or use of products or procedures is controlled

until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

Organizational responsibilities and management review are described and shall be conducted per QAP 1.1.

2.0 QUALITY ASSURANCE PROGRAM

This section defines the EPRI Nuclear Quality Assurance Program (the Program). The Program is documented in this manual, the associated QAPs, and Quality Project Instructions (QPIs), as applicable.

The Program was developed considering technical aspects of the activities affecting quality. Activities affecting quality are controlled to the extent necessary and consistent with their importance.

Terms used in the Program are defined in QAPs or related forms.

The Program provides for planning and accomplishing activities affecting quality, under suitably controlled conditions. Controlled conditions include the use of suitable procedures, appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The Program provides for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of quality, as applicable.

Implementation of the Program, or portions thereof, shall be regularly monitored and assessed by management for adequacy and effective implementation.

Basis of the Program

The Program is based on:

10 CFR 50, Appendix B	"Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"
10 CFR Part 21	"Reporting of Defects and Noncompliance"

The Program also is written to meet the applicable requirements of:

ASME NQA-1-2015	"Quality Assurance Requirements for Nuclear Facility Applications"

Applicability of the Program

The Program applies to services, software, and analyses EPRI provides that can directly affect the design, maintenance, or operation of nuclear Safety Related structures, systems and components (SSC). EPRI does not provide materials and components for installation in nuclear plants. However, the Program may be applied to materials and components procured or physical items fabricated to support analyses.

The Program also applies, in a graded manner, to certain areas and activities that are not identified as Safety Related but are required to meet unique customer requirements and other nuclear specific documents, including but not limited to other nuclear regulations (other than 10 CFR 50). EPRI calls this application Augmented Quality.

When requested by members/customers EPRI provides the services/products through the EPRI Quality Management Program and the Augmented Quality Program. The EPRI Quality Management Program and Augmented Quality Program are overseen by EPRI's Nuclear Quality Assurance Team. Details of EPRI's Quality Management Program and details of each of the relevant quality assurance procedures can be provided on request.

Periodic Review of Program Status, Adequacy, and Effectiveness

The status, adequacy, and effectiveness of the Program in meeting EPRI quality objectives, as well as compliance with requirements, shall be evaluated at specified intervals per QAP 1.1.

Indoctrination and Training

The Program provides for indoctrination and training, as necessary, of personnel performing activities affecting quality to ensure that suitable proficiency is achieved and maintained. Indoctrination and training shall be commensurate with the scope, complexity, importance of activities, and the education, experience, and proficiency of the person. Indoctrination and training shall be conducted per QAP 20.1.

3.0 DESIGN CONTROL

This section describes the measures taken to ensure that quality affecting design activities performed by EPRI are conducted in a planned, controlled, and correct manner.

EPRI does not design Safety Related structures, systems, and components (SSCs). Rather, EPRI provides Safety Related deliverables issued to members or customers consisting of reports or technical data that may be used by the member or customer as design inputs or bases, and software used in Safety Related applications. Design inputs or bases provided as deliverables are normally documented in formal technical reports or in EPRI project records. Design analyses are performed by EPRI to support the development of technical reports and other technical documents, as applicable. Additionally, EPRI applies appropriate design control measures to the design of nondestructive examination (NDE) mockups and other physical items used for design verification and qualification of personnel, processes, or equipment.

EPRI maintains procedures addressing design control requirements.

With the exception of software design activities, all design control and engineering activities are described and shall be conducted per QAP 3.2.

Computer software controls are described and shall be conducted per QAP 3.3.

Exceptions and Clarifications

NQA-1-2015, Requirement 3, Paragraph 600 describes methods of documenting design changes, by issuing a revision to the document or by issuing a separate design change document. EPRI issues technical reports that may constitute a design document. Technical reports may be revised and issued with a new document number and date.

4.0 PROCUREMENT DOCUMENT CONTROL

EPRI uses procurement document controls to ensure that applicable design bases and other requirements necessary to achieve adequate quality are included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require vendors to have a QA program if they are performing QA activities for EPRI that are not being performed under the control of the EPRI Nuclear Quality Assurance Program.

Preparation, review, approval, and issuance of procurement documents shall be conducted per QAP 4.1.

Exceptions and Clarifications

NQA-1-2015, Requirement 4, Section 100 requires the supplier (vendor) to have a documented QA program that implements portions or all of the requirements of NQA-1-2015. EPRI judges that it is sufficient that the vendor's QA program meets applicable requirements of 10 CFR 50 Appendix B or an approved quality standard. This can be accomplished through compliance with the applicable portions of any NRC-endorsed QA program standard or by compliance with the vendor's own program that has been evaluated as meeting an NRC-endorsed QA program standard and/or 10 CFR 50 Appendix B.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting quality are prescribed and accomplished by procedures, project level instructions, process control sheets, or drawings, as appropriate. Procedures shall be established to define controls for quality affecting document identification, review, approval, and revision control.

Instructions, procedures, process control sheets, or drawings shall include as appropriate, quantitative or qualitative acceptance criteria to determine that satisfactory results have been attained. Quality affecting activities shall be described to a level of detail commensurate with the complexity of the activity and the need to ensure consistent or acceptable results. The level of detail shall be determined based on the complexity and significance of the activity, worker proficiency, and competency.

The preparation, review, and approval of quality affecting documents shall be conducted per QAP 5.1.

The control and distribution of documents shall be conducted per QAP 6.1.

6.0 DOCUMENT CONTROL

Document control is the act of ensuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed. Only those documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings are required to be subject to document control provisions.
EPRI maintains procedures to ensure that the preparation, issuance, and change of documents that specify quality requirements or prescribe activities affecting quality are controlled to ensure that correct documents are being employed. Such documents, including changes to the document, are reviewed for adequacy and approved for release by authorized personnel.

The preparation, review, and approval of quality affecting documents shall be conducted per QAP 5.1.

The control and distribution of documents shall be conducted per QAP 6.1.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

EPRI contracts with vendors to provide services, software, and analyses that may affect design, maintenance, or operation of nuclear Safety Related structures, systems, and components. EPRI does not provide materials and components for installation in nuclear plants. However, the Program or portions thereof may be applied to materials and components procured or physical items fabricated to support analyses and to mockups fabricated to train and qualify NDE personnel.

EPRI maintains procedures to ensure these purchased items and services conform to specified requirements. As appropriate, procedures provide for source evaluation and selection, evaluation of objective evidence of quality furnished by the vendor, source inspection, audit, and examination of items or services upon delivery or completion.

Preparation, review, approval, and issuance of procurement documents at EPRI shall be conducted per QAP 4.1.

Vendor selection, qualification, and re-evaluation activities shall be conducted per QAP 7.1.

Commercial Grade Dedication is described and shall be conducted per QAP 7.2.

Inspection is described and shall be conducted per QAP 10.1.

Requirements for acceptance of services from an ISO 17025 calibration lab is described in QAP 12.1.

Exceptions and Clarifications

EPRI may use NEI-14-05-A Rev.01 dated September 2020, *Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services* for the acceptance of calibration and testing laboratories, in lieu of performing a commercial grade survey of the supplier.

For calibration or testing laboratories not accredited by an ISO/IEC 17025:2017 accrediting body, recognized by the ILAC MRA, a specific Commercial Grade Dedication Plan justifying usage shall be developed. This plan shall be documented as part of the Commercial Grade Survey Report.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

EPRI maintains procedures to ensure that materials, parts, and components used in project quality activities, including those items supplied by EPRI members, are properly identified and controlled. These procedures ensure that materials, parts, and components, including partially fabricated assemblies, maintain their proper identification throughout all phases of project activities and are controlled to prevent loss, damage, deterioration, and inadvertent use of incorrect or defective materials, parts, and components.

Identification and control of materials, parts, and components shall be conducted per QAP 8.1.

9.0 CONTROL OF PROCESSES

EPRI maintains procedures to ensure special processes that directly affect quality are conducted under controlled conditions by qualified personnel.

The PQP/QMP-2 Project Plan is the document through which quality-affecting project activities are identified, described, and controlled.

Quality instructions shall be developed and maintained, as applicable, to ensure that special processes, including welding, heat treating, and NDE are controlled and accomplished by qualified personnel using qualified procedures or instructions and, when required, proper, qualified, and calibrated equipment.
Qualification and certification of NDE personnel is the responsibility of the Nuclear Sector Plant Support Department, as specified in the governing PQP/QMP-2 Project Plan.

Control of special processes at EPRI shall be conducted per QAP 9.1.

10.0 INSPECTION

EPRI maintains procedures to ensure inspections required to verify conformance of a physical item or activity to specified requirements are planned and executed. Characteristics to be inspected and inspection methods to be employed are specified. Inspection results are documented.

Qualification and certification of Inspection and Test personnel at EPRI is the responsibility of the Nuclear Sector Plant Support Department, as specified in the governing PQP/QMP-2 Project Plan .

Inspection requirements and acceptance criteria for a project shall be specified per QAP 2.1.

Receipt, in-process, and final inspections are described and shall be conducted per QAP 10.1.

Inservice Inspection (ISI)

EPRI staff are occasionally requested by a member to consult on ISI activities, including NDE findings. These are a form of third-party consulting, and do not constitute examinations that may be credited to meet ASME Code or US regulatory ISI requirements. These activities, when performed, are covered by the member's contract and are performed under the member's QA program.

11.0 TEST CONTROL

EPRI maintains procedures to ensure that tests are performed to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service are planned and properly executed. Characteristics to be tested and test methods are specified. Test results are documented and their conformance with acceptance criteria are evaluated.

Qualification and certification of Inspection and Test personnel at EPRI is the responsibility of the Nuclear Sector Plant Support Department, as specified in the governing PQP/QMP-2 Project Plan.

Test control in general is described and shall be conducted per QAP 11.1.

Computer software testing shall be conducted per QAP 3.3.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

EPRI shall establish and maintain procedures to ensure that tools, gages, instruments, and other measuring and test equipment (M&TE) and inspection hardware (e.g., templates) used in project quality activities are properly identified and controlled and are calibrated and adjusted at specified periods to maintain accuracy within necessary limits.

Control of M&TE shall be conducted per QAP 12.1.

13.0 HANDLING, SHIPPING, STORAGE, AND PRESERVATION OF MATERIALS, PARTS, AND COMPONENTS

EPRI does not provide materials and components for installation in nuclear plants. However, the Program may be applied to materials and components procured or obtained from members or other sources, items fabricated to support analyses, and mockups fabricated to train and certify NDE personnel.

Where necessary, EPRI maintains procedures to ensure that handling, storage, cleaning, packaging, shipping, and preservation of such physical items are controlled to prevent damage or loss and to minimize deterioration.

Handling, shipping, storage, and preservation of materials, parts, and components is described and shall be conducted per QAP 13.1.

14.0 INSPECTION AND TEST STATUS

EPRI maintains procedures to ensure that inspection and test status is maintained. Such measures shall provide means for ensuring that required inspections and tests are performed and that acceptability of items with regard to inspections and tests performed is known throughout manufacturing or use. Nonconforming items shall be clearly identified.

Receipt, in-process, and final inspections are described and shall be conducted per QAP 10.1.

Test control in general is described and shall be conducted per QAP 11.1.

Control of M&TE shall be conducted per QAP 12.1.

Material, part, or component nonconformances are identified and processed per QAP 15.1.

15.0 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

EPRI maintains procedures to ensure that materials, parts, or components that do not conform to requirements are prevented from inadvertent use or installation. Identification of items not conforming to requirements will require generation of either a Nonconformance Report (NCR) or a Corrective Action Report (CAR), as applicable, in EPRI's Condition Reporting System. EPRI also uses these reporting tools to document and correct non-physical items such as technical reports and software.

Procedures for nonconforming items shall address identification, documentation, segregation, disposition, and notification to affected organizations. For distributed products and services, a review for potential 10 CFR Part 21 notification actions shall be performed. Part 21 notification procedures shall be defined and executed as required by the regulation.

Material, parts, or component nonconformances are identified and processed per QAP 15.1.

10 CFR 21 reporting shall be conducted per QAP 16.3.

16.0 CORRECTIVE AND PREVENTIVE ACTION

EPRI maintains procedures to ensure that conditions adverse to quality such as inadequate processes, procedures, adverse trends, audit findings, and deviations from documented requirements are identified, documented, and resolved. Conditions adverse to quality are documented in EPRI's Condition Reporting System. Corrective action procedures shall also provide for identification and review of conditions identified that are potentially reportable pursuant to 10 CFR Part 21.

The methods by which conditions adverse to quality or opportunities for improvement are identified, documented, evaluated, and resolved are described and shall be conducted per QAP 16.1.

10 CFR 21 reporting shall be conducted per QAP 16.3.

Specific requirements related to identification and documentation of issues identified during audits shall be conducted per QAP 18.1.

17.0 QUALITY ASSURANCE RECORDS

EPRI maintains procedures to ensure that records that furnish evidence of quality are specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

Requirements for electronic project and programmatic records shall be defined in applicable procedures. Both electronic and paper EPRI Nuclear Quality Assurance records are permitted for projects and programmatic activities. Paper, microfiche, and electronic records are permitted for record retention.

Generation and retention requirements for EPRI non-Nuclear Quality Assurance Department projects shall be determined and specified per QAP 2.1 and QAP 17.1.

NQA Department records are described and shall be controlled per QAP 17.4.

Exceptions and Clarifications

EPRI allows up to 90 days between the time that an EPRI Nuclear Quality Assurance record is completed and authenticated and the time the record is placed in an NQA-approved records storage location. The risk of damage, deterioration, or loss during this time period is negligible. Additionally, EPRI products generally require more than 90 days to be completed and delivered to members or customers. Since EPRI does not use its products directly in nuclear Safety Related applications, this time period is judged acceptable since most records will be in their EPRI Nuclear Quality Assurance-approved locations before actual delivery of products.

18.0 AUDITS

EPRI maintains procedures to ensure that planned and scheduled audits are performed to verify compliance with all aspects of the Program and to determine its effectiveness. These audits are performed per written procedures or checklists, by personnel who do not have direct responsibility for performing the activities being audited. Audit results are documented and provided to responsible management. Follow-up action is taken where indicated.

Audits shall be conducted per QAP 18.1.

Exceptions and Clarifications

NQA-1-2015; Requirement 18 paragraph 201.3 states that "*All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter"* The requirement allows for an extension of up to two years for a well-established program.

Conclusion:

Based on the allowance for extension for well-established programs, it is EPRI's position that all elements of EPRI's internal Nuclear Quality Assurance program shall be audited at least once within a period of two years. A statement that the EPRI Nuclear Quality Assurance Program is "being effectively implemented" resulting from the annual management review will suffice as justification for continuing the two-year interval.

19.0 ORDER ENTRY AND FUNDING AGREEMENT REVIEW

EPRI maintains procedures to ensure that incoming contractual orders (Funding Agreements) invoking EPRI Safety Related Nuclear Quality Assurance requirements are reviewed to ensure that EPRI has the capability to perform the stated scope of work, adhering to the specified EPRI Safety Related Nuclear Quality Assurance requirements.

Project quality requirements are determined and specified per QAP 2.1.

Order entry and funding agreement reviews shall be conducted per QAP 19.1.

Matrix of EPRI Nuclear Quality Assurance Program and Industry Requirements			
10 CFR 50 Appendix B Criteria (or other regulations)	***Nuclear Quality Assurance-1 / EPRI Nuclear Quality Assurance Manual Section***	***QAP***	***QAP Title***
1	Organization	1.1	Organizational Responsibilities and Management Review
2	Quality Assurance Program	18.1	Audits
		20.1	General Indoctrination and Training
3	Design Control	3.2	Control of Design and Engineering Activities
		3.3	Computer Software
4	Procurement Document Control	4.1	Procurement Documents
		19.1	Order Entry and Funding Agreement Review
5	Instructions, Procedures, and Drawings	5.1	Preparation, Review and Approval of Quality Affecting Documents
6	Document Control	6.1	Control and Controlled Distribution of Documents
7	Control of Purchased Items and Services	----	Control of purchased items & services by section/topic below
		2.1	Project Initiation, Management and Closure
		7.1	Vendor Selection, Qualification, and Re-Evaluation
		4.1	Procurement Documents
		10.1	Receipt, In-Process, and Final Inspection
		11.1	Test Control
		15.1	Nonconforming Materials, Parts and Components
		7.2	Nuclear Commercial Grade Dedication
8	Identification and Control of Items	8.1	Identification and Control of Materials, Parts, and Equipment
9	Control of Processes	9.1	Control of Processes
10	Inspection	10.1	Receipt, In-Process, and Final Inspection
11	Test Control	11.1	Test Control
		3.3	Computer Software
12	Control of Measuring and Test Equipment	12.1	Control of Measuring and Test Equipment
13	Handling, Storage, and Shipping	13.1	Handling, Shipping, Storage, and Preservation of Materials, Parts and Components

Matrix of EPRI Nuclear Quality Assurance Program and Industry Requirements			
10 CFR 50 Appendix B Criteria (or other regulations)	***Nuclear Quality Assurance-1 / EPRI Nuclear Quality Assurance Manual Section***	***QAP***	***QAP Title***
14	Inspection Test and Operating Status	10.1	Receipt, In-Process, and Final Inspection
		11.1	Test Control
		12.1	Control of Measuring and Test Equipment
		15.1	Nonconforming Materials, Parts, or Components
15	Control of Nonconforming Items	15.1	Nonconforming Materials, Parts, or Components
16	Corrective Action	16.1	Corrective and Preventive Action
		16.3	10 CFR 21 Reporting
17	Quality Assurance Records	17.1	Quality Records
		17.4	Quality Records – NQA Department
18	Audits	18.1	Audits
Subpart 2.7	Quality Assurance Requirements for Computer Software for Nuclear Facility Applications	3.3	Computer Software
10CFR21	PART 21 - REPORTING OF DEFECTS AND NONCOMPLIANCE	16.3	10 CFR 21 Reporting