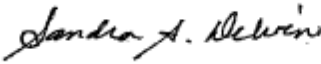
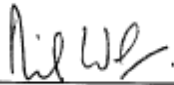


EPRI  
**QUALITY PROGRAM MANUAL**

REVISION 13

Effective Date: April 1, 2010

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## SUMMARY OF CHANGES

### SUMMARY OF SIGNIFICANT CHANGES FROM REVISION 2 TO REVISION 3

- Clarification on Table of Contents Headings regarding revisions.
- Change Science & Technology Development Division to Science & Technology Division.
- Add reference to new QAP 3.7 and change title of QAP 19.1.

### SUMMARY OF SIGNIFICANT CHANGES FROM REVISION 3 TO REVISION 4

- Clarify Section 19 to commit to review of orders for technical, QA and business requirements.
- Clarify Section 22 allowing the use of statistical techniques as needed.
- Reference to QAP 6.1 changed to reflect new title.

### SUMMARY OF SIGNIFICANT CHANGES FROM REVISION 4 TO REVISION 5

- Make Section 3 PQP requirements consistent with QAP 2.1. Clarify roles of implementing procedures under Section 3 by explanation of the interrelationship of QAP 3.1 through QAP 3.7.
- Eliminate reference to EPSC as providing audits to EPRI in Section 7.
- Add M&TE inspection (by reference) in Section 10.
- Clarify Section 16 relative to the Corporate Satisfaction Survey and the Nuclear Sector Self-Assessment and Corrective Action Program (SACAP) process.
- Added References in Sections 2, 3, 5, 9, 10, 11, 13, 14, and 21 to allow Process Control Sheets.
- Editorial changes, clarifications, and organizational edits throughout the Manual.
- Explanation of the interrelationship of QAP 3.1 through QAP 3.7.
- Clarified "independent review" in Section 5.
- Rename Procedures: QAP 3.2, 5.2, & 17.2. QAP References added to Sec. 2, 7, 9, 10, 11, 13, & 16.

### SUMMARY OF SIGNIFICANT CHANGES FROM REVISION 5 TO REVISION 6

- Policy statement clarified to indicate that EPRI QA Program consistent with ISO 9001 – 1994.
- Section 17 consistent with revisions to QAP 17.1, QAP 17.2, and QAP 17.3, which guide work on electronic project records and electronic and microfiche archiving of nuclear safety-related projects.
- Sections 3 and 20 show consolidation of QAP 3.6 contents into QAP 3.3 and consolidation of QAP 20.3 contents into QAP 20.2, and the elimination of QAP 3.6 and 20.3.
- Title of Section 20 changed from "Training" to "Competency".

### SUMMARY OF SIGNIFICANT CHANGES FROM REVISION 6 TO REVISION 7

- Changed to reflect delegation of QA Program responsibility to VP Nuclear Sector and CNO.
- Reflect consolidation of QAP 1.2 into 1.1, and QAP 5.2 into 5.1 and elimination of QAP 20.4.
- Section 22 "Statistical Techniques" of Revision 6 is consolidated into Section 2 of Revision 7.
- Grandfather quality affecting documents so updating QAP references of consolidations is not needed.
- Add reference to the Customer Satisfaction Improvement Program (CSIP) in Section 16.

### SUMMARY OF SIGNIFICANT CHANGES FROM REVISION 7 TO REVISION 8

- Reflect consolidation of QAPS 3.4, 3.5 and 3.7 into 3.2 and elimination of QAP 16.2 AND 17.3.
- Referring to SACAP and CSIP in order to eliminate QAP 16.2, "Customer Feedback".
- Capturing 1998 NUPIC Finding commitment on control of software developed under this QA Program
- Clarifications and administrative cleanup to various sections.

### SUMMARY OF SIGNIFICANT CHANGES FROM REVISION 8 TO REVISION 9

- A 90 day grace period shall apply to all provisions required to be performed on a periodic basis.
- Use of NAVLAP and A2LA Accreditation for Calibration Laboratories to qualify them for procurements.
- Editorial and typographical corrections do not require revision update.
- QA Procedure 4.1 name change and other minor changes and corrections.

### SUMMARY OF SIGNIFICANT CHANGES FROM REVISION 9 TO REVISION 10

- Old Section 21 contents now included in Section 2 of QA manual. Section 21 deleted.
- Section 14 now states that 10CFR50 Appendix B Criterion XIV does not apply to EPRI activities.
- QA Procedure 4.1 name change and other minor changes and corrections.
- Compliance with 10CFR50.34 (f) (3) (iii) (F) now referenced.

SUMMARY OF SIGNIFICANT CHANGES FROM REVISION 10 TO REVISION 11

- Reflect consolidation of Procedure QAP 20.2 into QAP 18.1.
- QAP 18.1 Finding guidance taking precedence over QAP 16.
- Section 18 aligned with NEI 06-14A, Revision 5. Internal audit cycle of all elements extended from 1 to 2 years.
- Use of ACLAS, L-A-B, and IAS Calibration Laboratories Accreditation to qualify vendors for procurements.
- Direction for and permission to convert to an electronic Condition Report System provided in Section 16.

SUMMARY OF SIGNIFICANT CHANGES FROM REVISION 11 TO REVISION 12

- Section 7 expanded to allow the use of audits performed by NIAC members and reorganization of material.
- Section 15 added specific reference to Part 21
- Section 16 modified for use of electronic Conditioning Reporting System (CRS) and elimination of Self Assessment and Corrective Action Program (SACAP).
- Section 18 the option to extend audit cycles to 4 years was eliminated

SUMMARY OF SIGNIFICANT CHANGES FROM REVISION 12 TO REVISION 13

- Section 2 Activities performed early require re-setting the interval clock based on date of performance, not originally scheduled due date.
- In Section 7 Deleted the use ACLAS, LAB or IAS accreditation for safety related calibration supplier qualification
- Section 16, Deleted requirement to determine "root" cause, retained requirement to determine cause.
- Section 17 Referenced new QAP 17.4 "Quality Records – QA Department"

Mapping EPRI Quality Program to 10CFR50 Appendix B, 10CFR21, and ISO 2001:1994

Corresponding 10 CFR 50 Appendix B Section Number	EPRI QA Manual Section Number	EPRI Quality Program Manual Section Title	ISO 9001 – 1994 Section Number	ISO 9001 – 1994 Section Title
		Policy Statement	4.1.1	Quality Policy
1	1	Organization	4.1.2 4.1.3	Organization Management Review
2	2	Quality Program	4.2 4.19 4.20	Quality Program Servicing Statistical Techniques
3	3	Design Control	4.4	Design Control
4	4	Procurement Document Control	4.6	Purchasing
5	5	Instructions, Procedures, and Drawings	4.9	Process Control
6	6	Document Control	4.5	Document and Data Control
7, 10CFR21	7	Control of Purchased Material, Equipment, and Services	4.6	Purchasing
8	8	Identification and Control of Materials, Parts, and Components	4.8	Product Identification and Traceability
9	9	Control of Special Processes	4.9	Process Control
10	10	Inspection	4.10	Inspection and Testing
11	11	Test Control	4.10	Inspection and Testing
12	12	Control of Measuring and Test Equipment	4.11	Control of Inspection, Measuring, and Test Equipment
13	13	Handling, Shipping, Storage, and Preservation of Materials, Parts, and Components	4.15 4.7	Handling, Storage, Packing, Preservation, and Delivery Control of Customer Supplied Product
14	14	Inspection and Test Status	4.12	Inspection and Test Status
15, 10CFR21	15	Nonconforming Materials, Parts, or Components	4.13	Control of Nonconforming Product
16, 10CFR21	16	Corrective and Preventive Action	4.14	Corrective and Preventive Action
17	17	Quality Records	4.16	Control of Quality Records
18	18	Audits	4.17	Internal Quality Audits
10CFR21	19	Order Entry and Funding Agreement Review	4.3	Contract Review
2	20	Competency	4.18	Training

Table 1: Mapping EPRI Quality Program to 10CFR50 Appendix B, 10CFR21, and ISO 9001: 1994.

## STATEMENT OF AUTHORITY

EPRI recognizes the importance of quality in industry and is committed to continuous improvement in the quality of work controlled under this Quality Program.

This manual has been prepared to describe the commitments made by EPRI to achieve continuous improvement and quality in the work it performs under this Quality Program.

This program meets the requirements of 10 CFR 50 Appendix B, ANSI N45.2., and the intent of ISO-9001 (1994).

Contractual arrangements between the customer and EPRI, which specify requirements in addition to those specified by this Quality Program, shall be applied at the project level providing such requirements do not compromise the quality of our service or this Quality Program.

## POLICY STATEMENT

### EPRI Quality Assurance Program

For certain products and activities, U.S. and International nuclear regulations require that special quality assurance processes be invoked to assure the quality of those products and services. When requested by member/customers, EPRI provides products and services in accordance with a quality program which meets the quality assurance (QA) requirements of 10CFR50 Appendix B, 10CFR21, and ANSI N45.2-1977 and intent of ISO 9001:1994.

NOTE: *The entire EPRI Quality Assurance Manual is reviewed and revised as a whole.*

## 1.0 ORGANIZATION

EPRI's Nuclear Sector is responsible for establishing a Quality Program for products and services delivered to our customers. Although authority for development and execution of the program may be delegated to other parties, such as consultants or contractors, EPRI's Nuclear Sector retains overall program responsibility.

EPRI Managers of quality affecting activities may delegate those activities to qualified individuals, where appropriate.

The EPRI Quality Assurance Manager has the responsibility for establishing the Quality Program and verifying that activities affecting the quality of deliverables are performed in accordance with this program. The EPRI Quality Assurance Manager is afforded sufficient authority and organizational freedom, including independence from the cost and schedule impacts of required quality assurance actions, to identify quality problems; to initiate, recommend, or provide solutions to quality problems; and to verify implementation of solutions to quality problems. All employees have the responsibility and authority to identify quality problems; to initiate and provide solutions to quality problems; to verify implementation; and to resolve deficiencies that affect quality.

The EPRI Quality Assurance Manager is the EPRI Management Representative and is responsible for ensuring that this quality system is maintained, understood and implemented at all levels of the organization. The Management Representative is also responsible for reporting on the performance of the Quality System to executive management for review and improvement.

The EPRI organizational structure is defined in an implementing procedure. In the event that any individual in the organization is absent or otherwise unavailable to perform functions or responsibilities, those functions and responsibilities may be performed by a superior or delegated to a qualified subordinate within the organization.

This Quality Program is authorized for all EPRI locations, including, but not limited to, employees situated in or reporting in to Palo Alto, California, Charlotte, North Carolina and Knoxville, Tennessee.

EPRI senior management has assigned trained personnel to manage, perform and verify activities affecting quality. Personnel assigned these tasks are qualified on the basis of experience and/or training.

All employees are responsible for the quality of the products and services under their control and for following procedural requirements during all processes in which they are involved.

In compliance with 10CFR50.34(f) (3) (iii) (F), EPRI Senior Management shall ensure that the size of the QA organization is commensurate with its duties and responsibilities.

Biennially, an independent assessment or audit of the EPRI Quality Assurance Organization shall be performed with results reported to the EPRI Quality Assurance Manager.

A formal management review of the quality system shall be performed annually to ensure its continuing suitability and effectiveness in satisfying EPRI's policies and objectives. Records of the management review meeting and associated completed action items shall be maintained in accordance with documented procedures.

### **Implementing Procedures**

QAP 1.1, "Organizational Responsibilities and Management Review"

QAP 17.1, "Quality Records"

QAP 20.1, "General Indoctrination and Training"

## 2.0 QUALITY PROGRAM

This Manual defines and establishes EPRI's Quality Program and Quality Policy. The EPRI Quality Program is implemented through Quality Procedures and Project Quality Plans, augmented with Quality Project Instructions, Process Control Sheets and Drawings as applicable to the scope of work.

Quality Assurance controls are applied to project activities that accept the requirements of 10CFR50 Appendix B, ANSI N45.2, 10CFR21, and/or the intent of ISO9001:1994, as applicable.

The status, adequacy, and effectiveness of this quality system in meeting EPRI business and quality objectives, as well as compliance to requirements, shall be evaluated at defined intervals. This management review shall evaluate the results of internal and external audits, corrective and preventive actions, customer feedback, product non-conformances, and staff training.

Unless otherwise noted, a grace period of 90 days without documented justification may be applied to provisions that are required to be performed on a periodic basis. The grace period shall not reset the "clock" for an activity forward. However, the clock for an activity is reset backwards by the amount the activity is performed early. Approved Vendor List re-qualification, triennial audits, Lead Auditor evaluations, and QA Training are examples where a grace period may be applied.

This EPRI Quality Program may be used for EPRI work at non-EPRI locations when approved by the EPRI Quality Assurance Manager.

EPRI may use statistical techniques in establishing, controlling, and verifying project or administrative activities as the need arises.

EPRI shall have documented procedures and/or project instructions and/or process control sheets to ensure that servicing requirements are translated and implemented. Servicing shall include the support of software user groups and maintenance activities.

### Implementing Procedures

QAP 1.1, "Organizational Responsibilities and Management Review"

QAP 2.1, "Project Initiation, Management, and Closure"

QAP 5.1, "Preparation, Review and Approval of Quality Affecting Documents"

QAP 15.1, "Nonconforming Materials, Parts, or Components"

QAP 16.1, "Corrective and Preventive Actions"

QAP 17.1, "Quality Records"

QAP 18.1, "Audits"

QAP 20.1, "General Indoctrination and Training"

### 3.0 DESIGN CONTROL

EPRI shall establish and maintain documented procedures and instructions to ensure that applicable regulatory, code, standard, and customer requirements are translated into design documents, procedures, and instructions.

These documents shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from defined requirements are controlled.

Provisions will be made in the procedures for generating Project Quality Plans, as appropriate, for projects conducted under the EPRI Quality Program. These Project Quality Plans shall define the scope of the project design activity, define project personnel responsibilities and interfaces, define the design documents required, and shall be updated periodically, as required by project development.

Design input requirements shall be established and their selection reviewed and approved for adequacy. Design input shall address the requirements in customer orders and EPRI Corporate and Technical Management policy. Design requirements shall be objective, quantitative, or capable of unambiguous determination of implementation.

Design output shall be documented and expressed in terms that can be verified against design input requirements and validated. Individuals or groups other than those that performed the original design shall review design output documents.

Independent design reviews shall occur at prescribed stages within the design process. The Project Quality Plan and/or Quality Project Instruction and/or Process Control Sheets shall define the design documents, project team, and other organizations that may be involved in the review. Records of design reviews shall be maintained.

Independent design verifications shall be performed in accordance with approved procedures and/or instructions to ensure that the design output meets the design input requirements. Independent design validations shall be performed to ensure that products conform to user needs and/or requirements. Records of design verifications shall be maintained.

Design and engineering reviews shall be performed by individuals other than those who performed the original technical work being reviewed. These individuals may be within the same organization.

Design changes shall be subject to design control measures commensurate with those applied to the original design.

Design documents, including revisions, shall be reviewed, approved, released, distributed, and controlled in accordance with prescribed procedures and/or instructions.

Depending on the nature of the work, implementing procedures QAP 3.1, 3.2, and/or 3.3 will normally be invoked for a given technical/engineering project. QAP 3.1 addresses technical work procured from a vendor under a contract or a purchase order. QAP 3.2 addresses in-house engineering services, except for software development. QAP 3.3 addresses in-house software development. Each of these three procedures shall be written to be sufficient for the scope addressed and may be invoked in parallel.

This Quality Program shall take precedence over all other EPRI corporate software quality processes and requirements. If a conflict exists, notification of this fact shall be clearly indicated in appropriate places. The EPRI Software Quality Control Manager shall implement corporate software quality testing requirements and quality requirements under this program when testing software developed under this program.

### **Implementing Procedures**

- QAP 2.1, "Project Initiation, Management, and Closure"
- QAP 3.1, "Control of Contracted Design and Engineering Activities"
- QAP 3.2, "Control of Internal Project Design and Engineering Activities"
- QAP 3.3, "Internal Software Development, Verification and Validation Activities"
- QAP 5.1, "Preparation, Review and Approval of Quality Affecting Documents"
- QAP 6.1, "Control and Controlled Distribution of Documents"
- QAP 10.1, "Receipt, In-Process, and Final Inspection"
- QAP 17.1, "Quality Records"
- QAP 19.1, "Order Entry and Funding Agreement Review"

#### 4.0 PROCUREMENT DOCUMENT CONTROL

EPRI shall establish and maintain documented procedures to ensure that a purchased product conforms to specified requirements. A product may include a service, research and development activities, hardware, processed materials, software, or a combination thereof.

Procedures shall assure that applicable regulatory, design basis, and other requirements which are necessary to assure adequate product quality are included or referenced in the procurement documents.

All contractors will be required to pass on appropriate quality requirements to subcontractors through subcontracts and purchase orders.

For all nuclear safety-related 10CFR50 Appendix B activities, the requirements of 10CFR21 shall apply.

Procurement documents shall be reviewed for adequacy and accepted by the EPRI Quality Assurance Manager prior to release. Changes to procurement documents shall be subject to the same level of review utilized in the preparation of the original document.

##### **Implementing Procedures**

QAP 4.1, "Preparation, Review, Approval, and Issuance of Procurement Documents"

QAP 17.1, "Quality Records"

## 5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

All quality affecting activities shall be prescribed and accomplished by documented procedures, or project level instructions, process control sheets, or drawings as appropriate to the circumstances. Procedures shall be established to define controls for quality affecting document identification, review and 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 assure consistent or acceptable results. The level of detail shall be determined based on the complexity and significance of the activity, and worker proficiency and competency.

Instructions, procedures, process control sheets, or drawings shall be reviewed and approved for adequacy by authorized personnel prior to use. Changes to these documents shall be reviewed and approved in a similar manner as the original review and approval. The designated organization/individual(s) shall have access to pertinent background information on which to base their review and approval.

Changes to quality documents shall be identified in the document or the appropriate attachments unless the changes were extensive: in this case the document shall indicate "General Change", "Complete Re-write", or equivalent in lieu of identifying each change.

Consolidation or elimination of Quality Procedures do not require an update to the Quality Assurance Procedure (QAP) references in the Quality Program Manual (QPM), QAPs, Project Quality Plans (PQPs), Quality Project Instructions (QPIs), Process Control Sheets (PCSs), or Drawings. QAP consolidation and elimination shall be documented in the Table of Contents of the Quality Assurance Procedure Manual. During the next revision of the QPM, QAPs, PQP, QPIs, PCSs, or Drawings, references to consolidated QAPs shall be accomplished on a going forward basis.

### Implementing Procedures

QAP 2.1, "Project Initiation, Management, and Closure"

QAP 3.2, "Control of Internal Project Design and Engineering Activities"

QAP 3.3, "Internal Software Development, Verification and Validation Activities"

QAP 5.1, "Preparation, Review and Approval of Quality Affecting Documents"

## 6.0 DOCUMENT CONTROL

Procedures are established by EPRI to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe activities affecting quality.

These procedures are established to assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed.

Minor changes to controlled documents, such as inconsequential editorial changes and typographical errors, do not require revised documents to receive the same level of review and approval. Revision control is not required for these changes.

Requirements are established for the same organizations that performed the original review and approval to review and approve changes to documents unless another responsible organization is designated.

### Implementing Procedures

QAP 5.1, "Preparation, Review and Approval of Quality Affecting Documents"

QAP 6.1, "Control and Controlled Distribution of Documents"

## 7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

EPRI shall establish and maintain documented procedures and processes to ensure that procured product or services conform to procurement document requirements.

Vendors listed on the EPRI Approved Vendors List shall be evaluated to assess vendor performance at intervals consistent with the importance and complexity of the product or service provided. U. S. Nuclear Utilities (10CFR50) Licensees, the National Institute of Standards and Technology, and other state or federal agencies do not require evaluation or audit.

Vendors performing nuclear safety-related work shall be evaluated by triennial audit, and approved by EPRI as meeting 10CFR50 Appendix B and 10CFR21. Audits may be performed by EPRI, provided by individual nuclear utility licensees, through the Nuclear Procurement Issues Committee (NUPIC), or by the Nuclear Industry Assessment Committee (NIAC).

Commercial Grade items and services procured for safety-related applications shall be controlled by a Commercial Grade Dedication process as defined by procedures.

Vendor surveys are not required for purchased Commercial Grade Calibration Services if the following conditions are met:

- (1) Procurement documents impose technical and administrative requirements, as needed to comply with this QA Program. The procurement document shall require the Calibration Certificate/Report identify the laboratory equipment/standard used.
- (2) Procurement documents require reporting as-found calibration data.
- (3) A review of the vendor's accreditation is documented including verification of:
  - (a) Accreditation to ISO 17025 by one of the accrediting bodies specifically approved by the US NRC in a Safety Evaluation Report (SER). As of this revision these include the following, although others so approved by the US NRC may be utilized without revision to this Manual.
    - National Voluntary Laboratory Accreditation Program (NVLAP), or
    - American Association for Laboratory Accreditation (A2LA)
  - (b) The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.

Augmented Quality ISO 9000/17025 accredited vendors not providing safety related or commercial grade products or services may be evaluated with a copy of their ISO Certificate in lieu of an on-site audit or survey.

For procured products or services, procedures shall define requirements for receipt inspection to assure that they conform to procurement documents, or for commercial grade products shall define requirements for procurement, inspection, and acceptance.

When required by procurement documents, EPRI, or a designee, shall verify purchased product at the vendor's facility. EPRI will evaluate each vendor's ability to sub-contract products or services, and preclude subcontracting if the evaluation so concludes.

**Implementing Procedures**

QAP 7.1, "Vendor Selection, Qualification, and Re-evaluation"

QAP 7.2, "Nuclear Commercial Grade Dedication"

QAP 10.1, "Receipt, In-Process, and Final Inspection"

QAP 17.1, "Quality Records"

QAP 18.1, "Audits"

## **8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS**

EPRI shall establish and maintain documented procedures to ensure that materials, parts, and components used in project quality activities, including those items supplied by EPRI customers, are properly identified and controlled.

These procedures shall 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, or deterioration, and inadvertent use of incorrect or defective materials, parts, and components.

### **Implementing Procedures**

QAP 2.1, "Project Initiation, Management, and Closure"

QAP 8.1, "Identification and Control of Materials, Parts, and Components"

QAP 15.1, "Nonconforming Materials, Parts, or Components"

## 9.0 CONTROL OF SPECIAL PROCESSES

EPRI shall establish and maintain documented procedures to ensure processes that directly affect quality are carried out under controlled conditions.

The Project Quality Plan is the document through which all quality affecting project activities are identified, described, and controlled. If required by the Project Quality Plan, implementing Quality Project Instructions or Process Control Sheets are developed to provide sufficient quantitative and qualitative criteria, and direction, for successfully fulfilling customer expectations and requirements.

Quality Project Instructions shall be developed to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures or instructions and, when required, qualified equipment. Records shall be maintained for qualified processes, equipment, and personnel when required by the Project Quality Plan.

### Implementing Procedures

QAP 2.1, "Project Initiation, Management, and Closure"

QAP 5.1, "Preparation, Review and Approval of Quality Affecting Documents"

QAP 9.1, "Control of Special Processes"

QAP 17.1, "Quality Records"

QAP 20.1, "General Indoctrination and Training"

QAP 20.5, "Qualification and Certification of Nondestructive Examination Personnel"

## 10.0 INSPECTION

EPRI shall establish and maintain documented procedures for inspection activities and inspection status in order to verify that the specified requirements are met in the Project Quality Plan, Quality Project Instructions, Process Control Sheets, or Drawings. The Project Quality Plan, Quality Project Instructions, or Process Control Sheets, shall define the inspections required, inspection records, and inspection status.

Receipt inspection shall be performed as described in implementing procedures, Project Quality Plans, Quality Project Instructions, and/or Process Control Sheets. EPRI shall ensure that incoming items are not used or processed until they have been inspected or otherwise verified as conforming to procurement documents. Items that have not been subject to receipt inspection shall not be released for use.

The Project Quality Plan, Quality Project Instructions, Process Control Sheets, and/or Drawings shall define a project specific program for all in-process and final inspection. Witness and hold points applied in the project documents shall be verified, and accepted, by personnel qualified in accordance with approved procedures. Final inspection shall verify that the finished item conforms to specified requirements and that all required inspections have been performed. No item may be unconditionally released until all inspections that have been defined in the Project Quality Plan or Quality Project Instructions or Process Control Sheets have been satisfactorily completed and the data, documentation, and records associated with these inspections are available and completed.

Individuals other than those who performed the activity being inspected shall perform inspections. Personnel performing inspections shall be trained and/or qualified in accordance with approved procedures.

Records of inspection activities shall be maintained according to approved procedures. Records shall identify the individual who did the inspection and authorized the release of items.

### Implementing Procedures

- QAP 2.1, "Project Initiation, Management, and Closure"
- QAP 5.1, "Preparation, Review and Approval of Quality Affecting Documents"
- QAP 10.1, "Receipt, In-Process, and Final Inspection"
- QAP 12.1, "Control of Measuring and Test Equipment"
- QAP 15.1, "Nonconforming Materials, Parts, or Components"
- QAP 17.1, "Quality Records"
- QAP 20.1, "General Indoctrination and Training"

## 11.0 TEST CONTROL

EPRI shall establish and maintain documented procedures for acceptance test activities and status in order to ensure that requirements, which are specified in the Project Quality Plan, Quality Project Instructions, or Process Control Sheets, are met. The Project Quality Plan, Quality Project Instructions, or Process Control Sheets shall define the required tests, test records, and test status.

Provision for, or identification of test instructions shall be described in the Project Quality Plan. Test instructions shall have provisions for assuring that test prerequisites have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Witness and hold points applied in the project documents shall be verified, and accepted, by trained and/or qualified personnel in accordance with approved procedures.

Test results shall be documented and evaluated to assure that specified test requirements have been satisfied. Records shall identify the personnel evaluating the test results. Records of test activities shall be maintained in accordance with approved procedures. No item may be unconditionally released until all tests that have been defined in the Project Quality Plan, Quality Project Instructions or Process Control Sheets, have been satisfactorily completed and the data, documentation, and records associated with these tests are completed.

### Implementing Procedures

QAP 2.1, "Project Initiation, Management, and Closure"

QAP 5.1, "Preparation, Review and Approval of Quality Affecting Documents"

QAP 11.1, "Test Control"

QAP 17.1, "Quality Records"

QAP 20.1, "General Indoctrination and Training"

## 12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

EPRI shall establish and maintain documented procedures to ensure that measuring and test equipment (M&TE) and inspection hardware (e.g., templates) used in project quality activities are properly identified, calibrated, and controlled.

The Project Manager shall identify or make provision to identify the M&TE needed to perform the required inspections and tests in the Project Quality Plan.

Measuring and test equipment shall be marked or labeled such that the current status of each instrument is readily discernible.

Measuring and test equipment shall be calibrated using reference standards traceable to national standards (e.g., National Institute of Standards and Technology, "NIST"), where such standards exist. If no national standards exist, the basis for calibration shall be documented.

Measuring and test equipment, which are not calibrated to full capability or which have limitations on their use shall be labeled or otherwise identified as to their limitations or restrictions.

Environmental conditions (e.g., temperature, humidity, static electricity) in which M&TE are calibrated shall be controlled and appropriate for the calibration being performed.

Measuring and test equipment found to be beyond calibration limits at the time of recalibration shall be identified and evaluated on a nonconformance report and a use history review conducted to ascertain the identity of components inspected with the M&TE since their last calibration.

Commercial measuring devices (rulers, tape measures, levels, etc.) will not be required to be calibrated if such commercial equipment provides adequate accuracy for the tests or inspections indicated.

Calibration service providers employed to calibrate M&TE for activities affecting quality shall be selected and qualified in accordance with the requirements of this program.

Records of calibration activities shall be maintained in accordance with approved procedures.

## Implementing Procedures

- QAP 2.1, "Project Initiation, Management, and Closure"
- QAP 4.1, "Preparation, Review, Approval, and Issuance of Procurement Documents"
- QAP 5.1, "Preparation, Review and Approval of Quality Affecting Documents"
- QAP 6.1, "Control and Controlled Distribution of Documents"
- QAP 7.1, "Vendor Selection, Qualification, and Re-evaluation"
- QAP 7.2, "Nuclear Commercial Grade Dedication"
- QAP 10.1, "Receipt, In-Process, and Final Inspection"
- QAP 11.1, "Test Control"
- QAP 12.1, "Control of Measuring and Test Equipment"
- QAP 13.1, "Handling, Shipping, Storage, and Preservation of Materials, Parts, and Components"
- QAP 15.1, "Nonconforming Materials, Parts, or Components"
- QAP 17.1, "Quality Records"
- QAP 20.1, "General Indoctrination and Training"

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

EPRI shall establish and maintain documented procedures for ensuring that the handling, packaging, shipping, storage, and preservation of items affecting quality meet requirements specified in the Project Quality Plan, Quality Project Instructions, or Process Control Sheets. The Project Quality Plan, Quality Project Instructions, or Process Control Sheets, shall define any customer requirements that exceed EPRI Quality Program requirements.

Items shall be handled in a manner not to cause them excessive vibration or damage. Carts may be used to move items around the EPRI facility. Lighter items can be hand carried to points of destination.

Special handling requirements shall be defined in the Project Quality Plan, Quality Project Instructions, or Process Control Sheets.

Equipment is staged on shelves, carts, or on the floor in the original container until receipt inspection is completed. In-process items shall be staged on pallets, shelves or containers in a manner to prevent damage or deterioration.

Protective environments, including atmosphere, moisture, and temperature parameters shall be established, as applicable, in the Project Quality Plan, Quality Project Instructions or Process Control Sheets.

Packaging will be performed using the original shipping container or in a manner that prevents damage or deterioration to the item shipped.

From time of receipt all items shall be stored to ensure that the integrity of the units is preserved (e.g., carts, tables, shelves, etc.).

Personnel performing activities affecting quality shall be trained in accordance with approved procedures.

#### **Implementing Procedures**

QAP 2.1, "Project Initiation, Management, and Closure"

QAP 5.1, "Preparation, Review and Approval of Quality Affecting Documents"

QAP 13.1, "Handling, Shipping, Storage, and Preservation of Materials, Parts, and Components"

QAP 17.1, "Quality Records"

QAP 20.1, "General Indoctrination and Training"

## 14.0 INSPECTION AND TEST STATUS

10CFR50 Appendix B Criterion XIV requires that “measures shall be established to indicate, by the use of markings, such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear power plant or fuel reprocessing plant. These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary preclude inadvertent bypassing of such inspections and tests.”

10CFR50 Appendix B Criterion XIV also requires that “measures shall also be established for indicating the operating status of structures, systems, and components in a nuclear power plant or fuel reprocessing plant, such as by tagging valves and switches, to prevent inadvertent operation.”

Since EPRI does not operate a nuclear power plant or a fuel reprocessing plant, and does not supply physical structures, systems, or components to be installed in them, 10CFR50 Appendix B Criterion XIV does not apply to EPRI’s quality activities or EPRI’s Quality Program.

ISO 9001 (1994) requirements on Inspection and Test Status will be accomplished as part of Sections 10 and 11 of this Quality Program.

### Implementing Procedures

None

## 15.0 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

EPRI shall establish and maintain documented procedures to ensure that materials, parts, or components which do not conform to requirements are prevented from use or installation. Identification of any of these items not conforming to requirements will require generation of a Nonconformance Report. The responsibility for review and authority for the disposition of nonconforming items shall be defined.

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

Nonconforming items shall be reviewed and accepted (use-as-is), rejected, repaired, or reworked in accordance with documented procedures. Disposition of the nonconforming items shall be documented on the Nonconformance Report.

The description of repairs, and of any nonconformity that has been accepted under authorized concession, shall be recorded to denote the actual condition. Repaired and/or reworked items shall be re-inspected in accordance with documented procedures.

### Implementing Procedures

QAP 15.1, "Nonconforming Materials, Parts, or Components"

QAP 16.3, "10 CFR 21 Reporting"

QAP 17.1, "Quality Records"

## 16.0 CORRECTIVE AND PREVENTIVE ACTION

EPRI shall establish and maintain documented procedures to ensure that conditions adverse to quality such as inadequate processes, procedures, adverse quality trends, audit findings, deviations from documented requirements, and customer feedback are identified, documented, and resolved. Procedures shall also provide for review for potential 10CFR Part 21 notification.

Procedures for significant conditions adverse to quality shall require identification of the cause, the actions taken to resolve and prevent the recurrence of the adverse condition, and the evaluation of proposed cause, corrective and preventive actions, and verification of the completion and efficacy and documentation of the effectiveness of the actions taken to eliminate the adverse condition.

Corrective and Preventive actions shall be documented and shall be commensurate with the severity of the adverse condition. Relevant information regarding corrective and preventive conditions shall be reported to, and evaluated by, EPRI management during the annual management review of the quality system.

### Implementing Procedures

QAP 1.1, "Organizational Responsibilities and Management Review"

QAP 16.1, "Corrective and Preventive Action"

QAP 16.3, "10 CFR 21 Reporting"

QAP 17.1, "Quality Records"

## 17.0 QUALITY RECORDS

Sufficient records are maintained by EPRI to demonstrate conformance to specified requirements and the effective operation of the quality management system.

Procedures are established for classifying, identifying, indexing, filing, accessing, storing, retrieving, protecting, and maintaining nuclear safety-related and ISO 9001 records.

Records are established and maintained that provide evidence that the product has been inspected and/or tested. These records identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.

Requirements are established covering record legibility, retention, including duration, location, and assigned responsibility, and disposition.

Requirements for electronic project and programmatic records shall be described in QAP 17.1, "Quality Records". Both electronic and paper Quality Assurance records are permitted for active projects and functional activities. Paper, microfiche and electronic records are permitted as archived records.

### Implementing Procedures

QAP 2.1, "Project Initiation, Management, and Closure"

QAP 17.1, "Quality Records"

QAP 17.4, Quality Records – QA Department

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## 18.0 AUDITS

EPRI shall establish necessary measures and governing procedures to implement audits to verify that activities covered by this Quality Assurance (QA) Program are performed in conformance with established requirements. The audit program is reviewed for effectiveness as a part of the overall audit process.

EPRI is responsible for conducting periodic internal and external audits. External audits determine the adequacy of supplier and contractor QA programs. Internal audits determine the adequacy of documented processes (by representative sampling), and determine if they are meaningful and comply with the overall EPRI QA Program. Internal audits shall cover as a minimum verification of compliance, effectiveness of the implementation and administrative controls established for implementing requirements of this QA Program. Internal audits of selected aspects of activities will be performed with a frequency commensurate with safety and quality significance, in a manner that assures audits of safety-related activities, all QA program elements, and each functional area are completed within a period of two years.

Audit focus will include, as a minimum, activities in the following areas:

- (1) Regulations.
- (2) The provisions for training, retraining, qualification, and performance of EPRI Nuclear Sector personnel performing activities covered by this QA Program.
- (3) The performance of activities required to meet 10 CFR 50, Appendix B.
- (4) Procurement
- (5) Corrective and preventive action
- (6) Functional areas
- (7) Observation of performance of fabrication, research, development, and engineering activities including associated records.

Other activities and documents considered appropriate by the Vice President of the Nuclear Sector/Chief Nuclear Officer or Quality Assurance Manager.

Audits are scheduled on a preplanned audit schedule, which is reviewed periodically and revised as necessary to assure coverage commensurate with current and planned activities. Additional audits may be performed as deemed necessary by management. The scope of an audit is determined by the quality status and safety importance of the activities performed. Audits are conducted by trained personnel not having direct responsibilities in the area they audit and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the EPRI QA Manager. Audit finding flexibility shall be provided for in QAP 18.1, "Audits" for less serious items and shall take precedence over identification requirements in QAP 16.1, "Corrective and Preventive Action". Requirements for Auditor and Lead Auditor training, qualification and certification shall be provided in QAP 18.1 "Audits".

The results of each audit shall be reported in writing to the responsible personnel.

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Additional internal distribution is made to other appropriate management levels.

Responsible personnel shall provide timely response to all audit findings, which shall be recorded as corrective actions. Where corrective actions are indicated, documented follow-up through inspections, review, re-audits, or other appropriate means shall be conducted to verify and record implementation and effectiveness of the actions.

Relevant results of the audits shall be provided to EPRI Management for review during the annual management review of the quality system or at other times.

### **Implementing Procedures**

QAP 1.1, "Organizational Responsibilities and Management Review"

QAP 16.1, "Corrective and Preventive Action"

QAP 17.1, "Quality Records"

QAP 18.1, "Audits"

## 19.0 ORDER ENTRY AND FUNDING AGREEMENT REVIEW

EPRI shall establish and maintain documented procedures to assure that customer orders are reviewed and accepted prior to project initiation.

Orders shall be reviewed for technical (scope of work), Quality Assurance and business requirements. Orders for delivery of off-the-shelf (previously developed) products do not require technical scope of work review if those products are to be delivered unchanged. Implementing procedures shall assure that customer requirements are reviewed and accepted by authorized EPRI personnel to ensure that EPRI has the capability to perform the stated scope of work. EPRI may receive customer requirements in the form of purchase orders, tailored collaboration and EPRI/customer co-funded agreements, or through advisory committee or Subscriber Requested Assistance (SRA) requests. Verbal authorization, by a customer, to initiate project work scope shall be documented and accepted by authorized EPRI personnel in accordance with implementing procedures.

EPRI Revenue Contracts shall be the official and formal contact with customer purchasing functions. Differences between EPRI proposals and customer authorizing documents shall be reconciled prior to acceptance of the order, unless documented rationale to do otherwise is made. Start of work or delivery of off-the-shelf products may be allowed by the Revenue Contracts Manager based on the disposition of differences, conditional to customer release. A stop work order will be issued if the customer rejects the disposition of differences and EPRI Revenue Contracts, Quality Assurance or Technical Management determines that a Stop Work is appropriate or if EPRI is instructed by the Customer to stop work.

Amendments to customer authorizing documents must be reviewed and accepted in the same manner as the original document.

Records of contract review shall be maintained.

### Implementing Procedures

QAP 2.1, "Project Initiation, Management, and Closure"

QAP 17.1, "Quality Records"

QAP 19.1, "Order Entry and Funding Agreement Review"

## 20.0 COMPETENCY

EPRI shall establish and maintain documented procedures to ensure that personnel who manage, perform or verify activities affecting quality are appropriately trained.

Personnel performing assigned tasks shall be qualified on the basis of appropriate education, training, and/or experience. Personnel hired by EPRI go through a screening and review process to assure that they are qualified and competent.

Training needs other than those defined herein shall be identified and documented during the annual management review of the quality system.

EPRI personnel shall receive general indoctrination and training in this Quality Program to enable them to fully participate in the operation of the Quality Program.

Qualification requirements for lead auditors, auditors, audit technical specialists, inspectors, and nondestructive examination (NDE) personnel shall be established. The Project Quality Plan or Quality Project Instructions, as required, shall identify project specific training needs.

Appropriate records of training shall be maintained in accordance with approved procedures.

### Implementing Procedures

QAP 1.1, "Organizational Responsibilities and Management Review"

QAP 17.1, "Quality Records"

QAP 18.1, "Audits"

QAP 20.1, "General Indoctrination and Training"

QAP 20.5, "Qualification and Certification of Nondestructive Examination Personnel"