Representative Chapter 17 Text
QUALITY ASSURANCE

17.0 INTRODUCTION

Section 17.1 describes the Quality Assurance Plan (QAP) used by AREVA NP Inc. for the design and deployment of commercial nuclear operating plants, specifically the U.S. EPR, and for products and services supplied by AREVA NP Inc. under nuclear safety related criteria.

The basis for Section 17.1 is the AREVA NP Inc. Topical Report ANP-10266NP, Revision 0, "AREVA NP Inc. Quality Assurance Plan (QAP) for Design and Deployment of the U.S. Evolutionary Power Reactor (U.S. EPR)," which has been submitted to the Nuclear Regulatory Commission (NRC) for review and approval. (Reference 17.1.19-1)

The QAP is organized and administered to comply with:

- 10 CFR 50, Appendix A, General Design Criteria 1(a), Appendix B, 50:55(a), and 50:55(b)
- 10 CFR 21
- Quality Assurance related NRC Regulatory Guide commitments as described in Appendix B of the QAP
- ANSI/ASME N45.2 and its daughter standards and/or ANSI/ASME NQA-1-1994
- AREVA NP Inc. Quality Management Manual, 56-5015885

AREVA NP Inc. is the design authority for the U.S. EPR. Design interfaces with domestic or international AREVA affiliate companies or interfaces with external design organizations are conducted in accordance with procurement document control requirements. All interfacing organizations are considered suppliers. Each organization utilized has been evaluated in accordance with QAP requirements and maintained on the AREVA NP Inc. Plants and Services Approved Suppliers List.

17.1 QUALITY ASSURANCE DURING DESIGN

The application of the Criteria of Appendix B and the Basic and Supplemental Requirements of ANSI/ASME NQA-1-1994 to the EPR Design Certification Project, including specific references to the applicable QAP sections, is shown in the subsections below. Typical implementing policies, procedures and instructions are included in Appendix A of Reference 17.1.19-1.

AREVA NP Inc.'s position, including clarifications, with respect to the NRC Regulatory Guides pertaining to Quality Assurance as they apply to the AREVA NP Inc. scope of supply is included in Appendix B of Reference 17.1.19-1.

AREVA NP Inc.'s conformance to additional Regulatory Guides is described in Chapter 1.9 of the Design Certification Document (DCD).

Addendum A to Reference 17.1.19-1 describes the Quality Assurance Plan (QAP) for the non-safety related products and services supplied by AREVA NP Inc.

17.1.1 Organization

See Section 1 of Reference 17.1.19-1.

AREVA NP Inc. has issued a QAP that establishes the organization's Quality Policies and commits the organization to implement these policies. The policies have the unqualified support of all levels of management within AREVA NP Inc.

The AREVA NP Inc. QAP describes the organization including the structure, responsibilities, authorities and interfaces.

This section complies with Criterion I of 10 CFR 50, Appendix B, Organization, and Basic Requirement 1, Organization and Supplementary Requirements for Organization, 1S-1, of ANSI/ASME NQA-1-1994.

17.1.2 Quality Assurance Program

See Section 2 of Reference 17.1.19-1.

The QAP, as defined in Section 2 of Reference 17.1 applies to nuclear safety-related activities of the U.S. EPR and for safety-related products and services supplied by AREVA NP Inc. Addendum A of Reference 17.1 describes the QAP applicable to non-safety related products and services.

The classification of items and services as safety related is made and documented by the responsible engineering and project management functions for AREVA NP Inc. The identification of safety-related structures, systems and components to be controlled by the QAP is provided in Chapter 3 of the DCD.

The QAP provides the scope, requirements, implementation, assessment, and indoctrination and training requirements for all personnel. In addition, the QAP provides for the qualification of personnel performing tests and inspections, surveillances and audit activities.

This section complies with Criterion II of 10 CFR 50, Appendix B, Quality assurance Program, and Basic Requirement 2, Quality Assurance Program, and the following supplemental requirements of ANSI/ASME NQA-1-1994:

2S-1, Supplementary Requirements for the Qualification of Test and Inspection Personnel

2S-2, Supplementary Requirements for the Qualification of Nondestructive Examination Personnel

2S-3, Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel

2S-4, Supplementary Requirements for Personnel Indoctrination and Training

17.1.3 Design Control

See Section 3 of Reference 17.1.19-1.

The Design Control Section of the QAP describes the methods used to provide control of design, design verification, and analysis activities.

The QAP provides the controls for Design Inputs, Design Interfaces, Design Verification, and Design Changes.

Verification methods include independent review of design documents, design analyses (calculations), design review boards, and design verification testing. The US EPR design organization determines the design verification methods to be used.

Design changes are subject to the same design controls and levels of review as were applicable to the original design. Such changes are documented, reviewed, approved and incorporated into the design documents as described in AREVA NP Inc. written procedures.

This section complies with Criterion III of 10 CFR 50, Appendix B, Design Control, and Basic Requirement 3, Design Control, and the following supplemental requirements and Subparts of ANSI/ASME NQA-1-1994:

3S-1, Supplementary Requirements for Design Control
11S-2, Supplementary Requirements for Computer Program Testing

Computer Software utilized for safety-related design analysis also complies with Subpart 2.7, Quality Assurance Requirements of Computer Software for Nuclear Facility Applications.

17.1.4 Procurement Document Control

See Section 4 of Reference 17.1.19-1.

The Procurement Document Control Section of the QAP defines the controls for the procurement of safety-related products and services.

For the Design Certification Project, the scope of procurement includes engineering, design and testing services as well as the procurement of safety-related software. No equipment or components are being procured as part of the Design Certification Project.

The QAP provides controls for ensuring that applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. The QAP provides the requirements for the procurement process, procurement document content, procurement document review and changes to procurement documents.

Plant Sector AREVA affiliate companies such as AREVA NP SAS, AREVA NP GmbH and the AREVA NP Plants Technical Centers, as well as cross sector affiliates such as the AREVA NP Nuclear Fuel or Jeumont SA are considered suppliers. Procurement activities with these internal interfacing organizations as well as any external organizations providing safety-related products or services are conducted in accordance with Procurement Document Control requirements. .

Each organization utilized has been evaluated in accordance with QAP requirements and maintained on the AREVA NP Inc. Plants and Services Approved Suppliers List.

This section complies with Criterion IV of 10 CFR 50, Appendix B, Procurement Document Control, and Basic Requirement 4, Procurement Document Control, and the following supplemental requirements of ANSI/ASME NQA-1-1994:

4S-1, Supplementary Requirements for Procurement Document Control.

17.1.5 Instructions, Procedures and Drawings

See Section 5 of Reference 17.1.19-1.

The Instructions, Procedures and Drawings Section of the QAP define the controls established for the preparation, review, approval and distribution of procedures, instructions, and drawings that prescribe activities affecting quality.

These controls ensure that activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. These documents include quantitative and qualitative acceptance criteria (or references which contain the criteria) to determine the satisfactory accomplishment of defined activities.

This section complies with Criterion V of 10 CFR 50, Appendix B, Instructions, Procedures and Drawings, and Basic Requirement 5, Instructions, Procedures and Drawings of ANSI/ASME NQA-1-1994.

17.1.6 Document Control

See Section 6 of Reference 17.1.19-1.

The Document Control Section of the QAP defines the system of controls for the preparation, review, approval, revision, distribution, and use of documents that prescribe activities affecting quality.

The AREVA NP Inc. Document Control System establishes the types of documents controlled, assures that documents are reviewed for adequacy and approved for release by authorized personnel to individuals and locations requiring the documents for work activity. The system also provides for document change control, release of documents, and for the handling of customer and supplier generated documents.

This section complies with Criterion VI of 10 CFR 50, Appendix B, Document Control and Basic Requirement 6, Document Control, and the following supplemental requirements of ANSI/ASME NQA-1-1994:

6S-1, Supplementary Requirements for Document Control.

17.1.7 Control of Purchased Material, Equipment and Services

See Section 7 of Reference 17.1.19-1

The Control of Purchased Material, Equipment and Services Section of the QAP governs the control of purchased safety related materials, items, and services including source evaluation and selection, source inspection, and receiving inspection.

As previously stated in Section 17.1.4, the scope of procurement for the Design Certification Project, includes engineering, design and testing services as well as the procurement of safety-related software. No equipment or components are being procured as part of the Design Certification Project.

Therefore, for the Design Certification Project, the controls associated with this section apply to the control of the applicable services only.

The QAP also addresses procurement process monitoring, item/service verification, supplier nonconformances, and commercial grade dedication.

The procurement of services is controlled to assure conformance with specified requirements. These controls include requirements for pre-award evaluations of suppliers' QA programs, annual evaluations, periodic audits/source inspections, and surveillances. Suppliers with an approved QA program, including AREVA affiliate suppliers, are placed on the AREVA NP Inc. Plants and Services Approved Suppliers List (ASL) prior to award of contract.

Source inspections and surveillances, evaluation of objective evidence of quality furnished by the supplier and maintaining the ASL are the responsibility of the AREVA NP Inc. QA organization.

This section complies with Criterion VII of 10 CFR 50, Appendix B, Control of Purchased Material, Equipment and Services and Basic Requirement 7, Control of Purchased Items and Services, and the following supplemental requirements of ANSI/ASME NQA-1-1994:

7S-1, Supplementary Requirements for Control of Purchased Items and Services.

17.1.8 Identification and Control of Material, Parts and Components

See Section 8 of Reference 17.1.19-1.

The Identification and Control of Materials, Parts and Components Section of the QAP defines the measures used to ensure the preparation and use of written

procedures for identification and control of safety related materials and items, and to ensure that only correct and accepted items are used or installed.

Based on the types of procurements previously stated for the Design Certification Project, the scope of the project does not include the identification and control of material, parts and components.

This element of Appendix B is therefore not applicable to the Design Certification Project.

This section complies with Criterion VIII of 10 CFR 50, Appendix B, Identification and Control of Materials, Parts and Components and Basic Requirement 8, Identification and Control of Items, and the following supplemental requirements of ANSI/ASME NQA-1-1994:

8S-1, Supplementary Requirements for Identification and Control of Items.

17.1.9 Control of Special Processes

See Section 9 of Reference 17.1.19-1.

The Control of Special Processes Section of the QAP defines Special Processes including but are not limited to welding, heat treating, and nondestructive examination (NDE). Cleaning is considered to be a special process when exceptional and unusual care in cleaning is necessary as defined in the applicable drawings and specifications. Written procedures establish the requirements for the control of special processes used by AREVA NP Inc.

This section complies with Criterion IX of 10 CFR 50, Appendix B, Control of Special Processes and Basic Requirement 9, Control of Processes, and the following supplemental requirements of ANSI/ASME NQA-1-1994:

9S-1, Supplementary Requirements for Control of Processes

However, due to the scope of the design certification project, which does not include fabrication, erection, installation or use, this element of Appendix B is not applicable.

17.1.10 Inspection

See Section 10 of Reference 17.1.19-1.

The Inspection Section of the QAP applies to all safety related items requiring inspection. Inspections required to verify conformance of an item or activity to specified requirements are planned and executed.

Inspections are performed by qualified personnel who are independent from the individual or group performing the activity being inspected. Inspection procedures, applicable drawings, travelers, and specifications define inspection criteria, identify mandatory inspection hold and witness points, and verify acceptable calibration equipment status. Inspection results are documented, evaluated, and accepted based on the acceptance criteria specified in the applicable document.

This section complies with Criterion X of 10 CFR 50, Appendix B, Inspection, and Basic Requirement 10, Inspection, and the following supplemental requirements of ANSI/ASME NQA-1-1994:

10S-1, Supplementary Requirements for Inspection.

17.1.11 Test Control

See Section 11 of Reference 17.1.19-1.

The Test Control Section of the QAP applies to the testing of safety related items that are required to demonstrate compliance with regulatory and contract requirements.

Tests required to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service are planned and executed. Characteristics to be tested and test methods to be employed are specified. Test results are documented and their conformance with acceptance criteria is evaluated.

The scope of the project does not include fabrication, erection, installation or use. Therefore testing and test control associated with proof tests prior to installation, preoperational tests, and operational tests during plant operations are not applicable to the scope of the project.

Test Control is applicable to tests and testing programs associated with design verification of the EPR. Tests may be conducted by AREVA NP Inc. or by qualified, approved suppliers. The requirements for such tests are included in test requirements documents prepared by the responsible technical manager. These

test requirement documents include, as appropriate, the requirements of this section of the QAP, scope of the test, technical requirements, and QA requirements.

Computer programs used for design analyses are certified or verified and validated as required. Computer Program Testing is addresses in Section 3, Design Control, of the QAP.

This section complies with Criterion XI of 10 CFR 50, Appendix B, Test Control, and Basic Requirement 11, Test Control, and the following supplemental requirements of ANSI/ASME NQA-1-1994:

11S-1, Supplementary Requirements for Test Control

11S-2, Supplementary Requirements for Computer Program Testing

17.1.12 Control of Measuring and Test Equipment

See Section 12 of Reference 17.1.19-1.

The Control of Measuring and Test Equipment (M&TE) Section of the QAP ensures that measures are established and documented to assure that tools, gages, instruments, and other M&TE used in construction, fabrication, testing, examination, or inspection activities affecting quality are of the range, type, and accuracy to verify conformance to established requirements. These measures are based upon the requirements of MIL-STD 45662A, "Calibration System Requirements," and ANSI/NCSL Z540-1, "Calibration Laboratories and M&TE General Requirements."

In addition, Suppliers of calibration services used to calibrate M&TE or reference standards are audited and approved by AREVA NP Inc. State and federal agencies such as the National Institute of Standards and Technology (NIST) are exempted from this requirement. Other methods, such as NAVLAP and A2LA, may be used to approve M&TE suppliers provided that conditions required by the Nuclear Regulatory Commission (NRC) are satisfied.

The scope of the design certification project does not include fabrication, erection, installation or use. Therefore the control of M&TE associated with proof tests prior to installation, preoperational tests, and operational tests during plant operations is not applicable to the scope of the project.

However, the control of M&TE associated with tests and testing programs utilized for design verification of the EPR are applicable to the project and to organizations that have conducted such tests.

The section addresses the preparation of Calibration procedures, the control of M&TE, the requirements of M&TE suppliers, M&TE Calibration Services, and the use of customer supplied M&TE.

This section complies with Criterion XII of 10 CFR 50, Appendix B, Control of Measuring and Test Equipment, and Basic Requirement 12, Control of Measuring and Test Equipment, and the following supplemental requirements of ANSI/ASME NQA-1-1994:

12S-1, Supplementary Requirements for Control of Measuring and Test Equipment.

17.1.13 Handling, Storage and Shipping

See Section 13 of Reference 17.1.19-1.

The Handling, Storage and Shipping Section of the QAP Handling ensures that storage, cleaning, packaging, shipping and preservation of items are controlled in accordance with requirements of this section to prevent damage or loss and to minimize deterioration.

The scope of the project does not include fabrication, erection, installation or use. Therefore Handling, Storage and Shipping are not applicable to the scope of the design certification project.

This section complies with Criterion XIII of 10 CFR 50, Appendix B, Handling, Storage and Shipping, and Basic Requirement 13, Handling, Storage and Shipping and the following supplemental requirements and subparts of ANSI/ASME NQA-1-1994:

13S-1, Supplementary Requirements for Handling, Storage and Shipping

The following subparts apply to scopes of work provided at plant sites or AREVA NP Inc. facilities.

- Subpart 2.1, “Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants,”
- Subpart 2.2, “Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants,”
- Subpart 2.15, “Quality Assurance Requirements for Hoisting, Rigging, and Transporting Items for Nuclear Power Plants.”

17.1.14 Inspection, Test and Operating Status

See Section 14 of Reference 17.1.19-1.

The Inspection, Test and Operating Status Section of the QAP defines methods ensuring that measures are taken to indicate the inspection, test, and operation status of safety related items.

The status of fabrication, assembly, inspection, test or field operations for items processed at AREVA NP Inc.'s facilities or in the field are indicated on travelers or in manufacturing/field procedures.

However, due to the scope of the design certification project, which does not include fabrication, erection, installation or use, this element of Appendix B is not applicable to the project.

This section complies with Criterion XIV of 10 CFR 50, Appendix B, Inspection, Test and Operating Status and Basic Requirement 14, Inspection, Test, and Operating Status, of ANSI/ASME NQA-1-1994.

17.1.15 Nonconforming Materials, Parts, or Components

See Section 15 of Reference 17.1.19-1.

The Control of Nonconforming Items Section of the QAP applies to safety related materials and items, and their supporting documentation. It addresses characteristics, documentation, or procedure deficiencies that render an item or activity unacceptable or indeterminate.

The section establishes measures to control documentation and items that do not conform to specified requirements. Specific requirements include procedures for controlling the identification, documentation, and segregation of nonconforming items pending notification of affected individuals and/or organizations, review of the nonconformance, and approval of disposition.

The scope of the design certification project does not include fabrication, erection, installation or use. Therefore, nonconforming materials, parts, or components are not applicable.

Nonconformities associated with services or documentation are processed in accordance with this section of the QAP under the AREVA NP Inc. Corrective Action Program.

This section complies with Criterion XV of 10 CFR 50, Appendix B, Nonconforming Materials, Parts, or Components, and Basic Requirement 15, Control of Nonconforming Items, and the following supplemental requirements of ANSI/ASME NQA-1-1994:

15S-1, Supplementary Requirements for the Control of Nonconforming Items.

17.1.16 Corrective Action

See Section 16 of Reference 17.1.19-1.

The Corrective Action Section of the QAP defines the elements of the corrective action program including the generation, implementation and verification system for safety related items or services.

Procedures are established by AREVA NP Inc. to ensure prompt identification and correction of conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances during the design, procurement, fabrication, inspection, and testing of items.

The documented procedures ensure that:

- Nonconformances and failures are evaluated to determine the need for corrective action, and that such action is taken as necessary.
- The cause of the nonconformance or failure is determined and action is taken to preclude recurrence.
- Appropriate levels of management are informed of significant conditions adverse to quality, the cause of the conditions, the corrective action taken, and the preventive action taken to preclude recurrence.
- Follow-up is conducted to verify proper implementation of both corrective and preventive actions and to close out the corrective action documentation.

This section complies with Criterion XVI of 10 CFR 50, Appendix B, Corrective Action, and Basic Requirement 16, Corrective Action, of ANSI/ASME NQA-1-1994.

17.1.17 Quality Assurance Records

See Section 17 of Reference 17.1.19-1.

The Quality Assurance Records Section of the QAP ensures that procedures are established to provide requirements and responsibilities for record generation, identification, transmittal, retention, and maintenance. QA records are filed and

maintained for defined durations. The AREVA NP Inc. Records Management System meets the requirements of ANSI N45.2.9.

In addition, this section complies with Criterion XVII of 10 CFR 50, Appendix B, Quality Assurance Records, and Basic Requirement 17, Quality Assurance Records and the following supplemental requirements of ANSI/ASME NQA-1-1994:

17S-1, Supplementary Requirements for Quality Assurance Records

The AREVA NP Inc. Records Management System also implements the requirements of the following:

- Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guide (TG) 11-1998, "Authentication of Records and Media"
- NIRMA TG 15-1998, "Management of Electronic Records"
- NIRMA TG 16-1998, "Software Configuration Management and Quality Assurance"
- NIRMA TG 21-1998, "Electronic Records Protection and Restoration"

17.1.18 Audits

See Section 18 of Reference 17.1.19-1.

The Audits Section of the QAP establishes the controls for the scheduling, preparation, execution, reporting, and follow-up methods to be used in implementing the audits program.

Audits are planned and scheduled and performed to verify compliance with all aspects of the QA Program and to determine its effectiveness. Audits are scheduled based upon the status and safety related importance of the activities being performed and are initiated early enough to assure effective QA during design, procurement, fabrication, inspection, and testing. Audits are performed in accordance with pre-established written procedures or checklists and conducted by personnel having no direct responsibilities in the areas being audited. Personnel who perform audits are qualified in accordance with the requirements of ANSI/ASME NQA-1, and ANSI N45.2.23.

This section complies with Criterion XVIII of 10 CFR 50, Appendix B, Audits, and Basic Requirement 18, Audits, and the following supplemental requirements of ANSI/ASME NQA-1-1994:

18S-1, Supplementary Requirements for Audits.

17.1.19 References

1. AREVA NP Inc. Topical Report ANP-10266NP, Revision 0, "AREVA NP Inc. Quality Assurance Plan (QAP) for Design and Deployment of the U.S. Evolutionary Power Reactor (U.S. EPR)," September, 2006.