AREVA

February 28, 2007
NRC:07:008

Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Response to a Request for Additional Information Regarding ANP-10266NP, "AREVA NP Inc. Quality Assurance Plan (QAP) for Design and Deployment of the U.S. Evolutionary Power Reactor (U.S. EPR) Topical Report"

Ref. 1: Letter, Ronnie L. Gardner (AREVA NP Inc.) to Document Control Desk (NRC), "Request for Review and Approval of ANP-10266NP, 'AREVA NP Inc. Quality Assurance Plan (QAP) for Design and Deployment of the U.S. Evolutionary Power Reactor (U.S. EPR) Topical Report'," NRC: 06:038, September 22, 2006.

Ref. 2: Letter, Getachew Tesfaye (NRC) to Ronnie L. Gardner (AREVA NP Inc.), "Request for Additional Information Regarding Topical Report (TR) ANP-10266NP, 'AREVA NP Inc. Quality Assurance Plan for Design and Deployment of U.S. Evolutionary Power Reactor (EPR), (TAC No. MD2402)'," January 31, 2007.

AREVA NP Inc. requested the NRC's review and approval of 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) Topical Report," in Reference 1. Requests for additional information were provided by the NRC in Reference 2. The responses to these requests are provided in Attachment A to this letter.

A conference call was held on January 4, 2007 to discuss the requests for additional information. During the conference call, the NRC requested that AREVA NP Inc. submit a revision of the topical report to clarify that the intended application of the report is for Design Certification. In accordance with the NRC's request, the enclosed CD contains Revision 1 of topical report ANP-10266. This revision also includes the responses to the requests for additional information provided by the NRC in Reference 2.

AREVA NP Inc. requests approval of the topical report by May 2007. If you have any questions related to this submittal, please contact Ms. Sandra M. Sloan, Regulatory Affairs Manager for New Plants Deployment. She may be reached by telephone at 434-832-2369, or by e-mail at sandra.sloan@areva.com.

Sincerely,

Ronnie L. Gardner

Ronnie L. Gardner, Manager
Site Operations and Regulatory Affairs
AREVA NP Inc.

D077

AREVA NP INC.
An AREVA and Siemens company

3315 Old Forest Road, P.O. Box 10935 Lynchburg, VA 24506-0935
Tel.: 434 832 3000 - Fax: 434 832 3840 - www.areva.com

Enclosures

cc: L. J. Burkhart
G. Tesfaye
Project 733

Attachment A

RESPONSE TO A REQUEST FOR ADDITIONAL INFORMATION
ANP-10266, "AREVA NP Inc. Quality Assurance Plan for Design and Deployment of U.S. EPR Topical Report"

PART I INTRODUCTION

RAI 1: *Draft Standard Review Plan (SRP) 17.5, dated September 22, 2006, states that a Quality Assurance Program Description (QAPD) submitted by a Design Certification (DC) applicant would only address design quality assurance (QA) activities in support of a DC. Revision 0 of the AREVA QAPD, Disclaimer, states, in part, that this topical report is being submitted by AREVA NP to the U.S. Nuclear Regulatory Commission (NRC) to facilitate future licensing processes that may be pursued by licensees or applicants that are customers of AREVA NP. The AREVA QAPD, Section 0.1, Purpose, further states, in part, that "this document describes the Quality Assurance Plan (QAP) for the design and* ***deployment*** *(emphasis added) of commercial nuclear operating plants." Given these statements in the AREVA QAPD, the staff needs clarification of the overall scope (e.g., DC, ESP, COL) and activities that apply to the AREVA QAPD.*

Specifically, 10 CFR 52.17 (a)(1)(xii) requires the applicant of an early site permit (ESP) to include a quality assurance program description (QAPD) that satisfies applicable portions of Appendix B to 10 CFR Part 50. 10 CFR 52.79 (a)(25) requires that the applicant of a combined license (COL) includes a QAPD to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility that satisfies applicable portions of Appendix B to 10 CFR Part 50.

For consistency with the above regulations, the staff needs clarification of the overall scope (e.g., DC, ESP, COL) and activities that apply to the QAPD.

Response 1: The topical report has been revised (see enclosed topical report revision) to specifically state that it applies to Design Certification activities only. In addition to Title, Purpose and Scope revisions, each section of the topical report has been revised to include the specific application of the criteria to the Design Certification. The title of the Topical report has been revised to "AREVA NP Inc. Quality Assurance Plan (QAP) for Design Certification of the U.S. EPR." Section 0.1, Purpose, has been revised. The following text replaces the existing Section 0.1 text in its entirety:

> "This document describes the Quality Assurance Plan applicable to the Design Certification of the U.S. EPR. The plan is based on the Eighteen (18) point criteria of 10 CFR 50, Appendix B, and ANSI/ASME NQA-1-1994.
>
> However, the scope of the design certification project does not include fabrication, erection, installation or operations.
>
> Therefore, this QAP provides the specific applicability and application of the Criteria of Appendix B and the Basic, Supplemental and applicable Subpart requirements of ANSI/ASME NQA-1-1994 to the U.S. EPR Design Certification Project.
>
> Each section of this QAP clearly delineates the applicability of the criteria to the U.S.

EPR Design Certification Project.

ASME Boiler & Pressure Vessel Code items are covered under a separate Quality Assurance Program. Addendum A of this Document describes the non-safety related QAP."

Section 0.1.1, Scope, has been revised. The following text replaces the existing Section 0.1.1 text in its entirety:

"The applicable scope and criteria as specified in Sections 1 – 18 of this document is mandatory for nuclear safety related activities associated with the U.S. EPR Design Certification Project. Addendum A of this Document describes the requirements for non-safety related activities. Refer to Appendix C for definitions of safety related and non-safety related.

This QAP is in compliance with the regulations, codes, standards, and other requirements listed in Section 2.1.3. Each section of this document provides the controls in place to accomplish compliance to the applicable criteria specified in each section. Typical policies, procedures, and instructions which detail how these controls are implemented are listed in Appendix A."

RAI 2: *Revision 0 of the AREVA QAP, Section 0.1.1, "Scope," describes that the QAP is in compliance with regulations, codes, standards, and other requirements listed in Section 2.3. Provide a copy of the referenced Section in the document.*

Response 2: The original reference to Section 2.3 was an error. The actual section reference should have been Section 2.1.3. This section was included in the original topical report. The section reference has been corrected.

RAI 3: *Revision 0 of the AREVA QAP, Section 0.1.1, "Scope," describes that the QAP is written to comply with NQA-1-1994. Since the QAP is written to comply with NQA-1-1994, clarify if the QAP commits to NQA-1-1994 and if any exception, alternative or clarification from NQA-1-1994 are applicable to the QAP.*

Response 3: Each applicable section of the topical report has been revised to indicate the commitment to meet the applicable criteria of Appendix B and the Basic, Supplemental and Subpart requirements of ANSI/ASME NQA-1-1994 to the U.S. EPR Design Certification Project. Any exceptions, alternatives and/or clarifications to the criteria are stated in the individual sections.

RAI 4: *Revision 0 of the AREVA QAP, Section 0.1.1, "Scope," describes that typical policies, procedures, and instructions (PP&Is) detail the implementation of the controls to accomplish compliance with NQA-1-1994. AREVA is proposing a unique approach in crediting their PP&Is to meet NQA-1-1994. The staff performs its reviews to the most current guidance draft SRP 17.5. Provide an outline or matrix of the criteria used in each PP&I for which the QAP takes credit to meet NQA-1-1994.*

Response 4: AREVA NP Inc. did not intend to propose a unique approach for complying with NQA-1-1994. The reference to policies, procedures and instructions was to provide information on AREVA NP Inc. documents used to implement the requirements of NQA-1-1994 committed to in the topical report. Each applicable section of the topical report has been revised to indicate the commitment to meet the applicable criteria of Appendix B and the Basic,

Supplemental and Subpart requirements of ANSI/ASME NQA-1-1994 to the U.S. EPR Design Certification Project.

PART II AREVA QAPD DETAILS

SECTION 1 ORGANIZATION

RAI 5: *Draft SRP 17.5, dated September 22, 2006, paragraph II.A.1 states that at the most senior management level, the applicant or holder is to issue a written quality assurance program description (QAPD) that establishes the quality policy and commits the organization to implement it. Revision 0 of the AREVA QAPD, Section 1.7, "U.S. Region Quality," describes the Vice President of U.S. Region Quality, as having the responsibility for the development, preparation, maintenance, and revision of the QAPD. Clarify if the Vice President of U.S. Region Quality is the most senior management level, and if not, the AREVA QAPD must be signed by the President and CEO or their designee.*

Response 5: T. A. Christopher is the President and CEO of AREVA NP Inc. As such, he is the most senior management level. AREVA NP Inc. has issued a Statement of Policy that is signed by Mr. Christopher. The policy establishes the company's quality policy and commits the organization to implement it. The Statement of Policy was inadvertently omitted from the original topical report. The topical report has been revised to include the Statement of Policy.

RAI 6: *Draft SRP Section 17.5, paragraph II.A.3, states that, for multiple organizations, the QA program organizational description should clearly define the interface responsibilities. Section 1.0, "Organization," of the AREVA QAPD, provides a description of the functions and responsibilities of the organizations of the company, and references "Exhibit 1A and Exhibit 1B." Provide a copy of each exhibit referenced in the document, and clarify how the multiple organizations described in the QAPD interface with each other.*

Response 6: Exhibit 1A and Exhibit 1B were inadvertently omitted from the original topical report. They have been included in the revised topical report. In addition, Exhibit 1A and the applicable Organization section titles and descriptions have been revised to reflect the latest version of the AREVA NP Inc. organization. In order to clarify the interfaces among multiple organizations, the following paragraphs have been added to Section 1.1, Purpose.

> "The U.S. EPR Design Certification Project falls under the responsibility of the NPD Organization. (See Section 1.3) AREVA NP Inc. is the design authority for the U.S. EPR. Design interfaces with domestic or international AREVA NP 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."

RAI 7: *Draft SRP Section 17.5, paragraph II.A.7, states that management should ensure that the size of the QA organization is commensurate with its duties and responsibilities. In order to satisfy the TMI-related requirement contained in 10 CFR 50.34(f)(3)(iii)(A), clarify how the QAPD provides this guidance as it applies to activities for the US EPR to ensure that the size of the QA organization is commensurate with its duties and responsibilities.*

Response 7: Section 1.1, Purpose, has been revised to include the following:

> "AREVA NP Inc. management is responsible to ensure that the size of the Quality Assurance organization is commensurate with the duties and responsibilities assigned."

RAI 8: *Draft SRP Section 17.5, paragraphs II.A.11 and II.A.12, discusses responsibilities and authority associated with the delegation of activities associated with the overall QA program. Section 1.0, "Organization," of the AREVA QAPD does not address this area. Provide a discussion of this topic, if applicable, in the AREVA QAPD.*

Response 8: AREVA NP Inc. does not delegate activities associated with the overall QA program. Section 1.8, U.S. Region Quality, has been revised to include the following:

> "AREVA NP Inc. does not delegate any of the activities associated with planning, establishing, or implementing the overall QA program to others and retains the responsibility for the program."

SECTION 2 QUALITY ASSURANCE PROGRAM

RAI 9: *Draft SRP Section 17.5, paragraphs II.B.2, states that the QAPD should include the criteria used to identify the items and activities to which the QA program applies. Section 2.1.2, "General," of the AREVA QAPD states that the criteria for determining this classification is contained in a procedure based on RG 1.26. Provide the information contained in this procedure related to the criteria used to identify these items and activities.*

Response 9: AREVA NP Inc. has established and implemented procedures which provide requirements and guidelines for establishing the safety classification of systems, structures, and components (SSC), and for determining the quality group classification, applicable quality standards, and the seismic design classification, applicable quality standards, and the seismic design classification of SSCs commensurate with their respective safety classification. Section 2.1.2, General, has been revised to address this area as follows:

> "AREVA NP Inc. has established and implemented procedures which provide requirements and guidelines for establishing the safety classification of systems, structures, and components (SSC), and for determining the quality group classification, applicable quality standards, and the seismic design classification, applicable quality standards, and the seismic design classification of SSCs commensurate with their respective safety classification.
>
> Structures, systems and components important to safety are designed, fabricated, erected and tested to quality standards commensurate with the importance of the safety functions to be performed. Where generally recognized codes and standards are used, they are justified and evaluated to determine their applicability, and supplemented or modified as necessary to assure a quality product in keeping with required safety functions."

RAI 10: *Draft SRP Section 17.5, paragraphs II.B.3, states that the QA program assures that activities affecting quality are accomplished under suitably controlled conditions. The AREVA QAPD does not address this criteria.*

Response 10: AREVA NP Inc. has established and implemented procedures, methods and controls that assure activities affecting quality are accomplished under suitably controlled conditions. Section 2.1.1, Scope, has been revised to address this criteria as follows:

> "The QAP assures that activities affecting quality are accomplished under suitably controlled conditions."

RAI 11: *Draft SRP Section 17.5; paragraph II.S.2, states the qualification requirements for individuals responsible for managing the implementation of the QA plan. Section 2.1.6, "QAP Indoctrination and Training," of the AREVA QAPD does not address the criteria described in the applicable section of the draft SRP. Provide a description of the qualification requirements.*

Response 11: AREVA NP Inc. conducts indoctrination and training of all AREVA NP Inc. personnel in accordance with the requirements of NQA-1-1994 including Supplement 2S-4, Supplementary Requirements for Personnel Indoctrination and Training. These requirements are documented in existing AREVA NP Inc. procedures. Section 2.0, Quality Assurance Program, has been revised to include the following text:

> "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"

RAI 12: *Draft SRP Section 17.5, paragraph II.S.3, states the qualification requirements for individuals responsible for planning, implementing, and maintaining the QA plan. Section 2.1.6, "QAP Indoctrination and Training," of the AREVA QAPD does not address the criteria described in the applicable section of the draft SRP. Provide a description of the qualification requirements.*

Response 12: AREVA NP Inc. conducts indoctrination and training of all AREVA NP Inc. personnel in accordance with the requirements of NQA-1-1994 including Supplement 2S-4, Supplementary Requirements for Personnel Indoctrination and Training. These requirements are documented in existing AREVA NP Inc. procedures. Section 2.0, Quality Assurance Program, has been revised to include the following text:

> "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"

SECTION 3 DESIGN CONTROL

RAI 13: *Draft SRP Section 17.5, paragraph II.C.1 and C.2 provides the design and design verification controls measures. Section 3.3, "Implementation," describes that design control measures are applied to safety related items and services as defined in written procedures and instructions. Provide a discussion of the criteria described in written procedures and instructions.*

Response 13: Section 3.3, Implementation, has been revised to include the following:

"These design control measures are implemented through procedures which include the provisions for the control of design inputs, processes, outputs, verification, independent review, analysis, verification testing, design changes, organizational interfaces within AREVA NP Inc. and with suppliers, records and QA reviews.

AREVA NP Inc. has established and implements a process to control the design and design changes of items that are subject to the provisions of this QAP. These provisions assure that design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output can be related to the design input in sufficient detail to permit verification.

The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution and revision of design inputs and outputs. Design changes are reviewed and approved by the AREVA NP Inc. design organization."

RAI 14: *Draft SRP Section 17.5, paragraph II.C.1.n, states that the QA role in design and analysis activities is defined, and design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements. The inclusion of these criteria satisfy the TMI-related requirement contained in 10 CFR 50.34(f)(3)(iii)(H). Section 3.0, "Design Control," of the AREVA QAPD does not address this criteria. Provide a discussion of this criteria as it applies to activities for the U.S. EPR.*

Response 14: AREVA NP Inc. design documents are reviewed by individuals knowledgeable and trained in QA and qualified to ensure the documents contain the necessary QA requirements. Section 3.6.1, Independent Review of Design Documents, has been revised to address this area as follows:

"Design documents are reviewed by individuals knowledgeable and trained in QA and qualified to ensure the documents contain the necessary QA requirements."

RAI 15: *10 CFR 50.34(f)(3)(iii)(c) requires that QA personnel are included in the documented review and concurrence of quality-related procedures associated with design, construction, and installation. Describe how AREVA will implement measures to control the documented review and concurrence of quality-related procedures consistent with the requirements of 10 CFR 50.34(f)(3)(iii)(c).*

Response 15: The requirements that QA personnel are included in the documented review and concurrence of quality-related procedures associated with design, construction and installation are provided in existing AREVA NP Inc. procedures. Quality-related procedures also require the approval of the Vice President, U.S. Region Quality. Section 5.2, General, has been revised to address this area as follows:

> "AREVA NP Inc. QA personnel are included in the documented review and concurrence of quality-related procedures associated with design, construction and installation."

RAI 16: *Section 3.4, "Design Inputs," of the AREVA QAPD, states, in part, that design documents shall be adequate to support facility design, construction, and operation. Define "adequate" and how the AREVA QAPD ensures that design document controls support activities for the U.S. EPR.*

Response 16: AREVA NP Inc. agrees the word "adequate" is ambiguous and has removed the wording from the applicable section of the topical report. Section 3.4, Design Inputs, has been revised to provide additional information on design records as follows:

> "AREVA NP Inc. design records are maintained to provide evidence that the design supports the facility design, construction and operations and that the design was properly accomplished. Records include not only the final design output and revisions to the final output, but also the important design steps (e.g., calculations, analyses, and computer programs) and the sources of input that support the final output."

RAI 17: *Draft SRP Section 17.5, paragraph II.C.1.p, states that where a significant design change is necessary because of an incorrect design, the design process and verification procedure is reviewed and modified as necessary. Section 3.0, "Design Control," of the AREVA QAPD does not address this criteria. Provide a discussion of this criteria as it applies to activities for the U.S. EPR.*

Response 17: If a significant design change is necessary on the U.S. EPR Design Certification project because of an incorrect design, the design change process would be instituted through the AREVA NP Inc. Corrective Action Process and applicable design change procedures. Condition reports are issued when a significant condition adverse to quality exists. The process ensures that conditions are evaluated to determine the need for corrective action, and that such action is taken as necessary. For a design change because of an incorrect design, these actions could include a review of the original design, including the review, approval and verification of the design as well as the procedures governing those processes. Changes or improvements to the design process and verification procedures shall be accomplished as required and as documented in the Condition report. Section 3.7, Design Changes, has been revised to address this area as follows:

> "Where a significant design change is necessary because of an incorrect design, the design process and verification procedure is reviewed and modified as necessary."

RAI 18: *Draft SRP Section 17.5, paragraph II.F.9.b, states that there should be coordination and control of interface documents. Section 6.0, "Document Control," of the AREVA QAPD does not address this criteria explicitly, although there is a brief description of both supplier-prepared and customer-prepared documents. Provide a discussion of the coordination and control of interface documents as it applies to activities for the U.S. EPR.*

Response 18: Interface documents may include those between engineering disciplines, engineering projects, affiliate companies, suppliers or customers. Requirements for coordinating and controlling interface documents are included in existing AREVA NP Inc. procedures. Section 6.2, General, has been revised to include the following after the first sentence:

> "In addition, procedures govern the coordination and control of interface documents. Interface documents may include those between engineering disciplines, engineering projects, affiliate companies, suppliers or customers."

Additionally, a bulleted item has been added to Section 6.3.1 as follows:

> "• Coordinating and controlling interface documents"

RAI 19: *Draft SRP Section 17.5, paragraph II.F.8 and paragraph II.F.10, discuss certain requirements placed on procedures as well as use of temporary instructions used during the operational phase of a nuclear power plant. Section 6.0, "Document Control," of the AREVA QAPD does not address these criteria. Provide a discussion of the these issues as they apply to activities for the U.S. EPR.*

Response 19: The subject area of this RAI is beyond the scope for the Design Certification and therefore is not applicable to this topical report for U.S. EPR Design Certification.

SECTION 7 CONTROL OF PURCHASED MATERIALS, ITEMS, AND SERVICES

RAI 20: *Draft SRP Section 17.5, paragraph II.G.6, states that the procurement of components, including spare and replacement parts, is subject to quality and technical requirements suitable for their intended service and to the purchaser's QA program requirements. Explain how this requirement is met in the AREVA QAPD.*

Response 20: The subject area of this RAI is beyond the scope for the Design Certification and therefore is not applicable to this topical report for U.S. EPR Design Certification.

RAI 21: *Draft SRP Section 17.5, paragraph II.G.9, states, in part, that the measures for evaluation and selection of procurement sources include "a direct evaluation of supplier facilities and personnel....." Section 7.3, "Supplier Evaluation and Selection," of the AREVA QAPD, states, in part, "An evaluation of their QA Program to 10 CFR Appendix B and NQA-1 to determine the capability to supply materials, items, or services ....." The term "Direct" was omitted and should be added to the affected section.*

Response 21: AREVA NP Inc. performs direct evaluation of procurement sources through implementation of Section 7 of the AREVA NP Inc. Quality Program. AREVA NP Inc. agrees the term "direct" should be added to this section of the topical report. Section 7.3, Supplier Evaluation and Selection, first bullet, has been revised to read as follows:

> "A direct evaluation of their QA Program to 10 CFR 50 Appendix B and NQA-1 to determine the capability to supply materials, items, or services meeting all procurement document requirements."

RAI 22: *Section 7.3, "Supplier Evaluation and Selection," of the AREVA QAPD, states, in part, "AREVA NP may verify acceptance of products by independent analysis." Provide a discussion of what the independent analysis is and the extent of its applicability to activities for the U.S. EPR.*

Response 22: Section 7.3, Supplier Evaluation and Selection, has been revised to provide additional information on this application and applicability to Design Certification as follows:

> "The AREVA NP Inc. acceptance of products by independent analysis is applicable only to the suppliers of ASME materials from suppliers that have not been audited by AREVA NP Inc. but who hold ASME Certificates. AREVA NP Inc. would conduct independent analysis prior to acceptance of the material. This method is not applicable to the Design Certification as no materials are being procured in the scope of the project."

RAI 23: *Draft SRP Section 17.5, paragraph II.G.16(a-f), describes the minimum acceptable list of criteria to be included in the Certificate of Conformance (COC). Section 7.8, "Certifications of Conformance (COC/QA Data Packages)," states, in part, that a QA Data Package provides objective evidence that the materials and items meet the requirements of the customer's order, but does not explicitly address the minimum acceptable list of criteria to be included in the COC. Provide a discussion of the these criteria as they apply to COCs related to activities for the U.S. EPR.*

Response 23: Section 7.8, Certifications of Conformance (CoC/QA Data Packages), has been revised to include the following:

> "AREVA NP Inc. procedures for QA Data Packages and CoCs contain provisions that establish the minimum acceptable list of criteria for documentary evidence that items and/or services procured from suppliers or from within AREVA NP Inc. conform to procurement document requirements and that those criteria are provided on the CoC. At a minimum, a stand alone CoC details and attests to the following, if applicable:
>
> - Customer/ Plant Site
> - AREVA NP Inc. QADP package number
> - Customer PO Number and Change Order Number
> - AREVA NP Inc. Contract No.
> - Item identification
> - Description of item or service provided
> - Technical Documents
> - Equipment Code Class and reference made to AREVA NP Inc. Certificate (for ASME supplied materials only)
> - Applicable QA program identification and revision number
> - Non-Conformances or exceptions to PO

- Non-conformances resolved
- Revision of CoC and description of revision
- General statements of compliance to applicable codes, standards, tests and quality assurance requirements
- Acceptance signature by AREVA NP Inc. Quality Representative (for ASME and safety related CoC only)"

The above criteria meet the requirements of Draft SRP Section 17.5, Paragraph II.G.16(a-d). Criteria (e&f) are supported through implementation of the AREVA NP Inc. QA audit program which is integral to the AREVA NP Inc. QA program, identified on the CoC.

RAI 24: *Draft SRP Section 17.5, paragraph II.G.19, states, in part, that receiving inspection is performed to verify by objective evidence such features as proper configuration; identification; dimensional; physical; and other characteristics; freedom from shipping damage; and cleanliness. Section 7.6.1, "Receiving Inspection," of the AREVA QAPD does not explicitly address these features. The QAPD does however, indicate that such receiving inspections may be conducted on an individual item or sampling basis. Provide a discussion of the these receiving inspection features, and the conduct of either individual or sampling inspection, as they apply to activities for the U.S. EPR.*

Response 24: The subject area of this RAI is beyond the scope for the Design Certification and therefore is not applicable to this topical report for U.S. EPR Design Certification.

RAI 25: *Draft SRP Section 17.5, paragraph II.G.2, states that the program should include provisions for evaluating prospective suppliers and selecting only qualified suppliers. Section 7.4 of the QAP describes that with project management and QA approval, suppliers not on the approved supplier list may be selected in situations where unique products or services are needed. Provide a discussion on the acceptability of vendors of unique components without performing an audit or survey.*

Response 25: Section 7.4, Approved Supplier List, second paragraph, has been revised to clarify the application as follows:

> "With project management and QA approval, suppliers not on the ASL may be selected in situations where unique products or services are needed. Suppliers may be utilized, as described above, provided work is conducted under applicable portions of the AREVA NP Inc. QA program at the supplier's location and provided AREVA NP Inc. Quality performs 100% surveillance of the supplier's activities."

SECTION 8 IDENTIFICATION AND CONTROL OF ITEMS AND MATERIALS

RAI 26: *Draft SRP Section 17.5, paragraph II.H.6, states, in part, that provisions are made for the control of an item's identification consistent with the planned duration and conditions of storage. Section 8.2, "General," of the AREVA QAPD does not explicitly address these criteria. Provide a discussion of the how the identification of items and materials consistent with the planned duration and conditions of storage apply to activities for the U.S. EPR.*

Response 26: The subject area of this RAI is beyond the scope for the Design Certification and therefore is not applicable to this topical report for U.S. EPR Design Certification.

SECTION 9 CONTROL OF SPECIAL PROCESSES

RAI 27: *Draft SRP Section 17.5, paragraph II.I.7, states that for special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment are specified or referenced in the procedures or instructions. Section 9.0, "Control of Special Processes," of the AREVA QAPD does not address this criteria. Therefore, provide a discussion of the how this criteria applies to activities for the U.S. EPR.*

Response 27: The subject area of this RAI is beyond the scope for the Design Certification and therefore is not applicable to this topical report for U.S. EPR Design Certification.

SECTION 10 INSPECTION

RAI 28: *Section 10.2, Scope," of the AREVA QAPD contains a spelling error. "Verily" should be changed to "verify."*

Response 28: The spelling error has been corrected.

SECTION 11 TEST CONTROL

RAI 29: *Draft SRP Section 17.5, paragraph II.K.6, provides a description of the minimum information to be included in test records, including, but not limited to, identification of item tested, recorder used, type of observation, action taken in connection with any deviation noted, and person evaluating the test results. Section 11.3, "Implementation," provides a brief description of test results indicating that these results will be documented, evaluated, and their acceptability determined, but does not explicitly address the criteria specified in the draft SRP. Therefore, provide a discussion of the how these criteria apply to activities for the U.S. EPR.*

Response 29: The above criteria regarding test records are included in existing AREVA NP Inc. procedures. Section 11.3, Implementation, has been revised to add the following new paragraph to the end of the section to address this criterion:

> "Test records, at a minimum, identify the item tested, date of test, tester or data recorder, type of observations, results and acceptability, action taken in connection with any deviations noted, and person evaluating test results."

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE)

RAI 30: *Draft SRP Section 17.5, paragraph II.L.4, states that, M&TE are calibrated, adjusted, at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration are documented. Section 12.0, "Control of Measuring and Test Equipment," of the AREVA QAPD does not explicitly address these criteria. Therefore, provide a discussion of the how these criteria apply to activities for the U.S. EPR.*

Response 30: AREVA NP Inc. agrees that the criteria is applicable to the AREVA NP Inc. program for control of M&TE and has revised Section 12.3.1, Procedures, to include the following:

> "Calibration procedures are prepared to define the method of calibration, means of identification, recalibration frequency, reference and transfer standards, and recall of subject or damaged M&TE. Calibration procedures are further prepared to assure M&TE are calibrated and adjusted at prescribed intervals or prior to use against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration are documented."

RAI 31: *Draft SRP Section 17.5, paragraph II.L.8, states that, for procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and Technology and by the American Association for Laboratory Accreditation (A2LA) and National Voluntary Accreditation Program (NAVLAP), as recognized through the mutual recognition arrangement of International Laboratory Accreditation Program (ILAC), are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance, provided that certain conditions are met. Section 12.3.3, "M&TE Suppliers and M&TE Calibration Services," of the AREVA QAPD states, in part, that other methods such as A2LA and NAVLAP may be used to approve M&TE suppliers provided that conditions required by the NRC are satisfied. The staff requests that the applicant explicitly identify those conditions required by the NRC consistent with the description provided in draft SRP Section 17.5, paragraph II.L.8 and that these conditions are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance.*

Response 31: Section 12.3.3, M&TE Suppliers and M&TE Calibration Services, has been revised to remove reference to "conditions required by the Nuclear Regulatory Commission..." Additionally, the following was added:

> "For procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and Technology and by the American Association for Laboratory Accreditation, as recognized through the mutual recognition arrangement of the International Laboratory Accreditation Program (ILAC), are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance provided that all of the following conditions are met:
>
> a. The alternative method is documented in the QA program description.
>
> b. Accreditation is to ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."
>
> c. Use of the alternative method is limited to the National Voluntary Accreditation Program and the American Association for Laboratory Accreditation, as recognized by ILAC signatories.
>
> d. The scope of the accreditation covers the contracted services.
>
> e. Purchase documents impose additional technical and administrative requirements to satisfy necessary QA program and technical requirements.

f. Purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

g. Purchase documents require identification of the laboratory equipment/standards used.

h. The alternative method is limited to domestic calibration service suppliers.

The alternative method is applicable to subsuppliers of calibration service suppliers, provided the above conditions are met."

In addition, Section 7.0, Control of Purchased Materials, Items, and Services, has been revised to provide clarifications and exceptions to NQA-1-1994, 7S-1, Supplementary Requirements for Control of Purchased Items and Services, to agree with the revisions made to Section 12.3.3.

SECTION 13 HANDLING, STORAGE, AND SHIPPING

RAI 32: *Draft SRP Section 17.5, paragraph II.M.5, states that operators of special handling and lifting equipment are experienced or trained in use of the equipment. Section 13.3.4, "Handling," of the AREVA QAPD does not address this issue. Provide a discussion of the how this criterion applies to activities for the U.S. EPR.*

Response 32: The subject area of this RAI is beyond the scope for the Design Certification and therefore is not applicable to this topical report for U.S. EPR Design Certification.

RAI 33: *Draft SRP Section 17.5, paragraph II.M.7, states that controls for hoisting, rigging, and transport activities are required to be established that protect the integrity of the item involved as well as potentially affected nearby structures and components. Applicable hoisting, rigging, and transportation regulations and codes are followed. Section 13.3.4, "Handling," of the AREVA QAPD does not address this issue. Provide a discussion of the how this criterion applies to activities for the U.S. EPR.*

Response 33: The subject area of this RAI is beyond the scope for the Design Certification and therefore is not applicable to this topical report for U.S. EPR Design Certification.

RAI 34: *Draft SRP Section 17.5, paragraph II.M.8, states that during operation, cleanliness controls for work on safety related and risk-significant non-safety related equipment are required to be established to the extent necessary to minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities. Section 13.3, "Implementation," of the AREVA QAPD does not address this issue. Provide a discussion of the how this criterion applies to activities for the U.S. EPR.*

Response 34: The subject area of this RAI is beyond the scope for the Design Certification and therefore is not applicable to this topical report for U.S. EPR Design Certification.

SECTION 14 INSPECTION, TEST AND OPERATING STATUS

RAI 35: *Draft SRP Section 17.5, paragraph II.N.3, states that measures are required to be established for indicating the operating status of SSCs of a nuclear power plant, such as by tagging valves and switches, to prevent inadvertent operation. Section 14.0, "Inspection, Test, and Operating Status," of the AREVA QAPD does not address this criterion. Provide a discussion of the how this criterion applies to activities for the U.S. EPR.*

Response 35: The subject area of this RAI is beyond the scope for the Design Certification and therefore is not applicable to this topical report for U.S. EPR Design Certification.

RAI 36: *Draft SRP Section 17.5, paragraph II.N.5, states that temporary modifications, such as temporary bypass lines, electrical jumpers, lifted electrical leads, and temporary trip point setting, are controlled by approved procedures, which include a requirement for independent verification. Section 14.0, "Inspection, Test, and Operating Status," of the AREVA QAPD does not address this criterion. Provide a discussion of the how this criterion applies to activities for the U.S. EPR.*

Response 36: The subject area of this RAI is beyond the scope for the Design Certification and therefore is not applicable to this topical report for U.S. EPR Design Certification.

SECTION 15 NONCONFORMING MATERIAL, PARTS, OR COMPONENTS

RAI 37: *Section 15.2, "General," of the AREVA QAPD, first sentence, should be revised to add the term "materials," to be consistent with the purpose description provided in Section 15.1, "Purpose," of the AREVA QAPD.*

Response 37: The subject area of this RAI is beyond the scope for the Design Certification and therefore is not applicable to this topical report for U.S. EPR Design Certification.

RAI 38: *Draft SRP Section 17.5, paragraph II.O.4, states that personnel performing evaluations to determine a disposition have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information. Section 15.0, "Control of Nonconforming Items," of the AREVA QAPD does not address this criterion. Provide a discussion of the how this criterion applies to activities for the U.S. EPR.*

Response 38: The above criteria regarding personnel performing evaluations to determine a disposition are included in existing AREVA NP Inc. procedures. Section 15.3.1, Nonconformances, second paragraph, has been revised to include the following:

> "Personnel performing evaluations to determine a disposition have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information."

RAI 39: *Draft SRP Section 17.5, paragraph II.O.6, states that reworked, repaired, and replacement items are inspected and tested in accordance with the original inspection and test requirements or specified alternatives. Section 15.0, "Control of Nonconforming Items," of the AREVA QAPD does not address this criterion. Provide a discussion of the how this criterion applies to activities for the U.S. EPR.*

Response 39: The subject area of this RAI is beyond the scope for the Design Certification and therefore is not applicable to this topical report for U.S. EPR Design Certification.

RAI 40: *Section 15.3.2, "Safety Concerns," of the AREVA QAPD, briefly describes those circumstances that may lead to initiating a 10 CFR Part 21 review. The term "substantial safety hazards" is used, but the term is not defined in the Section 15 or in Appendix C, "Definitions," of the AREVA QAPD. The staff requests that this term be defined within the AREVA QAPD.*

Response 40: The term "Substantial Safety Hazard" has been defined in an existing AREVA NP Inc. procedure as: a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any licensed facility. This definition has been added to Appendix C, Definitions, of the topical report as follows:

"Substantial Safety Hazard

A loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any licensed facility."

SECTION 16 CORRECTIVE ACTION

RAI 41: *Section 16.2, "General," of the AREVA QAPD, briefly describes conditions adverse to quality, including failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances. However, these terms are not defined in the Section 16 or in Appendix C, "Definitions," of the AREVA QAPD. The staff requests that these terms be defined within the AREVA QAPD.*

Response 41: The terms "Conditions adverse to quality" and "Nonconformance" are defined in Appendix C of the topical report. The terms "failures," "malfunctions," "deficiencies," and "defective material and equipment" have been added to Appendix C as follows:

"Failures

A failing (or number of failings) to perform a duty or expected action.

Malfunctions

To function imperfectly or badly, fails to operate in the normal or usual manner.

Deficiency

The quality or condition of being deficient; incompleteness or inadequacy.

Deviation

A nonconformance or departure of a characteristic from specified requirements.

Defective Material and equipment

A material or component which has one or more characteristics that do not comply with specified requirements."

RAI 42: *Draft SRP Section 17.5, paragraph II.P.3, states that specific responsibilities within the corrective action program may be delegated, but the applicant or holder maintains responsibility for the program's effectiveness. Section 16.0, "Corrective Action," of the AREVA QAPD does not address this criterion. Provide a discussion of the how this criterion applies to activities for the U.S. EPR.*

Response 42: AREVA NP Inc. maintains responsibility for the corrective action program and does not delegate those responsibilities. The corrective action process has been defined in AREVA NP Inc. procedures. Section 16.2, General, has been revised to add a new paragraph to the end of the section as follows:

> "Responsibilities within the Corrective Action program are not delegated. AREVA NP Inc. maintains responsibility for the program's effectiveness."

RAI 43: *Draft SRP Section 17.5, paragraph II.P.4, states that the program requires all personnel to identify conditions that are adverse to quality. Section 16.0, "Corrective Action," of the AREVA QAPD does not address this criterion. Provide a discussion of the how this criterion applies to activities for the U.S. EPR.*

Response 43: Section 16.2, General, has been revised to include a new bulleted item as follows:

> "• All personnel have the responsibility of reporting and/or recording known or identified conditions adverse to quality."

SECTION 17 QUALITY ASSURANCE RECORDS

RAI 44: *Draft SRP Section 17.5, paragraph II.Q.4, states that document access controls, user privileges, and other appropriate security controls must be established. Section 17.0, "Quality Assurance Records," of the AREVA QAPD does not address these criteria. Provide a discussion of the how these criteria apply to activities for the U.S. EPR.*

Response 44: Existing AREVA NP Inc. procedures and Records Management System for Document Control and QA Records include provisions for appropriate security controls for document access and user privileges. Section 17.2, General, has been revised to add the terms "document access" and "user privileges" as follows:

> "AREVA NP Inc. procedures are established to provide requirements and responsibilities for document access, user privileges, record generation, identification, transmittal, retention and maintenance including design documentation and records not only for the final design documents, such as drawings and specifications, and revisions thereto, but also documentation which identifies the important steps, including sources of design input that support the final design."

RAI 45: *Draft SRP Section 17.5, paragraph II.Q.5, states, in part, that design documentation and records include not only the final design documents, such as drawings and specifications, and revisions thereto, but also documentation which identifies the important steps, including sources of design inputs that support the final design. Section 17.0, "Quality Assurance Records," of the AREVA QAPD does not address the documentation which identifies the important steps, including sources of design inputs that support the final design. Provide a discussion of the how this criterion applies to activities for the U.S. EPR.*

Response 45: Section 17.2, General, has been revised to address the above criteria. See response to RAI 44.

RAI 46: *Draft SRP Section 17.5, paragraph II.Q.6, states, that the program requires records to be examined for adequacy, legibility and completeness. Section 17.0, "Quality Assurance Records," of the AREVA QAPD does not address this criterion. Provide a discussion of the how this criterion applies to activities for the U.S. EPR.*

Response 46: This criterion is applicable and is documented in the AREVA NP Records Management Program. Section 17.3, Implementation, has been revised to address this area as follows:

> "Documents being entered into the records management system are examined for adequacy, legibility and completeness."

RAI 47: *Draft SRP Section 17.5, includes Regulatory Issue Summary 2000-18 for several criteria related to the storing and maintaining QA records in electronic media including; II.Q.3, II.Q.7, II.Q.9, II.Q.10, II.Q.14, II.Q.15, II.Q.16, II.Q.17, and II.Q.18. Section 17.0, "Quality Assurance Records," of the AREVA QAPD does not address these criteria associated with electronic media. Provide a discussion of the how these criteria apply to activities for the U.S. EPR.*

Response 47: Section 17.2, General, has been revised to address this area as follows:

> "The AREVA NP Inc. records management program does not meet the requirements of NRC Generic Letter 88-18 for the storage of electronic media on optical discs. The AREVA NP Inc. records management program is written and implemented to satisfy the guidance provided in RIS 2000-18 and NIRMA Technical Guidelines TG-11, TG-15, TG-16 and TG-21."

SECTION 18 AUDITS

RAI 48: *Draft SRP Section 17.5, paragraphs II.R.4 and II.R.8, discusses the contents of the audit report and audit plan, respectively. Section 18.0, "Audits," of the AREVA QAPD does not address these criteria. Provide a discussion of the how these criteria apply to activities for the U.S. EPR.*

Response 48: This criterion is addressed in AREVA NP Inc. procedures. Sections 18.2 and 18.5 have been revised to clarify the program requirements. A new paragraph has been added at the end of Section 18.2, General, as follows:

> "Audit plans are developed and documented for each audit. The Audit Plan identifies the scope of the audit, applicable requirements and audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures

and checklists."

A new section 18.5, titled Audit Reports, has been added as follows:

"Audit Reports

The audit report is signed by the audit team leader and issued. The report includes the following information as appropriate:

- Description of audit scope
- Identification of auditors
- Identification of persons contacted during the audit activity
- Summary of audit results including a statement on the effectiveness of the QA program elements which were audited
- Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization"

RAI 49: *Draft SRP Section 17.5, paragraph II.R.5 discusses the audit process associated with electronic media as referenced in RIS 2000-18. Section 18.0, "Audits," of the AREVA QAPD does not address these criteria. Provide a discussion of the how these criteria apply to activities for the U.S. EPR.*

Response 49: Section 18.0 defines the audit process. The AREVA NP Inc. Records Management Program and procedures define process controls associated with electronic media. Section 17.2, General, has been revised to add the following:

"Scheduled inspections, surveillances or audits of the program software applications and media are performed that ensure electronic records retrievability, integrity and retention periods and meet the guidance provided in Regulatory Issue Summary 2000-18."

RAI 50: *Draft SRP Section 17.5, paragraph II.R.10, states that when any work carried out under the requirements of the QA program is delegated to others, the work is audited by the QA audit program. Section 18.0, "Audits," of the AREVA QAPD does not address this criterion. Provide a discussion of the how this criterion applies to activities for the U.S. EPR.*

Response 50: AREVA NP Inc. maintains responsibility for the audit program and does not delegate the requirements of the QA program to others. AREVA NP Inc. has revised Section 18.2, General, to clarify the delegation criterion as follows:

"Responsibilities within the audit program are not delegated; AREVA NP Inc. maintains responsibility for the audit program effectiveness."

RAI 51: *Draft SRP Section 17.5, paragraph II.R.11, states, in part, that such audits should be conducted as a minimum on a triennial basis and provides further criteria related to the performance of supplier audits. Section 18.4, "Supplier Audits," of the AREVA QAPD states, in part, that supplier audit frequency is based upon written criteria that incorporate the safety classification, importance, complexity, and quality requirements of the items or services being procured. The AREVA QAPD does not explicitly identify the triennial period for these reviews or address the additional criteria. Provide a discussion of how these criteria apply to activities for the U.S. EPR.*

Response 51: The criteria for conducting supplier audits on a triennial basis and its performance is addressed in AREVA NP Inc. procedures. Section 18.4, Supplier Audits, has been deleted in its entirety and replaced with the following:

> "Suppliers of safety-related items and services are evaluated to assure that only qualified suppliers are used. An audit is performed when sufficient work is in progress to demonstrate that the supplier is implementing a QA program. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period. AREVA NP Inc. may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet AREVA NP Inc. requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. Industry programs, such as those applied by ASME, Nuclear Industry Assessment Committee (NIAC), or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action."

RAI 52: *Draft SRP Section 17.5, paragraph II.R.12, discusses criteria associated with the ongoing evaluations of suppliers, and includes a description of acceptable methods for implementing such evaluations including, but not limited to, receipt inspections, operating experience, supplier evaluation programs, and source verifications. Section 18.4, "Supplier Audits," of the AREVA QAPD does not address these criteria. Provide a discussion of how these criteria apply to activities for the U.S. EPR.*

Response 52: The above criteria is addressed in AREVA NP Inc. procedures. Section 18.4, Supplier Audits, has been revised to clarify the program requirements. The following has been added at the end of the paragraph entered for response to RAI #51 above:

> "Evaluations of suppliers are documented and take into account the following, where applicable:
>
> - Receipt inspection, operating experience, and supplier evaluation programs are reviewed on an ongoing basis as the information becomes available. The results of the review are promptly considered for effect on a suppliers continued qualification and adjustments made as necessary (including corrective actions, adjustments of suppliers audit plans and input to third party auditing entities as warranted). Additionally, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.
>
> - If there is no ongoing receipt inspection or operating experience with which to analyze the supplier for a period of twelve (12) months, an annual evaluation shall be performed as follows:

- Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions
- Results of previous source verifications, audits and receiving inspections
- Operating experience of identical or similar products furnished by the same supplier
- Results of audits from other sources (e.g., customers, ASME, NIAC (Nuclear Industries Assessment Committee) or NRC audits)."

RAI 53: *Draft SRP, Section 17.5, paragraph II.S, discusses, in part, the training and qualification criteria associated with QA Auditors. Section 18.0, "Audits," of the AREVA QAPD does not address these criteria. Provide a discussion of the how these criteria apply to activities for the U.S. EPR.*

Response 53: AREVA NP Inc. Lead Auditors and Auditors are trained and qualified in accordance with NQA-1-1994 and Supplement 2S-3, Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel. In addition, personnel are also qualified in accordance with ANSI N45.2.23 requirements.

Section 18.2, General, has been revised to include the commitment to Supplement 2S-3 as follows:

> "Personnel who perform audits are qualified to the requirements of NQA-1-1994, Supplement 2S-3, and ANSI N45.2.23."

In addition, the commitment to Supplement 2S-3 has been added to Section 2.0, Quality Assurance Program.

RAI 54: *Draft SRP, Section 17.5 paragraph II.W, "Independent Review," provides a detailed description of those criteria, that are deemed important for the establishment and implementation of independent review activities associated with the fulfillment of the requirements promulgated in Appendix B to 10 CFR Part 50. Section 18.0, "Audits," of the AREVA QAPD does not address these criteria. Provide a discussion of the how these criteria apply to activities for the U.S. EPR.*

Response 54: The subject area of this RAI is beyond the scope for the Design Certification and therefore is not applicable to this topical report for U.S. EPR Design Certification.

Appendix B Regulatory Commitments: Compliance with Applicable Regulatory Guides

RAI 55: *Draft SRP, Section 17.5, paragraph II.U.1, lists those Regulatory Guides and Generic Letters applicable to the development and implementation of a quality assurance program consistent with the requirements promulgated in Appendix B to 10 CFR Part 50, and includes, but is not limited to, Generic letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," and Generic Letter 91-05, "Licensee Commercial-Grade Dedication Programs." Appendix B, "Regulatory Commitments: Compliance with Applicable Regulatory Guides," of the AREVA QAPD does not address these Generic Letters. Provide a discussion of the how these Generic Letters apply to activities for the U.S. EPR.*

Response 55: The criteria addressed in Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," and Generic Letter 91-05, "Licensee Commercial-Grade Dedication Programs," are addressed in AREVA NP Inc. procedures. The title of Appendix B has been revised to read:

> "Regulatory Commitments: Compliance with Applicable Regulatory Guides, Generic Letters, and Standards."

Appendix B, Section 1, has been revised to add the following generic letters:

"n. Generic Letter 89-02, "Actions to improve the dedication of counterfeit and fraudulent marketed products." AREVA NP Inc. conforms to the provisions of this generic letter.

o. Generic Letter 91-05, "Licensee Commercial Grade Dedication Programs." AREVA NP Inc. conforms to the provisions of this generic letter."

RAI 56: *Draft SRP, Section 17.5, paragraph II.U.2, lists those Standards applicable to the development and implementation of a quality assurance program consistent with the requirements promulgated in Appendix B to 10 CFR Part 50, and includes select subparts to ASME NQA-1-1994 Edition, "Quality Assurance Requirements for Nuclear Facility Applications," and select guidance embodied in Nuclear Information and Records Management Association, Inc. (NIRMA) technical guidelines. Section 0.1.1, "Scope," of the AREVA QAPD states, in part, that this QAP is in compliance with the regulations, codes, standards, and other requirements listed in Section 2.3. The Document is also written to comply with NQA-1-1994. Based on these statements;*

A. Confirm that the AREVA QAP commits to the specific subparts to ASME NQA-1-1994 Edition described in the Draft SRP, Section 17.5, paragraph II.U.2.

B. Appendix B, "Regulatory Commitments: Compliance with Applicable Regulatory Guides," of the AREVA QAPD does not address the NIRMA technical guidelines. Provide a discussion of the how these NIRMA technical guidelines apply to activities for the U.S. EPR.

C. The reference to "Section 2.3" in Section 0.1.1 of the AREVA QAPD above, is in error. The reference should be to "Section 2.1.3."

Response 56A: AREVA NP Inc. has reviewed the list of subparts to ASME NQA-1-1994 included in Draft SRP, Section 17.5, paragraph II.U.2. Based on the AREVA NP Inc. review, only Subpart 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Application" is applicable to the Design Certification Project. Appendix B of the topical report has been revised to include a commitment to Subpart 2.7. A new letter "p" has been added as follows:

"p. ANSI/ASME NQA-1-1994 Edition, Subpart 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Application." AREVA NP Inc. conforms to the provisions of this subpart."

In addition, in accordance with RAI Response # 3, each section of the topical report has been revised to include commitments to the basic, supplemental and applicable subparts of NQA-1-1994.

Response 56B: The AREVA NP Inc. Records Management Program Manual commits to and meets the requirements for the following NIRMA Technical Guidelines:

TG-11, Authentication of Records and Media;

TG-15, Management of Electronic Records;

TG-16, Software Configuration Management and Quality Assurance; and

TG-21, Electronic Records Protection and Restoration.

Records processed in accordance with the AREVA NP Inc. QA Program are stored in electronic media with the capability of producing legible, accurate and complete records during the required retention period. The preservation methods follow the guidance of NRC Regulatory Issue Summary 2000-18, "Guidance on Managing QA Records in Electronic Media." The Records Management Program Manual is referenced in Appendix A, QA Program, of the topical report.

The referenced Technical Guidelines and the NRC Regulatory Issues Summary 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," have been added to Appendix B, Regulatory Commitments.

Appendix B has been revised to include the following new lettered sections:

"q. Regulatory Issue Summary 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media." AREVA NP Inc. conforms to the provisions of this guidance.

r. Nuclear Information and Management Association Inc. (NIRMA) Technical Guide (TG) 11-1998, "Authentication of Records and Media." AREVA NP Inc. conforms to the provisions of this guide.

s. NIRMA TG-15-1998, "Management of Electronic Records." AREVA NP Inc. conforms to the provisions of this guide.

t. NIRMA TG-16-1998, "Software Configuration Management and Quality Assurance." AREVA NP Inc. conforms to the provisions of this guide.

u. NIRMA TG-21-1998, "Electronic Records Protection and Restoration." AREVA NP Inc. conforms to the provisions of this guide."

Response 56C: The reference in the topical report to Section 2.3 in Sections 0.1.1 and 2.1.6.2 is a typographical error and has been corrected to reflect the correct reference of Section 2.1.3.

Appendix C Definitions

RAI 57: *The definition of "Commercial Grade Item" contains a duplicated phrase "require in-process," which should be removed.*

Response 57: The duplicate phrase has been removed from the definition of "Commercial Grade" in the topical report.

RAI 58: *The definition of "Safety Related" is not consistent with the current definition provided in 10 CFR Part 50.49. The phrase "comparable to guideline exposures of 10 CFR 100" should be revised to be consistent with the language in 10 CFR 50.49(b)(1)(i)(c).*

Response 58: The Appendix C, Definition of "Safety Related" has been revised to be consistent with the language in 10 CFR 50.49(b)(1)(i)(c). The definition for "Safety Related" in Appendix C has been revised to the following:

> "Safety related items are the equipment that is relied upon to remain functional during and following design basis events to ensure:
>
> - The integrity of the reactor coolant pressure boundary.
> - The capability to shut down the reactor and maintain it in a safe shutdown; or
> - The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure comparable to the guidelines in 10 CFR 50.34(a)(1), 50.67(b)(2), or 100.11 of chapter 50.49, as applicable."

RAI 59: *Draft SRP Section 17.5, paragraph II.V.2 provides criteria that apply to non-safety related SSCs credited for regulated events, including fire protection (10 CFR 50.48), anticipated transient without scram (10 CFR 50.62), and station blackout (10 CFR 50.63). Addendum A, "Non-safety Related Products and Services," of the AREVA QAPD does not address the documents described in the draft SRP regarding the SSCs credited for regulated events. Provide a discussion of the how these documents described in draft SRP, Section 17.5, paragraphs II.V.2.a - c, apply to activities for the U.S. EPR.*

Response 59: The topical report has been revised to include the required criteria for fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), and station blackout (SBO) (10 CFR 50.63) SSCs that are not safety related. Addendum A of the topical report has been revised to include new Section A-19, as follows:

> "NONSAFETY-RELATED SSC's CREDITED FOR REGULATORY EVENTS
>
> The following criteria applies to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), the station blackout (SBO) (10 CFR 50.63) SSC's that are not safety related.
>
> AREVA NP Inc. implements quality requirements to the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Operating Nuclear Power Plants."
>
> AREVA NP Inc. implements quality requirements to ATWS equipment in accordance

with Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment that is not Safety Related."

AREVA NP Inc. implements quality requirements to SBO equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment that is not Safety-Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in Regulatory Guide 1.155, "Station Blackout.""