71-0003

AREVA

June 26, 2013
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U.S. Nuclear Regulatory Commission
Document Control Desk
11555 Rockville Pike
Rockville, MD 20852

Request for Review and Approval of "AREVA US Fuel Business Unit 10 CFR 71, Subpart H, Quality Assurance Program Description for Packaging and Transportation of Radioactive Material," FS1-0011462, Revision 2.0

AREVA NP Inc. (AREVA NP) requests the NRC's review and approval for referencing in licensing actions the Quality Assurance Program Description (QAPD) titled, "AREVA US Fuel Business Unit 10 CFR 71, Subpart H, Quality Assurance Program Description for Packaging and Transportation of Radioactive Material," FS1-0011462, Revision 2.0, dated June 14, 2013. Submission of the QAPD fulfills AREVA NP's commitment to an NRC request to submit a QAPD rather than the entire Fuel Management Manual (FMM) in accordance with Regulatory Guide 7.10. The primary reason for the NRC request was because the Fuel Management Manual fulfills other national and international standards that are not applicable to 10 CFR 71, Subpart H.

The submitted QAPD, upon NRC approval, will supersede and replace Revision 3 of the AREVA Fuel Business Unit Management Manual (FMM) which was previously approved by the NRC on July 26, 2012. This QAPD is submitted for approval as required by 10 CFR 71, Subpart H, Section 71.101(c).

If you have any questions related to this submittal, please contact Mr. Alan B. Meginnis, Product Licensing Manager at 509-375-8266 or by e-mail at Alan.Meginnis@areva.com.

Sincerely,

Pedro Salas, Director
Regulatory Affairs
AREVA NP Inc.

Enclosures

cc: J. K. Rowley
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Project 728

Q004
NMSS

IDENTIFICATION	REVISION	
FS1-0011462	2.0	AREVA Front End BG Fuel BU
TOTAL NUMBER OF PAGES: 12		

AREVA US Fuel Business Unit 10 CFR 71, Subpart H Quality Assurance Program Description for Packaging and Transportation of Radioactive Materials

ADDITIONAL INFORMATION:

PROJECT	
HANDLING	Restricted AREVA
CATEGORY	QAP - Quality Plan
STATUS	

DISTRIBUTION TO	PURPOSE OF DISTRIBUTION

ROLES	NAMES	DATES	ORGANIZATIONS	SIGNATURES
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RELEASE DATA:

CHANGE CONTROL RECORDS:
This document, when revised, must be reviewed or approved by the following regions:
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REVISIONS

REVISION	DATE	EXPLANATORY NOTES
1.0	6/14/2013	Original Issue
2.0	See 1st page release date	Document is being versioned to fix PDF software errors during rendition.

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TABLE OF CONTENTS

LIST OF APPENDICES

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0. INTRODUCTION

The AREVA Fuel Business Unit employs an Integrated Management System (IMS) to ensure all applicable quality and regulatory requirements are implemented and met while performing activities. This IMS is defined and specified in the Fuel Business Unit Management Manual (FMM). The AREVA FMM implements a Management System that complies with 10 CFR 50, Appendix B; 10 CFR 7, Subpart H; and NQA 2008 and NQA 2009a.

This Quality Assurance Program Description (QAPD) describes all of the FMM provisions in place to ensure compliance with 10 CFR 71, Subpart H. These provisions are applicable to all activities associated with the design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, testing, use, maintenance, and modification of components of approved containers used to ship radioactive materials that fall under the jurisdiction of 10 CFR Part 71 Subpart H.

This QAPD does not specify additional requirements or supersede requirements specified in the FMM, but merely provides a description of the requirements applicable to 10 CFR 71, Subpart H work contained in the FMM.

The QAPD applies to the following AREVA locations and other service locations when required by customer contract provisions:

AREVA Inc.
2101 Horn Rapids Road
Richland, WA 99354

The AREVA Management System is comprised of the Fuel Business Unit Management Manual (FMM) and associated implementing procedures. The AREVA implementing procedures are designed and administered to meet the applicable requirements of 10 CFR Part 71, Subpart H; 10 CFR Part 50, Appendix B; and ANSI/ASME NQA-1 2008 and Addenda ASME NQA-1a 2009.

1. ORGANIZATION

The AREVA organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality, safety and environment described within this QAPD are defined within the FMM, and implementing documents.

The responsibilities and authorities are presented in the Fuel Business Unit Management Manual (FMM); the FMM provides an organization chart and corresponding job descriptions that define job titles as well as respective duties and responsibilities.

The Senior Vice President of the US Fuel BU is responsible to implement the Fuel Quality Policy as defined in the FMM and manages the US organizational structure and assures that all key position incumbents are qualified to execute their assigned functions and responsibilities.

The US Fuel BU Management System and Continuous Improvement (MSCI) Manager is vested with the authority to ensure that activities affecting quality are performed and documented in accordance with established requirements. The MSCI Manager is independent and has no direct responsibilities for product design, engineering services, and production.

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Qualified personnel perform monitoring activities and verification of regulatory, contractual and/or technical requirements in accordance with controlled documents.

2. QUALITY ASSURANCE PROGRAM

The US Fuel BU Integrated Management System described by this QAPD is defined in the Fuel Business Unit Management Manual (FMM). The hierarchy of documents used to implement the IMS is defined within the FMM and uses common procedures and requirements wherever possible. These documents define the requirements to effectively and efficiently implement the requirements of the 10 CFR 71 Subpart H to comply with codes, standards, regulatory and contract requirements.

Activities within this scope of the IMS include design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, testing, use, maintenance, and modification of components of approved containers used to ship radioactive materials and regulated under 10 CFR 71 Subpart H.

AREVA complies with 10 CFR Part 21.

The AREVA hierarchy of documents provides for the planning and execution of activities affecting quality under suitably controlled conditions and ensures the provided prerequisites for the given activities are satisfied. Procedures have been established to ensure personnel are properly trained to achieve the required level of competence to perform activities affecting quality.

3. DESIGN CONTROL

AREVA has established procedures to control design and licensing activities to ensure that:

A. Design and licensing activities are planned, controlled and documented.
B. Regulatory requirements, stakeholders' requirements, design bases and appropriate quality, environmental and safety standards are correctly translated into design and procurement documents.
C. Qualified personnel independently review design documents for completeness and technical accuracy. Verification methods may include independent review of design documents and design analyses, or design verification testing.
D. Design interface controls are established and adequate to ensure the appropriate design, organizational and technical interfaces are considered.
E. Design and development changes are identified, documented and controlled in the same manner as the original documents.
F. Design errors and nonconformances are documented and corrected.
G. Design organization(s) and their responsibilities and authorities are defined and controlled through written procedures.

4. PROCUREMENT DOCUMENT CONTROL

Procedures have been established to ensure that procurement documents are prepared to clearly define the requirements of the IMS, including requirements specified in customer contracts, regulatory standards or legal requirements.

Procurement activities are performed in accordance with procedures that establish requirements for preparation, review, approval and control of procurement documents. Changes to procurement documents are subject to the same review and approval as the original documents.

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Procedures have been established to assure the assignment of quality requirements for the procurement of items or services important to safety or safety related. These procedures assure the procurement documents specify the scope of procurement, and include the following:

A. Technical requirements,
B. Quality, Safety and/or Environmental requirements,
C. Right of access to supplier facilities for source inspection and/or audit,
D. Inspection and Test requirements,
E. Requirements specifying supplier must flow down requirements to sub-tier suppliers,
F. Special process requirements,
G. Documents required for submittal for AREVA review and/or approval,
H. Documentation requirements such as inspection and test records, certification documents,
I. Record retention requirements,
J. Reporting and disposition of nonconformances, and
K. Reporting defects and nonconformance per the requirements of 10 CFR Part 21

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Procedures have been established to ensure the activities affecting quality are controlled in accordance with appropriate instructions, procedures and design documents necessary for complying with the FMM requirements for items and services classified as important to safety or safety related.

Changes to instructions, procedures and/or design documents receive the same level of review and approval as the original.

Compliance with approved instructions, procedures and design documents is mandatory for all performance of work activities in accordance with the FMM and implementing procedures.

6. DOCUMENT CONTROL

Procedures have been established to control the issuance of documents that prescribe requirements for activities affecting quality associated with items or services classified as important to safety or safety related. These procedures ensure adequate preparation, review, approval, distribution, release, use and revision of documents.

Measures are taken to ensure that only current documents are available at the locations where documents are used. These measures include the control of electronic data bases used to control documents.

Changes to documents are reviewed and approved by the same organizations that reviewed and approved the original.

7. CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

Procedures have been established to ensure purchased material, equipment and services conform to procurement documents.

Procurement documents are reviewed and approved by authorized personnel for acceptability of proposed suppliers based on the classification of the item being purchased.

Approved suppliers are listed on the AREVA Approved Supplier List Fuel (ASL) for items and services they provide. The ASL is controlled in accordance with approved procedures.

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Procedures have been established to ensure suppliers are adequately selected and evaluated according to the importance of the purchased item or service. These evaluations are based one or all of the following criteria:

a. Supplier's third party certificates and references.
b. Evaluation of the ability of the supplier's quality program to meet the technical and quality requirements applicable to the scope of work.
c. Review of previous records to establish past performance of the supplier.
d. Review of supplier's facility, technical equipment and/or personnel.

Qualified personnel perform supplier assessments and surveys. Assessment and survey results are maintained as a quality record. Suppliers are assessed at planned intervals to verify compliance with quality requirements and to assess continued effectiveness of their QA program.

8. IDENTIFICATION AND CONTROL OF MATERIAL, PARTS AND COMPONENTS

Procedures have been established for the identification and control of materials, parts and components. These procedures are designed to prevent inadvertent use of incorrect or nonconforming items. Additionally, these procedures are established to indicate the status of inspections and tests of items by appropriate means, from receipt of the item to end use.

Requirements for identification are established during the preparation of design drawings and specifications.

Items having limited shelf or operating life are controlled to prevent their inadvertent use.

9. CONTROL OF SPECIAL PROCESSES

Procedures have been established to control special processes such as welding, heat treatment, and nondestructive examination. Special Processes are performed by qualified personnel using qualified procedures in accordance with applicable requirements.

Procedures and personnel qualifications associated with special processes are maintained as Quality Assurance Records.

10. INSPECTION

Procedures have been established to verify conformance with specified requirements for accomplishing activities affecting quality.

Inspection/surveillance and process monitoring are both required where either one by itself will not provide assurance of quality.

Inspection and surveillance activities are performed in accordance with procedures and results are documented. Personnel performing inspection and surveillance activities are trained and qualified in accordance with these approved procedures. Inspection(s) and surveillance(s) are performed by individuals other than those who performed or supervised the subject activities.

Inspection and surveillance planning includes the determination of hold points, inspection equipment requirements, acceptance criteria, personnel qualification requirements, variable and/or attribute recording instructions, reference documents, and other requirements as applicable.

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11. TEST CONTROL

Procedures have been established to assure that proof, acceptance and operational tests are controlled by approved written procedures.

Tests are performed by qualified personnel in accordance with approved procedures.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

Procedures have been established to ensure that tools, gages, instruments and other measuring and testing equipment (M&TE) used in important to safety or safety related activities are properly controlled, calibrated and adjusted to maintain accuracy within required limits.

Calibration of M&TE is performed in accordance with approved procedures. These procedures include the following requirements:

a. Traceability of calibration standards to national or international standards.
b. Basis of calibration is documented when no national or international standard exists.
c. M&TE is calibrated to the required degree of accuracy, repeatability, and traceability.
d. Calibration intervals are based on required accuracy and stability of the equipment.
e. M&TE calibration status is identified by tag, label or other appropriate means.
f. Nonconforming M&TE is clearly identified and its use prohibited or suitably restricted until repaired or calibrated.
g. Environmental conditions for calibration.
h. Handling and safeguarding of equipment.
i. Use of test hardware.

M&TE used to determine product acceptance that is found to be out of calibration will be removed from service and recalibrated prior to reuse. Furthermore, an evaluation is performed and documented determining acceptability of items inspected or tested using that M&TE since the last acceptable calibration.

13. HANDLING, STORAGE, AND SHIPPING

Procedures have been established to ensure that materials, parts, assemblies, spare parts, special tools, and equipment are handled, stored, packaged and shipped in a manner to prevent damage, loss of identity or deterioration.

When necessary, storage procedures address special requirements for environmental protection such as inert gas atmospheres, moisture control and temperature levels, etc.

14. INSPECTION, TEST, AND OPERATING STATUS

Procedures have been established to ensure that the inspection, test and operating status of materials, items, structures, systems and components throughout fabrication, installation, operation and testing are clearly indicated by suitable means (e.g. tags, labels, lot cards, followers, etc.).

Bypassing of required inspections, testing or other critical operations is prevented through the use of approved procedures.

As appropriate, the operating status of nonconforming, inoperative, or malfunctioning components (e.g. valves, switches, etc.) is indicated to prevent inadvertent operation. The

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application and removal of status indicators is performed in accordance with approved instructions and procedures.

15. CONTROL OF NONCONFORMING ITEMS

Procedures have been established to control items which do not conform to requirements in order to prevent their inadvertent use. These procedures include, as appropriate instructions, for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items are reviewed, accepted, repaired, reworked, and/or rejected in accordance with applicable procedures.

Rework and/or repair of nonconforming items are inspected with the applicable inspection requirements applied to the original items or as specified in the rework or repair procedures.

Nonconforming conditions are documented in Condition Reports within the Corrective Action Program (CAP) and affected organizations are notified. These conditions reports include a description of the nonconformance, disposition of use including technical justification, corrective and/or preventive actions and other supporting evidence in accordance with written procedures.

16. CORRECTIVE ACTION

Procedures have been established to ensure conditions adverse to quality, such as nonconforming conditions; unsatisfactory conditions revealed by audit; inspection or surveillance of products; and customer complaints are promptly identified and corrected to prevent recurrence. Such situations are classified by significance level, and are analyzed for root or apparent causes. Results are reported to appropriate levels of management for review and disposition.

Conditions adverse to quality are documented in the CAP and reported to the appropriate level of management. When necessary, follow up is performed to verify corrective action requirements have been completed and are effective in preventing recurrence. Periodically, CAP trends are evaluated and appropriate corrective actions taken.

Compliance with the evaluation and reporting requirements of 10 CFR Part 21 related to defects and noncompliance is controlled in accordance with approved procedures.

17. QUALITY ASSURANCE RECORDS

Procedures have been established to ensure the control of quality records, including those prepared by customers and external sources. The purpose of the quality assurance records system is to ensure that documented evidence pertaining to the important to safety or safety related activities is maintained in accordance with AREVA, customer and/or regulatory requirements, as applicable.

Procedures have been established to ensure Quality Assurance Records are identified as to the type of record to be retained and classified as permanent or non-permanent records. The measures also include instructions for filing and archiving of records, as well as preservation, retrieval and disposition.

Records are provided to customers in accordance with contract requirements.

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18. AUDITS

Procedures have been established to provide a comprehensive system of planned and periodic audits. Audits are performed to verify compliance with all aspects of the IMS. Those areas and activities to be audited, such as design, procurement, fabrication, and inspection and testing of storage/transportation systems, are identified in audit planning.

Audits are planned and scheduled in a manner to provide coverage and coordination with ongoing Management System activities commensurate with the status and importance of the activities.

Audits are performed by trained and qualified personnel not having direct responsibilities in the areas being audited and are conducted in accordance with approved procedures. Audit results are documented and reviewed with the appropriate level of management having the responsibility for the area audited. Audit reports include an objective evaluation of the quality-related practices, procedures, and instructions for the areas or activities being audited and of the effectiveness of the implementation.

Responsible management undertakes corrective actions as a follow-up to audit reports when appropriate. Audit results are evaluated for indications of adverse trends that could affect quality. When results of such assessments so indicate, appropriate corrective actions are implemented.

Follow-up of actions including re-audit of deficient areas are performed when determined necessary to ensure corrective actions taken are effective.

Requirements for audit of supplier activities are provided in Section 7.0 of this QAPD.

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Appendix 1: For Information Only – IMS Implementing Procedures Matrix

Implementing Document	Title	Regulatory Position	Description
FMM Section 4.4, Responsibility and Authority QAP-01	Organization	71.103	Identifies the QA organization, its relationship to other organizations within the company, and its responsibilities for activities affecting quality.
FMM Section 3.0, Integrated Management System FMM Section 4.0 Management Responsibility FMM Section 6.0 Resources Management All Listed QA Procedures	Quality Assurance Requirements and Quality Assurance Program	71.101 & 71.105	Describes the method for establishment and implementation of a documented Integrated Management System to meet the requirements of Subpart H of 10CFR71 and identifies the activities to which it applies.
FMM Section 7.3, Design and Development Process QAP-04	Package design control	71.107	Describes the design control measures established to for structures, systems and components.
FMM Section 7.4, Purchasing QAP-06	Procurement document control	71.109	Describes the measures established to ensure the necessary technical and quality requirements are included or referenced in procurement documents for items and services.
FMM Section 7.5, Production and Service Processes All Listed QA Procedures	Instructions, procedures, and drawings	71.111	Describes the measures established to assure items important to safety or activities affecting quality are prescribed by, and performed in accordance with documented instructions, procedures, or drawings.
FMM Section 3.4, Control of Documents and Data FMM Section 3.5, Control of Records QAP-05	Document Control	71.113	Describes the measures established to ensure control the issuance of documents that prescribe requirements for activities affecting quality associated with items or services classified as important to safety or safety related.
FMM Section 7.4, Purchasing FMM Section 7.5.2, Qualification or Validation of Production and Service Processes QAP-06, QAP-07	Control of purchased material, equipment, and services	71.115	Describes the measures established to ensure the procurement of items or services classified as important to safety or safety related conforms to specified requirements. Measures include source selection and evaluation, source inspection, audit, and receipt inspection of items or services upon delivery or completion.
FMM Section 7.5.3, Identification, Traceability and Status Control QAP-08	Identification and control of materials, parts, and components	71.117	Describes the measures established to ensure for the identification and control of materials, parts and components from receipt to end use.
FMM Section 7.5.2, Qualification or Validation of Production and Service Processes QAP-09	Control of Special Processes	71.119	Describes the measures established to ensure control special processes in accordance with specified requirements.

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FMM Section 8.2.5, Monitoring and Measurement of Product QAP-10	Internal inspection	71.121	Describes the measures established to ensure inspections required to verify conformance with specified requirements are accomplished.
FMM Section 7.5.3, Identification, Traceability and Status Control QAP-10	Test Control	71.123	Describes the measures established to ensure tests area controlled and performed by qualified personnel in with written procedures.
FMM Section 7.6, Control for Measuring and Test Equipment QAP-11	Control of measuring and test equipment	71.125	Describes the measures established to ensure measuring and test equipment used in important to safety or safety related activities are controlled, calibrated and adjusted to the accuracy required.
FMM Section 7.5.5, Preservation of Product QAP-15	Handling, storage, and shipping control	71.127	Describes the measures established to ensure products handled, stored, or shipped are maintained to preserve the quality of the product.
FMM Section 7.5.3, Identification, Traceability and Status Control QAP-12	Inspection, Testing, and Operating Status	71.129	Describes the measures established to ensure that the inspection, test and operating status of items are clearly indicated by suitable means.
FMM Section 8.3.1, Control of Nonconforming Product QAP-13	Nonconforming materials, parts, or components	71.131	Describes the measures established to ensure product which to do not conform to requirements are controlled to prevent their inadvertent use.
FMM Section 8.6, Corrective and Preventive Action QAP- 13	Corrective Action	71.133	Describes the measures established to ensure that conditions adverse to quality are promptly identified and corrected to prevent recurrence.
FMM Section 3.5, Control of Records QAP-16	QA Records	71.135	Describes the measures established to ensure the control of quality records related to important to safety or safety related activities.
FMM Section 8.2.3, Audits QAP-17	Audits	71.137	Describes the measures established to ensure internal and external audits are performed.

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