Department of Energy
National Nuclear Security Administration
P.O. Box 5400
Albuquerque, NM 87185

October 13, 2016

U. S. Nuclear Regulatory Commission
Attn: Document Control Desk M/S 3W/4C68
11555 Rockville Pike
Rockville, MD 20852

Dear Sir:

This letter is in regard to Docket No. 71-9370, CAC No. L25109. The purpose of this letter is to submit the National Nuclear Security Administration's (NNSA) response to the Nuclear Regulatory Commission's (NRC) Request for Supplemental Information (RSI) for the Model 380-B Transport Package. The NRC's request was contained in the NRC letter from Norma Garcia-Santos to Ahmad M. Al-Daouk, subject: *Application for the Model No. 380-B Transport Package – Supplemental Information Needed*, dated June 10, 2016. NNSA's responses are contained in the Attachment. Please note that this response addresses only the RSI, and that NNSA will address the observations by separate correspondence.

As stated in previous correspondence, the Model 380-B Transport Package will be used to support the NNSA Offsite Source Recovery Project. This will ensure the safe and secure long-term use of radioactive materials in the U.S.

Questions regarding this application may be addressed to me at 505-845-4607 or Kathy Schwendenman of my staff at 505-845-4185.

Sincerely,

A.M. Al-Daouk

Ahmad M. Al-Daouk
NNSA Certifying Official
Deputy Associate Administrator for Enterprise Stewardship

Enclosure:
Responses to the NRC Request for Supplemental Information

cc w/o enclosure:
Norma Garcia-Santos, NRC NMSS/DSFM/SFLB MS:4 B34
Kathy Schwendenman, NA-531
Chad E. Thompson, NA-531
Tameka Taplin, NA-212

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Responses to the NRC Request for Supplemental Information
U.S. Department of Energy
National Nuclear Security Administration
Docket No. 71-9370
CAC No. L25109

By letter dated June 10, 2016, the Nuclear Regulatory Commission (NRC) requested supplemental information on the stated application. The requested information, followed by the National Nuclear Security Administration (NNSA) response, is included below.

REQUEST FOR SUPPLEMENTAL INFORMATON

Quality Assurance (QA)

QA-1. Provide a description of the quality assurance program that will be used for the Model No. 380-B including

a) For a NRC-approved quality assurance program, reference the applicable docket No. of the NRC-approved quality assurance program in the application.
b) For a quality assurance program not previously approved by NRC, provide:
    1) A detailed description of how the applicant will ensure compliance with 10 Code of Federal Regulations (CFR) Part 71, Subpart H, "Quality Assurance."
    2) Quality requirements for each individual component consistent with the component function and safety requirements

In Section 8.1, "Acceptance Tests," of the application, the applicant states the following:

"Deviations from requirements will be recorded and dispositioned in accordance with the cognizant quality assurance program."

The application for the Model No. 380-B does not include a description of the quality assurance program that the applicant will use to ensure that the package will be in compliance with the requirements of 10 CFR Part 71.

This information is needed to determine compliance with 10 CFR 71.31(a)(3), 10 CFR 71.37 and 71.101(b).

Response:

QA-1.a) The Design Agency for the 380B is AREVA Federal Services LLC (AREVA). AREVA has a QA Program approved by NRC, ref Approval No. 71-0938.

QA-1.b) Los Alamos National Laboratory (LANL) is the Package Owner and the Design Authority for the 380-B package. LANL's Type B and Fissile Radioactive Materials Quality Assurance Plan (QAP) complies with 10 CFR 71 Subpart H and is the governing QA Program for the 380-B. The NNSA Certifying Official approved LANL's QAP, P&T-PLAN-028, R4 dated January 2016.

QA-1.b)(1) A more detailed description of QA for the LANL 380-B Transport Package is provided below.

Quality Assurance Organization

The LANL 380-B Transport Package was designed for LANL by AREVA. Package operations will be managed by LANL, with support from AREVA.

LANL is the 380-B Packaging Owner. The LANL owner organization of the package is the Offsite Source Recovery Program (OSRP). The owner organization that accepts the packaging from the supplier documents that the packaging is acceptable for use in accordance with the Certificate of Compliance (CoC). The owner may delegate the performance of these responsibilities.

The LANL Operations Support-Packaging and Transportation (OS-PT) organization is the Design Authority for the 380-B package. The Design Authority is responsible for the design and use of the packaging, as well as changes to, and final acceptance of the package design. The Design Authority may delegate any of these activities to others as long as they retain the responsibilities. The Design Authority is also responsible for securing regulatory concurrence and interpretation of the Safety Analysis Report (SAR) and CoC.

AREVA, with QA oversight by the LANL OS-PT organization, is the LANL Contractor acting on behalf of the packaging owner as the Design Agency to provide design, licensing documentation, and certification expertise. The Design Agency determines the package's safety-related items and the appropriate level of QA according to the NRC Guide 7.10. The Design Agency may delegate any of these activities as long as they retain the responsibilities.

Quality Assurance Program

The design, procurement, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair and modification of components of Type B and A(F) packagings are controlled at LANL by the LANL Type B and Fissile Radioactive Materials QAP.

The technical services, i.e., licensing documentation, design, and certification expertise for the 380-B package shall be provided by AREVA, with QA oversight by LANL OS-PT. AREVA has an established QA program qualified to 10 CFR 71 Subpart H, and DOE Order 414.1D (including American Society of Mechanical Engineers NQA-1 2008/2009a) and is documented on the LANL Institutional Evaluated Suppliers List (IESL).

In addition to 10 CFR71 Subpart H requirements, LANL organizations and contractors must also comply with LANL's institutional Quality Assurance Plan for Type B and fissile radioactive materials, i.e., P&T-PLAN-028, *LANL Type B and Fissile Radioactive Materials Quality Assurance Plan (QAP),* as well as SD330, *Los Alamos National Laboratory Quality Assurance Program.*

SD330 is the approved LANL description of the overall quality management system that provides a level of confidence that both LANL's business management and technical processes are effective and efficient. It is issued under the authority of the Laboratory Director. It is consistent with requirements of the prime contract and LANL Governing Policies on performance, safety, and safeguards and security, and it promotes compliance with federal, state, and local regulations and codes.

SD330 establishes the LANL QA program requirements for site-wide implementation and is to serve as the basis for LANL QA program acceptability. It is designed such that implementation of the full scope of requirements as stated in DOE Order 414.1D, Quality Assurance (current contractual version), constitutes compliance to nuclear safety QA criteria required by 10 CFR 830, Subpart A, *Nuclear Safety.* SD330 also addresses the evaluation of subcontractor quality programs. When found acceptable, such suppliers are added to the LANL IESL.

A package User ships and receives materials in that specific packaging. LANL OSRP and Department of Energy Complex-Wide Users are responsible for the QA controls necessary to ensure that the certified packages and their use, maintenance, and testing meet the requirements of this SAR and the CoC.

The Table below depicts how the requirements of 10CFR 71, Subpart H are addressed within the LANL QA program for the LANL 380-B.

Responses to the NRC Request for Supplemental Information
U.S. Department of Energy
National Nuclear Security Administration
Docket No. 71-9370
CAC No. L25109

10 CFR 71 Subpart H Requirement	Title	LANL QAP Section	AREVA QAP Section	Description	Application to LANL Implementation	Application to AREVA Implementation
1 (71.103)	QA Organization	2.0	1.0	Identifies organizations and their relationships in performance of activities affecting quality.	Applicable	Applicable
2 (71.105)	QA Program	3.0	2.0	Describes basic methods for establishing a documented QA program that implements requirements of 10 CFR 71, Subpart H.	Applicable	Applicable
3 (71.107)	Package Design Control	4.0	3.0	Describes design control measures established for structures, systems, and components.	Applicable	Applicable
4 (71.109)	Procurement Document Control	5.0	4.0	Describes procedures for ensuring that applicable regulatory requirements, design bases, and other requirements necessary to ensure adequate quality are suitably included or referenced in documents for procurement of material and services.	Applicable	Applicable
5 (71.111)	Instructions, Procedures, and Drawings	6.0	5.0	Describes documentation of instructions, procedures, or drawings to ensure that safety criteria have been met. Also describes QA review and concurrent processes.	Applicable	Applicable
6 (71.113)	Document Control	7.0	6.0	Describes documents to be maintained by the QA program and how those documents may be changed, reviewed, approved, and issued.	Applicable	Applicable
7 (71.115)	Control of Purchased Material, Equipment, and Services	8.0	7.0	Describes procurement planning, sources, bids, evaluations, awards, performance control, verification activities, control of nonconformance's, and records.	Applicable	Applicable
8 (71.117)	Identification and Control of Materials, Parts, and Components	9.0	8.0	Describes procedures to track materials to prevent the use of incorrect or defective items.	Applicable	Applicable
9 (71.119)	Control of Special Processes	10.0	9.0	Describes procedures to monitor special processes such as welding, radiography, and heat- treating.	Applicable	Applicable
10 (71.121)	Internal Inspection	11.0	10.0	Describes the planning and use of inspection procedures, instructions, and checklists.	Applicable	Applicable

10 CFR 71 Subpart H Requirement	Title	LANL QAP Section	AREVA QAP Section	Description	Application to LANL Implementation	Application to AREVA Implementation
11 (71.123)	Test Control	12.0	11.0	Describes requirements and procedures for testing materials in accordance with original design and testing requirements. Also ensures that the test results are documented and evaluated by qualified individuals.	Applicable	Applicable
12 (71.125)	Control of Measuring and Test Equipment	13.0	12.0	Describes procedures for ensuring that measuring and test equipment is properly calibrated and appropriate actions should the equipment be out of calibration.	Applicable	Applicable
13 (71.127)	Handling, Storage, and Shipping Control	14.0	13.0	Describes procedures for ensuring that containers and packaging are preserved, prepared, released, and delivered in good condition.	Applicable	Applicable
14 (71.129)	Inspection, Test, and Operating Status	15.0	14.0	Describes methods for the identification of the inspection, test, and operating status of items including the application/removal of tags, markings, or stamps.	Applicable	Applicable
15 (71-131)	Nonconforming Materials, Parts, or Components	16.0	15.0	Describes the identification, segregation, disposition, and evaluation of items that do not conform to design and construction criteria.	Applicable	Applicable
16 (71-133)	Corrective Action	17.0	16.0	Described procedures for identifying, reporting, and obtaining corrective actions from suppliers for defective material.	Applicable	Applicable
17 (71-135)	Quality Assurance Records	18.0	17.0	Describes the establishment of quality assurance records, content, indexing and classification, and appropriate methods for storage, preservation, and safekeeping.	Applicable	Applicable
18 (71.137)	Audits	19.0	18.0	Describes internal and external audit programs applicable to both in- house and major suppliers.	Applicable	Applicable

QA-1.b)(2)

Quality requirement for individual components:

Materials and components of the 380-B are designed, procured, fabricated, assembled, and tested using a graded approach under the QA Program described above. The Design Agency, AREVA, determines quality categories for all 380-B packaging components and subcomponents important to safety. The NRC approved AREVA's QA plan (Approval No. 71-0938). These defined quality categories consider the impact to safety if the component were to fail or perform outside design parameters. The quality categories are compiled in a Quality List which is a controlled document. Quality categories are not included on the design drawings in the SAR. During fabrication, the quality categories are transposed from the Quality List to the fabrication drawings for the components. The extent of quality effort given to an activity or packaging component is controlled by the quality level assigned and the attendant QA requirements.

Deviations from requirements during acceptance testing:

Acceptance testing is performed by approved suppliers. During testing, nonconforming data, materials, parts, or components are controlled in accordance with Nonconformance Reporting procedures. These procedures require the approval of the LANL Design Authority and Design Agency, as appropriate, for nonconformance report dispositions of "repair" or "use-as-is." In all cases, final disposition of non-conformances is identified and documented, and the documentation is maintained as a QA record. Deviations from requirements that are requested by the fabricator are documented in a Supplier Deviation Disposition Request that is used to document the details and obtain approvals as necessary. Any deviations that are not nonconformances must be approved by the proper engineering and/or quality disciplines, and any resultant changes to design documents controlled and documented.