



**DEFENSE THREAT REDUCTION AGENCY**  
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September 12, 2019

ATTN: Christian Araguas, Chief  
Inspections and Operations Branch  
Division of Spent Fuel Management  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

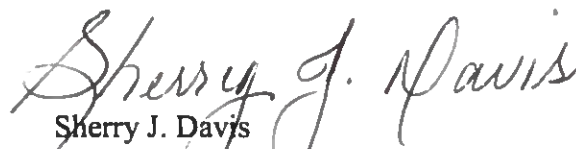
Subject: Response to NRC Request for Additional Information for Review of the Defense Threat Reduction Agency (DTRA) Amendment Request for Part 71 Quality Assurance Program (QAP) for Packaging and Transportation of Fissile Material Approval, Docket No. 71-0958

Dear Mr. Araguas,

Per the telephone conversation, NRC (Terry)/DTRA (Hart), on 21 August 2019, and NRC Memorandum dated 10 July 2019, Docket No. 71-0958, additional information is provided in Enclosure 1 to assist in your review of DTRA's Part 71 Quality Assurance Program amendment request. Enclosure 1 provides the NRC Request Statement and DTRA's corresponding response.

DTRA's QAP will be used specifically for shipping Type A quantities of special nuclear materials (fissile material) in Type A packaging, as required by Part 71.22 of Title 10, Code of Federal Regulations (CFR). If you have questions or need additional information, please contact Mr. Timothy Hart at (571) 616-5189 or by email at [timothy.p.hart1.ctr@mail.mil](mailto:timothy.p.hart1.ctr@mail.mil).

Sincerely,

  
Sherry J. Davis  
Director, Environmental, Safety, and  
Occupational Health

Enclosure:

1. DTRA's Response to Telephone Conversation, NRC (Terry)/DTRA (Hart), of 21 August 2019 and NRC Memorandum dated 10 July 2019, Docket No. 71-0958

cc:

Jeremy Tapp  
Tomeka Terry

**DTRA's Response to Telephone Conversation, NRC (Terry)/DTRA (Hart), of 21 August 2019 and NRC Memorandum dated 10 July 2019, Docket No. 71-0958**

**NRC Request 1: 3.2-1** Please include the organizational structure diagram as part of your DTRA Instruction 4540.01, dated April 18, 2019, Quality Assurance Program for Shipping Special Nuclear Material.

This revision is required to verify the organizational freedom and independence from cost and schedule for the quality assurance organization and ensure this information is part of the QA program document.

This information is needed to determine compliance with 10 CFR 71.103.

**DTRA Response:** Insert the following into DTRA Instruction 4540.01, Quality Assurance Program for Shipping Special Nuclear Material, as Paragraph 3.2.d:

"DTRA's organization is such that ES reports directly and independently to the Director of DTRA. As discussed above ES is responsible for program development, implementation, training, auditing, recordkeeping, and oversight of the QAP. The Research & Development Directorate (R&D) and Nuclear Enterprise Directorate (NE) report through a separate line of authority to the Director of DTRA. R&D and NE are the production directorates responsible for maintaining quality during shipping and transportation of SNM."

**Background** NRC Regulatory Guide 7.10, Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material, Section B, states, "For example, a QA program user who has a general license solely to transport radioactive materials in packages purchased or leased for that purpose would be expected to address criteria governing such activities (e.g., procurement, shipment, and handling). By contrast, a QA program user who designs and fabricates a package would be expected to address criteria for design and testing, as well as activities related to procuring the component materials. Elements that are common to all QA program descriptions include the quality organization and program, corrective actions, QA records, and audits (among others)." DTRA will use the general license solely to transport radioactive materials in packages provided by Department of Energy (DOE) and for this reason DTRA's QAP only addresses criteria governing those activities (e.g., procurement, shipment, and handling)."

As discussed in our initial submission, DTRA's QAP will be used specifically for shipping Type A quantities of special nuclear materials (fissile material) in Type A packaging, as required by Part 71.22 of Title 10, Code of Federal Regulations (CFR). The packaging will be limited to Skolnik Industries Inc. model CQ0502Q, open head, carbon steel, five-gallon drum using a lever-lock closure ring, UN 1A2/X60/S. Per the contract that provides the SNM to DTRA, all Type A packaging is provided by the DOE. As we stated in our initial submission, DTRA is not permitted to design, fabricate, assemble, or test packages under this QAP. As such, DTRA will not conduct activities related to procuring component materials, equipment, or services. DTRA will not establish measures for the identification and control of materials, parts, and components associated with the design or fabrication of packaging. Because the end user of the Skolnik

Industries Inc. model CQ0502Q, Type A package has no testing requirements, therefore DTRA will not establish a test control program.

Furthermore, the General License in 10 CFR 71.22 provides the NRC's approval for SNM to be packaged and shipped. Per 10 CFR 71.22(a), DOT Specification 7A Type A packages are NRC approved per 49 CFR 173.465(c)(2):

"The fissile material need not be contained in a package which meets the standards of subparts E [Package Approval Standards] and F [Package, Special Form, and LSA-III Tests] of this part; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a)[(1)(i)]."

The package vendor is not required and will not provide any documentation that a Safety Analysis Report for Packaging (SARP) to the NRC for assessment. For that reason, the NRC did not issue a Certificate of Compliance (CoC) for the Skolnik Industries Inc. model CQ0502Q, Type A package. There is no requirement for Skolnik Industries Inc. to obtain NRC approval of its model CQ0502Q, Type A package, because NRC does not have a package vendor approval evaluation process for DOT Specification 7A Type A packaging.

**NRC Request 2: 4.2-1** Provide a description of how measures are established to assure the procured material, equipment, and services, as applicable conform to the procurement documents.

This information is required to verify, at a minimum, the adequacy of the procured transportation packaging and associated materials and equipment that is planned for use under 10 CFR Part 71. A description is also necessary for any required services, such as calibration of measuring and test equipment, which will be procured via current procedures.

This information is needed to ensure compliance with 10 CFR 71.115.

**DTRA Response:** Because DTRA is not purchasing material, equipment, or services directly or through contractors or subcontractors for fabrication of packaging we have not established procedures to assure these items conform to procurement documents. As stated in Section 5.2 of DTRA Instruction 4540.01, dated April 18, 2019, Quality Assurance Program for Shipping Special Nuclear Material (QAP SNM) we will establish a document management program to allow for the retention, retrieval, revision, and review of all documentation associated with the QAP. As discussed Section 5.2.a, Procurement Document Control, of DTRA Instruction 4540.01, dated April 18, 2019 establishes measures to control the preparation, review, concurrence, and approval of all procurement documents.

DTRA will retain documentary evidence that the packaging received from DOE conforms to the specifications for the Skolnik Industries Inc. model CQ0502Q before installation or use of the material and equipment. As stated in Section 5.2.a(3), Procurement Document Control, of DTRA Instruction 4540.01, dated April 18, 2019, "requests to procure replacement parts will include the same technical and QA requirements provided as part of the initial procurement. For replacement parts purchased from other than the original manufacturer of the packaging, DTRA

will ensure that the replacement parts meet requirements at least as stringent as the original criteria.”

DTRA Instruction 4540.01, dated April 18, 2019, Section 5.3, Internal Inspection, establishes requirements for initial receipt inspections of the packaging to ensure DOE provides packaging that meets the established degree of quality. DTRA Instruction 4540.01, dated April 18, 2019, Section 5.4 establishes an audit program that requires management to perform an independent annual audit designed to assess the overall effectiveness and implementation of the QAP. This audit will include an assessment of the effectiveness of the control of quality by DOE at intervals consistent with the importance, complexity, and quantity of the product or services.

**NRC Request 3: 4.3-1** Provide a description of how measures are established to assure that quality materials, parts, and components are identified and controlled to prevent the use of incorrect or defective items.

This information is required to verify, at a minimum, the adequacy of the measures in place to ensure any items provided for 1) use of the packaging or 2) as replacement items are adequately identified and controlled.

This information is needed to ensure compliance with 10 CFR 71.117.

**DTRA Response:** DTRA Instruction 4540.01, dated April 18, 2019, Section 5.3.a states that; “DTRA has established procedures for conducting initial receipt, in-use package, and post maintenance inspections.” Section 4.7.b of DTRA Instruction 4540.01, dated April 18, 2019 establishes measures to indicate the operational status of individual items of the packaging. Section 4.7.c of DTRA Instruction 4540.01, dated April 18, 2019 provides a description of the measures established to assure that quality materials, parts, and components are identified and controlled to prevent the use of incorrect or defective items.

**NRC Request 4: 4.5-1** Provide a description of how measures are established to assure that applicable test programs are accomplished in accordance with written procedures.

This information is required to verify establishment of a test program necessary to demonstrate that the packaging will perform satisfactorily in use and follows the requirements of this part and the pertinent requirements and acceptance limits contained in the package approval.

This information is needed to ensure compliance with 10 CFR 71.123.

**DTRA Response:** Section 4.7.b of DTRA Instruction 4540.01, dated April 18, 2019, Quality Assurance Program for Shipping Special Nuclear Material (QAP SNM) provides a description of the measures established to assure that applicable test programs are accomplished per written procedures. As we stated above, because the Skolnik Industries Inc. model CQ0502Q, Type A package has no testing requirements, DTRA will not establish a test control program.