DEFENSE THREAT REDUCTION AGENCY
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22 April 2019

ATTN: Document Control Desk
Director, Division of Spent Fuel Management
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Araguas,

This letter requests an amendment of the Defense Threat Reduction Agency's (DTRA) Quality Assurance Program (QAP). The attached instruction provides a description of the DTRA's QAP, specifically for shipping special nuclear materials (fissile material) in Type A packaging, as required by Part 71.22 of Title 10, Code of Federal Regulations (CFR). Section 3, Figure 1. further illustrates the elements of the DTRA's organization that perform the shipping work and related activities.

The enclosures rescind and replace the DTRA's application on 5 August 2015 and supplemental information provided by the letter dated 23 October 2015. The enclosures provide a description of how the applicable requirements of 10 CFR 71 will be satisfied.

If there are any questions or additional information needed, please contact Mr. Timothy Hart at (571) 616-5189 or by email at timothy.p.hart1.ctr@mail.mil.

Sincerely,

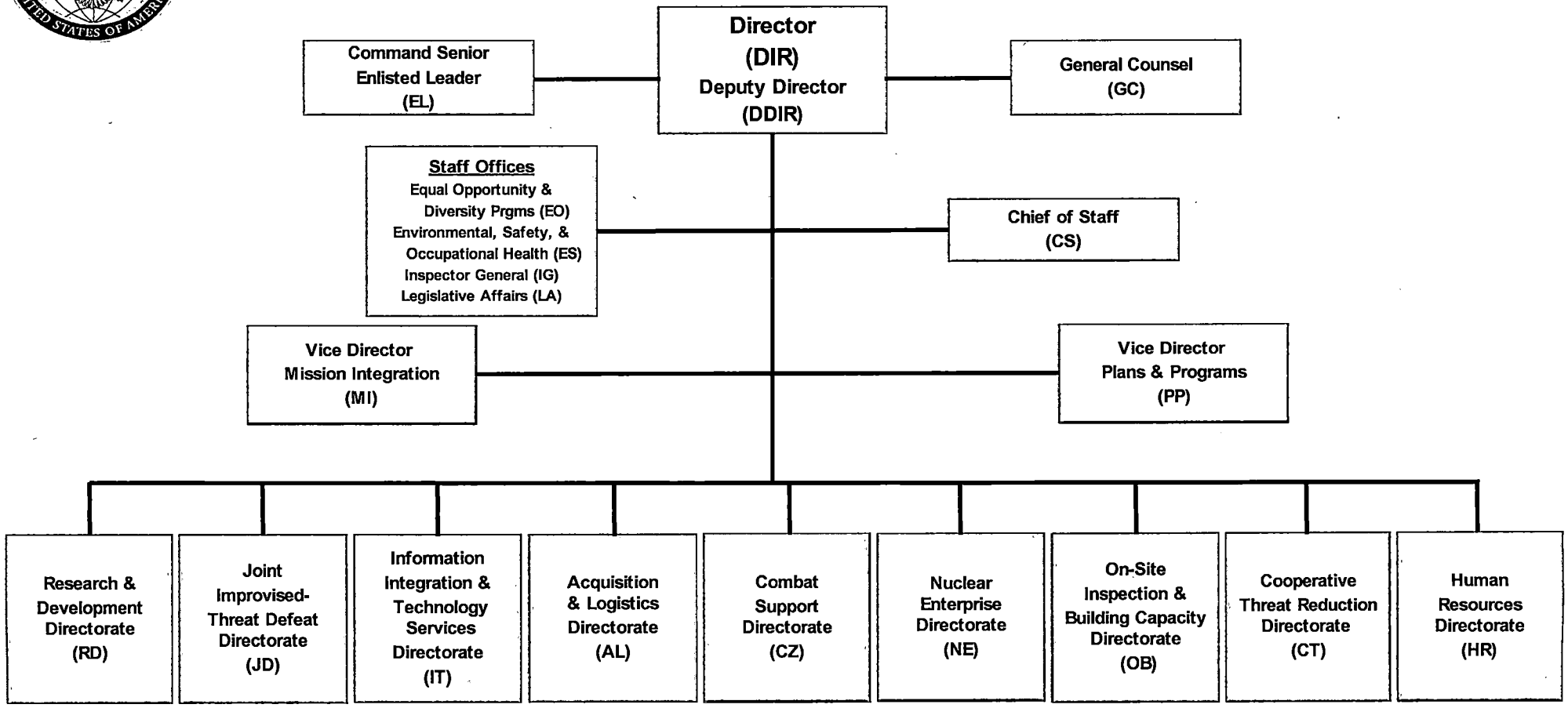
DAVIS.SHERRY.J.1105036910 Digitally signed by DAVIS.SHERRY.J.1105036910 Date: 2019.04.22 09:24:08 -04'00'

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

Enclosures:
DTRA Instruction 4540.01, Quality Assurance Program for Shipping Special Nuclear Material (QAP SNM)
DTRA Organizational Chart

cc:
Jeremy Tapp

Organizational Structure



CAO: 7 December 2018

DTRA INSTRUCTION 4540.01

QUALITY ASSURANCE PROGRAM FOR SHIPPING SPECIAL NUCLEAR MATERIAL (QAP SNM)

Originating Component:	ES
Effective:	April 18, 2019
Releasability:	Cleared for public release. Available on the DTRA*1* Portal issuances library at https://dtra1/j0cs/IssuanceLib/Pages/iLib.aspx.
Incorporates and Cancels:	DTRA Memorandum, "Quality Assurance Program for Packaging and Transportation of Fissile Material," July 29, 2015
Approved by:	Kyle M. Lampela, Chief of Staff

Purpose: This issuance reissues the July 29, 2015 Defense Threat Reduction Agency (DTRA) Memorandum to:

- Establish the DTRA QAP SNM in accordance with the requirements contained in Part 71 of Title 10, Code of Federal Regulations (CFR).
- Establish policy and responsibilities in accordance with all references included in the reference list of this issuance (see last page).

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FIGURES

SECTION 1: GENERAL ISSUANCE INFORMATION

1.1. APPLICABILITY. This instruction applies to all entities of DTRA shipping or receiving licensed Special Nuclear Materials (SNMs) and takes precedence over all related internal standard operating procedures (SOPs) or guidance.

1.2. POLICY. It is DTRA policy that:

a. DTRA will establish implementing instructions that will ensure compliance with statutory and departmental guidance. The QAP is applicable to the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety for the use in the transportation of SNM.

b. Compliance with the requirements and procedures established is mandatory. Failure to ship or receive SNM per the procedures or requirements established herein may result in disqualification as a certified shipper and Authorized User (AU) of radioactive material (RAM).

SECTION 2: RESPONSIBILITIES

2.1. DIRECTOR (DIR). The DIR is responsible for the safe handling, use, and shipping of licensed RAM at DTRA.

2.2. DIRECTOR, ENVIRONMENTAL, SAFETY, AND OCCUPATIONAL HEALTH (ES). As the senior management representative for DTRA, the ES will maintain a continuing involvement to ensure that the QAP is effective. The ES:

a. Establishes and executes the QAP. This includes approval of all changes to the program.

b. Establishes the policy and procedures to perform work on items important to quality and safety per the requirements of Subpart H, Part 71 of Title 10, CFR and implements the QAP SNM.

c. Approves resumptions of operations resulting from a health or safety termination.

2.3. QUALITY ASSURANCE PROGRAM MANAGER (QAPM). The QAPM reports to the Director, ES for all matters pertaining to the QAP. The QAPM:

a. Ensures radiological safety, security, and compliance with the U.S. Nuclear Regulatory Commission (NRC), U.S. Department of Transportation (DOT), and U.S. Department of Defense (DoD) regulations and the conditions of the QAP.

b. Implements the provisions of the QAP.

c. Reviews proposed revisions to the QAP and forwards to the ES for approval, if appropriate.

d. Ensures all individuals involved in the QAP receive appropriate initial and refresher training. The required training will include didactic and on-the-job training as appropriate. The QAPM will specify the indoctrination, training, and qualification programs necessary for performing those activities.

e. Assesses the scope, status, implementation, and effectiveness of the QAP. This includes:

(1) Assigning at least one qualified Lead Auditor to each QAP audit. Assigning additional auditors as necessary to audit the QAP.

(2) Ensuring the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for at least 3 years from the date of the audit) and provided to management for review. Ensuring prompt action is taken to correct deficiencies.

(3) Reviewing and approving all actions taken to correct deficiencies identified during internal or external inspections or audits.

(4) Communicating audit results and corrective actions to all individuals participating in QAP operations.

(5) Establishing measures to control the release of documents (e.g., instructions, procedures, and drawings) which prescribe all activities affecting quality. These measures must assure that QA documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, distributed, and used at the location(s) where prescribed activities are performed.

(6) Immediately terminating operations that may cause an unsafe condition or an activity found to be a threat to public health and safety or property. The QAPM will recommend, and the Director, ES will approve, resumptions of operations resulting from a health or safety termination.

(7) Acting as liaison with the NRC and other regulatory authorities on all matters associated with the QAP.

SECTION 3: QAP FRAMEWORK

3.1. QUALITY ASSURANCE (QA) REQUIREMENTS (REFERENCE (REF): 10 CFR 71.101).

a. As stated in Subpart H, Part 71 of Title 10, CFR, the QAP is applicable to the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety for the use in the transportation of SNM. This document will be filed with the NRC, Office of Nuclear Material Safety and Safeguards (NMSS) and will be established, maintained, and executed in a manner that satisfies applicable regulatory requirements.

b. QA comprises all of those planned and systematic actions necessary to provide adequate confidence that a system or component will perform as designed. QA includes QC, which includes those actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

c. Each of the applicable criteria given in Subpart H, Part 71 of Title 10, CFR and any specific provisions that are applicable to activities conducted by DTRA, including procurement of packaging, are established, maintained, and executed according to the QAP. Applicable criteria will be applied in a graded approach, i.e. to an extent that is consistent with its importance to safety. SNM shipments will be prepared, shipped and received using written guidance (procedures, instructions, checklists, etc.) by properly trained personnel. DTRA has developed and implemented lower-level (internal, working-level) documents to govern the conduct of QA activities that are important to safety based on the applicable NRC regulations and the approved QAP.

d. DTRA places the following limitations on this program:

(1) DTRA is not permitted to design, fabricate, assemble, or test packages under this QAP.

(2) Appendix B, Part 50 of Title 10, CFR is not applicable to DTRA.

(3) Materials shipped by DTRA per Subpart 71.22 of Title 10, CFR are "sealed sources" and the fissile material cannot be readily separated from the structure of the source.

(4) DTRA does not own or directly use radiographic exposure devices regulated under Part 34 of Title 10, CFR. DTRA will obtain the appropriate license if it becomes necessary for DTRA to conduct gamma radiography operations.

3.2. QUALITY ASSURANCE ORGANIZATION (REF: 10 CFR 71.103).

a. ES is responsible for the establishment and execution of the QAP. The Director, ES may delegate QAP duties to others, such as employees, contractors, or consultants, but the Director, ES retains responsibility for the program. All individuals engaged in activities associated with

the QAP are authorized to halt operations for conditions adverse to quality or safety, or a threat to public health, safety, or property.

b. An organization shipping RAM under an NRC QAP requires two independent individuals or groups of individuals to achieve safe, reliable, and efficient shipment, receipt, management, and use of RAM.

(1) Quality Control Technician (QCT). The first of these individuals or group of individuals, the QCT, performs the QC functions. QC functions are comprised of actions related to controlling the physical characteristics and quality of the materials or components per predetermined requirements.

(2) Quality Assurance Inspector (QAI). The second of these individuals or group of individuals, the QAI, provides the QA functions. The responsibility of this group is to verify the QA actions are completed in conformance with established requirements.

c. ES has been specifically tasked and has the authority to perform these safety related inspections and audits as a separate entity. Figure 1 is DTRA's QAP organizational chart. The latest DTRA organizational chart can be found on the DTRA*1* website at https://dtra1/DTRA1_Organizational_Chart_Home/default.aspx.

Figure 1. DTRA QAP Organizational Chart

DTRA Quality Assurance Program	
Director, DTRA (DIR)	Responsible for the safe handling, use and shipping of licensed RAM at DTRA.
Director, Environmental, Safety, & Occupational Health (ES)	Responsible for the establishment and execution of the quality assurance program.
ES Staff	Responsible for execution and oversight of the QAP.

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ES Health Physics Staff	
Quality Assurance Program Manager (QAPM)	Responsible for radiological safety, security, and compliance with NRC, DOT, and DoD regulations and the conditions of the QAP.
Lead Auditor	Responsible for organizing, scheduling, and conducting QAP audits as directed.

↓

Nuclear Enterprise (NE)			
AU	Responsible for providing supervision during the shipping process	QAI	Responsible for conducting quality assurance inspections
QCT	Responsible for performing quality control functions		

Research & Development (RD)			
AU	Responsible for providing supervision during the shipping process	QAI	Responsible for conducting quality assurance inspections
QCT	Responsible for performing quality control functions		

3.3. QUALITY ASSURANCE PROGRAM (REF: 10 CFR 71.105). The scope of the DTRA QAP will be limited to using a general license solely for transportation of SNM in packages purchased or leased for that purpose. The QAP will address the QA organization and program, corrective actions, QA records, audits, and the regulations governing procurement, shipment, and handling.

a. Safety control will be commensurate with the radioactivity and the form of the material being shipped.

b. This QAP is established, maintained, and executed by the Director, ES as required by Subpart H, Part 71 of Title 10, CFR, DTRA Policy, and NRC Material License.

c. Shipment of any fissile material in Type A packaging will be performed per approved procedures and guidance written to meet requirements in applicable federal and State regulations (e.g., Parts 20, 30, and 70 of Title 10, CFR; Title 49, CFR). The DTRA QAP establishes measures to ensure that the:

(1) ES and the QAPM establish, review and approve detailed procedures and technical requirements necessary to ensure quality.

(2) Indoctrination, training, and qualification (as appropriate) will be required for personnel performing those activities important to safety. The QAPM will specify the indoctrination, training, and qualification programs necessary for performing those activities.

(3) Activities affecting quality or safety are accomplished under controlled conditions and include the use of appropriate equipment, suitable environmental conditions (such as adequate cleanliness), and assurance that all prerequisites have been satisfied. Special controls, processes, test equipment, tools, and skills will be taken into account to attain the required quality. This requirement is met by the preparation, review, and approval of and adherence to the QAP and support documents (such as procedures, instructions, and checklists).

(4) Procedures and instructions describe all activities important to safety, procurement, use of packaging, and shipment. The procedures and instructions will be in place before implementing the QAP. Figure 2 below provides a matrix of the QA procedures that implement each section of Subpart H, Part 71 of Title 10, CFR.

Figure 2. DTRA QAP Implementation of Title 10 CFR Part 71

Implementing Document	Regulatory Position per NRC Regulatory Guide (RG) 7.10 with 10 CFR Part 71 Reference	Description
RMS QAP, Para. 3.1	RG 7.10, Sec. B 10 CFR 71.101	Quality Assurance Requirements
RMS QAP, Para. 3.2	RG 7.10, Sec. C, Para. 1 10 CFR 71.103	Quality Assurance Organization
RMS QAP, Para. 3.3	RG 7.10, Sec. C, Para. 2 10 CFR 71.105	Quality Assurance Program
RMS QAP, Para. 3.4	RG 7.10, Sec. B 10 CFR 71.106	Changes to the Quality Assurance Program
RMS QAP, Para. 4.1	RG 7.10, Sec. C, Para. 3 10 CFR 71.107	Package Design Control
RMS QAP, Para. 5.2.a	RG 7.10, Sec. C, Para. 4 10 CFR 71.109	Procurement Document Control
RMS QAP, Para. 5.2.b	RG 7.10, Sec. C, Para. 5 10 CFR 71.111	Instructions, Procedures, and Drawings
RMS QAP, Para. 5.2.c	RG 7.10, Sec. C, Para. 6 10 CFR 71.113	Document Control
RMS QAP, Para. 4.2	RG 7.10, Sec. C, Para. 7 10 CFR 71.115	Control of Purchased Material, Equipment, and Services
RMS QAP, Para. 4.3	RG 7.10, Sec. C, Para. 8 10 CFR 71.117	Identification and Control of Materials, Parts, and Components
RMS QAP, Para. 4.4	RG 7.10, Sec. C, Para. 9 10 CFR 71.119	Control of Special Processes
RMS QAP, Para. 5.3	RG 7.10, Sec. C, Para. 10 10 CFR 71.121	Internal Inspection
RMS QAP, Para. 4.5	RG 7.10, Sec. C, Para. 11 10 CFR 71.123	Test Control
RMS QAP, Para. 4.6	RG 7.10, Sec. C, Para. 12 10 CFR 71.125	Control of Measuring and Test Equipment
RMS QAP, Para. 4.7.a	RG 7.10, Sec. C, Para. 13 10 CFR 71.127	Handling, Storage, and Shipping Control
RMS QAP, Para. 4.7.b	RG 7.10, Sec. C, Para. 14 10 CFR 71.129	Inspection, Test, and Operating Status
RMS QAP, Para. 4.7.c	RG 7.10, Sec. C, Para. 15 10 CFR 71.131	Nonconforming Materials, Parts, or Components
RMS QAP, Para. 4.7.d	RG 7.10, Sec. C, Para. 16 10 CFR 71.133	Corrective Action
RMS QAP, Para. 5.1	RG 7.10, Sec. C, Para. 17 10 CFR 71.135	Quality Assurance Records
RMS QAP, Para. 5.4	RG 7.10, Sec. C, Para. 18 10 CFR 71.137	Audits

3.4. CHANGES TO THE QAP (REF: 10 CFR 71.106). Per Subpart 71.1(a) of Title 10, CFR, any proposed change(s) that will reduce commitments in the QAP will be submitted to the NRC for review and receive approval prior to implementation.

a. The following information will be submitted for changes that reduce commitments made to the approved QAP:

(1) A description of the proposed changes to the QAP.

(2) The reason for the change.

(3) The basis for concluding that the revised program incorporating the change continues to satisfy the requirements of Subpart H, Part 71 of Title 10, CFR.

b. Administrative changes (e.g., revisions to format, font size or style, paper size for drawings and graphics, or revised paper color) and clarifications, spelling corrections, and non-substantive editorial or punctuation changes will not require NRC approval.

c. Changes to reporting responsibilities, functional responsibilities, and functional relationships may be substantive and have the potential to reduce commitments made to the NRC and, in these instances, would require prior NRC approval before being implemented. Subpart 71.106(b) of Title 10, CFR lists changes that are not considered to reduce commitments made to the NRC.

d. All changes made to the approved QAP must be reported to the NRC every 24 months. If no changes have been made during the preceding 24-month period, then the Director, ES will notify the NRC that no changes have been made to the QAP. A record of all QAP changes will be retained for three years beyond the date DTRA last engaged in the activity for which the QAP was developed.

SECTION 4: QAP CONTROLS

4.1. PACKAGE DESIGN CONTROL (REF: 10 CFR 71.107). DTRA is not permitted to design, fabricate, assemble, or test packages under this QAP. As such, DTRA will not establish measures for the adequate commitment to control of design activities.

4.2. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES (REF: 10 CFR 71.115). 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.

4.3. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS (REF: 10 CFR 71.117). DTRA is not permitted to design, fabricate, assemble, or test packages under this QAP. As such, DTRA will not establish measures for the identification and control of materials, parts, and components.

4.4. CONTROL OF SPECIAL PROCESSES (REF: 10 CFR 71.119). DTRA is not permitted to design, fabricate, assemble, or test packages under this QAP. The user of packaging does not normally perform special processes. As such, DTRA will not establish measures to control special processes (such as welding or heat-treating) or nondestructive testing.

4.5. TEST CONTROL (REF: 10 CFR 71.123). DTRA is not permitted to design, fabricate, assemble, or test packages under this QAP. As such, DTRA will not establish a test control program.

4.6. CONTROL OF MEASURING AND TEST EQUIPMENT (REF: 10 CFR 71.125). DTRA has established processes to assure that tools, gauges, instruments, and other measuring and testing devices used in QA procedures are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits.

a. Selection of precision measuring devices such as gauges, meters, and torque wrenches will be based on the type, range, accuracy, and tolerance needed to determine conformance to specified requirements.

b. DTRA will use applicable national or international consensus standards, as appropriate, to determine the periodicity and procedures for measuring device calibration. DTRA will document the basis for calibration if no known recognized national or international consensus standards exist.

c. Measuring device calibration will be conducted using reference or transfer standards or test equipment traceable to nationally or internationally recognized standards.

d. Measuring devices will be clearly marked, labeled, or tagged to indicate the date of its next calibration.

e. Records of calibration will be retained for reference and review.

f. Out-of-calibration equipment will immediately be removed from use. DTRA will tag or label out-of-calibration instrumentation and place into segregated storage to prevent inadvertent use.

g. If calibrated equipment is not found to be functioning correctly (i.e. acting erratically, inconsistently, is dropped or damaged) during use, the equipment will immediately be removed from use. The QAPM will be promptly notified and will take measures to validate previous inspection and test results up to the time of previous calibration. DTRA will repair or replace any measuring equipment consistently found to be out of calibration.

4.7. PACKAGING AND MATERIAL CONTROL.

a. Handling, Storage, and Shipping Control (Ref: 10 CFR 71.127). DTRA has established procedures to ensure proper cleaning, handling, storage, and shipping are accomplished per design requirements to prevent damage or deterioration by environmental conditions such as temperature and humidity.

(1) When necessary, the QAPM will establish provisions for the use of special handling, lifting, or storage devices (e.g., cranes, shock absorbers, or special markings) to adequately identify and preserve packaging components or assemblies.

(2) DTRA has established procedures to ensure that all NRC and DOT requirements have been satisfied and all shipping papers have been prepared and reviewed by qualified personnel to verify completeness and accuracy before delivery to a carrier.

b. Inspection, Test, and Operating Status (Ref: 10 CFR 71.129). DTRA has established measures to indicate the operational status of individual items of the packaging.

(1) DTRA will designate packaging and replacement parts as "ready-for-issue" (RFI), or "not-ready-for-issue" (NRFI). RFI and NRFI material will be tagged clearly indicating their status.

(2) The DTRA QAPM will maintain an inventory of controlled material. The inventory will include the name of the material, physical description, model, serial number, storage location, and operational status.

(3) DTRA will use separate controlled (locked) storage areas for RFI and NRFI material.

(4) Material that has not completed a receipt inspection, has been identified as nonconforming, or the condition of which is otherwise unknown will be tagged as NRFI, stored in the appropriate storage area and reported to the QAPM as NRFI.

c. Nonconforming Materials, Parts, or Components (Ref: 10 CFR 71.131). DTRA has established procedures to prevent the inadvertent use or installation of materials, parts, or components that do not conform to the QAP requirements.

(1) Notify the QAPM as soon as practical after identifying that a controlled item is nonconforming.

(2) Nonconforming materials, parts, or components will be identified (tagged as NRFI), placed in the NRFI storage area, and tracked.

(3) A formal evaluation of nonconforming material will be performed to determine the disposition of the material.

(4) The QAPM will assign a qualified QA inspector in writing to perform a formal evaluation of the nonconforming material. Personnel performing evaluations to determine a disposition will have demonstrated competence in the specific area they are evaluating, an adequate understanding of the requirements, and access to pertinent background information.

(5) The results of the evaluation will include a recommended disposition, such as use-as-is, reject, repair, or rework of nonconforming items. The DTRA QAPM will determine and document the final disposition, to include the technical justification for the decision to repair or use-as-is.

(6) DTRA will return material dispositioned as "to be repaired" to the manufacturer for rework. Reexamine repaired items per the applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.

d. Corrective Action (Ref: 10 CFR 71.133). DTRA policy requires prompt identification and correction of conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformance.

(1) DTRA will conduct a root cause analysis for significant conditions adverse to quality. The root cause analysis will assure that the cause of the condition is determined and corrective action taken to preclude repetition. If appropriate, DTRA will obtain input for corrective actions from suppliers.

(2) The QAPM will document any significant condition adverse to quality, the root cause analysis, and the corrective action(s) taken. Submit a written report to the Director, ES upon completion of the corrective actions.

(3) The QAPM will verify the completion and effectiveness of corrective actions to preclude recurrence.

SECTION 5: RECORDKEEPING, INSPECTIONS, AND AUDITS

5.1. QUALITY ASSURANCE RECORDS (REF: 10 CFR 71.135).

a. Per Part 1220 of Title 36, CFR and NRC Regulatory Guide 7.10, for the purposes of this instruction, DTRA records associated with RAM shipping are defined as:

(1) Permanent Records. Records pertaining to package fabrication and those associated with a particular item while it is installed in the packaging or stored for future use. These records demonstrate the capability for safe operation; provide evidence of repair, rework, replacement, or modification; aid in determining the cause of an accident or malfunction of an item; and provide a baseline for in service inspection.

(2) Temporary Records. Records that show evidence that an activity has been performed but do not meet the criteria for permanent records. Records pertaining to use of a package should be retained for a period of 3 years after each shipment.

(a) DTRA will maintain the results of the preliminary determinations required by Subpart 71.85 of Title 10, CFR as permanent records.

(b) DTRA will retain records to demonstrate that packages offered for shipment to a carrier satisfy all NRC and DOT requirements as temporary records. Inspection records will contain a description of the observation, evidence of completion of the inspection, results of inspections with appropriate data, conditions detrimental to quality, names of inspectors, and evidence of acceptability.

(c) When necessary to change the QAP, DTRA will retain copies of those portions of the QAP, written procedures, or instructions for 3 years after the change.

b. To ensure QAP documents are retrievable, legible, understandable, and reliable, they will be stored electronically on the DTRA's Radiation Safety SharePoint system. The Radiation Safety File Manager (RSFM) will control QAP document access as directed by the QAPM.

(1) QAP records will be stored on the Radiation Safety SharePoint to avoid unnecessary access delays.

(2) All QAP documents will be digitized and forwarded to the RSFM and the QAPM immediately upon completion of the operation generating the record.

(3) The RSFM will provide a digital receipt for electronically transferred QAP documents.

c. DTRA electronic storage system configuration is standardized and centrally controlled. The Radiation Safety SharePoint system complies with the current DoD security and configuration control requirements. The system is redundant, reliable and uses token and password authentication for access control. The RSFM controls the number of personnel who

have authorized access to QAP records and will control privileges, such as "read only" or "read and add only."

5.2. QAP DOCUMENT MANAGEMENT. DTRA has established a document management program to allow for the retention, retrieval, revision, and review of all documentation associated with the QAP.

a. Procurement Document Control (Ref: 10 CFR 71.109). The QAP establishes measures to control the preparation, review, concurrence, and approval of all procurement documents.

(1) Per this QAP, DTRA may not design, fabricate, assemble, or test packaging. DTRA will, prior to procurement, establish the design-basis technical requirements (or references thereto), including applicable regulatory requirements, specifications, codes and standards, and inspection requirements for the packaging.

(2) DTRA will only procure packaging for fissile materials that meets NRC regulatory requirements; and, when applicable, from vendors approved by the NRC to design, fabricate, assemble, and test such packaging.

(3) 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.

(4) The DTRA QAPM will review and approve all procurement requests, including for replacement parts, prior to releasing the request to any supplier(s). The review, revision (if applicable), and approval of procurement documentation will be recorded and retained.

b. Instructions, Procedures, and Drawings (Ref: 10 CFR 71.111). Activities affecting quality or safety will be conducted using instructions, procedures, and drawings in approved SOPs.

(1) Prior to use, the DTRA QAPM will review and approve all SOPs affecting quality or safety, including any proposed revisions to SOPs.

(2) Activities affecting quality or safety will be coordinated with QAPM to ensure that the SOPs are up-to-date and incorporate appropriate inspection and hold points.

(3) To assure satisfactory accomplishment of all QA activities, the SOPs will include appropriate quantitative or qualitative acceptance criteria.

(4) The SOPs will be followed whenever QA activities are conducted to ensure compliance with all applicable sections of Subpart H, Part 71 of Title 10, CFR.

(5) DTRA has established measures to ensure that the QAPM reviews and concurs with all procurement documentation, inspection plans, specifications, calibration, and completed QA documentation.

c. Document Control (Ref: 10 CFR 71.113). DTRA has established procedures to control the issuance of documents such as design documents (e.g., drawings, specifications, and computer codes), procurement documents, QA and QC manuals, operating, maintenance, and modification procedures, inspection and test procedures, nonconformance reports, design change requests, and corrective action reports.

(1) DTRA will control QA documentation using a Master Document List (MDL). The DTRA QAPM is responsible for keeping the MDL current.

(2) Only the most current version of the MDL will be available for use. Upon issue of an update to the MDL, the DTRA QAPM will remove all previous revisions of the MDL from circulation. Retain a record copy of each revision of the MDL for 3 years beyond the date DTRA last engaged in the activity for which the QAP was developed.

(3) DTRA has established procedures to assure that QAPM reviews, approves, and releases all QA documents, including changes, for distribution.

(4) The QAPM will assign a revision number to each document upon completion of document review and approval.

(5) The MDL will identify the approved revision of each QA document. Only the authorized revision will be listed on the MDL for use during QA activities.

(6) QAP documents will be stored on the DTRA's Radiation Safety SharePoint system. The RSFM will control QAP document access as directed by the QAPM.

5.3. INTERNAL INSPECTION (REF: 10 CFR 71.121). DTRA has established a program for inspection of activities affecting quality that will verify conformance with the documented instructions, procedures, and drawings. Individuals independent of those performing the QC activity will perform the inspections. Inspections will be performed for each operation necessary to assure quality. Work may not proceed beyond mandatory inspection hold points without written consent of the QAPM.

a. DTRA has established procedures for conducting initial receipt, in-use package, and post maintenance inspections. The inspection procedures will:

(1) Be conducted by qualified inspectors to ensure that all inspection requirements have been satisfied.

(2) Include the prerequisites to be completed before the inspections are conducted.

(3) Be available for each work operation necessary to ensure quality.

(4) Include the methods for the identifying characteristics and activities to be inspected, and the acceptance and rejection criteria. The inspection procedures will establish the criteria for acceptance, as well as the action to be taken, if noncompliance is encountered.

(5) Include sign-offs at critical points to document completion of required inspections.

b. Initial receipt inspections will ensure items important to safety meet the requirements specified on the purchase order when received from the manufacturer.

(1) The inspections will include an examination of features such as the surface conditions, weld and structural integrity, the condition of flange faces or sealing areas, gaskets, seals, gauges, rupture disks, valves, and pressure relief devices, the condition of tie-down members, labeling and marking, and leak-tightness of the packaging as appropriate.

(2) Packaging and replacement parts will be controlled per local procedures until they are placed in stock or released for use. QA procedures will provide instructions for the proper disposition of rejected items.

c. In-use package inspection procedures will:

(1) Include the prerequisites to be completed before the inspections are conducted.

(2) Follow the manufacturer's recommended procedures.

(3) Require inspections during assembly are conducted and documented as appropriate.

(4) Ensure packages are properly assembled.

(5) Ensure moderators and neutron absorbers are present (if applicable).

(6) Ensure packages are conspicuously and durably marked as required by the regulations set forth by the DOT.

(7) Ensure all shipping papers are properly completed.

d. Post maintenance inspections will be conducted to ensure adequate maintenance of packaging. This inspection procedure identifies the items to be maintained, criteria for acceptability or replacement, and the frequencies of inspection assigned to each item.

5.4. AUDITS (REF: 10 CFR 71.137). DTRA has established a comprehensive system of planned and periodic audits to verify compliance with all aspects of the QAP and to determine the effectiveness of the program. The Director, ES has committed to the development of a robust QAP audit program that has organizational independence and the necessary staffing and funding to achieve excellence.

a. The QAPM will maintain a list of the activities important to safety. These areas are audited at a frequency based on each activity's importance to safety. Each activity is audited at least annually.

b. The QAPM will establish the audit schedule. The schedules will ensure all activities important to safety receive priority consideration.

c. Program Management will perform an independent annual audit designed to assess the overall effectiveness and implementation of the QAP.

d. Personnel conducting program audits will complete training and qualifications commensurate with their assigned duties. The QAPM will establish and administer the training and qualification program.

e. Personnel assigned to conduct QAP audits will have reasonable and timely access to facilities, documents, and qualified personnel necessary for performing audits. Audit teams will have access to all levels of management of the organization responsible for the area audited.

f. Prior to the audit, the Lead Auditor will specify the nature and scope the audit to the management of the organization having responsibility in the area being audited.

g. Audits will be conducted using approved procedures and checklists by appropriately trained personnel. Personnel performing audits will not have direct responsibilities in the areas being audited or rated by personnel that have direct responsibility for areas being audited.

h. The Lead Auditor will conduct a post-audit conference with the management of the organization having responsibility in the area audited to present the results and clarify any questions that may arise.

i. The Lead Auditor will submit a formal report within 30 days of completing a QAP audit to the Director, ES; QAPM; and management of the organization having responsibility in the area audited.

j. Management having responsibility in the area audited will review the audit report, determine corrective actions if necessary, and promptly inform the QAPM of the corrective actions taken and their effectiveness.

(1) Management of the organization responsible for the area audited will report the corrective actions taken to prevent recurrence of non-conformances to the QAPM.

(2) Within 30 days of the audit report being issued, management for the responsible organization will report corrective actions taken, in writing, to the QAPM.

(3) For corrective actions that cannot be taken immediately, the audit response will include scheduled dates for initiation and completion of the corrective action.

k. The QAPM will schedule follow-up actions, including re-audits to verify that the corrective actions are effective and complete. Auditors verifying corrective actions will have access to all levels of management with authority for corrective action in the area audited.

GLOSSARY

G.1. ACRONYMS.

AU	Authorized User
CFR	Code of Federal Regulations
DIR	Director
DoD	Department of Defense
DOT	Department of Transportation
DTRA	Defense Threat Reduction Agency
ES	Director, Environmental, Safety, and Occupational Health Office
MDL	Master Document List
NE	Director, Nuclear Enterprise
NMSS	Nuclear Material Safety and Safeguards
NRC	Nuclear Regulatory Commission
NRFI	not-ready-for-issue
QA	Quality Assurance
QAI	Quality Assurance Inspector
QAP	Quality Assurance Program
QAPM	Quality Assurance Program Manager
QCT	Quality Control Technician
QC	Quality Control
RAM	radioactive materials
RD	Research and Development Directorate
REF	Reference
RFI	ready-for-issue
RG	NRC Regulatory Guide
RSFM	Radiation Safety File Manager
SNM	Special Nuclear Material
SOP	standard operating procedure

G.2. DEFINITIONS (REF: 10 CFR 71.1). The following definitions are provided to assure a uniform understanding of select terms as they are used in this instruction.

acceptance criteria. Specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

audit. A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

audit, external. An audit of those portions of another organization's QAP not under the direct control or within the organizational structure of the auditing organization.

audit, internal. An audit of those portions of an organization's QAP retained under its direct control and within its organizational structure.

characteristic. Any property or attribute of an item, process, or service that is distinct, desirable, and measurable.

condition adverse to quality. An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and non-conformances. A significant condition adverse to quality is one that, if uncorrected, could have a serious effect on safety or operability.

configuration. The physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing facility.

corrective action. Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

deviation. A departure from specified requirements.

document. Any written, pictorial, or electronic information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a quality assurance record until it satisfies the definition of a quality assurance record as defined in this instruction.

document control. The act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.

graded approach. The process employed, once the applicability of the requirement to the scope of the organization's activity has been determined, to ensure that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with the following:

- The relative importance to nuclear safety.
- The magnitude of any hazard involved.
- The life-cycle stage of a facility or item.
- The mission of a facility.

- The particular characteristics of a facility or item.
- The relative importance to radiological and non-radiological hazards.
- Any other relevant factors.

guidance. A suggested practice that is not mandatory in programs intended to comply with this instruction. The word should denotes guidance, the word will denotes a requirement, and the word may denotes permission.

inspection. Examination or measurement to verify whether an item or activity conforms to specified requirements.

inspector. A person who performs inspection activities to verify conformance to specific requirements.

item. An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

may. See Guidance.

nonconformance. A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

objective evidence. Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity based on observations, measurements, or tests that can be verified.

procedure. A document that specifies or describes how an activity is to be performed.

procurement document. Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

purchaser. The organization responsible for establishment of procurement requirements and for issuance or administration, or both, of procurement documents.

QA. All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

QA record. A completed document that furnishes evidence of the quality of items and/or activities affecting quality. Types of record media may include paper, electronic (e.g., magnetic or optical), or specially processed media, such as radiographs, photographs, negatives, and microforms. The term record, as used throughout the instruction, is to be interpreted as QA record.

qualification, personnel. The characteristics or abilities gained through education, training, or experience as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

receiving. Taking delivery of an item at a designated location.

repair. The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.

rework. The process by which an item is made to conform to original requirements by completion or correction.

service. The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

should. See Guidance.

special process. A process the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

supplier. Any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub tier levels.

surveillance. The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

testing. An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

use-as-is. A disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use.

verification. The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

REFERENCES

Code of Federal Regulations, Title 10, Part 71

Code of Federal Regulations, Title 36, Part 1220

Code of Federal Regulations, Title 49

DTRA Radiation Safety Program Guide, September 14, 2015

U.S. Nuclear Regulatory Committee Regulatory Guide 7.10., "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material," June 2015, Revision 3