



Department of Energy

Washington, DC 20585

JUL 28 2010

MEMORANDUM FOR DISTRIBUTION

FROM:

FRANK MARCINOWSKI
HEADQUARTERS CERTIFYING OFFICIAL
DEPUTY ASSISTANT SECRETARY FOR
TECHNICAL AND REGULATORY SUPPORT

A handwritten signature in black ink, appearing to read "Frank Marcinowski", with the word "for" written below it.

SUBJECT:

Quality Assurance Program Approval Requirements

On May 14, 2010, the Deputy Secretary approved a revised Order, Department of Energy (DOE) O 460.1C, *Packaging and Transportation Safety*. In that Order subparagraph 4.a.(3), *Quality Assurance (QA)*, directs that each entity that participates in the design, fabrication, procurement, use, or maintenance of a hazardous materials packaging must have a QA Program approved and audited by the Headquarters Certifying Official (HCO) that satisfies the requirements of 10 CFR Part 71, Subpart H, QA, for certified Type B and fissile radioactive materials packagings. The Contractors Requirements Document (CRD) in paragraph 6 of the Order imposes the same requirement on DOE contractors. This requirement is a change from the previous Order, which assigned the responsibility for approval and audit to the Heads of Operations Offices or Field Offices/Site Office Managers for the many of the packaging QA Program requirements.

As a result, the DOE Packaging Certification Program (PCP) within the Environmental Management Office of Packaging and Transportation (EM-45) has developed a process for meeting its responsibilities under the Order as well as ensuring that entities subject to the Order and CRD can continue to operate effectively and efficiently. The process includes the completion of the attached compliance matrix per the instructions provided. The completed matrix and supporting documentation must be mailed to the DOE PCP Manager, Dr. James Shuler, by October 1, 2010.

The QA Program requirements have not changed under DOE O 460.1C. Therefore, DOE contractors performing applicable activities under the Order are expected to already have QA Programs in place that meet the requirements of Subpart H. As a result, DOE sites will be considered in compliance with the Order and may continue to operate under existing QA Programs as long as they submit the required matrix by the requested due date. Sites and contractors who submit the matrix may continue to use their existing QA Programs subject to review, approval and audit by the PCP. Sites and contractors who do not submit a matrix by the due date will not be in compliance with the Order, and will not conduct any activities requiring a QA Program for certified Type B and fissile radioactive materials packagings.



Also, please ensure each entity that offers for transportation or transports radioactive material in a Type B or fissile material packaging certified by the HCO or the U.S. Nuclear Regulatory Commission has registered in writing with the HCO. The user registration list is maintained on the DOE Radioactive Material Packaging (RAMPAC) website (www.rampac.energy.gov).

If you have any questions, please contact Mr. Stephen O'Connor, Director, Office of Packaging and Transportation, at (301) 903-7854 or Dr. James Shuler, PCP Manager, at (301) 903-5513.

Attachment

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DOE Packaging Quality Assurance Program Compliance Matrix

Background

In January 2010, the Department of Energy (DOE) Packaging Certification Program (PCP) staff developed DOE/EM/PCP/QA-2010-1, *Quality Assurance Guidance for Packaging of Radioactive and Fissile Materials* to provide DOE and DOE Contractors with a consistent, systematic approach for implementing the 10 CFR Part 71, Subpart H, *Quality Assurance* requirements. This document provides guidance on the criteria used by the PCP in reviewing and approving quality assurance (QA) Programs. The Guide is available online at <http://rampac.energy.gov/PBoK.htm#DOE>

The purpose of the following compliance matrix is to identify and provide documentation that implements the requirements of 10 CFR Part 71, Subpart H. The Subpart H requirements are applicable to DOE and DOE Contractors participating in the design, fabrication, procurement, use or maintenance of NRC or DOE certified Type B and fissile radioactive materials packaging.

Instructions

1. Column 1 – Subpart H, requirement section reference
2. Column 2 – Subpart H, requirement section title
3. Column 3 – Does this section of Subpart H apply to the QA Program (e.g., Section 71.107, *Design Controls*, would not necessarily apply to a user only)?
4. Column 4 – Applicable section, criterion, and page reference from DOE/EM/PCP/QA-2010-1, *Quality Assurance Guidance for Packaging of Radioactive and Fissile Materials*

Refer to the Section, Criterion, and page reference in the Guide to identify the requirements and applicability of your participation (e.g., design, fabrication, procurement, use, or maintenance).

5. Column 5 - Implementing Documents (i.e., Plans, Manuals and/or Procedures)

Provide a listing of reference documents that are used to implement the applicable QA requirements.

DOE Element (e.g., site office, field office, etc.) or DOE Contractor responsible for radioactive material packaging safety should provide the completed matrix in a transmittal letter along with any reference documents on a CD/DVD using portable document format (PDF) files. The transmittal letter should include relevant activities for Type B and fissile material packaging (e.g., design, fabrication, procurement, testing, use, maintenance, and/or repair) that apply to DOE element or DOE contractor's packaging responsibilities. The letter and other information should be mailed to:

Dr. James Shuler
US Department of Energy
Office of Packaging and Transportation
EM-45, CLOV-2047
1000 Independence Avenue SW
Washington, DC 20585

DOE Packaging Quality Assurance Program Compliance Matrix

10CFR71 Subpart H Section	Title	Applicable Section (Y or N)	DOE/EM/PCP/QA-2010-1 QA Guidance (Ref - Section/Criterion/Page#)	Implementing Documents (i.e., Plans, Manuals and/or Procedures)
71.103	Quality Assurance Organization		Section 2.1. Criterion I: Quality Assurance Organization, page 13	
71.105	Quality Assurance Program		Section 2.2. Criterion II: Quality Assurance Program, page 18	
71.107	Package Design Control		Section 2.3. Criterion III: Package Design Control, page 22	
71.109	Procurement Document Control		Section 2.4. Criterion IV: Procurement Document Control, page 27	
71.111	Instructions, Procedures, and Drawings		Section 2.5. Criterion V: Instructions, Procedures, & Drawings, page 30	
71.113	Document Control		Section 2.6. Criterion VI: Document Control, page 33	
71.115	Control of Purchased Material, Equipment, and Services		Section 2.7. Criterion VII: Control of Purchased Material, Equipment, & Services, page 36	
71.117	Identification and Control Materials, Parts, and Components		Section 2.8. Criterion VIII: Identification & Control of Materials, Parts, & Components, page 40	
71.119	Control of Special Processes		Section 2.9. Criterion IX: Control of Special Processes, page 41	
71.121	Internal Inspection		Section 2.10. Criterion X: Internal Inspection, page 44	

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71.123	Test Control		Section 2.11. Criterion XI: Test Control, page 48	
71.125	Control of Measuring and Test Equipment		Section 2.12. Criterion XII: Control of Measuring & Test Equipment, page 51	
71.127	Handling, Storage, and Shipping Control		Section 2.13. Criterion XIII: Handling, Storage, & Shipping Control, page 53	
71.129	Inspection, Test, and Operating Status		Section 2.14. Criterion XIV: Inspection, Test, & Operating Status, page 56	
71.131	Nonconforming Materials, Parts, or Components		Section 2.15. Criterion XV: Nonconforming Materials, Parts, or Components, page 58	
71.133	Corrective Action		Section 2.16. Criterion XVI: Corrective Action, page 60	
71.135	Quality Assurance Records		Section 2.17. Criterion XVII: Quality Assurance Records, page 62	
71.137	Audits		Section 2.18. Criterion XVIII: Audits, page 66	