MEMORANDUM FOR DISTRIBUTION

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

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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    Scott Wade, NS
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)?

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
<table>
<thead>
<tr>
<th>10CFR71 Subpart H Section</th>
<th>Title</th>
<th>Applicable Section (Y or N)</th>
<th>DOE/EM/PCP/QA-2010-1 QA Guidance (Ref - Section/Criterion/Page#)</th>
<th>Implementing Documents (i.e., Plans, Manuals and/or Procedures)</th>
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<tr>
<td>71.105</td>
<td>Quality Assurance Program</td>
<td>Y</td>
<td>Section 2.2. Criterion II: Quality Assurance Program, page 18</td>
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<td>71.107</td>
<td>Package Design Control</td>
<td>Y</td>
<td>Section 2.3. Criterion III: Package Design Control, page 22</td>
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<td>71.109</td>
<td>Procurement Document Control</td>
<td>Y</td>
<td>Section 2.4. Criterion IV: Procurement Document Control, page 27</td>
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<td>71.111</td>
<td>Instructions, Procedures, and Drawings</td>
<td>Y</td>
<td>Section 2.5. Criterion V: Instructions, Procedures, &amp; Drawings, page 30</td>
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<td>71.113</td>
<td>Document Control</td>
<td>Y</td>
<td>Section 2.6. Criterion VI: Document Control, page 33</td>
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<td>71.115</td>
<td>Control of Purchased Material, Equipment, and Services</td>
<td>Y</td>
<td>Section 2.7. Criterion VII: Control of Purchased Material, Equipment, &amp; Services, page 36</td>
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<td>71.117</td>
<td>Identification and Control Materials, Parts, and Components</td>
<td>Y</td>
<td>Section 2.8. Criterion VIII: Identification &amp; Control of Materials, Parts, &amp; Components, page 40</td>
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<td>71.119</td>
<td>Control of Special Processes</td>
<td>Y</td>
<td>Section 2.9. Criterion IX: Control of Special Processes, page 41</td>
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<td>71.121</td>
<td>Internal Inspection</td>
<td>Y</td>
<td>Section 2.10. Criterion X: Internal Inspection, page 44</td>
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<td>71.123</td>
<td>Test Control</td>
<td>Y</td>
<td>Section 2.11. Criterion XI: Test Control, page 48</td>
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<td>71.125</td>
<td>Control of Measuring and Test Equipment</td>
<td>N</td>
<td>Section 2.12. Criterion XII: Control of Measuring &amp; Test Equipment, page 51</td>
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<td>71.127</td>
<td>Handling, Storage, and Shipping Control</td>
<td>N</td>
<td>Section 2.13. Criterion XIII: Handling, Storage, &amp; Shipping Control, page 53</td>
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<td>71.131</td>
<td>Nonconforming Materials, Parts, or Components</td>
<td>N</td>
<td>Section 2.15. Criterion XV: Nonconforming Materials, Parts, or Components, page 58</td>
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<td>71.133</td>
<td>Corrective Action</td>
<td>N</td>
<td>Section 2.16. Criterion XVI: Corrective Action, page 60</td>
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<td>71.137</td>
<td>Audits</td>
<td>N</td>
<td>Section 2.18. Criterion XVIII: Audits, page 66</td>
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