



Department of Energy
Washington, DC 20585

April 30, 2019

MEMORANDUM FOR: JOHNNY O. MOORE
MANAGER
OAK RIDGE NATIONAL LABORATORY SITE OFFICE

FROM: JOANNE D. LORENCE 
HEADQUARTERS CERTIFYING OFFICIAL
DIRECTOR
OFFICE OF PACKAGING AND TRANSPORTATION

SUBJECT: Quality Assurance Program Approval Renewal for Type B and Fissile
Radioactive Materials Packages

Attached is Department of Energy (DOE), Quality Assurance Program (QAP) Approval Number 0012, Revision 3, for UT-Battelle, LLC (UT-Battelle), in response to your request dated October 19, 2018, as supplemented March 29 and April 25, 2019, to Dr. James M. Shuler of my staff. This approval is based on independent review by the DOE Packaging Certification Program (PCP) of the Oak Ridge National Laboratory/UT-Battelle *Packaging Quality Assurance Program Description Applicable to Type B or Fissile Packaging (PQPD)* submittal on April 25, 2019. PCP concurs that the PQPD continues to meet the compliance requirements of 10 CFR 71 Subpart H, *Quality Assurance*. Please provide PCP with the final PQPD printed from the Standards Based Management System (SBMS) that shows the effective date of implementation, for our reference.

This DOE QAP Approval satisfies DOE Order 460.1D, *Hazardous Materials Packaging and Transportation Safety*, and therefore complies with the provisions in 49 CFR 173.7(d) for the DOE to maintain packaging standards equivalent to those specified in 10 CFR Part 71.

The expiration date of DOE QAP Approval Number 0012, Revision 3, is April 30, 2024. If you wish to renew, revise, or terminate approval of QAP Approval 0012, please request this action in writing. Any revisions to the PQPD, except for spelling corrections and nonsubstantive changes to punctuation or editorial items, must be submitted and approved by the DOE PCP prior to implementation of the proposed changes. Revisions to the PQPD for spelling corrections and nonsubstantive changes to punctuation or editorial items should be submitted to PCP for reference.

If you have any questions, please contact me or Dr. Shuler at (301) 903-5513.

Attachment

cc James Barnard, SC-OSO
Angela McGee, ORNL
James M. Shuler, EM-4.24
QA Docket 2011-005



U.S. Department of Energy
 QUALITY ASSURANCE PROGRAM APPROVAL
 For Type B and Fissile Radioactive Material Packages

1. APPROVAL NUMBER
0012

REVISION
 3

Pursuant to DOE Order 460.1D, *Packaging and Transportation Safety*, subparagraph 4.a.(3), *Quality Assurance (QA)* directs that each Departmental element that participates in the use, design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of Type B or fissile materials packaging must have and maintain a quality assurance (QA) program in accordance with 10 CFR Part 71, Subpart H that is approved by the NRC or the DOE Certifying Official, prior to the performance of those operations. The Contractors Requirements Document in Attachment 1 of Paragraph 5.a. of the Order imposes the same requirement on DOE contractors. Based on the reliance on statements and representations heretofore made in Block 5 by the organization named in Block 2, the Quality Assurance Program Description identified in Block 5 is hereby approved. This approval is issued to satisfy the requirements of the Order, 49 CFR 173.7.(d), and 10 CFR 71.101. This approval is subject to all applicable rules, regulations, and orders of the U.S. Department of Energy now or hereafter in effect and to any conditions specified below.

2. ORGANIZATION NAME
 Oak Ridge National Laboratory/UT-Battelle

3. EXPIRATION DATE

April 30, 2024

STREET ADDRESS
 P.O. Box 2008

4. DOCKET NUMBER

CITY
 Oak Ridge

STATE
 TN

ZIP CODE
 37831

2011-005

5. QUALITY ASSURANCE PROGRAM DESCRIPTION, REVISION, and DATE
Packaging Quality Assurance Program Description Applicable to Type B or Fissile Packaging (PQPD), application dated 4/25/2019.

6. CONDITIONS

1. Activities conducted regarding Type B and fissile material transportation packagings are to be executed under applicable criteria of 10 CFR Part 71 Subpart H. Authorized activities include: design, procurement, fabrication, assembly, testing, modification, maintenance, repair and use of transportation packagings.
2. Records shall be maintained in accordance with the provisions of 10 CFR Part 71. Specifically:
 - a. Records of each shipment of licensed material shall be maintained for 3 years after that shipment [10 CFR 71.91(a)].
 - b. Records providing evidence of packaging quality shall be maintained for 3 years after the life of the packaging [10 CFR 71.91(d)].
 - c. Records describing activities affecting packaging quality shall be maintained for 3 years after this Quality Assurance Program Approval is terminated [10 CFR 71.135].
3. Planned and periodic audits of all aspects of the Quality Assurance Program shall be conducted in accordance with written procedures or checklists, by appropriately trained personnel not having direct responsibility in the areas being audited, in accordance with 10 CFR 71.137.
4. In addition to the requirements of Subparts G and H of 10 CFR 71, and except as specified in Section 5(d), "Conditions," of applicable Certificates of Compliance, each package must be designed, fabricated, acceptance tested, operated, and maintained in accordance with applicable Safety Analysis Report for Packaging requirements; specifically, Chapter 7, "Operating Procedures," Chapter 8, "Acceptance Tests and Maintenance Program," and Chapter 9, "Quality Assurance."

FOR THE U.S. DEPARTMENT OF ENERGY

SIGNATURE

DATE OF ISSUANCE

04/30/2019

Joanne D. Lorence
 DOE Headquarters Certifying Official
 Director, Office of Packaging and Transportation