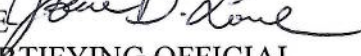


Department of Energy
Washington, DC 20585

July 3, 2018

MEMORANDUM FOR JOHN A. MULLIS
MANAGER
OAK RIDGE OFFICE OF ENVIRONMENTAL MANAGEMENT

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

SUBJECT: Approval of Isotek Quality Assurance Program Description

Attached is Department of Energy (DOE) Quality Assurance Program (QAP) Approval Number 0017, Revision 1, for Isotek Systems, (Isotek), in response to email from Steven Stone to James Shuler of my staff dated April 24, 2018, as supplemented June 5, 2018. This approval is based on independent review by the DOE Packaging Certification Program (PCP) of Isotek's *Quality Assurance Program Description for Using Type B and Fissile Radioactive Material Packages*, ISO-QAC-005, Revision 4 dated June 2018.

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 Approval Number 0017, Revision 1, is December 31, 2019. If you wish to renew, revise, or terminate approval of the QAP Approval 0017, please request this action in writing. Any revisions to the Isotek QAP Description, ISO-QAC-005, Revision 4, except for spelling corrections and nonsubstantive changes to punctuation or editorial items, shall be submitted and approved by the DOE PCP prior to implementation of the proposed changes.

This approval memorandum also serves as a reminder that the Order requires that for offsite transportation each Departmental element that uses a Type B or fissile package certified by DOE must register with the DOE Certifying Official prior to first use of the package. Refer to the following URL for registration instructions: <https://rampac.energy.gov/home/package-certification-information/guidance/doe-guidance>.

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

cc: Steven Stone, OREM
James Shuler, EM-4.24



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

1. APPROVAL
 NUMBER
0017

REVISION
 1

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
 Isotek Systems, LLC

STREET ADDRESS
 701 Scarboro Rd., Suite 301

CITY
 Oak Ridge

STATE
 TN

ZIP CODE
 37830

3. EXPIRATION DATE
 December 31, 2019

4. DOCKET NUMBER
 2011-014

5. QUALITY ASSURANCE PROGRAM DESCRIPTION, REVISION, and DATE
Quality Assurance Program Description for Using Type B and Fissile Radioactive Material Packages, ISO-QAC-005, Revision 2, May 2014, as amended by ISO-QAC-005, Revision 4, June 2018.

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

07/03/2018

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