



Department of Energy

Washington, DC 20585

December 9, 2014

MEMORANDUM FOR: SUSAN M. CANGE,
ACTING MANAGER
OAK RIDGE OFFICE

FROM: FRANK MARCINOWSKI 
HEADQUARTERS CERTIFYING OFFICIAL
DEPUTY ASSISTANT SECRETARY FOR
WASTE MANAGEMENT

SUBJECT: Approval of Isotek Quality Assurance Program Description

Attached is the Department of Energy (DOE), Quality Assurance Program Approval, Approval Number 0017, Revision 0, for Isotek Systems, LLC, in response to the memorandum from Mark Whitney dated May 12, 2014. Based on review by DOE Packaging Certification Program (PCP) staff, Isotek's *Quality Assurance Program Description for Using Type B and Fissile Radioactive Material Packages* (QAPD), ISQ-QAC-005, Revision 2, dated May 2014, satisfies the quality assurance requirements of 10 CFR 71, Subpart H, as required by DOE Order 460.1C, and therefore complies with the provisions in 49 CFR 173.7(d) for DOE to maintain packaging standards equivalent to those specified in 10 CFR Part 71.

The expiration date of Approval Number 0017 is December 31, 2019. If you wish to renew, revise, or terminate the QAPD, please request this action in writing. Any revisions to the QAPD shall be submitted and approved by DOE PCP prior to implementation of the proposed changes.

This approval memorandum also serves as a reminder that DOE Order 460.1C requires each DOE entity that offers for transportation or transports radioactive material for DOE in Type B or fissile material packaging certified by the Headquarters Certifying Official (HCO) or the U.S. Nuclear Regulatory Commission shall be registered in writing with the HCO. Refer to the following URL site for registration instructions: <http://rampac.energy.gov>

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

Attachment

cc: Dana Willaford, OR
Lawrence Gelder, SRNL
Bud Fabian, ANL
Roberta Riel, ANL





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

| |
|-----------------------------------|
| 1. APPROVAL NUMBER 0017 |
| REVISION 0 |

Pursuant to DOE Order 460.1C, *Packaging and Transportation Safety*, 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 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 in Attachment 1 of Paragraph 6 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

3. EXPIRATION DATE
December 31, 2019

STREET ADDRESS
701 Scarboro Rd.

4. DOCKET NUMBER

CITY
Oak Ridge

STATE
TN

ZIP CODE
37830

2011-014

5. QUALITY ASSURANCE PROGRAM DESCRIPTION, REVISION, and DATE
Quality Assurance Program Description for Using Type B and Fissile Radioactive Material Packages, ISQ-QAC-005, Revision 2, May 2014

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

12/9/14

Frank Marcinowski
 DOE Headquarters Certifying Official
 Deputy Assistant Secretary for Waste Management