71-0703

nordion
SCIENCE ADVANCING HEALTH

September 1, 2016

ATTN: Document Control Desk,
Director, Division of Spent Fuel Storage and Transportation,
Office of Nuclear Material Safety and Safeguards,
U.S. Nuclear Regulatory Commission,
Washington, DC
20555-0001

Re: Amendment to Nordion's QA Program Approval

Nordion currently holds a limited scope Quality Assurance Program Approval from the NRC (approval number 0703). As discussed with the NRC on June 28, 2016, Nordion will be seeking a Certificate of Compliance for the F-339 Type B transport package later this year. To support this approval, Nordion will need to broaden the scope of our QA Program Approval to include elements of design control and manufacturing.

In support of this request, I am providing information relating to the eighteen areas described in 10 CFR part 71, along with a copy of Nordion document IN/QA 0224 Z000, "Radioactive Material Transport Package Quality Plan" and a copy of the current QA Program approval. It is worth noting that the quality procedures and processes are well established and in place at Nordion. These same processes were in place prior to 2012, the last time Nordion held a full scope QA Program Approval from the NRC. They have been accepted by our local regulator, the Canadian Nuclear Safety Commission, in support of our domestic transport package approvals.

You will also find attached a copy of an affidavit to support a request to withhold Nordion document IN/QA 0224 Z000 from public disclosure. This document contain proprietary information specific to Nordion's programs that would enable a third party to register a similar program.

If you have any questions or require any further information please feel free to contact me.

Sincerely,

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Encl: IN/QA 0224 Z000, "Radioactive Material Transport Package Quality Plan"
Nordion Organizational Charts

NM5524

Limited Scope NRC QA Program Approval

Document	Title	Regulatory Position	Description
Org Charts	Organization	1	Identifies individuals involved in QA organization and relationship between functions.
IN/QA 0224 Z000 QSF-00	QA Program	2	Quality plans describe the requirements for quality in transport package programs.
IN/QA 0224 Z000	Design Control	3	Describes design control requirements for transport packages.
IN/QA 0224 Z000	Procurement Document Control	4	Includes references to procurement procedure, order requirements and control of records.
IN/QA 0224 Z000	Instructions, Procedures and Drawings	5	Detail inspection and maintenance, and shipping and handling instructions.
IN/QA 0224 Z000	Document Control	6	Lists the control requirements for quality records.
IN/QA 0224 Z000 P-002, P-310, P-322, 4808	Control of Purchased Material, Equipment and Services	7	Provides requirements for procurement including supplier qualification and reassessment.
IN/QA 0224 Z000	Identification and Control of Materials, Parts and Components	8	References identification and traceability controls for transport packages.
IN/QA 0224 Z000	Control of Special Processes	9	References Design, Manufacturing and Operating Specification for packages that include requirements for control of Special Processes
IN/QA 0224 Z000	Internal Inspection	10	Details requirements for inspection and testing of transport packages.
IN/QA 0224 Z000	Test Control	11	Details requirements for inspection and testing of transport packages.
QSF-00	Control of Measuring and Test Equipment	12	Description of calibration program.
IN/QA 0224 Z000	Handling, Storage and Shipping Control	13	Description of procedures for shipping and handling.
Description below	Inspection, Test and Operating Status	14	Description of product release process.
QSF-00	Nonconforming Materials, Parts or Components	15	Description of nonconforming materials process.
QSF-00	Corrective Action	16	Description of corrective and preventative action process.
IN/QA 0224 Z000	Quality Assurance Records	17	Description of records process specific to transport packages.
QSF-00	Audits	18	Description of audit program.

Nordion is applying for a full scope QA Program approval. In support of the table, a description of the element is provided where required.

1. Organization

   Organization charts are provided to demonstrate the Quality reporting structure at Nordion. Nordion is structured into two business units; Gamma Technologies and Medical Isotopes. Each business unit has a separate Quality group. In Gamma Technologies, the Director, QA EHS Compliance has oversight for quality programs. In Medical Isotopes it is the Vice President QA, Regulatory and EHS Compliance that has oversight for quality.

2. QA Program

   Nordion's Quality Policy states "Nordion is committed to meeting regulatory requirements and providing high quality, world-class products. Our highly specialized and experienced team seeks to continually improve the effectiveness of our processes, products and Quality Management System. We are dedicated to customer satisfaction and work diligently to understand requirements in order to meet and exceed customer expectations". Nordion has a Quality Manual (QSF-00) that provides a description of the overall quality program at Nordion. Additionally Nordion has a quality plan for transport packages (IN/QA 0224 Z000) that is included with this submission.

3. Design Control

   Nordion's design control program, as it relates to transport packages, is defined in section 4.2 of IN/QA 0224 Z000. The element of design control includes; planning, inputs, outputs, documentation requirements, verification and review, and change requirements. The design control program addresses requirements for documentation, drawings and computer systems associated with transport packages.

4. Procurement Document Control

   For the purpose of this application, the scope of procurement is limited to transport packages and their components. All results of supplier evaluations and subsequent necessary actions are maintained as quality records. Purchasing documents, typically in the form of a purchase order, describe the product to be purchased, including where appropriate:

   - Requirements for approval of product, procedures, processes, and equipment,
   - Requirements for the qualification of personnel,
   - Quality management system requirements.

   To ensure that all requirements have been adequately specified, procurement documents for raw material, equipment, parts, assemblies, or services are reviewed prior to their communication to the supplier. Any amendments to a procurement document are processed and reviewed in the same manner as the original document. Documentation control for procurement is described in sections 4.3 and 4.9 of IN/QA 0224 Z000.

5. Instructions, Procedures and Drawings

Documents required for the quality management system such as procedures, instructions, checklists, drawings and quality system forms are developed, reviewed, approved, distributed and controlled. Processes for various instructions, procedures, specifications and drawings are detailed in IN/QA 0224 Z000. The table below provides specific section references;

Area	Section (in IN/QA 0224 Z000)
Design	4.2.3.1 to 4.2.3.6
Manufacturing	4.6
Inspection / Testing	4.7
Handling, Storage, Packaging	4.8

6. Document Control

All Quality documents are reviewed for adequacy and completeness and approved by the responsible personnel prior to issue. All documents are legible, readily identifiable and retrievable. Nordion's Document Management group maintains a master listing of all documents and data generated. This master listing is readily available to personnel and identifies the current revision status of each document and its date of effectiveness. Changes or additions to approved documents and data are reviewed, updated as necessary and re-approved. All changes to documents require a Change Form as per QAP AP-45, "Change Control Procedure". Approved documents are transmitted to all functional areas and locations where they apply and are made readily accessible to the personnel concerned. Invalid and/or obsolete documents are promptly removed from all points of issue or use. Obsolete documents retained for the purposes of legal and/or knowledge-preservation are identified as "Obsolete" and controlled. Procedures are established to define the retention period of obsolete controlled documents. Documentation control is described in section 4.9 of IN/QA 0224 Z000.

7. Control of Purchased Material, Equipment and Services

For the purpose of this application, the scope of this element is limited to transport packages and components for transport packages. To ensure that purchased products conform to all quality and contractual requirements, Nordion conducts and controls all of its purchasing processes. These procedures ensure all relevant purchasing data is retained. The methodology used and the personnel responsible for evaluating and selecting suppliers is based on their ability to meet the contract or order specifications and quality requirements prior to the start of work. The criterion for supplier selection, evaluation and re-evaluation is based on the criticality and classification of the products to be purchased. The control of purchased material is described in section 4.3 and 4.4 of IN/QA 0224 Z000.

8. Identification and Control of Materials, Parts and Components

A suitable identification system is maintained throughout the product realization cycle. This includes identification of inspection and test status, unique identification of items where traceability is required, and identification of product returned by the customer. Identification and traceability programs are referenced in section 4.5 of IN/QA 0224 Z000.

9. Control of Special Processes

   Requirements for special processes, including welding, heat treating, and nondestructive testing are detailed in Technical Specifications and Design, Manufacturing and Operating Specifications. A description of these procedures is found in IN/QA 0224 Z000, sections 4.2.3.2 and 4.2.3.5 respectively. These documents ensure that special processes are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

10. Internal Inspection

    Internal inspection of transport packages is described in section 4.7 of IN/QA 0224 Z000.

11. Test Control

    With respect to operational and maintenance tests, applicable procedures and acceptance tests required for transport packages is listed in sections 4.7 of IN/QA 0224 Z000. Additional information pertaining to routine transport package shipping preparations can be found in section and 4.8.2 of IN/QA 0224 Z000.

12. Control of Measuring and Test Equipment

    Nordion's calibration program ensures that monitoring and measuring equipment used for package testing and inspection are properly controlled and calibrated. Calibration is performed using reference equipment whose calibration is traceable to nationally or internationally recognized standards. Where no recognized standard exists, the basis used for calibration is recorded. Nordion's calibration program is described in QSF-00, "Quality Manual".

13. Handling, Storage and Shipping Control

    Details on handling, storage and shipping controls are listed in section 4.8 of IN/QA 0224 Z000.

14. Inspection, Test and Operating Status

    Nordion uses an Oracle database for ongoing container management. The inspection, test and operating status of each package is maintained in this system. The service history and inspection record for each transport package is maintained electronically. Controls are in place within the container management system to ensure that packages have successfully completed routine and detailed inspection as per requirements prior to use in operations.

15. Nonconforming Materials, Parts or Components

    Nordion's Nonconforming Materials procedure ensures that nonconforming product is identified and controlled to prevent unintended use or delivery. Nonconforming material is identified, documented, segregated (where practical), evaluated and dispositioned. Records of dispositions are maintained which include the justification for use of nonconforming product, any subsequent actions taken and signature of the individual authorizing the use. Nordion's Nonconforming Materials program is described in QSF-00, "Quality Manual".

16. Corrective Action

Nordion promptly corrects non-conformances and conditions adverse to quality when discovered. To prevent recurrence, these non-conformances are investigated in order to:

- determine the root causes of the nonconformity;
- evaluate the need for actions to prevent recurrence;
- determine and implement required corrective action (short and long term);
- record results of action taken;
- review the results and effectiveness of the corrective action taken to ensure its effectiveness.

Corrective and preventive action taken is appropriate to the magnitude of the problem(s) and risk(s) involved. The methods used and the personnel responsible for determining the steps required to deal with problems requiring either corrective or preventive action, for initiating these actions and for establishing controls to ensure their effective implementation is as defined within Nordion's corrective action procedure.

17. Quality Assurance Records

Documents required for the quality management system such as quality assurance procedures, instructions, checklists, drawings and quality system forms are developed, reviewed, approved, distributed and controlled. Documents of external origin such as regulations, standards, specifications, customer drawings and other documents determined to be necessary for the planning and operation of the Quality Management System are also controlled.
Records have been established to provide evidence of conformity to requirements and of the effective operation of the quality management system. These records are legible, readily identifiable and retrievable. The methodology used for the identification, storage, protection, retrieval, retention and disposition of quality records is defined within applicable procedures. Specific references relating to records for procurement, use, repair and maintenance of transport packages and sealed sources are be found in the attached Quality Plans. Section 4.9 of IN/QA 0224 Z000 refers to the control of Quality Records.

18. Audits

Nordion's internal Quality Audit system is used to assess compliance with the quality system. The audit scope, frequency, methodology used and the personnel responsible for planning, conducting, reporting and following up on internal quality audits is as defined within Nordion's audit procedure. Audits are conducted by personnel who are independent of those who have direct responsibility for the activity being audited. Records of audits and their results are maintained. Results of audits are brought to the attention of the management having responsibility for the area being audited. When nonconformities are identified Management responsible for the area of interest will take immediate actions required to prevent non-conformities (where the issue is known and root cause identified). Follow-up evaluation of corrective action taken is performed to verify the actions taken. Results of verification are documented. A re-audit of deficient matters, is conducted when necessary.