nordion
SCIENCE ADVANCING HEALTH

April 11, 2012

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 Application for Limited Scope QA Program Approval

Further to Nordion's application for a Limited Scope QA Program Approval, dated March 19, 2012, Nordion requests to amend the application to include an improved description of the company organization around quality.

In support of this request, I am providing information relating to the eighteen areas described in 10 CFR part 71. Specifically, Section 1, Organization, has been supplemented with additional information on Nordion's management responsibilities

Please include this revision along with my previous application for review.

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

Sincerely,

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Q004

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 IN/QA 0562 A000	QA Program	2	Quality plans describe the requirements for quality in transport packages and sealed source programs.
	Design Control	3	
IN/QA 0224 Z000 IN/QA 0562 A000	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 IN/QA 0562 A000	Document Control	6	Lists the control requirements for quality records.
IN/QA 0224 Z000 IN/QA 0562 A000	Control of Purchased Material, Equipment and Services	7	Includes references to procurement procedure
IN/QA 0224 Z000 IN/QA 0562 A000	Identification and Control of Materials, Parts and Components	8	References identification and traceability controls for transport packages and sealed sources.
	Control of Special Processes	9	
IN/QA 0224 Z000 IN/QA 0562 A000	Internal Inspection	10	Details requirements for inspection and testing of transport packages and sealed sources.
IN/QA 0224 Z000 IN/QA 0562 A000	Test Control	11	Details requirements for inspection and testing of transport packages and sealed sources.
IN/QA 0562 A000 + description	Control of Measuring and Test Equipment	12	Description of calibration program.
IN/QA 0224 Z000 IN/QA 0562 A000	Handling, Storage and Shipping Control	13	Description of procedures for shipping and handling.
IN/QA 0562 A000 + description	Inspection, Test and Operating Status	14	Description of product release process.
IN/QA 0562 A000 + description	Nonconforming Materials, Parts or Components	15	Description of nonconforming materials process.
IN/QA 0562 A000 + description	Corrective Action	16	Description of corrective and preventative action process.
IN/QA 0224 Z000 IN/QA 0562 A000 + description	Quality Assurance Records	17	Description of records process specific to transport packages and sealed sources.
IN/QA 0562 A000 + description	Audits	18	Description of audit program.

Nordion is applying for a limited scope QA Program approval. The scope of the program is limited to use, maintenance/repair and shipping of transport packages. Elements of design and manufacturing controls are not within the scope of this application. The table above references sections in Nordion procedures Radioactive Material Transport Package Quality Plan (IN/QA 0224 Z000) and Sealed Source Quality Plan (IN/QA 0562 A000). 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.

   The responsibility, authority and the interrelation of personnel who manage, perform and verify work affecting quality have been defined, documented and communicated within the organization.

   The Senior Vice-President of Quality and Regulatory Affairs has been appointed as the Management Representative having responsibility and authority that includes:
   - ensuring that processes of the quality management system are established, implemented and maintained;
   - reporting to the Executive Management on the performance of the quality management system, including needs for improvement;
   - promoting awareness of customer requirements throughout the organization;
   - liaison with external parties on matters relating to the quality management system.

   The processes of the quality management system and their effectiveness are adequately communicated and understood within the organization. This is achieved by means such as:
   - management review meetings;
   - company intranet;
   - company meetings;
   - team meetings;
   - other forms of communication.

   Nordion management reviews the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. The management review team evaluates the need for improvement and/or changes to the organization's quality management system, including the Quality Policy and quality objectives. Records of these reviews are maintained.

NORDION MANAGEMENT RESPONSIBILITIES

President: has the primary responsibility to ensure that Nordion conforms with the overall quality program and to review the quality policy on a regular basis to ensure consistency and relevance with changing objectives and evolving, long term marketing conditions.

Senior Vice-President Quality & Regulatory Affairs: has the overall responsibility for the implementation and compliance of the quality, regulatory, environmental and safety programs. This individual has responsibility for supply chain management for Nordion.

Senior Vice-President Finance & Operations: has the overall responsibility for financial and manufacturing operations.

Senior Vice-President Sales & Marketing: has the overall responsibility for sales and promotion of Nordion products.

Senior Vice-President Corporate Services: has the overall responsibility for ensuring that the right people are selected based on qualifications and experience and that the quality commitment is reflected in sound policies which motivate and support all employees through appropriate rewards and recognition.

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". As mentioned the scope of this application is limited to the procurement, repair, maintenance and shipment of packages. Nordion has documented two quality plans for transport packages and sealed sources respectively. IN/QA 0224 Z000 and IN/QA 0562 A000 are included with the submission.

Function	Regulation	Evidence
Procurement	§ 71.109, § 71.115, § 71.131, § 71.133, § 71.135, § 71.137	IN/QA 0224 Z000, IN/QA 0562 A000
Maintenance, Inspection, Repair	§ 71.111, § 71.113, § 71.117, § 71.121, § 71.123, § 71.125, § 71.129, § 71.131, § 71.133, § 71.135, § 71.137	IN/QA 0224 Z000, IN/QA 0562 A000
Handling, Packaging, Shipping	§ 71.111, § 71.113, § 71.117, § 71.127, § 71.129, § 71.135, § 71.137	IN/QA 0224 Z000, IN/QA 0562 A000

3. Design Control

Nordion's design control processes are not within the scope of this application. No further description is provided.

4. Procurement Document Control

For the purpose of this application, the scope of procurement is limited to transport packages, sealed sources 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 as well as 4.6 and 4.16 of IN/QA 0562 A000.

5. Instructions, Procedures and Drawings

For the purpose of this application, the scope of this element is limited to procurement, maintenance/repair, handling and use of transport packages. Documents required for the quality management system such as procedures, instructions, checklists, drawings and quality system forms are developed, reviewed, approved, distributed and controlled. Specific requirements for maintenance/repair and shipment are listed in sections 4.7.3 and 4.8.2 of IN/QA 0224 Z000 respectively.

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 as well as 4.16 of IN/QA 0562 A000.

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 of IN/QA 0224 Z000 as well as 4.6 of IN/QA 0562 A000.

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 and section 4.8 of IN/QA 0562 A000.

9. Control of Special Processes

   Nordion's special process controls are not within the scope of this application. No further description is provided.

10. Internal Inspection

Internal inspection with respect to use and maintenance of transport packages and sealed sources is described in section 4.7 of IN/QA 0224 Z000 and section 4.10 of IN/QA 0562 A000 respectively.

11. Test Control

With respect to operational and maintenance tests, applicable procedures and acceptance tests required for transport packages and sealed sources are listed in sections 4.7.2 and 4.7.3 of IN/QA 0224 Z000 and section 4.10 of IN/QA 0562 A000. Additional information pertaining to routine transport package shipping preparations can be found in section and 4.8.2 and 4.8.3 of IN/QA 0224 Z000.

12. Control of Measuring and Test Equipment

Nordion's calibration program ensures that monitoring and measuring equipment employed for the purpose of verifying product quality or monitoring processes are assigned a unique identification control number. The calibration status of monitoring or measuring equipment is indicated by an appropriate label affixed to the calibrated item.

At defined intervals, as necessary, based on stability, purpose and degree of usage, measuring and monitoring equipment are subject to calibration, verification, or both. The specific measurements to be made, the accuracy required and the comparator to be used is identified within documented calibration instructions.

Calibration is performed using reference standards and/or equipment whose calibration is traceable to nationally or internationally recognized standards. Where no recognized standard exists, the basis used for calibration is recorded.

Any monitoring or measuring equipment observed during calibration as beyond the acceptance criteria limits established for that equipment type is removed from service and processed. When any measuring and test equipment is found not to conform to requirements, the validity of the previous measuring results is assessed. The results of the calibration and verification are recorded and maintained. Appropriate corrective action is initiated on the measuring and test equipment and any affected product.

All monitoring and measuring equipment is removed from use by the date that calibration is due and is protected against damage and deterioration during handling, maintenance and storage. Calibration records are maintained and updated throughout the life of each monitoring or measuring equipment. These records reflect the dates on which calibrations were performed, the accuracy of results obtained during calibration and any adjustments or re-adjustments made. Calibration certificates received from outside laboratories and internally generated calibration records, are retained on file in accordance with documentation control requirements.

A reference to the calibration program is provided in section 4.11 of IN/QA 0562 A000.

13. Handling, Storage and Shipping Control

Details on handling, storage and shipping controls are listed in section 4.8 of IN/QA 0224 Z000 and section 4.15 of IN/QA 0562 A000.

14. Inspection, Test and Operating Status

All quality records identify the personnel responsible for authorizing product release for distribution to the customer are filed and maintained as per Nordion's document control procedures. Inspection and test records indicate the acceptance activity performed, date of activity, results of activity, signature of personnel conducting the acceptance activity and if appropriate the equipment and

materials used. These records are maintained as per Nordion's document control procedures. A reference to the Inspection and Test Status program is provided in section 4.12 of IN/QA 0562 A000.

15. Nonconforming Materials, Parts or Components

Nonconforming product is controlled as defined within Nordion's Nonconforming Materials procedure. This 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. The evaluation of nonconforming product includes a determination of the need for an investigation, determination of root cause and notification of the responsible party for the nonconformance. All evaluations, investigations and corrective actions are documented. 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. Where required, acceptance by the customer or relevant external authority will be obtained. In the event that non-conformances are detected after delivery or use has started, Nordion notifies the customer, end user, and/or regulatory body. A reference to the Nonconforming materials program is provided in section 4.13 of IN/QA 0562 A000.

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. A reference to the Corrective Action program is provided in section 4.14 of IN/QA 0562 A000.

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. Specifically section 4.9 of IN/QA 0224 Z000 and section 4.16 of IN/QA 0562 A000 refer to the control of Quality Records.

18. Audits

Nordion's internal Quality Audit system is implemented and maintained by the Quality Assurance department. 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. Audits are scheduled on the basis of the status and importance of the activity being audited as well as results of previous audits. 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). Quality Assurance will oversee the required actions and they will be documented. 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. A reference to the Audit program is provided in section 4.17 of IN/QA 0562 A000.