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**A Successful and Effective Transportation Program for the Shipment of
Type A and Type B Quantities of Radioactive Material**

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ABSTRACT

There are several requirements that make up a successful global transportation program for radioactive materials. This starts with a management system that oversees and supports detailed program elements. Management System requirements are well detailed in certain publications such as IAEA guidelines and NRC regulations and in a more general manner in other regulations such as CNSC and ADR. A successful and effective program must be aligned with the individual company and the various roles they fulfill in the transport chain.

Nordion is a world leader in the manufacture of sealed sources for industrial and medical applications. We have an extensive fleet of Type B and Type A packages that are approved for use around the world. Our transportation program must cover many areas of the transport chain from receipt of raw materials and components to transport of finished goods and waste from our facilities. It spans the transport package lifecycle from design to decommissioning. First and foremost our Management System must align with the requirements of our facility license issued by the CNSC. It must be integrated within our CNSC issued License Condition Handbook, our ISO 9001 and 13485 certification and our QA Program for Safety. The Management System must support all elements of the transportation program.

This presentation will discuss key elements of Nordion's transport program and management system. It will highlight our practices and how they follow a graded approach with respect to detail and oversight. I will discuss how our program has been implemented, how it is assessed and how adjustments to the program have made as required. This presentation will serve as a working example of how a transport program and its overseeing management system are matched with the requirements of a sealed source manufacturer/distributor.

INTRODUCTION

Understanding both a company's packaging and transport requirements as well as the regulatory environment are fundamental to putting in place a successful transportation program. The foundation of those requirements is a Management System. While the requirement for a Management System is embedded in the regulations, it is likely that a company will have other regulatory and business requirements that will impress a need for such systems. At Nordion we have a well-developed transportation program that relies heavily on our management system.

Nordion is a world leader in the manufacture of Cobalt 60 sealed sources for industrial and medical applications. We have an extensive fleet of Type A and Type B packages that are used to transport raw materials, final product, spent sources and process waste to and from Nordion. Our transportation program is supported by our Radioactive Materials Transport Package Quality Plan (referred to as the Quality Plan in this paper). This plan forms a bridge between our company wide Quality Management System, that oversees all work at our facility, and the expectations of our key regulators such as CNSC, DOT and NRC.

ABOUT NORDION

Nordion, a Sotera Health company, has been a leading provider of Cobalt-60 to global customers for more than 70 years. Nordion's processing facility and head office is located in Ottawa, Canada.

Cobalt-60 is produced in power reactors throughout the world. Cobalt-60 emits high energy gamma rays used to eliminate harmful organisms in a variety of products: medical devices, pharmaceutical products, cosmetics, spices, consumer products, fruit, seafood, poultry, red meat and more. Cobalt-60 gamma rays are also used in the treatment of cancers. High Specific Activity (HSA) Cobalt-60 is at the forefront of innovative new medical technologies.

With safety as our number one priority, we have an extensive fleet of regulatory-approved transport packages that have allowed us to transport Co-60 sources to customers throughout the world for over 50 years safely, efficiently and reliably. Nordion provides full lifecycle management for our sealed sources.

Nordion is a highly regulated company. We host routine regulatory inspections and maintain compliance requirements from the CNSC, Transport Canada, DOT, NRC and other regulators. As well, since we ship around the world, we must remain compliant with international regulations.

TRANSPORT PROGRAM SCOPE

Annually, millions of Curies of Cobalt 60 are transported to and from Nordion. Many different types of shipments will arrive and depart from our facility.

- Cobalt-60 raw material is sourced from multiple power reactors around the world. That material is shipped by sea and/or road to our processing facility in Ottawa, Canada.
- Raw material Cobalt-60 is manufactured into sealed sources. These sources are manufactured based on customer requirements and are shipped from Ottawa via road, air and/or sea to customer sites.
- Customers will return older Cobalt 60 sources to our facility as part of Nordion's recycling program. While these sources may be decayed, the source components still have a high degree of radioactivity and are able to be repurposed.
- Nordion will also ship radioactive waste that is generated during processing. This waste is shipped in Type A and Type B packages.

The heart of the transport program is the transport package fleet. Each transport package has a life cycle as shown in Figure 1. Nordion uses a variety of transport packages, some of which were designed internally and others which have been designed by and procured through a third party.

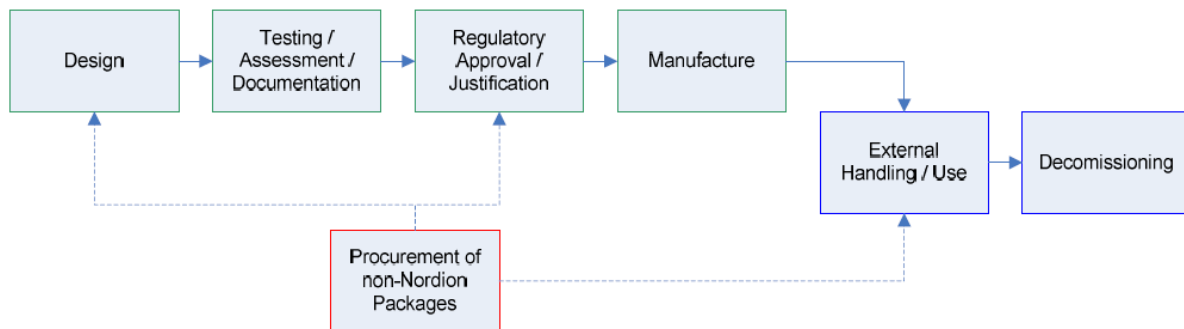


Figure 1 Transport Package Life Cycle

The package life cycle begins with a design. Typically prototypes are made, tested and evaluated. Regulatory approval is required for Type B (and other) packages. As such, a regulatory submission, which will include test reports, regulatory justifications, procedures, drawings and other documentation, is prepared and provided to the competent authority. While there is no regulatory approval of Type A packages, these must be also be supported by test reports and justifications supporting the package's ability to meet the regulatory requirements. Formal documents and procedures are also generated for all package types. In the case of Nordion's fleet, there are campaigns where new packages are manufactured to the approved design requirements. The newly built packages must be evaluated and accepted into the fleet. They are then fit for use and are available for use. Some packages may be single use only

(example – cardboard box with lead pot), others are reusable. Nordion will also use packages that have been designed and manufactured by a third party. In these cases, Nordion’s obligation is to ensure that the design is approved for use and that we have all required documentation required as per the approval. The package life cycle ends at decommissioning. This is the process when packages are removed from the fleet.

Some transport packages are designed for repeated use (returnable), others are designed for one-time shipments. Many transport packages will be used for multiple shipments throughout their lifetime. An extension of the usage cycle is demonstrated in Figure 2. Nordion maintains responsibilities for the package throughout this cycle.

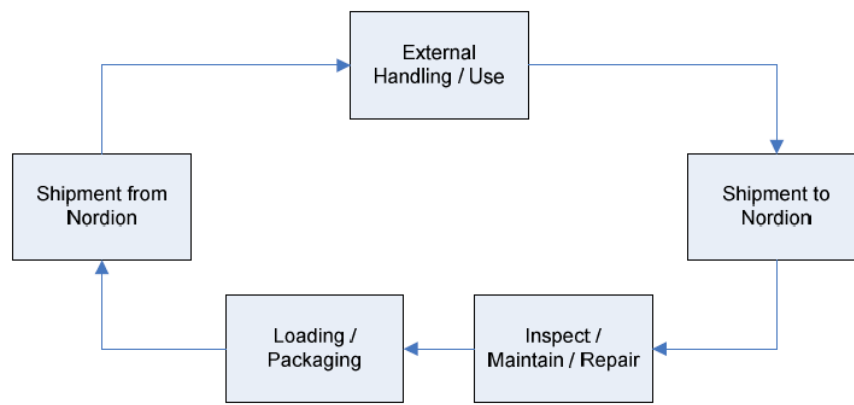


Figure 2 Transport Package Usage Cycle

TRANSPORT PROGRAM ELEMENTS

In building the transport program, both the transport package lifecycle as well as the transport package usage cycle were used as a basis. Key elements of the program come directly from those processes:

- Design
- Package Testing & Assessment
- Regulatory Approvals & Justification
- Manufacturing & Procurement
- Inspection & Maintenance
- Loading & Packaging
- Shipment
- Decommissioning

Other elements of the program relate to other internal programs that intersect with transport.

- Security
- Import / Export Controls
- Sealed Source Tracking and Reporting
- Safety
- Quality
- Regulatory

The transportation program is summarized in a single controlled document. This document defines the responsibilities for all groups involved in transport. It provides a description of each element and as required references internal operational procedures and regulatory references.

The Quality element of the transport program directly references the Quality Plan.

MANAGEMENT SYSTEM REQUIREMENTS

The requirement for a management system is listed in many transport and packaging regulations. Nordion is subject to regulatory oversight from many regulators. An example of the regulatory reference to management systems is provided:

- CNSC requires that every person who designs, produces, tests, uses, inspects, maintains or repairs prescribed equipment must implement and maintain a management system in accordance with the IAEA Regulations [1]
- The IAEA states that a management system based on international, national or other standards acceptable to the competent authority shall be established and implemented for all activities within the scope of the Regulations. [2]
- NRC has a detailed section of 10 CFR dedicated to Quality Assurance and requirements for certificate or license holders. DOT will reference these requirements on each transport certificate.
- ADR has adopted the IAEA wording and requires that a management system based on international, national or other standards acceptable to the competent authority shall be established and implemented for all activities within the scope of its regulations. [3]

On top of the specific transport and packaging requirements, Nordion's Quality Management System must also support other regulatory requirements (ex. Facility Licensing requirements) as well as other management system certification (ex. ISO 9001, ISO 14001). These requirements although similar are not always complementary.

Nordion has developed a Quality Plan to address the specific management system requirements listed above. This ensures a link between the relevant pieces of our larger Quality Management System and addresses specific requirements for packaging.

QUALITY PLAN

As aforementioned, the Quality Plan serves to ensure compliance with regulatory requirements for management systems. It also is a link between the transport program and regulatory requirements. As such the elements of the plan will be similar to those elements listed in both the transport program as well as the more descriptive regulatory requirements.

The Quality Plan clearly defines the requirements for key roles in the program such as; Quality Assurance, Regulatory, Engineering, Procurement. It also provides a description as to how quality is maintained for each element. As required, reference to external standards and internal procedures is provided. Elements of the Quality Plan include:

- Contract Review
- Design Control
- Procurement
- Control of Customer Supplied Product
- Identification and Traceability
- Process Control
- Inspection and Testing
- Handling, Storage, Packaging, Preservation and Delivery
- Control of Quality Records
- Training

PROGRAM ELEMENTS (Examples)

Two key elements of the transport program are; 1) transport package design and 2) handling and shipping of transport packages. These elements are defined in both Nordion's Quality Plan and the Transportation Program. While both elements are captured differently between the two, they provide a good example as to how the Transport Program and Quality Plan work together.

With respect to the Design element, the Transportation Program document simply provides reference to two internal procedures; Requirements and Guidelines for Control of Design and the Quality Plan. The Quality Plan provides additional references and a much more detailed explanation of the responsibilities, process and control points. Key design elements discussed in the Quality Plan include: Planning, Input, Output, Changes, and Verification/Review. Design

Control is a key requirement for management systems as such, there is greater detail on this element in the Quality Plan and less in the Transport Program document.

The element supporting Handling and Shipping is very detailed in the Transportation Program document. Handling and Shipping are more operationally focussed and subject to high level quality control. There is more detail for this element in the Transport Program document than in the Quality Plan. Details on the process are spread out over several sections of the program; Loading/Packaging, Shipment from Nordion, Third Party Use of Packages and Return Shipment to Nordion. Each section of the program provides a scope of work along with references to internal procedures. Reference to handling/shipping in the Quality Plan fall under the heading Handling, Storage, Packaging, Preservation and Delivery. There are references to internal procedures for preparation of shipments and receiving packages in both the Transport Program document and Quality Plan.

SUMMARY

A transportation program is a customized summary of how a company will ship/receive/handle materials for transport. It must take into account how the company performs transportation functions. It should delineate the responsibilities for individuals or groups with critical transport roles. The transportation program provides a summary of; What activities are performed, Who performs them and How they are performed.

A management system is a requirement of many transport regulations. It is in place to ensure control over aspects of the transportation program. These systems provide details on how elements of the transportation program are controlled and how compliance is assured.

Transport of Radioactive Materials is a complex process. It has many inputs stemming from regulatory, operational and quality management systems requirements. Nordion has navigated through this complexity and linked these requirements together. We have developed a Radioactive Material Transport Package Quality Plan that links our transportation processes to the compliance obligations. Both the Quality Plan and Transportation Program are key foundations that are vital to ensuring that Nordion's transportation activities remain safe, effective and compliant.

REFERENCES

- [1] Packaging and Transportation of Nuclear Substances, 2015
- [2] Regulations for the Safe Transport of Radioactive Materials, SSR-6, 2018 Edition
- [3] European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR 2019)