Regulatory Requirements for the Transport of Radioactive Materials in Canada

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1. Introduction

Canada is a major producer and shipper of radioactive material. Each year more than a million packages are transported in Canada. The safety record with the transport of RAM in Canada has historically been excellent. There have never been any serious injuries, overexposure or fatality or environmental consequences attributable to the radioactive nature of such material being transported or being involved in a transport accident.

In Canada, the Canadian Nuclear Safety Commission (CNSC) is the prime agency of the federal government entrusted with regulating all activities related to the use of nuclear energy and nuclear substances including the packaging and transport of nuclear substances. The mission of the CNSC is to *regulate the use of nuclear energy and materials to protect health, safety, security of the person and the environment and to respect Canada's international commitments on the peaceful use of nuclear energy.*

The division of responsibility for the regulation of transport of radioactive material has been split between Transport Canada and the CNSC. The governing Transport Canada's regulations are *Transport of Dangerous Goods (TDG) Regulations* and the CNSC regulations are *Packaging and Transport of Nuclear Substances Regulations (PTNSR)*.

Canada has actively participated in the development of the IAEA regulations for the safe transport of radioactive material since 1960. As an IAEA member state, Canada generally follows the requirements of IAEA regulations with few deviations. The Nuclear Safety and Control Act (NSCA) strongly supports Canada's international obligations *to ensure safe packaging, transport, storage and disposal of nuclear substances, prescribed equipment and prescribed information.* Prescribed equipment and prescribed information are defined in the CNSC General Nuclear Safety and Control Regulations.

This paper presents the current CNSC regulatory requirements and initiatives taken by the CNSC to improve its effectiveness and efficiency.

2. Competent Authorities in Canada

The responsibility of regulating the transport of radioactive material is shared by the two federal Government departments in Canada: Transport Canada (TC) and the Canadian Nuclear Safety Commission (CNSC). TC and the CNSC jointly share some of the responsibilities through consultation with each other.

Transport Canada is primarily responsible for:

- establishing and enforcing any transportation requirements for carriers, vehicles or other conveyances except for the radiation protection program requirements for the carriers
- setting up requirements and doing compliance inspections for transportation aspects such as training, documentation, marking, labelling and placarding
- setting the requirements of Emergency Response Assistance Plan and reviewing and approving them
- plan and prepare emergency procedures and execute in the event of any transport incident or accident
- compliance inspection primarily to ensure that the TDG regulations are met

We, the CNSC, are primarily responsible for:

- the packaging aspects such as setting the package design requirements and reviewing the safety case
- establishing and enforcing the radiation protection program for the carriers
- investigating in the event of a dangerous occurrence
- issuing licenses for shipments that require license to transport in accordance with the PTNSR
- all aspects of physical security measures of nuclear substances and prescribed equipment against sabotage or theft for all modes and phases of transport
- compliance inspection to ensure that the TDG regulations and the PTNSR requirements are met

3. Nuclear Safety and Control Act and the Associated Regulations

The Nuclear Safety and Control Act (NSCA) authorises the CNSC to make regulations including regulations for safe transport of radioactive material in a manner that is consistent with Canada's international obligations, of the risks to national security, the health and safety of persons and the environment that are associated with the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information. The transport regulations are one of ten sets of regulations in support of Canadian Nuclear Safety Act. The other regulations deal with such things such as mining, security, nuclear facilities, import and export, radiation protection, nuclear substances and devices, cost recovery and rules of procedures.

The NSCA defines general terms such as Nuclear Energy Worker, designated officer, license, inspector and nuclear substances.

The NSCA and the associated regulations can be accessed through the CNSC's web site at URL www.nuclearsafety.gc.ca.

Following is a brief overview of the CNSC regulations as they pertain to the transport of radioactive material:

3.1. General Nuclear Safety and Control Regulations

The revised General Nuclear Safety and Control Regulations came into effect in February 2004. These Regulations contain the general requirements that apply to all licensees. In accordance with these regulations, the transport package and special form radioactive materials, as defined in the PTNSR, are prescribed equipment and the route or schedule for the transport of Category I, II or III nuclear material, as defined in the Nuclear Security Regulations, is prescribed information. These regulations provide general application requirements for licenses and obligations of licensees and workers. The regulations do not exempt naturally occurring nuclear substances (NORM), having a specific activity greater than 70 kBq/kg, from the transport regulations. PTNSR references these regulations, for ex., it requires that application for a license to transport Category I, II or III nuclear material and license to package or transport under special arrangement shall contain information as required by these regulations in addition to the information required by PTNSR.

3.2. Radiation Protection Regulations

These Regulations contain the radiation protection requirements and as such they apply to all licensees and nuclear energy workers. The regulations require every licensee to implement a radiation protection program and as part of that program:

a) apply the ALARA principles to limit the amount of exposure to radon progeny and the dose received, and

b) ascertain the quantity and concentration of any nuclear substance released as a result of the licensed activity either by direct measurement or by estimating them.

3.3. Nuclear Security Regulations

The Nuclear Security Regulations apply in respect of transport of Category I, II and III nuclear materials. Category I, II and III materials consists of Plutonium, Uranium 233, Uranium 235 with different levels of enrichment and fuel consisting of depleted or natural uranium, thorium or low enriched fuel as further defined in these regulations.

These regulations define the additional requirement of a written security plan to obtain a license to transport Category I, II or III nuclear material.

3.4. Nuclear Substances and Radiation Devices Regulations

These regulations apply in respect of all nuclear substances, sealed sources, exposure devices and all radiation devices except Class II prescribed equipment. The regulations provide the radionuclide specific "exemption quantities" below which a license is not required.

3.5. Nuclear Non-proliferation Import and Export Control Regulations

These regulations apply in respect of the import and export of controlled nuclear substances, controlled nuclear equipment and controlled nuclear information as defined in these regulations.

3.6. Cost Recovery Fees Regulation

The revised CNSC cost recovery fees regulation came into effect in July 2003. The regulation allows the CNSC to recover from fee paying licensees their portion of the actual cost of regulation. Fixed fees applies to applicants applying for licenses and certificates for the transport of nuclear substances under the PTNSR, except for applicants applying for licenses to package or transport under special arrangement and certifications of designs for special form radioactive material for which the fees are calculated based on actual direct regulatory activities. The fees may vary from $500 for an application for a license to transport nuclear material to $32,000 for an assessment of a new package design having an "A" value greater than 3000 with fissile material.

3.7. Packaging and Transport of Nuclear Substances Regulations (PTNSR)

These regulations apply in respect of the packaging and transport of nuclear substances, including the design, production, use, inspection, maintenance and repair of packaging and packages and the preparation, consigning, handling, loading, carriage, storage during transport, receipt at final destination and unloading of packages. Both the Transport Canada, TDG regulations and the CNSC, PTNSR adopt applicable IAEA regulations for the transport of radioactive material in Canada. These regulations are really an administrative framework that incorporates most of IAEA requirements by reference.

4. Technical Differences between PTNSR and IAEA Regulations

The CNSC PTNSR has adopted the technical requirements of the *IAEA regulations for the Safe Transportation of Radioactive Material 1996 edition (Revised) No. TS-R-1* (hereafter referred as IAEA regulations) by reference. However, there are some technical differences between the two regulations that are listed below. Some of these changes are expected to be incorporated in the TS-R-1, 2003 edition.

4.1. "A" Values for Mo-99 and Cf-252

The A_1 value of 0.05 TBq for californium 252 (Cf-252) shown in Table 1 of the IAEA regulations is replaced by 0.1 TBq. The A_2 value of 0.6 TBq shown in Table 1 of the IAEA regulations for molybdenum-99 (Mo-99) is replaced by 0.8 TBq. The replaced values do not apply for air shipments outside Canada and are therefore only useful for shipments within Canada.

4.2. Definition for LSA-I Material

The difference in the definition of LSA-I in the PTNSR and the IAEA regulations are as follows:

(a) The LSA-I definition for uranium and thorium ores has been restricted to 2% concentration in PTNSR whereas there is no restriction in the IAEA regulations. The IAEA definition was developed in the 1960's when the known ore grades were lower than 1% concentration, and did not consider the much higher grade ores which are now mined in Canada. The 2% ore concentration limit takes into consideration that the LSA-I material should be very low hazard material that can be routinely transported unpackaged or in IP-1 packages under exclusive use. Ores greater than 2% are classified as LSA-II material which require higher standard of packaging.

(b) The LSA-I definition of radioactive material having "unlimited" A_2 values excludes uranium and thorium ores that exceed the 2% concentration limit in paragraph (a).

(c) The definition of unirradiated thorium or unirradiated natural or depleted uranium concentrates as LSA-I is equivalent to the IAEA definitions.

(d) A new LSA-I definition has been added to clarify that innocuous wastes of a very low hazard, such as demolition rubble and other wastes from decommissioning activities, may be classified as LSA-I. The radioactive material must be essentially uniformly distributed and the average specific activity cannot exceed 10^{-6} A_2 per gram.

4.3. Definition for LSA-II Material

The difference in the definition of LSA-II in the PTNSR and the IAEA regulations are as follows:

(a) A package limit of 225 L of water has been applied for tritiated water classified as LSA-II material up to a specific activity of 0.8 TBq/l. The original IAEA definition was based on tests where the package contents were limited to 225 L, however this limit was not included in the IAEA regulations.

(b) Materials in which the activity is uniformly distributed throughout and the specific activity does not exceed 10^{-4} A_2 per gram for solids and gases, and 10^{-5} A_2 per gram for liquids, may be classified as LSA-II. The word "other" has been deleted from the IAEA LSA-II definition so that tritiated water that does not exceed 10^{-5} A_2 per gram (or 0.4 TBq/kg) can be shipped as LSA-II.

4.4. IP-3 packages for LSA and SCO not under exclusive use

The industrial package types listed in the column headed "Not under exclusive use" in Table IV of the IAEA regulations are replaced by Type IP-3. PTNSR requires Type IP-3 packages for LSA and SCO material when transportation is "Not under exclusive use". In the case of LSA and SCO material transported not under exclusive use the packaging requirements are more restrictive than required in the IAEA regulations to require Type IP-3 packaging in all cases.

4.5. Phrase "other than ores containing only naturally occurring radionuclides" in paragraph 523 (a) of the IAEA regulations is deleted

All LSA-I or SCO-1 materials when transported unpackaged, including ores containing only naturally occurring radionuclides, must be transported in such a manner that under conditions likely to be encountered in routine transport, there will be no escape of the contents from the conveyance nor will there be any loss of shielding.

4.6. Figures 2 to 4, 6 and 7 in section V of the IAEA regulations are replaced by the corresponding figures illustrating the labels, the placard for substances of Class 7 and the orange panel specified in the Transport Canada's Transportation of Dangerous Goods (TDG) Regulations.

The specifications for the labels for Class 7 in the TDG regulations are bilingual (English and French). The use of labels and placards without the word "radioactive" is optional as detailed in the TDG regulations.

4.7. PTNSR replaces paragraph 514 of the IAEA regulations.

The changed paragraph does not include "overpack" and the paragraph applies only to "unpackaged radioactive materials".

4.8. Markings and labeling of exposure devices and exclusive use shipments of LSA-1

PTNSR allows transportation for an exposure device that is not labelled in accordance with paragraphs 541 to 543 of the IAEA regulations, if the package meets requirements specified in section 16 (5) of the PTNSR. TDG regulations do not recognize this PTNSR deviation and therefore issues an equivalent level of safety (ELS) permit.

4.9. Type H(U) and Type H(M) packages

PTNSR defines Type H(U) packages as an excepted package, Type IP-1 package, Type IP-2 package, Type IP-3 package or a Type A package that meets the requirements of IAEA regulations paragraph 629 of the IAEA regulations and contains more than 0.1 kg of uranium hexafluoride that is not fissile material. Similarly Type H(M) packages are defined as packages that meet the requirements of IAEA regulations paragraph 632 of the IAEA regulations and contain more than 0.1 kg of uranium hexafluoride that is not fissile material.

IAEA regulations although identifies H(U) and H(M) certificates for transportation of uranium hexafluoride, but, it does not define a Type H(U) and Type H(M) package.

5. Other Differences

5.1. Endorsement of Type B(U) packages

The IAEA regulations require unilateral approval for Type B(U) packages except those containing fissile material and those designated for low dispersible radioactive material, which require multilateral approval. Unilateral ap-

proval is defined by the IAEA regulations as approval of a design which is required to be given by the competent authority of the country of origin of the design only. However, Canada currently performs its own review of a foreign unilateral package design before endorsing it.

5.2. State variations in ICAO regulations

Canada has few provisions that are different than the provisions adopted by the ICAO, *Technical Instructions for the Safe Transport of Dangerous Goods by Air* for air transport of radioactive material. These provisions are listed in the State Variations in the ICAO Technical Instructions. Some of these variations as they pertain to radioactive material are:

- Fissile material in any quantity may not be transported by aircraft to, from or over Canada without prior permission. CNSC issues an overflight permit for transporting any quantity of fissile material over Canada.
- Type B(U) radioactive material packages must be of a design approved by the CNSC.
- Air transport from, to or within Canada must be made in accordance with the PTNSR

6. Administrative Requirements of PTNSR

Following are some of the administrative requirements by the PTNSR for the transport of radioactive material:

6.1 Exemptions

Section 2 (2) of the PTNSR lists the nuclear substances for the transport of which these regulations do not apply except for the licensing requirements. Some of these exemptions to the nuclear substances where these regulations do not apply in respect of the packaging and transport of a nuclear substance are:

- that is implanted into a person or an animal for medical purposes
- that is contained in a sample of material taken for bioassay purposes
- by a licensee on a private property for the purposes of a licensed activity, where access to the property is controlled
- that is contained in consumer product where no license is required under sections 5 to 8 of the *Nuclear Substances and Radiation Devices Regulations*, following sale to the end user
- that is an integral part of a conveyance and required for transport purposes

6.2 Transport Licenses

In Canada, most carriers and forwarding agents are not licensed. However, a license is required to transport the following nuclear substances in accordance with the PTNSR:

1. category I, II or III nuclear material
2. more than 0.1 kg of Uranium hexafluoride while in transit
3. nuclear substance that is required to be transported in a package of a certified design and is transported while in transit, and
4. nuclear substance is transported under special arrangement.

6.3 Registration of Use of Certified Packages

PTNSR requires that all users of a certified package shall be registered for its use with the CNSC. The registration ensures that the CNSC has a current list of package users who can be quickly contacted should safety problems arise in the use of the package. In addition, it provides verification that the applicant possesses the preparation for shipment instructions referenced in the applicable package design approval certificate.

6.4 Reporting Requirements

PTNSR requires that every consignor, carrier, consignee or holder of a license to transport the nuclear substance who becomes aware of any dangerous occurrence shall immediately make a preliminary report to the CNSC.

Dangerous occurrences are as defined in PTNSR and include:

- conveyance carrying radioactive material is involved in an accident

- package shows evidence of damage, tampering or leakage of its contents
- radioactive material is lost or stolen
- radioactive material has escaped from a containment system, a package or a conveyance during transport
- fissile material is outside the confinement system during transport, or,
- the level of non-fixed contamination during transport exceeds the limits specified in paragraphs 508 and 509 of the IAEA regulations.

A full report shall be provided by the consignor, carrier and the holder of a license to transport the nuclear substance while in transit within 21 days after a dangerous occurrence. An immediate report and a follow up report are also required by the Transport Canada within 30 days after the occurrence of the incident or accident.

6.5 Records

PTNSR defines the information and documents that shall be kept and retained concerning the Type IP-2, Type IP-3 and a Type A package. These records shall be retained for the period ending two years after the date on which the packaging occurs.

7. Radiation Protection Program (RPP) Requirements for Carriers

When the CNSC enforced the PTNSR in May 2000, two new requirements were imposed on the carriers of radioactive material: 1) Section 15 (7) of these regulations requires carriers to implement and maintain work procedures, and 2) section 18(1) requires carriers to develop and implement a RPP. An exemption to these two requirements was granted until May 31, 2004.

The CNSC recognizes a risk based approach for the development of such a program. It defines three risk categories based on the dose that can be potentially received by transport workers: Low, medium and high risk. Carriers employing workers who have little chance of receiving a dose in excess of 1 mSv per year are considered Low Risk. Carriers employing workers who can potentially receive a dose greater than 1 mSv per year but less than 5 mSv per year are considered Medium risk. The High Risk category covers all carriers employing workers who can potentially receive a dose greater than 5 mSv per year.

For carriers at low risk of exposure, the basic elements of an RPP may be covered in work procedures. A separate RPP is not required. However, carriers at high risk are responsible for a detailed and complete RPP. The CNSC has developed a guidance material that will assist carriers in developing an RPP for the transport of radioactive material.

8. Initiatives taken by the Directorate of Nuclear Substance Regulations (DNSR) of the CNSC

The Directorate of Nuclear Substance Regulations (DNSR) of the CNSC under whose responsibility falls the Packaging and Transport Licensing Division (PTLD) has taken several initiatives to improve its effectiveness and efficiency with respect to the licensing and compliance of the packaging and transport of nuclear substances. Some of these initiatives are discussed below:

8.1 Licensing, Certification and Compliance Database

The CNSC has developed an in-house program, *Licensing (L) Operations (O) User (U) Integration (I) System (S)* known as LOUIS in order to create a more efficient and centralized licensing tool. Currently, transport package certificates and licenses are managed through a separate process, involving multiple antiquated systems and significant manual effort. By enabling LOUIS support, management of transport package certificates and licenses will become more automated and will be consistent with the handling of other license types such as Nuclear substance and radiation device licenses.

The Packaging and Transport Licensing Division of the CNSC generates tracks and enforces the following three main documents:

* Transport package certificates

At April 2003, there were 108 valid certificates tracked within the system. Approximately 50 certificates are added, revised or amended annually. The PTLD of the CNSC receives an estimated 500 requests for copies of valid cer-

tificates. Currently, Transport package certificates are managed in a dbase III application, but are manually produced using a word processor. Full versions of the certificates are only available in paper archives.

* Transport Package Registered users

At April, 2003, there existed approximately 400 registered users tracked within the system used by PTLD. Currently, transport package registered users are managed in the same dBase III application, but all interaction with users is done manually.

* Transport Package Licenses

At April, 2003, there existed approximately 178 valid transport package licenses tracked within the system used by the transport division. Approximately, 40 transport package licenses are active at any given time.

The purpose and scope of the new program is to track and produce transport package certificates, registered users and transport licenses. The program will also have the ability to update and modify data on line with respect to transport package documents and tie transport package documents into the centralized repository for all CNSC licensees.

8.2 Standardising the Review Process for Packages Requiring Unilateral Approval

Currently, Canada and some other competent authorities perform its own reviews of foreign approved unilateral package designs before endorsing them. These multiple reviews delay the application process for certification of packages requiring unilateral approval and cost the competent authorities additional manpower. The CNSC proposes to develop and adopt a standard quality assurance and compliance assurance (QA/CA) program which would make package testing, review of performance data, the standards against which the performance is measured and package acceptance criteria more uniform.

Some of the concerns that the CNSC has raised in accepting these certificates are:

- Lack of standards and codes for engineering assessment of transport package design
- Lack of specified Quality Assurance program standards for package design
- Variation in interpretation of package performance requirements
- Lack of standard compliance program requirement
- Lack of a standard safety report format

At this time, Canada and the United States have started discussions on a North American system for the unilateral approval of Type B(U) packages.

8.3 Risk Based Regulatory Program (RBRP)

The Directorate of Nuclear Substance Regulation (DNSR) of the CNSC has developed a risk based regulatory program (RBRP) that recognises the need for improved information exchange between the CNSC and the licensee, the need to inform licensees of DNSR's expectations and to develop performance indicators for the licensees and for our own program. The CNSC has always practiced risk management; however, previous approaches to managing risk were too often based on intuition rather than on structured, systematic decision-making. Some of the CNSC's traditional operating methods have not always been supportive of an efficient and effective regulatory regime. At times, similar levels of resources were allocated to relatively minor and major risks alike.

The RBRP was designed based on the national risk management standard: CAN-CSA Q850/97 *Risk Management: Guideline for Decision-Makers.* It is a systematic, consistent and transparent program which integrates all regulatory effort being applied to licensing and compliance activities. The program enables a better identification of resource requirements and a more efficient management of regulatory effort. The program also serves as a source of compliance information to increase a licensee's awareness of requirements and CNSC's expectations. The degree to which a licensee deviates from the expectations will establish a compliance performance grade with subsequent consequences.

The first step in the RBRP involved the identification and review of all regulatory requirements that impact on DNSR operations such as the NSCA, CNSC regulations and the license conditions. The PTNSR requirements are currently reviewed only in a cursory manner. The criteria used for the risk ranking is based upon the health, safety

or security risk due to any non-compliance of regulatory requirements. Non-compliance of some high risk regulatory requirements might pose an immediate health, safety or security risk. If the non-compliance is serious, then one of the regulatory tools in place (e.g. issue an Order) may be used. If non-compliance poses a health, safety or security risk, but the risk is not immediate, then risk-ranking would be considered moderate. If there is no health, safety or security risk, then the regulatory requirements are considered too low to result in the issuance of an Order.

DNSR conducts two types of licensee transport compliance inspections: Type I (Audit) and Type II (typical inspection). A performance rating of A, B, C or D is given based on the inspection results. These ratings are defined as:

Rating A: Meets and consistently exceeds CNSC expectations
Rating B: Meet the intent or objectives of CNSC requirements and performance expectations. There is only minor deviation from requirements or the expectations
Rating C: Performance is deteriorating and falling below expectations
Rating D: Evidence of either an absence, total inadequacy, breakdown, or loss of control of the CNSC expectations

8.4 Security

The CNSC is actively pursuing regulatory initiatives aimed at addressing concerns raised by increased threats to nuclear substances used or transported in Canada. It has adopted risk based regulatory licensing and compliance programs pertaining to the safety and security of transport of radioactive material that is consistent with the international practices.

9. Emergency Preparedness

The CNSC has a publicly accessible 24-hour Duty Officer Phone line. The CNSC is immediately notified in the event of a dangerous occurrence, as defined in the PTNSR, involving transport of radioactive material in Canada. The initial event information is immediately transferred from the Duty Officer to the appropriate CNSC subject matter experts as well as the CNSC emergency response organization's prime contact.

Decisions are quickly made by CNSC staff with regard to the level of activation required of the CNSC emergency response team and whether or not to dispatch the necessary and appropriate response resources.

10. Summary

The responsibility of regulating the transport of radioactive material is shared by the two federal Government departments in Canada: Transport Canada and the Canadian Nuclear Safety Commission. Canada generally follows the requirements of IAEA regulations for the Safe Transport of Radioactive Material with few deviations. However, there are some technical differences between the CNSC regulations and the IAEA regulations. The CNSC regulations also impose several administrative requirements for the transport of radioactive material. The Directorate of Nuclear Substance Regulations of the CNSC has taken several initiatives to improve the effectiveness and efficiency with respect to the licensing and compliance of the packaging and transport of nuclear substances.