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| Packaging and Transport of Nuclear Substances Regulations, 2014

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Packaging and Transport of Nuclear Substances Regulations, 2014

Statutory authority

Nuclear Safety and Control Act

Sponsoring agency

Canadian Nuclear Safety Commission

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Background

More than a million packages containing nuclear substances are transported safely in Canada each year. The responsibility for ensuring their safe transport is jointly shared between the Canadian Nuclear Safety Commission (CNSC) and Transport Canada. Transport Canada's *Transportation of Dangerous Goods Regulations* deal with the transport of all classes of dangerous goods, while the CNSC's *Packaging and Transport of Nuclear Substances Regulations* (PTNSR) are focused on the health, safety and security of the public, and protection of the environment with respect to the special characteristics related to nuclear substances.

Canada's PTNSR are based on the *Regulations for the Safe Transport of Radioactive Material* (IAEA Regulations) established by the International Atomic Energy Agency (IAEA). In order to address Canadian-specific issues, the PTNSR include certain variations (i.e. definitions, classifications). The IAEA Regulations, which all IAEA member states follow, assure consistent, safe practices internationally.

With the input of IAEA member states, including Canada, the IAEA Regulations are periodically reviewed and new editions are published. Currently, the latest published version of these regulations is the 2012 edition.

In 2011, Canada hosted an IAEA Integrated Regulatory Review Service (IRRS) mission that included an assessment of the CNSC's regulatory practices related to the packaging and transport of nuclear substances. In their follow-up report, the members of the IRRS mission concluded that the CNSC's "regulatory framework for transport of radioactive materials is well established and commensurate with the large scope and volume of transport activities in Canada."

In addition, the IRRS team recommended updating the PTNSR to reference the latest edition of the IAEA Regulations (the PTNSR currently reference the 1996 [revised] edition). It also recommended that the CNSC consider options to increase clarity and ease of use of the PTNSR. Specifically, the review team recommended increasing clarity and user-friendliness with respect to the relevant IAEA requirements, and investigating

opportunities to better harmonize definitions in the PTNSR and the IAEA Regulations. In 2012, the CNSC initiated the project to revise the PTNSR.

Issues

The proposed Regulations would address the following issues:

Alignment with the IAEA Regulations

1. The PTNSR currently reference the 1996 (revised) edition of the IAEA Regulations. The 2012 edition of the IAEA Regulations introduces a number of new provisions, including new approval requirements. These changes should be incorporated into the PTNSR through new licensing and certification requirements so that Canada remains aligned with international practices for the packaging and transport of nuclear substances.

Improvements to the current PTNSR

Licensing

2. All in-transit shipments of nuclear substances, transported in packages of a certified design or in certain types of packages approved by a foreign competent authority (in accordance with the IAEA Regulations), that stop in Canada, must be licensed by the CNSC. Licensing of these shipments ensures there is regulatory oversight of the shipment while it is in Canada. The current PTNSR have proven confusing to some members of the regulated community with respect to licensing requirements for in-transit shipments of nuclear substances by air or sea.

Classification of ore as LSA material

3. Under the current *Packaging and Transport of Nuclear Substances Regulations*, low specific activity (LSA) material may fall under three different classifications, LSA-I, LSA-II or LSA-III, depending on the activity concentration and the form of the material. Within the PTNSR, the activity concentration limit for a material to be classified as LSA-I is in the order of 10^{-6} A₂/g, while the one applicable to LSA-II is 10^{-4} A₂/g.

As the packaging requirements associated with material classified as LSA-II are more stringent than for material classified as LSA-I, the cost of packaging LSA-II material may also be higher.

With regard to ores containing naturally occurring nuclear substances to be classified as LSA-I material, the Regulations currently limit their uranium and thorium concentration to a maximum of 2%. Ores above this concentration limit must be classified as LSA-II material. The International Atomic Energy Agency (IAEA) *Regulations for the Safe Transport of Radioactive Material* do not specify any limits on the ore concentration for their classification as LSA-I material since, in general, the ore concentration mined around the world is very low. However, some uranium ores currently mined in Canada have a concentration significantly higher than the 2% limit noted above. These are very high-grade ores which are not typically encountered in other mining operations. The ore concentration limit was established with the coming into force of the PTNSR in 2000 for consistency with other types of material also classified as LSA-I material under the PTNSR.

Transport documents

4. Under the current PTNSR, there is limited information required to be included in the transport documents for excepted packages. The risk associated with these shipments is generally low; however, in the event of an accident involving the transport of an excepted package, some basic information (consignor/consignee names and addresses and identification mark for each certification) would be beneficial as it could assist responders in handling the accident appropriately (i.e. selecting the appropriate response based on the UN number of the nuclear substance). This would also align the Canadian Regulations with the IAEA Regulations and is consistent with other regulators.
5. Under the current PTNSR, every consignor of a shipment is required to provide a "consignor's declaration" indicating that the contents of the consignment have been fully and accurately described, and that it complies with applicable international and national regulations. Even without such a declaration, the

consignor is responsible for ensuring the package and contents are compliant with the regulations. Such a requirement therefore adds very little value.

Radiation protection programs

6. Under the current PTNSR, all consignors, carriers and consignees must have a radiation protection program. While there is a guidance document available to assist carriers in developing a program, the actual regulatory requirements are vague and may not be suitable for the varying levels of doses received by transport workers.

Dangerous occurrences

7. Under the current PTNSR, package defects and instances of non-compliance with the regulations are only reported to the CNSC if they may reasonably be expected to lead to a situation that adversely affects the environment, the health and safety of persons or national security (i.e. a dangerous occurrence). Occurrences where a package is used improperly or does not meet performance expectations could be symptomatic of larger problems associated with the manufacturing, maintenance, and use of packages in the transport of nuclear substances. Such occurrences should be monitored and tracked.

Comprehension/readability

8. The current PTNSR, which came into force in 2000, replaced the *Transport Packaging of Radioactive Materials Regulations*, which came into force in 1983. There have been only a few amendments to the Regulations since they came into force, but the CNSC has received feedback from stakeholders that the structure and the language of the current PTNSR are unclear and confusing. They could therefore benefit from a rewrite.

9. The exemption for the transport of naturally occurring nuclear substances found in the *General Nuclear Safety and Control Regulations* (GNSCR) has proven confusing to some members of the regulated community. They may be unaware of the exemption under the GNSCR and expect that the PTNSR would contain all exemptions and requirements related to the packaging and transport of nuclear substances.

Other transport issues

Unidentified loads

10. Under the current PTNSR, unidentified nuclear substances in loads of waste or scrap cannot be transported until the load is properly characterized. Typically, the unidentified nuclear substances are detected by a radiation portal monitor, which may not be located at an adequate site to perform the characterization of the load. This could represent a safety issue, depending on the quantity and/or type of radiation detected. In addition, not all loads that trigger a portal monitor may be required to comply with the PTNSR, due to level/type of radiation or false alarms, but this cannot be confirmed until proper characterization has been completed.

Industry has also indicated that the cost implications (e.g. loss of revenue, overnight expenses for the driver, potential fines for leaving the vehicle on the side of the road for a long period of time) associated with these situations can be significant, since the vehicle may be required to remain stationary for a prolonged period of time, depending on the time needed to do the characterization.

Special arrangement and transport of large objects

11. As the nuclear industry in Canada ages, the CNSC expects to receive more applications for transport under "special arrangement" for the transport of large objects (such as steam generators) from decommissioning and refurbishment activities. Current requirements for these types of shipments are intentionally left in general terms, in order to accommodate the broad range of cases covered by these types of shipments. However, this does not provide clarity to the applicant as to the CNSC's expectations for such applications. In addition, the public has questioned the term "special arrangement" when a company applies for this type of approval. However, complete removal of this type of approval is not suitable as there will always be instances where it would not be possible to transport nuclear substances

in full compliance with all packaging requirements specified in the PTNSR.

Objectives

The objectives of the proposed Regulations are to

- ensure Canada's continued alignment with current and future international regulations for the transport of nuclear substances;
- ensure that Canada's regulatory regime for the packaging and transport of nuclear substances is based on risk, provides enhanced protection where needed, and reduces regulatory burden where there is little or no risk;
- clarify existing requirements to improve compliance with the PTNSR; and
- ensure continued safe and efficient transport of nuclear substances throughout Canada and internationally.

Description

Alignment with the IAEA Regulations

The proposed Regulations would be based on the 2012 edition of the IAEA Regulations and would introduce an ambulatory reference (as amended from time to time) instead of a static reference to the IAEA Regulations. This proposed change would ensure Canada's continued alignment with international regulations. Additional licensing and certification requirements would be included in the proposed Regulations as part of this initiative.

Licences would be required for the transport of nuclear substances by special use vessels and shipments requiring multilateral approvals. These have been described in the IAEA Regulations, but not previously incorporated into the PTNSR.

The new certification requirements would apply to the following: radioactive material that has a basic radionuclide value not currently listed in the IAEA Regulations; instruments and articles having an alternative activity limit for an exempt consignment; and certain fissile-excepted radioactive material. The IAEA Regulations contain lists of common values and activity limits, which are used to determine the applicability of the Regulations as well as the type of packaging necessary for the transport of the nuclear substance. With respect to basic radionuclide values, a new certification is being proposed for cases where the isotope is not listed in the IAEA Regulations. For the alternative activity limit for an exempt consignment, a new certification is being proposed for cases where someone seeks to use limits higher than those currently listed in the IAEA table. For fissile-excepted radioactive material, a new type of certification is being proposed to account for potential criticality safety concerns related to the possible accumulation of fissile-excepted material within a conveyance. The CNSC does not expect to receive many requests for these types of certifications, as the lists already contain values/limits that regulatees can use for packaging and shipment without having to obtain additional certification — which would otherwise impose additional burden and costs.

Improvement of the *Packaging and Transport of Nuclear Substances Regulations*

Licensing

The proposed Regulations would clarify licensing requirements, making it clear that licences are required for in-transit shipments of nuclear substances transported in certified packages or packages that require competent authority approval in accordance with the IAEA Regulations (packages containing a quantity of nuclear substances that pose a high risk) that are stopping in Canada, regardless of mode of transport, confirming the CNSC's regulatory oversight over such shipments.

Transport documents

The proposed Regulations would require transport documents for excepted packages to contain additional information such as the names and addresses of the consignor/consignee and the identification mark for any certifications. This new requirement would align the Canadian regulations with the IAEA Regulations.

The proposed Regulations would also remove the requirement for a consignor's declaration and align with the requirement of Transport Canada's *Transport of Dangerous Goods Regulations*. The declaration would still be required for shipments by air as per the *Technical Instructions for the Safe Transport of Dangerous Goods by Air*, and for international shipments by sea as per the *International Maritime Dangerous Goods Code*.

Classification of ore as LSA material

Under the new PTNSR, the uranium and thorium concentration limit would be increased from 2% to 3% for ores containing naturally occurring nuclear substances to be classified as LSA-I material. Consequently, ores above the 3% concentration limit would remain classified as LSA-II material. Calculations demonstrate that this higher limit still maintains an activity concentration limit that is within the limit of 10^{-6} A₂/g applicable to LSA-I material.

The modification will allow ores of low grade (lesser concentration) to be classified as LSA-I rather than LSA-II, reducing the cost associated with their packaging while maintaining the more stringent requirements for ores of higher grade.

Radiation protection programs

The proposed Regulations would enhance existing requirements for radiation protection programs by introducing new obligations for consignors, carriers and consignees with workers who could be exposed to radiation doses higher than the regulatory limits prescribed in regulation for members of the public (i.e. 1 millisievert per year). These new obligations would include notifying workers of the risks associated with higher radiation doses and individual/workplace dose monitoring. An exemption from requirements to develop a radiation protection program for consignors, carriers and consignees who only handle and transport excepted packages (i.e. low risk) would also be included. The proposed changes are aligned with existing regulatory requirements in the *Radiation Protection Regulations*.

Dangerous occurrences

The list of events considered to be dangerous occurrences would be amended to include package defects where the integrity of the package is degraded in a manner that could impair its ability to comply with the Regulations. As a result, such events would require notification and reporting to the CNSC. In addition, similar notification and reporting provisions are also being proposed for failure to comply with the packaging requirements in the proposed Regulations.

Comprehension/readability

The proposed Regulations would replace the existing PTNSR (first published in 2000) and have been rewritten using modern drafting techniques and plain language to improve the clarity and readability of the regulatory text.

The exemption for the transport of naturally occurring nuclear substances would be moved from the GNSCR to the PTNSR. In addition, the existing exemption for the transport of nonradioactive solid objects with nuclear substances present on the surface in quantities less than those defined as "contamination" would be clarified to specifically state that it is not subject to the Regulations. An exemption for the transport of contaminated persons would also be added.

Other transport issues

Unidentified loads

The movement of an unidentified load would be permitted for proper characterization, if specific conditions are met (i.e. level of radiation detected and no dispersal of the nuclear material). This exemption allows for the one-time transport of a shipment to a safer location for proper characterization. The use of such an exemption would also trigger additional notification and reporting to the CNSC, so it can monitor the situation and ensure the characterization has been completed and the nuclear substance has been disposed of safely.

Special arrangement and transport of large objects

The proposed Regulations would create a new type of licence for the transport of large objects in an effort to add specific relevant requirements. These requirements would provide greater clarity to the regulated community, by specifying the tests and calculations required to demonstrate the transport could occur safely. There is little or no information related to the CNSC's expectations regarding the type of information required for transporting large objects in the current regulations.

In addition, the term "special arrangement" would be removed from the Regulations, but the actual provision for this type of transport would remain. Therefore, a person would still be able to apply for a transport licence when transport could not be made in full compliance with packaging requirements specified in the PTNSR.

Consultation

On August 23, 2012, the CNSC issued discussion paper DIS-12-06, entitled "Proposals to Amend the *Packaging and Transport of Nuclear Substances Regulations*," for a 60-day comment period. The purpose of the discussion paper was to seek input from stakeholders and the general public on the CNSC's proposal to update the PTNSR to incorporate the most recent version of the IAEA Regulations, and to address issues that had arisen with respect to the packaging and transport of nuclear substances since the last significant amendment of the Regulations.

An invitation to comment on the discussion paper was posted on the CNSC's Web site, a notification was posted on the CNSC's Facebook page, an information bulletin was forwarded to CNSC stakeholders, and an article was published in the summer 2012 edition of the CNSC *DNSR Newsletter*. Notice of the consultation was also posted on the Government of Canada's Consulting with Canadians Web site.

The CNSC received six submissions from stakeholders representing nuclear power plant operators, a regional health authority and industry associations. On November 6, 2012, the CNSC posted these comments on its Web site and invited stakeholders to provide feedback on the comments received for a 10-day period. Two additional submissions were received.

In general, stakeholders supported the initiative to amend the PTNSR, especially with regard to ensuring consistency between the PTNSR and the IAEA Regulations. Additional information and clarification on the proposed Regulations was sought, particularly on the following issues:

How future revisions to the IAEA Regulations would be implemented

Stakeholders suggested that instead of using an ambulatory reference to the IAEA Regulations, the amendments should only align with the 2012 edition of the IAEA Regulations, and that the CNSC should commit to more frequent, minor revisions to incorporate future editions of the IAEA Regulations. The CNSC has considered this option, but has proposed the use of an ambulatory reference to the IAEA Regulations (as amended from time to time), as it would ensure that the PTNSR remain up to date with the newest version of the IAEA Regulations.

Revisions to the IAEA Regulations come into force when they are incorporated into a member state's legislation or international regulations, such as the *Technical Instructions for the Safe Transport of Dangerous Goods by Air*. Internationally, this process typically takes two years. The proposed Regulations specify that for the purposes of the regulations, the incorporation by reference of any revision to the IAEA Regulations would be effective two years after the publication of the revision, or no less than six months after the date the revision is available in both official languages. The proposed Regulations also require the CNSC to post on its Web site the date on which the revised version of the IAEA Regulations is expected to become effective.

In addition, the CNSC is developing guidance materials to assist stakeholders in complying with the proposed Regulations.

Removal of Canadian-specific variations in the PTNSR

Several stakeholders supported removing Canadian-specific variations in the PTNSR, particularly in the definition related to LSA-I material, as they differ significantly from the IAEA Regulations. They noted that a misalignment with international practices would risk putting Canada at a competitive disadvantage for the packaging and transport of nuclear substances, as transport companies would be forced to comply with both international and Canadian-specific practices. Where appropriate, the CNSC is proposing to remove the Canadian-specific variations in the existing PTNSR to better align it with the IAEA Regulations.

“Special arrangement” provisions and transport of large objects

Stakeholders expressed some reservations with the proposed removal of the term “special arrangement,” noting that the term is well understood and has been used by the international transport community for many years and that its removal could lead to confusion. Stakeholders suggested keeping the term, but providing specific requirements in the PTNSR for these types of shipments. While the CNSC appreciates this concern, it is proposing to repeal the term “special arrangement” from the Regulations while retaining the necessary elements of the provision, recognizing there may still be a need to transport nuclear substances where the transport cannot fully comply with all the packaging requirements specified in the PTNSR. An example of this would be the transport for final disposal purposes of an old irradiator for which there is no certified package in existence. As a result, transport may require provisions not foreseen in the Regulations. Under the existing Regulations, a company would have to apply for a “special arrangement” licence and demonstrate that the transport would still be done with a level of safety similar to that used if it had been done in full compliance with all the packaging requirements specified in the PTNSR. Under the proposed Regulations, a similar licence would be needed.

Stakeholders also responded favorably to new provisions for the transport of large components (now called “large objects”). They suggested that the IAEA concept of performance packaging and classification limits be used as the basis for these provisions, and recommended alignment with requirements from other countries. The proposed new provisions are based on IAEA guidance developed by member states tasked with development of packaging and transport requirements for large objects, for inclusion in a future revision of the IAEA Regulations. This guidance is currently used by member states for the transport of large objects.

Radiation protection program requirements for carriers

In the discussion paper, the CNSC initially proposed two options to enhance the radiation protection program requirements for consignors, carriers and consignees of nuclear substances. The first option was to move the requirement to the *Radiation Protection Regulations* (RPR), where all other radiation protection requirements are currently found; the second option was to maintain the existing radiation protection requirements in the PTNSR, but include provisions that would regulate workplace and individual dose monitoring. It was also proposed that carriers who only handled and transported excepted packages be exempt from all radiation protection program requirements. Several stakeholders were concerned that moving the requirements for radiation protection programs to the RPR would result in increased requirements for carriers, as the RPR have more radiation protection program requirements than the existing PTNSR. Stakeholders noted this would not be practical for carriers operating on an international level and that the radiation protection program requirements within the PTNSR should continue to align with the IAEA requirements. In addition, stakeholders indicated that it could result in extra costs to carriers. Stakeholders noted that moving the radiation protection program requirements to the RPR might limit the number of carriers who would be willing or able to transport nuclear substances. Taking into consideration these comments, the CNSC is proposing to keep the radiation protection program requirements for consignors, carriers and consignees within the PTNSR. Additional provisions have, however, been included, most notably those regarding workplace and individual dose monitoring for workers who may receive high doses of radiation. This is expected to enhance worker protection from the risks associated with the packaging and transport of nuclear substances, in cases where workers could potentially receive an annual dose above the limit set for members of the public.

Treatment of unidentified loads

Further to comments from stakeholders, iodine 123 and iodine 124 have been added to the list of exempted medical isotopes, as they also have a short half-life.

Stakeholders also recommended establishing a maximum activity or dose rate for the exemption of loads containing medical isotopes. This would allow differentiation between cross-contamination and potential

indications of waste disposal issues, or deliberate attempts to dispose of nuclear substances through pathways not intended for them. The CNSC has proposed to add an exemption for all unidentified loads containing medical isotopes, regardless of intent. Shipments contaminated with medical isotopes pose very little risk due to the short half-life of the material and will decay quickly to a point where the radiation will no longer be detectable.

Changes to dangerous occurrence reporting

There were also a number of specific comments on the proposed changes to the provisions related to “dangerous occurrences.” Stakeholders cautioned that this section should not be used to capture errors related to “administrative” requirements, such as issues or non-compliance related to transport documents. The CNSC concurs. This section of the proposed Regulations is not intended to be used to capture errors related to administrative requirements, but rather to focus on instances of package defect or package non-compliance. Since the overall safety of a shipment is ultimately related to its correct handling and packaging, any events of packaging defect or package non-compliance could be evidence of larger systemic issues which, if left unaddressed, could result in a “dangerous occurrence.” With the new notification and reporting provisions, the CNSC would be in a position to monitor the actions of regulatees to ensure they have taken adequate measures to prevent the event from recurring.

“One-for-One” Rule

The “One-for-One” Rule applies to the proposed Regulations, as they would result in an increase in administrative burden on business representing a total annualized average administrative cost of approximately \$27,769, which is \$16 per business. This average administrative cost is determined using a 10-year forecast period. This proposal is therefore considered an “IN” under the “One-for-One” Rule.

To determine the administrative cost associated with the proposed Regulations, the CNSC estimates the number of identifiable regulatees affected to be approximately 1 700 stakeholders representing small, medium and large businesses. The number of regulatees was calculated using the number of CNSC licensees (approximately 1 600), plus the approximately 100 third-party carriers not currently licensed by the CNSC but who are known to transport nuclear substances.

A value of 1 600 will be used to calculate costs associated with the regulatory requirements affecting only applicants, consignors and consignees. To calculate costs associated only with carriers, a value of 500 is used, assuming that one quarter of all licensees transport their own nuclear substances (i.e. the 100 unlicensed carriers and 400 [one quarter of 1 600] licensees who transport their own nuclear substances as opposed to using a third-party carrier).

While it is expected that the proposed Regulations will introduce a new administrative burden, the increase is associated with activities that would take place primarily in the first year following the coming into force of the proposed Regulations, and would be reduced in subsequent years. These administrative costs relate to training, licensing/certification, radiation protection programs and transport documents.

Training

The costs relate to the one-time training required by businesses to familiarize staff with the proposed Regulations. Depending on the size and type of business, this training could take many different forms. In order to quantify costs associated with training, the CNSC assumes that all businesses train their employees similarly, and that all businesses already have some type of training program in place that would only need to be modified to address the changes found in the proposed Regulations. Assuming all potential regulatees modify and deliver this training material (administrative burden), an overall one-time cost of approximately \$153,255 is expected across all impacted businesses. This is based on the assumption that it would take each business one hour to modify the training material and two hours to deliver the new training at a cost of \$30/hour.

Licensing and certification

While alignment with the 2012 edition of the IAEA Regulations would introduce new licence and certification requirements, the CNSC does not expect to receive many of these types of applications (no more than one

per year per application type overall). Accordingly, it is expected that these changes would result in minimal additional administrative burden on industry. The CNSC assumes that the overall cost associated with completing an application for a licence for shipments requiring a special use vessel/or multilateral approval to be approximately \$85 per application. For applications requiring complex calculations (e.g. basic radionuclide value that is not listed in the IAEA Regulations) the overall administrative cost per application would be approximately \$685. These costs would be ongoing (annual) and would be incurred only by regulatees who apply for such licences or certifications. Assuming one of each type of application per year overall (e.g. new licences and certifications: special use vessel licence, multilateral approval licence, certification of basic radionuclide value not listed in the IAEA Regulations), the annual cost of the new applications would be approximately \$1,540 per year overall or approximately \$0.96 per year per business.

The costs described above do not include the costs for licences and certification under the *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*, which are not part of the "One-for-One" Rule calculations. The current fee for a transport licence is \$500, and the associated cost for obtaining the new special use vessel or multilateral approval licence will be the same, as the process is very similar. For applications requiring complex calculations, such as applications for basic radionuclide values not listed in the IAEA Regulations, it would cost more as the CNSC would require more time to verify the calculations. These types of applications are subject to special project fees under the *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations* and the associated cost would be approximately \$1,000 per application.

Radiation protection programs

New obligations for consignors, carriers and consignees with workers who could be exposed to radiation doses higher than the regulatory limit for members of the public (1 millisievert per year) would also result in additional compliance and administrative costs. The CNSC expects most of the additional burden would not affect regulatees who are already licensed by the CNSC, as they must already comply with requirements in the *Radiation Protection Regulations* (RPR) and the new requirements are similar to those found in the RPR. As a result, the CNSC assumes that the additional cost would only apply to carriers and to a very small portion of the regulated community that is not already licensed and whose workers could potentially receive annual doses above the limit for members of the public (approximately five carriers).

Specifically, incremental administrative burden would result from the paperwork associated with notification and acknowledgement of the change in status of these workers (i.e. normal worker to nuclear energy worker). The CNSC assumes that only approximately five carriers would have to develop a document to meet the requirements of the new provisions (notification and acknowledgement), and that it would take one hour at a cost of \$30/hour to produce a document, for an overall one-time cost of \$150 or \$30 per business. There is also additional administrative cost associated with businesses completing documentation, and the affected workers reviewing it and signing the acknowledgement — but it is expected to be insignificant.

There would also be a decrease in administrative burden for those who only package and transport excepted packages, since they are no longer required to develop and implement a radiation protection program. However, the exact number of businesses affected is unknown and it is therefore difficult to quantify this potential reduction.

Transport documents

Other changes in the proposed Regulations would have some increase in administrative burden (i.e. additional information in transport documents of excepted packages and change in order of the information in the transport documents), but it is expected that the overall administrative burden associated with these changes would be low and result in minimal additional cost to the regulated community. The administrative costs associated with these changes are difficult to quantify, since the CNSC does not monitor what portion of shipments of nuclear substances in Canada are excepted packages. The CNSC assumes that all consignors (approximately 1 600 stakeholders) would have to modify the template for their existing transport documents and this modification would take one hour at a cost of \$30/hour, for an overall one-time cost of \$48,000 or \$30 per business.

There are also some other proposed changes to the Regulations that would lessen the administrative burden for some licensees, such as the removal of the requirement for the consignor's declaration, but this reduction in burden is expected to be minimal and is difficult to quantify as the exact number of shipments and stakeholders affected is unknown.

The removal of the consignor's declaration and the changes to the order of the information in the transport documents would only affect those transporting by road. The consignor's declaration would still be required for shipments by air and by sea which are subject to the *Technical Instructions for the Safe Transport of Dangerous Goods by Air* and the *International Maritime Dangerous Goods Code*. In addition, the proposed changes to the order of the information required for transport documents have already been incorporated into the *Technical Instructions for the Safe Transport of Dangerous Goods by Air* and the *International Maritime Dangerous Goods Code*.

Many of the new reporting provisions relate to events (e.g. unidentified loads triggering of radiation portal monitor alarm or events of package defect/non-compliance) that are not part of day-to-day packaging and transport of nuclear substances. Therefore, the potential for additional administrative burden is not considered in the calculation for the total annualized administrative cost increase attributed to the proposal.

Given that the level of administrative burden associated with an application for the transport of a large object would not change as a result of this proposal, it has not been included in the total annualized administrative cost increase attributable to this proposal. The information requirements associated with this section of the PTNSR would not change; however, they would be clarified by including specific requirements to demonstrate that the shipment of the large object can occur safely even if it is not packaged in full accordance with all packaging requirements specified in the PTNSR. It is believed that this clarification of the requirements would actually result in a decrease in burden, as applicants would need less time to prepare the licence application and the CNSC could review applications more quickly.

Small business lens

The small business lens does not apply to this proposal.

Rationale

This proposal would modernize the PTNSR by clarifying the language used in the regulatory text, ensuring that the level of regulatory burden is proportional to the level of risk associated with the packaging of nuclear substances, and ensuring that the Canadian regulations are consistent with international regulations. This will contribute to enhancing public and worker safety and ensure that Canadian businesses remain competitive at the international level.

Implementation, enforcement and service standards

The proposed Regulations add new requirements for the packaging and transport of nuclear substances. The CNSC will assist regulatees in complying with these new provisions with the development of guidance materials, which would be made available on the CNSC's Web site when the final regulations come into force.

Since an ambulatory reference to the IAEA Regulations is included in the proposed Regulations, the CNSC would ensure that stakeholders are made aware of the content (e.g. through the CNSC's Web site and newsletter) of future editions of the IAEA Regulations and how these could affect compliance with the PTNSR. The CNSC is developing guidance materials to help stakeholders comply with the proposed Regulations. This guidance will be updated to address any changes in future editions of the IAEA Regulations that may impact compliance with the PTNSR.

Enforcement of the proposed Regulations would be done in accordance with the CNSC's existing enforcement policy. CNSC inspectors regularly verify that licensees and carriers are complying with the PTNSR. When conducting inspections, they verify, for example, proof of training for transport workers, review transport documents, and inspect packages to ensure they are prepared for transport in accordance with regulations. If a licensee or carrier is found to be non-compliant with these regulations, the CNSC uses a graded enforcement approach for the implementation of corrective measures. Additional training would be provided to CNSC enforcement staff on the proposed Regulations.

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PROPOSED REGULATORY TEXT

Notice is given that the Canadian Nuclear Safety Commission, pursuant to subsection 44(1) ([see footnote a](#)) of the *Nuclear Safety and Control Act* ([see footnote b](#)), proposes to make the annexed *Packaging and Transport of Nuclear Substances Regulations, 2014*.

Interested persons may make representations concerning the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Brian Torrie, Director General, Regulatory Policy Directorate, Canadian Nuclear Safety Commission, P.O. Box 1046, Station B, 280 Slater Street, Ottawa, Ontario K1P 5S9 (tel.: 613-947-3728; fax: 613-995-5086; email: consultation@cnsccsn.gc.ca). Please note that all representations will be posted on the Commission's website in their original language.

Ottawa, June 17, 2014

JURICA ČAPKUN
Assistant Clerk of the Privy Council

PACKAGING AND TRANSPORT OF NUCLEAR SUBSTANCES REGULATIONS, 2014

INTERPRETATION

Definitions

1. (1) The following definitions apply in these Regulations.

"A₁"
« A₁ »

"A₁" has the same meaning as in the IAEA Regulations.

"A₂"
« A₂ »

"A₂" has the same meaning as in the IAEA Regulations.

"Act"
« Loi »

"Act" means the *Nuclear Safety and Control Act*.

"activity"
« activité »

"activity" means the number of nuclear transformations occurring per unit of time, as measured in Bq.

“alternative activity limit for an exempt consignment”
« *autre limite d’activité pour un envoi exempté* »

“alternative activity limit for an exempt consignment”, in respect of an instrument or article, means an activity limit for a consignment that is above the activity limit for an exempt consignment set out in the IAEA Regulations and that has been approved as meeting the exemption criteria set out in those Regulations for an instrument or article.

“basic radionuclide value”
« *valeur de base pour un radionucléide* »

“basic radionuclide value” means either an A_1 in TBq, an A_2 in TBq, an activity concentration limit for an exempt material in Bq/g or an activity limit for an exempt consignment in Bq, as set out in the IAEA Regulations.

“carrier”
« *transporteur* »

“carrier” has the same meaning as in section 1.4 of the *Transportation of Dangerous Goods Regulations*.

“certificate”
« *document d’homologation* »

“certificate” means a document issued by the Commission under paragraph 21(1)(h) of the Act or by a designated officer authorized under paragraph 37(2)(a) of the Act, indicating the certification of

- (a) a package design;
- (b) a design for special form radioactive material;
- (c) a design for low dispersible radioactive material;
- (d) the calculation demonstrating that fissile-excepted radioactive material will remain subcritical;
- (e) the calculation of the basic radionuclide value for radioactive material that has a basic radionuclide value that is not listed in the IAEA Regulations; or
- (f) the calculation, for an instrument or article that has an alternative activity limit for an exempt consignment, of the alternative activity limit.

“confinement system”
« *système d’isolement* »

“confinement system” means the assembly of fissile material and packaging components intended to preserve criticality safety.

“consignee”
« *destinataire* »

“consignee” has the same meaning as in the IAEA Regulations.

“consignment”
« *envoi* »

“consignment” has the same meaning as in the IAEA Regulations.

“consignor”
« *expéditeur* »

“consignor” has the same meaning as in section 1.4 of the *Transportation of Dangerous Goods Regulations*.

“containment system”
« *enveloppe de confinement* »

“containment system” has the same meaning as in the IAEA Regulations.

“contamination”
« *contamination* »

“contamination” has the same meaning as in the IAEA Regulations.

“conveyance”
« *moyen de transport* »

“conveyance” has the same meaning as in the IAEA Regulations.

“criticality safety index”
« *indice de sûreté-criticité* »

“criticality safety index” has the same meaning as in the IAEA Regulations.

“effective dose”
« *dose efficace* »

“effective dose” has the same meaning as in subsection 1(1) of the *Radiation Protection Regulations*.

“excepted package”
« *colis excepté* »

“excepted package” means a package that is designed in accordance with the applicable requirements of the IAEA Regulations.

“exclusive use”
« *utilisation exclusive* »

“exclusive use” has the same meaning as in the IAEA Regulations.

“fissile-excepted radioactive material”
« *matière radioactive fissile exceptée* »

“fissile-excepted radioactive material” means fissile radioactive material that is

- (a) excepted from being classified as fissile in accordance with the IAEA Regulations; or
- (b) contained in a package that is excepted from being classified as fissile in accordance with those Regulations.

“fissile material”
« *matière fissile* »

“fissile material” has the same meaning as in the IAEA Regulations.

“freight container”
« *conteneur* »

“freight container” has the same meaning as in the *International Maritime Dangerous Goods Code*.

“IAEA Regulations”
« *Règlement de l’AIEA* »

“IAEA Regulations” means the *Regulations for the Safe Transport of Radioactive Material*, published by the International Atomic Energy Agency, as amended from time to time.

“instrument or article”
« *Appareils ou objets* »

“instrument or article” means any tool, implement or object, or its components, that encloses nuclear substances and that is fabricated for a particular use other than solely for enclosing those nuclear substances.

“*International Maritime Dangerous Goods Code*”
« *Code maritime international des marchandises dangereuses* »

“*International Maritime Dangerous Goods Code*” means the document of that name published by the International Maritime Organization, as amended from time to time.

“large object”
« *objet de grande dimension* »

“large object” means an object that has been decommissioned from a nuclear facility, that is internally contaminated with nuclear substances and that cannot be transported in a type of package described in these Regulations due to its dimensions.

“low dispersible radioactive material”
« *matière radioactive faiblement dispersable* »

“low dispersible radioactive material” has the same meaning as in the IAEA Regulations.

“LSA material”
« *matière LSA* »

“LSA material” has the meaning assigned by the definition “low specific activity (LSA) material” in the IAEA Regulations.

“management system”
« *système de gestion* »

“management system” has the same meaning as in the IAEA Regulations.

“overpack”
« *suremballage* »

“overpack” has the same meaning as in the IAEA Regulations.

“package”
« *colis* »

“package” means packaging with its radioactive contents, as presented for transport.

“packaging”
« *emballage* »

“packaging” has the same meaning as in the IAEA Regulations.

“prescribed equipment”
« *équipement réglementé* »

“prescribed equipment” means equipment that is prescribed under paragraph 20(a) of the *General Nuclear*

Safety and Control Regulations.

“radioactive material”
« *matière radioactive* »

“radioactive material” means a nuclear substance that is a radioactive material, as defined in the IAEA Regulations.

“registered user”
« *usager inscrit* »

“registered user” means a person who has received confirmation under subsection 19(3) from the Commission that their use of a package has been registered.

“SCO”
« *SCO* »

“SCO” has the meaning assigned by the definition “surface contaminated object (SCO)” in the IAEA Regulations.

“special form radioactive material”
« *matière radioactive sous forme spéciale* »

“special form radioactive material” has the same meaning as in the IAEA Regulations.

“specific activity”
« *activité spécifique* »

“specific activity” has the same meaning as in the IAEA Regulations.

“*Technical Instructions for the Safe Transport of Dangerous Goods by Air*”
« *Instructions techniques pour la sécurité du transport aérien des marchandises dangereuses* »

“*Technical Instructions for the Safe Transport of Dangerous Goods by Air*” means the document of that name, designated as Doc 9284, published by the International Civil Aviation Organization, as amended from time to time.

“transit”
« *transit* »

“transit” means the process of being transported through Canada after being imported into and before being exported from Canada, in a situation where the place of initial loading and the final destination are outside Canada.

“transport index”
« *indice de transport* »

“transport index” has the same meaning as in the IAEA Regulations.

“Type A”
« *type A* »

“Type A”, in respect of a package, means that the package is designed in accordance with the applicable requirements of the IAEA Regulations.

“Type B”
« *type B* »

“Type B”, in respect of a package, means that the package is classified as either a Type B(U) or a Type B(M) package in accordance with the IAEA Regulations and is designed in accordance with the applicable requirements of those Regulations.

“Type C”
« *type C* »

“Type C”, in respect of a package, means that the package is designed in accordance with the applicable requirements of the IAEA Regulations.

“Type H(M)”
« *type H(M)* »

“Type H(M)”, in respect of a package, means that the package has a type code of H(M) in accordance with the IAEA Regulations and is an excepted package, Type IP-1 package, Type IP-2 package, Type IP-3 package or Type A package that is designed to contain more than 0.1 kg of uranium hexafluoride that is non-fissile material or is fissile-excepted radioactive material.

“Type H(U)”
« *type H(U)* »

“Type H(U)”, in respect of a package, means that the package has a type code of H(U) in accordance with the IAEA Regulations and is an excepted package, Type IP-1 package, Type IP-2 package, Type IP-3 package or Type A package that is designed to contain more than 0.1 kg of uranium hexafluoride that is non-fissile material or is fissile-excepted radioactive material.

“Type IP-1”
« *type IP-1* »

“Type IP-1”, in respect of a package, means that the package is designed in accordance with the applicable requirements of the IAEA Regulations.

“Type IP-2”
« *type IP-2* »

“Type IP-2”, in respect of a package, means that the package is designed in accordance with the applicable requirements of the IAEA Regulations.

“Type IP-3”
« *type IP-3* »

“Type IP-3”, in respect of a package, means that the package is designed in accordance with the applicable requirements of the IAEA Regulations.

Incorporation by reference of IAEA Regulations

(2) For the purposes of these Regulations, the incorporation by reference of any particular amendment of the IAEA Regulations is effective two years after the day on which the amendment is initially published or six months after the day on which the amendment is available in both of the official languages of Canada, whichever is later.

Notice of effective date

(3) The Commission must note the effective date of the incorporation by reference on its website.

References in French version

(4) In the French version of these Regulations,

- (a) other than in paragraphs 6(1)(f), 7(h) and 11(3)(f) and subparagraph 26(1)(b)(iv), “approbation” is to be read to include “certificat d’agrément” and “certificat d’approbation” as used in the IAEA Regulations; and
- (b) “approuvé” is to be read to include “agrée” as used in the IAEA Regulations.

References in English version

(5) In the English version of these Regulations, other than in paragraphs 6(1)(f), 7(h) and 11(3)(f) and subparagraph 26(1)(b)(iv), “approval” means “certificate of approval” as used in the IAEA Regulations.

APPLICATION

Application

2. (1) Subject to subsection (2), these Regulations apply in respect of the packaging and transport of

- (a) prescribed equipment; and
- (b) nuclear substances, including
- (i) the design, production, use, inspection, maintenance and repair of packaging and packages for nuclear substances, and
 - (ii) the preparation, consigning, handling, loading, carriage, storage during transport, receipt at final destination and the unloading of packages and unpacking of their contents.

Exception

(2) These Regulations, except for sections 6 and 7, do not apply in respect of the packaging and transport of a nuclear substance

- (a) that is naturally occurring and has not been processed or has been processed only for purposes other than its extraction and that is not intended to be processed for its use, provided that it has
- (i) a specific activity less than or equal to 70 kBq/kg, or
 - (ii) an activity concentration that does not exceed 10 times the activity concentration limit for exempt material values set out in the IAEA Regulations;
- (b) that is implanted in or incorporated into a person or an animal for medical diagnosis or treatment purposes, or that subsists in their remains;
- (c) that is contained in a sample of material taken for bioassay purposes;
- (d) that is used by a holder of a licence on private property for the purpose of an activity described in paragraphs 26(a) to (c) of the Act that the licence authorizes the holder to carry on, if access to the property is controlled;
- (e) that is contained in human or animal tissue samples or animal remains, or a liquid scintillation medium, if the specific activity of the nuclear substance averaged over the mass of the material does not exceed 10^{-6} A₂/kg;
- (f) that is contained in a product for which no licence is required under sections 6 to 8 of the *Nuclear Substances and Radiation Devices Regulations* following the sale of the product to an end user;
- (g) that is an integral part of a conveyance and is required for transport purposes;
- (h) that has an activity concentration that does not exceed the values for an exempt material set out in the IAEA Regulations or in a certificate for a basic radionuclide value that is not listed in the IAEA Regulations;
- (i) that is in a consignment that has a total activity that does not exceed the values for an activity limit for an exempt consignment set out in the IAEA Regulations, in a certificate for a basic radionuclide value that is not listed in the IAEA Regulations or in a certificate for an instrument or article that has an alternative activity limit for an exempt consignment;

- (j) that is contained in a check source for which no licence is required under section 8.1 of the *Nuclear Substances and Radiation Devices Regulations* following the sale of the check source to an end user;
- (k) that is contained in a radiation device for which no licence is required under paragraph 5(1)(c) of the *Nuclear Substances and Radiation Devices Regulations* following the sale of the device to an end user;
- (l) that consists of non-radioactive solid objects with radioactive material present on any surface in quantities not exceeding 0.4 Bq/cm² for beta and gamma emitters and low toxicity alpha emitters and 0.04 Bq/cm² for all other alpha emitters;
- (m) that is in or on a person who is transported for medical treatment because the person has been subject to an accidental or deliberate intake or contamination;
- (n) that is present in a load of waste that is in transport and not classified as radioactive material and that has triggered a radiation monitor alarm if the nuclear substance in the load has been determined only to be one or more of the following medical isotopes and if there is no loss or dispersal of the material during the transport:
- (i) Chromium 51,
 - (ii) Indium 111,
 - (iii) Iodine 123, 124 or 131,
 - (iv) Gallium 67,
 - (v) Technetium 99m,
 - (vi) Thallium 201; or
- (o) that is in transport to another location for proper characterization in accordance with section 3, if
- (i) it is present in a load that was already in transport,
 - (ii) it is not classified as radioactive material,
 - (iii) it has triggered a radiation monitor alarm and the maximum dose rate is less than or equal to 500 µSv/h, and
 - (iv) there is no loss or dispersal of the material during the transport.

Characterization

3. (1) The nuclear substance referred to in paragraph 2(2)(o) must be characterized at the earliest possible time to determine the extent to which it is subject to these Regulations and the *Nuclear Substances and Radiation Devices Regulations*.

Licensable quantity

- (2) For the purpose of this section, a licensable quantity in respect of a nuclear substance is a quantity
- (a) in respect of which the activity exceeds the exemption quantity, as defined in section 1 of the *Nuclear Substances and Radiation Devices Regulations*; or
 - (b) in respect of which there is no exemption from licensing under sections 5 to 8.1 of those Regulations.

Documentation of characterization

- (3) The person who performs the characterization must
- (a) keep a record of the radiation detection and the disposition of the nuclear substance for two years;
 - (b) file an annual report with the Commission by April 30 that contains a summary of radiation detections for the calendar year before the date of the report; and
 - (c) immediately notify the Commission if the source of the radioactivity in the load is determined to be a licensable quantity of nuclear substance.

Dose rate greater than 5 µSv/h and less than or equal to 25 µSv/h

(4) If the measured dose rate at the time that the alarm is triggered is greater than 5 µSv/h and less than or equal to 25 µSv/h and there is no loss or dispersal of the nuclear substance during the transport, the consignor, the carrier and the consignee must

- (a) immediately make a preliminary report to the Commission indicating the alarm level, the details of the transport and information on the location and circumstances of the detected radiation and any action that they have taken or propose to take in respect of it; and
- (b) characterize the source of the radiation within 10 days after its detection and make a follow-up report
 - (i) immediately, if the source of the radioactivity in the load is determined to be a licensable quantity of a nuclear substance, or
 - (ii) within 21 days, if the nuclear substance in the load is determined not to be of a licensable quantity, with a summary of the radiation detection and the disposition of the substance and a confirmation that it is not of a licensable quantity.

Dose rate greater than 25 µSv/h and less than or equal to 500 µSv/h

(5) If the measured dose rate at the time that the alarm is triggered is greater than 25 µSv/h but less than or equal to 500 µSv/h and there is no loss or dispersal of the nuclear substance during the transport, the consignor, carrier and consignee must

- (a) immediately make a preliminary report to the Commission indicating the alarm level, the details of the transport and information on the location and circumstances of the detected radiation and any action that they have taken or propose to take in respect of it;
- (b) isolate the load, prevent dispersal of the nuclear substance and control access to it to ensure that persons are not exposed to effective doses that exceed the limits set out in section 13 of the *Radiation Protection Regulations*;
- (c) have an expert in radiation protection assess the situation; and
- (d) report the results of the assessment to the Commission within 10 days after the detection and make a follow-up report
 - (i) immediately, if the source of the radioactivity in the load is determined to be a licensable quantity of a nuclear substance, or
 - (ii) within 21 days, if the nuclear substance in the load is determined not to be of a licensable quantity, with a summary of the radiation detection and disposition of the substance and a confirmation that it is not of a licensable quantity.

CLASSIFICATION OF MATERIAL AND PACKAGES

General classification

4. Subject to section 5, packages and radioactive material must be classified in accordance with the IAEA Regulations.

LSA material

5. (1) LSA material is classified as LSA-I material if it is either non-fissile material or fissile-excepted radioactive material and if it consists of

- (a) ores that contain naturally occurring radionuclides with a uranium and thorium concentration not greater than 3% by mass;
- (b) radioactive material for which the A_2 value is unlimited, except for ores that contain naturally occurring radionuclides with a uranium and thorium concentration greater than 3% by mass;
- (c) concentrates of unirradiated thorium, of natural uranium or of depleted uranium, as those terms are defined in the IAEA Regulations, or their unirradiated compounds or mixtures in solid or liquid

form;

(d) any mill tailings, contaminated earth, concrete, rubble, other debris and activated materials in which the radioactive material is essentially uniformly distributed and for which the average specific activity does not exceed 10^{-6} A₂/g; or

(e) other radioactive material in which the activity is distributed throughout and for which the estimated average specific activity does not exceed 30 times the activity concentration limit for exempt material values set out in the IAEA Regulations or in a certificate for a basic radionuclide value that is not listed in those Regulations.

LSA-II material

(2) LSA material is classified as LSA-II material if it consists of material

(a) that is less than 225 L of water with a tritium concentration that has an activity level not greater than 0.8 TBq/L; or

(b) in which the activity is distributed throughout and the estimated average specific activity does not exceed 10^{-4} A₂/g for solids and gases, and 10^{-5} A₂/g for liquids.

LSA-III material

(3) LSA material is classified as LSA-III material if it consists of solid material that is not in powder form and that meets the applicable requirements of the IAEA Regulations.

LICENCE

Licence exemptions

6. (1) A person may transport a nuclear substance without a licence issued under subsection 24(2) of the Act for that purpose, except in the following cases:

(a) the nuclear substance is a Category I, II or III nuclear material, as defined in section 1 of the *Nuclear Security Regulations*, and is transported outside the area in which the material is required, under section 7 of those Regulations, to be processed, used or stored;

(b) the nuclear substance is in transit in a package of a certified design or in a package that has been approved as Type B(U)-96, Type C-96 or Type H(U)-96 by a foreign competent authority in accordance with the IAEA Regulations unless, in the case of transport by aircraft or ship, there is no scheduled stop in Canada;

(c) the nuclear substance is contained in a large object;

(d) the transport of the nuclear substance cannot meet all of the requirements of these Regulations;

(e) the transport of the nuclear substance requires a special use vessel; or

(f) the transport of the nuclear substance requires multilateral approval of shipments in accordance with the IAEA Regulations.

Activity exemptions

(2) A person may possess, transfer, import, export or use prescribed equipment without a licence issued under subsection 24(2) of the Act for that purpose.

Packaging exemptions

(3) A person may package a nuclear substance without a licence issued under subsection 24(2) of the Act for that purpose.

Requirements imposed by s. 26 of Act

(4) For greater certainty, the exemptions established in subsections (1) to (3) relate only to the packaging and transport of nuclear substances and do not derogate from the licence requirements imposed by section 26 of the Act.

Application for licence

7. An application for a licence under subsection 24(2) of the Act to transport a nuclear substance must contain

(a) the applicable information required by section 3 of the *General Nuclear Safety and Control Regulations*;

(b) the information required by section 5 of the *Nuclear Security Regulations* if the substance is a Category I, II or III nuclear material, as defined in those Regulations;

(c) the name, postal address and telephone number of each consignor and consignee;

(d) if the nuclear substance is one of those referred to in paragraph 6(1)(b),

(i) a description of the nuclear substance, including the name, chemical form and physical state, the activity — or in the case of fissile material, the mass — of each nuclear substance in a package and the total activity or mass in the consignment,

(ii) the country of origin of the nuclear substance,

(iii) details of the applicable management system,

(iv) the reason for selecting a route through Canada,

(v) the name of each carrier,

(vi) the dates, times and locations of its arrival into and departure from Canada and of any scheduled stop or transshipment in Canada,

(vii) the number of the certificate or approval applicable to the package,

(viii) the number of packages to be transported,

(ix) the types of conveyance to be used during transit,

(x) if a vessel is to be used as a conveyance during transit, the name of the vessel and its flag state,

(xi) the United Nations number for the nuclear substance, and

(xii) the identification number of the emergency response assistance plan that is approved under section 7 of the *Transportation of Dangerous Goods Act, 1992* or a reference to the effect that a plan is not required, as the case may be;

(e) if the nuclear substance is contained in a large object,

(i) information that demonstrates that the internal contamination

(A) is contained within the object and that all openings are sealed,

(B) meets the requirements applicable to SCO-I or SCO-II,

(C) is classified as non-fissile or fissile-excepted radioactive material, and

(D) is in solid form and that any liquid content is negligible,

(ii) information that demonstrates that the large object

(A) meets the free drop test requirements set out in the IAEA Regulations for the industrial package type referred to in section 27 for the SCO classification determined for the internal contamination,

(B) does not have a dose rate on contact of more than 2 mSv/h from the accessible surfaces of the object, as prepared for shipment, and

(C) does not have more than 4 Bq/cm² of contamination on the exterior surfaces,

(iii) a detailed transport plan covering all activities associated with the shipment, including

- (A) radiation protection,
 - (B) emergency response, and
 - (C) any special precautions or special administrative or operational controls to be employed during transport, and
- (iv) details of the applicable management system;
- (f) if the transport of the nuclear substance cannot meet all the requirements of these Regulations,
- (i) information that demonstrates that the overall level of safety in transport is at least equivalent to that which would be provided if all the applicable requirements of these Regulations were met,
 - (ii) a statement of the reasons why the consignment cannot be made in accordance with these Regulations, and
 - (iii) a statement of any special precautions or special administrative or operational controls that are to be employed during transport to compensate for the inability to meet the requirements of these Regulations;
- (g) if the transport of the nuclear substance requires a special use vessel,
- (i) the vessel owner's and the operator's contact information, including, as applicable, their names, postal addresses, email addresses, telephone numbers and fax numbers,
 - (ii) a copy of the radiation protection program applicable to the shipment,
 - (iii) details of the consignment,
 - (iv) information on the stowage arrangements for the duration of the voyage, including for any consignments loaded or unloaded at ports of call en route,
 - (v) the dates, times and locations of arrival into and departure from Canada and of any scheduled stop in Canada,
 - (vi) a copy of any certificate or approval applicable to packages or materials in the consignment,
 - (vii) the name of the vessel and its flag state, and
 - (viii) a copy of any document issued by the competent authority of the vessel's flag state approving the radiation protection program; and
- (h) if the transport of the nuclear substance requires approval of shipment in accordance with the IAEA Regulations,
- (i) the period of time, related to the shipment, for which the approval is sought,
 - (ii) information on the radioactive contents, the expected types of conveyance and the probable or proposed route,
 - (iii) details of how the precautions and administrative or operational controls referred to in the approval for the package design, if applicable, that was issued in accordance with the IAEA Regulations, are to be put into effect,
 - (iv) a copy of the applicable approvals for the package design, and
 - (v) in the case of fissile material, information on the sum of criticality safety indexes and any related safety assessment, emergency response plan and administrative or operational controls.

PACKAGING REQUIREMENTS

Type H(M) packages

8. Type H(M) packages must meet the following requirements:

- (a) they must be designed and maintained to national or international standards other than the International Organization for Standardization standard ISO 7195 entitled *Packaging of uranium hexafluoride (UF₆) for transport*, as amended from time to time, provided that an equivalent level of safety is maintained;

- (b) they must withstand, without leakage and without unacceptable stress, a hydraulic test at an internal pressure of at least 1.38 MPa;
- (c) they must withstand, without loss or dispersal of uranium hexafluoride, the free drop test set out in the IAEA Regulations for normal conditions of transport;
- (d) they must withstand, without rupture of the containment system, the thermal test set out in the IAEA Regulations for accident conditions of transport, unless they are designed to contain 9 000 kg or more of uranium hexafluoride; and
- (e) they must not be equipped with pressure relief devices.

Type H(U) packages

9. Type H(U) packages must meet the following requirements:

- (a) they must withstand, without leakage and without unacceptable stress, as specified in the International Organization for Standardization standard ISO 7195 entitled *Packaging of uranium hexafluoride (UF₆) for transport*, as amended from time to time, the hydraulic test set out in the IAEA Regulations;
- (b) they must withstand, without loss or dispersal of the uranium hexafluoride, the free drop test set out in the IAEA Regulations for normal conditions of transport;
- (c) they must withstand, without rupture of the containment system, the thermal test set out in the IAEA Regulations for accident conditions of transport; and
- (d) they must not be equipped with pressure relief devices.

CERTIFICATION

Requirement to certify design of prescribed equipment

10. (1) The design of the following types of prescribed equipment must be certified by the Commission or a designated officer before the design is used:

- (a) Type B and Type C packages;
- (b) packages used to transport fissile material;
- (c) packages used to transport 0.1 kg or more of uranium hexafluoride;
- (d) special form radioactive material; and
- (e) low dispersible radioactive material.

Certification of subcriticality of fissile-excepted radioactive material

(2) The calculation of a value demonstrating that fissile-excepted radioactive material will remain subcritical must be certified by the Commission or a designated officer before the value is used, except in relation to the following materials:

- (a) uranium enriched in uranium-235 to a maximum of 1% by mass and with a plutonium and uranium-233 content not exceeding 1% of the mass of uranium-235, provided that the fissile nuclides are distributed essentially homogeneously throughout the material and any uranium-235 that is present in metallic, oxide or carbide forms must not form a lattice arrangement;
- (b) liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2% by mass, with a plutonium and uranium-233 content not exceeding 0.002% of the mass of uranium, and with a minimum nitrogen to uranium (N/U) atomic ratio of 2;
- (c) uranium with a maximum uranium enrichment of 5% by mass of uranium-235 provided that
 - (i) there is no more than 3.5 g of uranium-235 per package,
 - (ii) the plutonium and uranium-233 content does not exceed 1% of the mass of uranium-235 per package, and
 - (iii) the amount of fissile nuclides in the consignment is limited to 45 g;

- (d) fissile nuclides with a total mass not greater than 2.0 g per package, provided that the amount of fissile nuclides in the consignment is limited to 15 g; and
- (e) fissile nuclides with a total mass not greater than 45 g per consignment, either packaged or unpackaged, provided that it is transported under exclusive use.

Certification of calculation of values

(3) The calculation of the following values must be certified by the Commission or a designated officer before the value is used:

- (a) the basic radionuclide value for radioactive material that has a basic radionuclide value that is not listed in the IAEA Regulations; and
- (b) the value of an alternative activity limit for an instrument or article that has an alternative activity limit for an exempt consignment.

Application for certification of design

11. (1) An application for certification of a design for the types of prescribed equipment referred to in subsection 10(1) must include the information required for the applicable approval under the IAEA Regulations, and

- (a) the number of any applicable approval issued by a foreign competent authority, in accordance with the IAEA Regulations;
- (b) in respect of a package design,
 - (i) the recommended inspection and servicing program, and
 - (ii) instructions for packing, transport, receiving, maintenance and unpacking; and
- (c) any other information necessary to demonstrate that the design meets the requirements of these Regulations.

Observing of test

(2) An applicant must give the Commission, or a designated officer, a reasonable opportunity to observe any test that the applicant intends to conduct to demonstrate the compliance of a design with these Regulations, including reasonable notice of the date and time of the test.

Application for recertification

(3) No later than 60 days after the day on which the certificate of a design expires, an applicant may make a new application to the Commission or a designated officer to certify the design if the technical specifications of the design have not changed. The application must include the following information and documents:

- (a) a statement confirming that the drawings and procedures previously submitted have not changed or, if they have changed, a copy of the revised drawings and procedures and a statement confirming that the changes are without technical significance and do not affect the safety of the design;
- (b) a statement confirming that each type of prescribed equipment referred to in subsection 10(1) has been produced and maintained in compliance with the drawings and procedures previously submitted;
- (c) a statement confirming that the instructions previously submitted in respect of the certified design have not been modified;
- (d) unless previously submitted, the model number and drawings of any capsule containing radioactive material;
- (e) a list of the serial numbers used for the certified design, other than a certified design referred to in paragraph (f);
- (f) in respect of a design that was certified after approval by a foreign competent authority in accordance with the IAEA Regulations, a list of the serial numbers currently in use or intended for

use in Canada;

(g) a list of the known users of the latest certified design;

(h) a summary of the maintenance performed and any operational or maintenance problems encountered with the certified design, including the date, the nature of the problem and any action taken;

(i) a copy of any applicable approval issued by the foreign competent authority in accordance with the IAEA Regulations since the last certification;

(j) a copy of the documents submitted to the foreign competent authority to obtain each approval; and

(k) any other information necessary to demonstrate that the design meets the applicable requirements of these Regulations.

Application for certification of subcriticality

12. (1) An application for certification of the calculation referred to in subsection 10(2), must include the following information and documents:

(a) a description of the fissile-excepted radioactive material, including its name, chemical form and physical state;

(b) the calculation demonstrating that the material will remain subcritical without the need for accumulation control under the conditions described in the IAEA Regulations, including tests performed, principles used, assumptions made, scenarios considered, limitations that should be applied and any data, formulae or analysis tool used;

(c) a copy of any applicable approval issued by a foreign competent authority in accordance with the IAEA Regulations;

(d) a copy of any applicable approval issued by a foreign competent authority in accordance with the IAEA Regulations or of any applicable certificate issued in respect of a special form radioactive material;

(e) a copy of any applicable certificate issued in respect of low dispersible radioactive material;

(f) details of the applicable management system;

(g) details of any actions needed to be taken before shipment; and

(h) any other information necessary to demonstrate that the calculation meets the applicable requirements of these Regulations.

Application for recertification

(2) No later than 60 days after the day on which the certificate expires, an applicant may make a new application for certification to the Commission or a designated officer if the calculation has not been modified. The application must include the following information and documents:

(a) a statement confirming that the calculation demonstrating that the material remains subcritical without the need for accumulation control under the conditions described in the IAEA Regulations has not been modified, and that the tests performed, principles used, assumptions made, scenarios considered, limitations that should be applied and any data, formulae or analysis tool used have not changed;

(b) a copy of any applicable approval issued by the foreign competent authority in accordance with the IAEA Regulations since the last certification;

(c) a statement confirming that the details of the applicable management system and any actions needed to be taken before shipment that were previously submitted have not changed; and

(d) any other information necessary to demonstrate that the calculation meets the applicable requirements of these Regulations.

Application for certification of calculated values

13. (1) An application for certification of the calculation referred to in subsection 10(3) must include the following information and documents:

- (a) a description of the nuclear substance, including its name, chemical form and physical state;
- (b) the calculation of the basic radionuclide value, including the principles used, assumptions made, scenarios considered and any data or formulae used to determine the value;
- (c) a copy of any applicable approval issued by a foreign competent authority in accordance with the IAEA Regulations;
- (d) in respect of an instrument or article,
 - (i) details of the instrument or article that will contain the nuclear substance, including its identification, details of its construction, location of the nuclear substance and the intended uses of the instrument or article,
 - (ii) the maximum activity of the instrument or article,
 - (iii) the maximum external radiation level arising from the instrument or article,
 - (iv) details of the management system for the design and production of the instrument or article, and
 - (v) instructions for the use, inspection, maintenance and disposal of the instrument or article; and
- (e) any other information necessary to demonstrate that the calculation meets the applicable requirements of these Regulations.

Application for recertification

(2) No later than 60 days after the day on which the certificate expires, an applicant may make a new application for certification to the Commission or a designated officer if the calculation has not been modified. The application must include the following information and documents:

- (a) a statement confirming that the calculation of the basic radionuclide value, including the principles used, assumptions made, scenarios considered and any data or formulae used to determine the calculation has not been modified;
- (b) in respect of an instrument or article, a statement confirming that the information previously submitted has not changed or, if it has changed, the revised information and a statement confirming that the changes are without technical significance and do not affect safety;
- (c) a copy of any applicable approval issued by the foreign competent authority in accordance with the IAEA Regulations since the last certification;
- (d) a statement confirming that the instructions previously submitted in respect of the certified calculation have not been modified; and
- (e) any other information necessary to demonstrate that the calculation meets the applicable requirements of these Regulations.

Application for certification

14. (1) The applications for certification referred to in sections 11 to 13 must be made to the Commission or a designated officer.

Modifications require recertification

(2) If the certified design or calculation referred to in section 10 has been modified in a manner that affects the safety of the prescribed equipment referred to in that section the certificate is void and a new application for certification must be made.

Notice of refusal to certify

15. (1) The Commission, or the designated officer, must notify a person who has applied for certification, of a proposed decision not to certify as well as the basis for the proposed decision, at least 30 days before making the decision.

Right to be heard

(2) The notice must include a description of the person's right to be provided with an opportunity to be heard in accordance with section 17.

Notice of decertification

16. (1) The Commission, or the designated officer, must notify a person to whom a certificate has been issued and, in the case of a certificate for a package design, any registered user of a package of that design, of a proposed decision to decertify, as well as the basis for the proposed decision, at least 30 days before making the decision.

Right to be heard

(2) The notice must include a description of the person's and the registered user's right to be provided with an opportunity to be heard in accordance with section 17.

Opportunity to be heard

17. (1) The Commission, or the designated officer, must provide the person referred to in section 15 or 16 or the registered user referred to in section 16 with an opportunity, in respect of the proposed decision, to be heard either orally or in writing if, within 30 days after the date of the notice, they request that opportunity.

Notification of final decision

(2) Every person and registered user who is notified in accordance with section 15 or 16 must be notified of the final decision and the reasons for it.

PRODUCTION, USE AND POSSESSION OF PRESCRIBED EQUIPMENT

Producing package of certified design

18. Every person who produces a package of a certified design must

- (a) produce the package in accordance with the requirements set out in the certificate; and
- (b) clearly mark the package with the certificate number, design number and serial number.

Application for registration

19. (1) A person who intends to use a package of a certified design must apply to the Commission to register their use of the package.

Information for registration

(2) The Commission must register the person's intended use of a package of a certified design on receipt of an application containing the following:

- (a) the person's contact information, including, as applicable, their name, postal address, email address, telephone number and fax number;
- (b) the name of a person who can be contacted for transport purposes;
- (c) the number of any licence that the person holds in respect of the contents of the package;
- (d) the number of any applicable approval issued by a foreign competent authority in accordance with the IAEA Regulations;
- (e) the package's design and serial numbers; and
- (f) a statement confirming that the person possesses the instructions necessary to prepare the package for shipment, as set out in the certificate for the package design.

Confirmation

(3) A person may use a package of a certified design only if they have received confirmation from the Commission that their use of the package has been registered.

Producing special form radioactive material

20. (1) Every person who produces special form radioactive material must

(a) use a certified design and produce the material in accordance with the requirements set out in the certificate; and

(b) clearly mark the material, or any source holder to which it is permanently attached, in a unique, legible and durable manner.

Transporting special form radioactive material

(2) A person may only transport special form radioactive material if it has been produced in accordance with a certified design or a design approved by a foreign competent authority in accordance with the IAEA Regulations.

Prior approvals

(3) Every person who possesses special form radioactive material, the design of which was approved under the 1973, 1973 (as amended), 1985 or 1985 (as amended in 1990) edition of the IAEA Regulations, must ensure that the material was produced before January 1, 2004 and that it is used in compliance with section 24.

Producing low dispersible radioactive material

21. (1) Every person who produces low dispersible radioactive material must

(a) use a certified design and produce the material in accordance with the requirements set out in the certificate; and

(b) clearly mark the material in a unique, legible and durable manner.

Transporting low dispersible radioactive material

(2) A person may only transport low dispersible radioactive material if it has been produced in accordance with a certified design.

Instrument or article having alternative activity limit

22. (1) Every person who produces an instrument or article that has an alternative activity limit for an exempt consignment must use the applicable certified calculation and produce the instrument or article in accordance with the requirements set out in the certificate.

Transporting instrument or article having alternative activity limit

(2) A person may only transport an instrument or article that has an alternative activity limit for an exempt consignment if it has been produced using the applicable certified calculation.

Producing fissile-excepted radioactive material

23. (1) Every person who produces fissile-excepted radioactive material that requires a certified calculation demonstrating that the material will remain subcritical must do so in accordance with the requirements set out in the certificate.

Transporting fissile-excepted radioactive material

(2) A person may only transport fissile-excepted radioactive material that requires a certified calculation demonstrating that the material will remain subcritical if it has been produced in accordance with the requirements set out in the certificate.

MANAGEMENT SYSTEM

Management system

24. Every person who designs, produces, tests, uses, inspects, maintains or repairs prescribed equipment must

- (a) implement and maintain a management system in accordance with the IAEA Regulations;
- (b) keep a record of the system and of any information collected under it; and
- (c) retain the record for a period ending two years after the day on which the prescribed equipment is removed from service.

PACKAGING AND TRANSPORT OF RADIOACTIVE MATERIAL

General obligations

25. (1) Every person who transports, or presents for transport, radioactive material must comply with the requirements of the *Transportation of Dangerous Goods Regulations*.

Consignor's responsibilities

(2) Every consignor, other than a consignor of an excepted package, must comply with the requirements of the IAEA Regulations in respect of

- (a) the provision of information for carriers;
- (b) the notification of competent authorities; and
- (c) the possession of certificates and instructions.

Advising consignee

(3) The consignor must advise the consignee that the material is going to be transported.

Carrier's responsibilities

(4) Every carrier of radioactive material must

- (a) comply, in respect of transport and storage, with the requirements of the IAEA Regulations except in respect of placarding;
- (b) transport the material in accordance with the consignor's instructions; and
- (c) implement and maintain work procedures to ensure compliance with these Regulations and keep a record of those procedures.

Packages for transport

26. (1) A consignor may present for transport and a carrier may transport

- (a) radioactive material if the material is contained in
 - (i) an excepted package,
 - (ii) a Type IP-1, Type IP-2 or Type IP-3 package,

- (iii) a Type A package,
- (iv) a Type B or Type C package of a certified design,
- (v) a package of a certified design used to transport fissile material, or
- (vi) a package of a certified design used to transport 0.1 kg or more of uranium hexafluoride;

(b) the following if a licence has been issued for that purpose under subsection 24(2) of the Act:

- (i) a nuclear substance contained in a large object,
- (ii) a nuclear substance whose transport does not meet all of the requirements of these Regulations,
- (iii) a nuclear substance whose transport requires a special use vessel,
- (iv) a nuclear substance whose transport requires multilateral approval of shipments in accordance with the IAEA Regulations, and
- (v) a package that is in transit and is of a design that has been approved as a Type B (U)-96 or Type C-96 package by a foreign competent authority in accordance with the IAEA Regulations;

(c) unpackaged LSA-I material or an unpackaged SCO-I, in accordance with the IAEA Regulations; and

(d) a package that contains 0.1 kg or more of uranium hexafluoride and that is of a design that has been approved as a Type H(U)-96 package by a foreign competent authority in accordance with the IAEA Regulations.

Activity or mass limits

(2) The activity or mass of the radioactive material contained in the package must be within the applicable limit for that type of package as set out

- (a) in the IAEA Regulations;
- (b) in any applicable certificate; and
- (c) in any applicable approval issued by a foreign competent authority in accordance with the IAEA Regulations.

Previously not requiring certification

(3) Despite subsection (1), a package that does not require certification by the Commission and whose design meets the requirements of the 1985 or 1985 (as amended in 1990) edition of the IAEA Regulations may be used if

- (a) the package meets the applicable requirements of section 25; and
- (b) the packaging was neither manufactured nor modified after December 31, 2003.

Previously certified

(4) Despite subsection (1), a package manufactured to a package design certified under the requirements of the 1973, 1973 (as amended), 1985 or 1985 (as amended in 1990) edition of the IAEA Regulations may continue to be used if

- (a) the package meets the applicable requirements of section 25;
- (b) its manufacture began before
 - (i) January 1, 1996, for designs that meet the requirements of the 1973 or 1973 (as amended) edition of the IAEA Regulations, or
 - (ii) January 1, 2007, for designs that meet the requirements of the 1985 or 1985 (as amended in 1990) edition of the IAEA Regulations; or

(c) it contains fissile material that meets the applicable requirements for fissile material of the editions of the IAEA Regulations issued after 2009.

Requirements

(5) For packages prepared in accordance with the requirements of an edition of the IAEA Regulations before the 2012 edition, if the material was considered fissile-excepted radioactive material under that earlier edition, and if it is neither excluded from the definition of fissile material nor excepted from the provisions applicable to fissile material in the editions of those Regulations issued after 2009, the package may be transported, provided that it is under exclusive use and the following formula yields a result of less than one:

$$(A/B) + (C/D)$$

where

A is the mass in grams of uranium-235;

B is 400 if the fissile material is mixed with substances that have an average hydrogen density less than or equal to water, otherwise it is 290;

C is the mass in grams of all other fissile nuclides, as defined in the IAEA Regulations; and

D is 250 if the fissile material is mixed with substances that have an average hydrogen density less than or equal to water, otherwise it is 180.

Transport requirements for LSA and SCO

27. (1) Subject to subsections (2) and (3), both LSA material and an SCO must be transported in Type IP-3 packages.

No escape of radioactive contents

(2) LSA-I material and an SCO-I may be transported unpackaged in accordance with the IAEA Regulations, but must be transported in a manner that ensures that, under routine conditions of transport, there will be no escape of the radioactive contents from the conveyance or any loss of shielding.

Transport in accordance with IAEA Regulations

(3) LSA material and an SCO may be transported in Type IP-1 packages and Type IP-2 packages in accordance with the IAEA Regulations if the LSA material and the SCO

(a) are transported in conveyances that are not carrying passengers;

(b) are transported in conveyances or freight containers from one consignor only; and

(c) are only loaded at the consignor's location and unloaded at the consignee's location.

Responsibilities of consignors and carriers under IAEA Regulations

28. (1) Consignors and carriers of radioactive material must comply with the IAEA Regulations in respect of

(a) requirements to be met before the first shipment and before each shipment;

(b) requirements for the transport of other goods;

(c) requirements and controls for contamination and for leaking packages;

(d) requirements and controls for transport of excepted packages;

(e) the determination of the transport index;

(f) the determination of the criticality safety index;

(g) the limits on the transport index, criticality safety index and radiation levels;

(h) the determination of categories for packages, overpacks and freight containers; and

(i) the marking and labelling of packages, overpacks and freight containers, except that the figures illustrating labels found in the IAEA Regulations must be replaced by the corresponding illustrations for Class 7 radioactive materials that are set out in the Appendix to Part 4 of the *Transportation of*

Dangerous Goods Regulations.

Exceptions

(2) Despite subsection (1), a consignor may present for transport and a carrier may transport, by road, radioactive material in a package, or a package within an overpack, that is not labelled in accordance with the IAEA Regulations, if

(a) the package or overpack contains or is an exposure device of a certified model, as that device is defined in section 1 of the *Nuclear Substances and Radiation Devices Regulations* and

- (i) the package or overpack is transported with material from one consignor only and in a conveyance that is not carrying passengers,
- (ii) the package or overpack is transported in a conveyance that displays on each side and on each end a placard for Class 7 radioactive materials as set out in the Appendix to Part 4 of the *Transportation of Dangerous Goods Regulations*, and
- (iii) both the package and the overpack, if one is used, are clearly marked with the word "RADIOACTIVE" or "RADIOACTIF";

(b) the package is an excepted package; or

(c) the package or overpack contains only LSA-I material other than uranium hexafluoride and

- (i) the package or overpack is transported with material from one consignor only and in a conveyance that is not carrying passengers,
- (ii) the package or overpack is only loaded at the consignor's location and unloaded at the consignee's location,
- (iii) the package or overpack is transported by road in a conveyance or freight container that displays on each side and on each end a placard for Class 7 radioactive materials as set out in the Appendix to Part 4 of the *Transportation of Dangerous Goods Regulations*, and
- (iv) both the package and the overpack, if one is used, are clearly marked with the words "RADIOACTIVE LSA-I" or "LSA-I RADIOACTIF".

Exceptions

(3) Despite subsection (1), a consignor may present for transport and a carrier may transport radioactive material in accordance with the *International Maritime Dangerous Goods Code* or the *Technical Instructions for the Safe Transport of Dangerous Goods by Air*.

English or French may be used

(4) If the English and French versions of the IAEA Regulations each prescribe the use of a word, the word prescribed by either version may be used.

Particulars of consignment

29. (1) Every consignor of radioactive material must include in the transport documents for the consignment the particulars of consignment that are required by the IAEA Regulations, which particulars must be clearly and indelibly printed.

Exceptions

(2) Subsection (1) does not apply

(a) in respect of an excepted package if the transport documents contain the following information:

- (i) the identification of the consignor and consignee,
- (ii) the United Nations number assigned to the material as set out in the IAEA

- Regulations, preceded by the letters “UN”,
- (iii) the proper shipping name as set out in the IAEA Regulations,
- (iv) the identification mark for the certification described in each of sections 12 to 14, as applicable, and
- (v) the identification mark of any applicable special form radioactive material approval issued by a foreign competent authority in accordance with the IAEA Regulations; and

(b) to a consignor who provides transport documents that have been prepared in accordance with the *International Maritime Dangerous Goods Code* or the *Technical Instructions for the Safe Transport of Dangerous Goods by Air*.

Obligation

(3) Every carrier who transports a consignment of radioactive material must ensure that it is accompanied by the transport documents referred to in subsection (1) or (2).

Exception for exposure devices

(4) The transport documents in respect of radioactive material that is in an exposure device of a certified model transported in accordance with paragraph 28(2)(a) do not need to satisfy the requirements set out in the IAEA Regulations for the category of the package and transport index.

RADIATION PROTECTION

DEFINITIONS

Definitions

30. For the purposes of sections 31 and 33, “committed”, “equivalent dose” and “radon progeny” have the same meaning as in subsection 1(1) of the *Radiation Protection Regulations*.

RADIATION PROTECTION PROGRAM

Radiation protection program

31. (1) Every consignor, carrier or consignee of radioactive material, other than one who only handles or transports excepted packages, must implement a radiation protection program and must, as part of that program,

(a) keep the amount of exposure to radon progeny and the effective dose and equivalent dose received by and committed to persons as low as reasonably achievable, taking into account social and economic factors, through the implementation of

- (i) management control over work practices,
- (ii) personnel qualification and training,
- (iii) control of exposure to radiation by personnel and the public, and
- (iv) planning for unusual situations;

(b) prevent persons from receiving doses of radiation higher than the radiation dose limits prescribed by the *Radiation Protection Regulations*;

(c) assess the radiation at the workplace and

- (i) conduct workplace or individual monitoring if it may reasonably be expected that the doses of radiation received by persons at the workplace will be 1 mSv or more but less than 5 mSv a year, or
- (ii) conduct individual monitoring if it may reasonably be expected that the doses of radiation received by persons at the workplace will be 5 mSv a year or more; and

(d) train the persons referred to in the program on the application of the program.

Requirement to keep records

(2) Every consignor, carrier or consignee must

- (a) keep a record of their radiation protection program and of any information collected under it; and
- (b) retain the record for a period ending two years after the day on which the information is collected.

When dose limit exceeded

32. Every consignor, carrier or consignee who becomes aware that a dose of radiation received by a person may have exceeded an applicable dose limit prescribed by the *Radiation Protection Regulations* must

- (a) immediately notify the person and the Commission of the dose;
- (b) conduct an investigation to determine the magnitude of the dose and to establish the causes of the exposure;
- (c) take any action required to prevent the occurrence of a similar incident; and
- (d) within 21 days after becoming aware that the dose limit may have been exceeded, report to the Commission the results of the investigation or the progress that has been made in conducting it.

Provision of information

33. (1) Every consignor, carrier or consignee must inform every nuclear energy worker that they employ, in writing,

- (a) of the fact that the worker is a nuclear energy worker;
- (b) of the risks associated with the radiation to which the worker may be exposed in the course of their work, including the risks associated with the exposure of embryos and fetuses to radiation;
- (c) of the applicable effective dose limits and equivalent dose limits prescribed by sections 13 and 14, respectively, of the *Radiation Protection Regulations*; and
- (d) of the worker's radiation dose levels.

Obligation to inform

(2) In the case of a female nuclear energy worker, the consignor, carrier or consignee must

- (a) inform her, in writing, that she is required, as soon as she is aware that she is pregnant, to inform her employer of that fact in writing;
- (b) inform her, in writing, of the applicable effective dose limits prescribed by the *Radiation Protection Regulations*; and
- (c) on being informed of the pregnancy, make any accommodation that will not occasion costs or business inconvenience constituting undue hardship to it to comply with the effective dose limits prescribed by section 13 of the *Radiation Protection Regulations*.

Acknowledgement of information

(3) Every consignor, carrier or consignee must obtain from each nuclear energy worker that they employ who is informed of the matters referred to in paragraphs (1)(a) and (b) and subsection (2) a written acknowledgement that the worker has received the information.

PERSONAL INFORMATION

Collection of personal information

34. (1) If a consignor, carrier or consignee collects personal information, as defined in section 3 of the *Privacy Act*, that may be required to be disclosed to the Commission, another government institution or a dosimetry service, the consignor, carrier or consignee must inform the person to whom the information relates of the purpose for which it is being collected.

Required information

(2) Every nuclear energy worker whose work requires that they engage in activities that are subject to these Regulations must provide the following information to their employer:

- (a) their given names, surname and any previous surname;
- (b) their Social Insurance Number;
- (c) their gender;
- (d) their date, province and country of birth; and
- (e) their dose record, as applicable, for the current one-year dosimetry period and five-year dosimetry period as those terms are defined in subsection 1(1) of the *Radiation Protection Regulations*.

DANGEROUS OCCURRENCES

Reporting dangerous occurrences

35. (1) Every consignor, carrier, consignee and holder of a licence to transport a package while in transit must immediately make a preliminary report to the Commission and to the holder, if any, of a licence to import radioactive material on becoming aware of a failure to comply with the requirements of section 26 or of any of the following dangerous occurrences involving the package or the radioactive material:

- (a) a conveyance carrying radioactive material is involved in an accident;
- (b) a package shows evidence of damage, tampering or leakage of its contents, or its integrity is degraded in a manner that may reasonably be expected to impair its ability to comply with these Regulations or its certificate;
- (c) radioactive material is lost, stolen or no longer in the possession and control of a person who is required to have control of it under the Act;
- (d) radioactive material has escaped from a containment system, a package or a conveyance during transport;
- (e) fissile material is outside the confinement system during transport;
- (f) the level of non-fixed contamination, as defined in the IAEA Regulations, during transport exceeds the following limits as applicable when averaged over any area of 300 cm² of any part of the surface of the package or the conveyance:
 - (i) 4 Bq/cm² for beta and gamma emitters and low toxicity alpha emitters, and
 - (ii) 0.4 Bq/cm² for all other alpha emitters; and
- (g) there is a failure to comply with the provisions of the Act, any provision of these Regulations or any licence or certificate that is applicable to a package that may reasonably be expected to lead to a situation in which the environment, the health and safety of persons or national security is adversely affected;

Exception

(2) No preliminary report is required for the dangerous occurrence referred to in paragraph (1)(f) in respect of the internal surfaces of a tank or intermediate bulk container, as those terms are defined in the IAEA Regulations — or of a freight container or conveyance — that is dedicated to the transport of unpackaged radioactive material under exclusive use and for as long as it remains under that specific exclusive use.

Informing consignor

(3) Every carrier, consignee and holder of a licence referred to in subsection (1) must immediately make a preliminary report to the consignor if that person is not already aware of the failure to comply or of the occurrence.

Contents of preliminary report

(4) The preliminary reports referred to in subsections (1) and (3) must include information on the location and circumstances of the failure to comply or of the dangerous occurrence and on any action that the consignor, carrier, consignee or holder of a licence to transport a package while in transit has taken or proposes to take with respect to it.

Requirements in event of dangerous occurrence

(5) Immediately after the dangerous occurrence, the consignor, carrier, consignee or any other person who controls any area affected by it must

- (a) limit, to the extent possible, the dispersal of any radioactive material;
- (b) place barriers, signs or personnel at every point of entry into the affected area to control the entry of persons into that area;
- (c) record the name, postal address and telephone number of any person who may have been exposed to or contaminated by radioactive material and request that the person remain available for assessment by an expert in radiation protection;
- (d) have an expert in radiation protection assess the situation; and
- (e) report the results of the assessment to the Commission.

Full report

(6) Within 21 days after the failure to comply or the dangerous occurrence, the consignor, carrier, consignee and the holder of a licence, if any, to transport a package while in transit must file a full report with the Commission that includes the following information about the failure to comply or the occurrence:

- (a) the date, time and location of the failure to comply or the occurrence;
- (b) the names of the persons involved;
- (c) the details of the packaging and packages;
- (d) the probable cause;
- (e) the effects on the environment, the health and safety of persons, and national or international security that have resulted or may result;
- (f) the doses of radiation that any person has received or is likely to have received; and
- (g) the actions taken to remedy the failure to comply or the dangerous occurrence and to prevent its recurrence.

“RELEASE” UNDER THE TRANSPORTATION OF DANGEROUS GOODS ACT, 1992

Levels of ionizing radiation

36. For the purpose of the definition “release” in section 2 of the *Transportation of Dangerous Goods Act, 1992*, the following levels of ionizing radiation are established:

- (a) in respect of a package that is being transported under exclusive use
 - (i) 10 mSv/h on the external surface of the package,
 - (ii) 2 mSv/h on the surface of the conveyance, and
 - (iii) 0.1 mSv/h at a distance of 2 m from the surface of the conveyance; and
- (b) in respect of a package that is not being transported under exclusive use
 - (i) 2 mSv/h on the external surface of the package,

- (ii) 0.1 mSv/h at a distance of 1 m from the package,
- (iii) 2 mSv/h on the surface of the conveyance, and
- (iv) 0.1 mSv/h at a distance of 2 m from the surface of the conveyance.

OPENING OF PACKAGES

Package opened by other authorities

- 37.** (1) A person, other than the consignor or the consignee of the package, may only open a package if
- (a) measures are taken to prevent persons from receiving doses of radiation higher than the radiation dose limits prescribed by the *Radiation Protection Regulations*; and
 - (b) the package is opened in the presence of an expert in radiation protection.

Restoring opened package

(2) If a person other than the consignor or the consignee opens a package while in transport, the person must restore the package to a condition that meets the requirements of these Regulations before forwarding it to the consignee.

Responsibilities on opening package

(3) Every person who receives a package or who opens a package must, at that time, determine if any of the following conditions exist:

- (a) the package is damaged;
- (b) the package has been tampered with;
- (c) if the package contains fissile material, whether any portion of the fissile material is outside the confinement system; and
- (d) any portion of the contents of the package is outside the containment system or the package.

Preliminary report

(4) If any of the conditions exist the person must immediately make a preliminary report to the Commission and to the consignor.

Contents of preliminary report

(5) The preliminary report must include information on how and where the condition occurred and on any action that the person has taken or proposes to take with respect to it.

Full report

(6) Within 21 days after the condition has been discovered the consignor and the person who made the preliminary report must file a full report with the Commission that includes the following information:

- (a) the date, time and location of the discovery of the condition;
- (b) the names of the persons involved;
- (c) the details of the packaging and packages;
- (d) the probable cause of the condition;
- (e) the effects on the environment, the health and safety of persons, and national or international security that have resulted or may result;
- (f) the doses of radiation that any person has received or is likely to have received; and
- (g) the actions taken to remedy the condition and to prevent its recurrence.

Undeliverable consignments

38. If a consignment cannot be delivered to the consignee, the carrier must

- (a) notify the consignor, the consignee and the Commission; and
- (b) keep the consignment in an area to which access is controlled by the carrier until it can be delivered to the consignor or the consignee.

RECORDS

Records to be kept and retained

39. (1) Every person who packs radioactive material in a Type IP-2, Type IP-3 or Type A package must keep a record of the following information and documents concerning the package:

- (a) the technical specifications of its design;
- (b) the type, quantity and physical state of the radioactive material that it is designed to contain;
- (c) any document that demonstrates that the package meets the requirements of these Regulations and the management system; and
- (d) instructions for packing, transport, receiving, maintenance and unpacking.

Period of retention

(2) Every person who is required to keep a record must retain it for a period ending two years after the day on which the packing occurs.

CONSEQUENTIAL AMENDMENTS

GENERAL NUCLEAR SAFETY AND CONTROL REGULATIONS

40. (1) Paragraph 3(1)(e) of the *General Nuclear Safety and Control Regulations* ([see footnote 1](#)) is replaced by the following:

(e) the proposed measures to ensure compliance with the *Nuclear Security Regulations*, the *Radiation Protection Regulations* and the *Packaging and Transport of Nuclear Substances Regulations, 2014*;

(2) Subsection 3(2) of the Regulations is amended by replacing “*Packaging and Transport of Nuclear Substances Regulations*” with “*Packaging and Transport of Nuclear Substances Regulations, 2014*”.

41. Paragraph 10(a) of the Regulations is replaced by the following:

(a) the provisions that govern the transport of nuclear substances;

42. Paragraph 20(a) of the Regulations is replaced by the following:

(a) a package, special form radioactive material, low dispersible radioactive material, fissile-excepted radioactive material, radioactive material that has a basic radionuclide value that is not listed in the IAEA Regulations and an instrument or article that has an alternative activity limit for an exempt consignment, as those terms are defined in subsection 1(1) of the *Packaging and Transport of Nuclear Substances Regulations, 2014*;

RADIATION PROTECTION REGULATIONS

43. Paragraph 20(2)(d) of the *Radiation Protection Regulations* ([see footnote 2](#)) is amended by replacing “*Packaging and Transport of Nuclear Substances Regulations*” with “*Packaging and Transport of Nuclear Substances Regulations, 2014*”.

NUCLEAR SECURITY REGULATIONS

44. The portion of section 5 of the *Nuclear Security Regulations* (see footnote 3) before paragraph (a) is replaced by the following:

5. An application for a licence to transport Category I, II or III nuclear material shall contain, in addition to any other information required by section 7 of the *Packaging and Transport of Nuclear Substances Regulations, 2014*, a written transportation security plan that includes

CANADIAN NUCLEAR SAFETY COMMISSION COST RECOVERY FEES REGULATIONS

45. Paragraph 25(a) of the *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations* (see footnote 4) is replaced by the following:

(a) licences to package or transport required under paragraph 6(1)(d) of the *Packaging and Transport of Nuclear Substances Regulations, 2014*;

46. The Regulations are amended by replacing “*Packaging and Transport of Nuclear Substances Regulations*” with “*Packaging and Transport of Nuclear Substances Regulations, 2014*” in the following provisions:

- (a) paragraphs 21(a) and (b);
- (b) paragraphs 25(a) and (b); and
- (c) the note at the end of Schedule 2 to the Regulations.

ADMINISTRATIVE MONETARY PENALTIES REGULATIONS (CANADIAN NUCLEAR SAFETY COMMISSION)

47. Part 8 of the schedule to the *Administrative Monetary Penalties Regulations (Canadian Nuclear Safety Commission)* (see footnote 5) is replaced by the following:

PART 8

PACKAGING AND TRANSPORT OF NUCLEAR SUBSTANCES REGULATIONS, 2014

Item	Column 1 Provision	Column 2 Short-form Description	Column 3 Category
1.	3(1)	Failure to characterize nuclear substance at earliest possible time	A
2.	3(3)(a)	Failure to keep record of radiation detection and nuclear substance disposition for specified period	A
3.	3(3)(b)	Failure to file annual report containing required information by specified time	A
4.	3(3)(c)	Failure to immediately notify if source of radioactivity in load is licensable quantity of nuclear substance	B
5.	3(4)(a)	Failure to immediately make preliminary report containing required information	B
6.	3(4)(b)	Failure to characterize source of radiation within specified period and make follow-up report	B
7.	3(5)(a)	Failure to immediately make preliminary report containing required information	B
8.	3(5)(b)	Failure to prevent dispersal of nuclear substance	B
9.	3(5)(b)	Failure to isolate load and control access	C
10.	3(5)(c)	Failure to have situation assessed	B
11.	3(5)(d)	Failure to report results	B
12.	4	Failure to classify packages and radioactive material	B
13.	5	Failure to correctly classify LSA material	B

14.	10	Failure to certify design or calculation of value for prescribed equipment	B
15.	18(a)	Production of certified design package contrary to requirements	B
16.	18(b)	Failure to mark package with required information	A
17.	19(3)	Use of package of certified design without confirmation that use is registered	A
18.	20(1)(a)	Production of special form radioactive material not in accordance with certificate	B
19.	20(1)(b)	Failure to mark special form radioactive material	A
20.	20(2)	Transport of special form radioactive material that has not been produced in accordance with certified design or design approved by foreign competent authority	A
21.	21(1)(a)	Production of low dispersible radioactive material not in accordance with certificate	B
22.	21(1)(b)	Failure to mark low dispersible radioactive material	A
23.	21(2)	Transport of low dispersible radioactive material that has not been produced in accordance with certified design	A
24.	22(1)	Production of instrument or article that has alternative activity limit for exempt consignment that has not been produced using certified calculation	B
25.	22(2)	Transport of instrument or article that has alternative activity limit for exempt consignment that has not been produced using certified calculation	B
26.	23(2)	Transport of fissile-excepted radioactive material that has not been produced in accordance with requirements	B
27.	24(a)	Failure to implement and maintain management system	B
28.	24(b) and (c)	Failure to keep and retain record of management system	A
29.	25(1)	Failure to comply with <i>Transportation of Dangerous Goods Regulations</i>	C
30.	25(2)	Failure of consignor to comply with IAEA Regulations	B
31.	25(3)	Failure of the consignor to advise consignee of transport of material	A
32.	25(4)(a)	Failure of carrier to comply with IAEA Regulations	B
33.	25(4)(b)	Failure of carrier to transport in accordance with consignor's instructions	B
34.	25(4)(c)	Failure of carrier to implement, maintain and keep record of work procedures	A
35.	26(1)(a)	Presentation for transport or transport of radioactive material in package not meeting requirements	B
36.	26(1)(b)	Presentation for transport or transport of radioactive material requiring licence if no licence issued	B
37.	26(1)(c)	Failure to present for transport or to transport unpackaged LSA-I material or unpackaged SCO-I in accordance with IAEA Regulations	B
38.	26(1)(d)	Presentation for transport or transport of package containing 0.1 kg or more of uranium hexafluoride in unapproved package	B
39.	27(1)	Failure to transport in required package	C
40.	28(1)	Failure of consignor or carrier to comply with IAEA Regulations	B
41.	29(1)	Failure of consignor to include required information in transport documents	A
42.	29(3)	Transportation of consignment of radioactive material without required documents	B
43.	31(1)(a)	Failure to keep exposure and effective and equivalent doses low	B
44.	31(1)(b)	Failure to prevent persons from receiving high radiation doses	C
45.	31(1)(c)	Failure to assess radiation at workplace and conduct monitoring	B
46.	31(1)(d)	Failure to train specified persons on application of radiation protection program	B
47.	31(2)	Failure to keep and retain radiation protection program records	A
48.	32(a)	Failure to immediately notify if person may have received dose	B

		that exceeded the prescribed limit	
49.	32(b)	Failure to conduct investigation	B
50.	32(c)	Failure to take action to prevent recurrence	B
51.	32(d)	Failure to report results of investigation within specified time	A
52.	33(1)	Failure to inform each nuclear energy worker in writing	A
53.	33(2)	Failure to inform pregnant nuclear energy workers of their rights and obligations	B
54.	35(1) and (3)	Failure to immediately make required preliminary report following failure to comply or dangerous occurrence	B
55.	35(5)	Failure to take immediate required action after dangerous occurrence	B
56.	35(6)	Failure to file full report of failure to comply or dangerous occurrence within specified period	B
57.	37(1)	Opening package without taking required measures	B
58.	37(2)	Failure to restore package to required condition before forwarding	B
59.	37(3)	Failure to verify package integrity on receipt	B
60.	37(4)	Failure to immediately make preliminary report if package shows evidence of problem conditions	A
61.	37(5)	Failure to include specified information in preliminary report	A
62.	37(6)	Failure to file full report within the specified period	A
63.	38(a)	Failure to notify consignor, consignee and Commission of undeliverable consignment	B
64.	38(b)	Failure to place undeliverable consignment in access-controlled area	B
65.	39	Failure to keep and retain records with specified information and documents concerning certain packages	A

REPEAL

Repeal

48. The *Packaging and Transport of Nuclear Substances Regulations* ([see footnote 6](#)) are repealed.

COMING INTO FORCE

Registration or approval

49. These Regulations come into force on the day on which they are registered but, if they are approved by the Governor in Council after that day, they come into force on the day on which they are approved.

[26-1-o]

[Footnote a](#)

S.C. 2012, c. 19, s. 129(1)

[Footnote b](#)

S.C. 1997, c. 9

[Footnote 1](#)

SOR/2000-202

[Footnote 2](#)

SOR/2000-203

[Footnote 3](#)

SOR/2000-209

[Footnote 4](#)

SOR/2003-212

[Footnote 5](#)

SOR/2013-139

[Footnote 6](#)

SOR/2000-208

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