

**OPG Comments on CNSC’s Proposed Packaging and Transport of Nuclear Substances Regulations, 2014
as published in Canada Gazette, Part I.**

#	Document Section/ Excerpt of Section	Issue	Suggested Change (if applicable)	Critical or Major Comment/ Request for Clarification	Impact, if critical or major comment
1.	General	Some requirements are subjective and are open to interpretation, e.g. Comment #6 on dose rates, and Comment #16 on negligible liquid content.	Provide precise (e.g. objective, using defined terms, quantitative) requirements.	Major Comment	Demonstration of compliance will be inconsistent between licensees.
2.	General	The proposed Regulations use “must” instead of “shall” for obligatory requirements. “Shall” is typically used in other regulations.	Change document to be consistent with other regulations.	Request for Clarification	
3.	1.(1), definition of “freight container”	The proposed Regulations refer to the definition for “freight container” from the International Maritime Dangerous Goods (IMDG) Regulations instead of the very similar definition in the IAEA Regulations. Anyone using the PTNSR will have access to the IAEA Regulations, but may not have the IMDG Regulations unless they make marine shipments.	Refer to the IAEA definition of “freight container” instead of the IMDG definition.	Request for Clarification	
4.	1.(1), definition of “over-pack”	The definition of “overpack” in the IAEA regulations differs from the definition in the newly revised Transportation of Dangerous Goods (TDG) Regulations. The IAEA definition applies to any enclosure that contains one or more packages, whereas the TDG definition only applies to enclosures that consolidate small means of containment and it does not apply to large means of containment. This difference in definitions could lead to situations where the marking and labelling of overpacks differs between PTNSR/IAEA and TDG.	Refer to the TDG definition of “overpack” instead of the IAEA definition.	Major Comment	Ambiguity and inconsistency in what is or is not an “overpack” in Canada can lead to inconsistencies in marking and labelling. This can make it difficult for licensees to demonstrate compliance.

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5.	2.(2)(l)	The term “low toxicity alpha emitters” is used in Sections 2(2) (l) and 35(1) (f) (i) but it is not defined in the Regulations.	Add “low toxicity alpha emitters” to the Definitions (Section 1. (1)) and indicate that it has the same meaning as in IAEA Regulations.	Request for Clarification	
6.	3.	Dose rates specified in this section do not identify a distance from the material where the measurements must be taken. If a trailer of scrap metal sets off an alarm, are the dose rates measured at 1 meter from the trailer, on contact with the trailer, on contact with the material, on contact with the radioactive component of the load only, etc.?	Clarify the dose rate measurement requirements.	Major Comment	It is not possible for licensees to show compliance with the requirements as currently written.
7.	3. (1) to (5)	<p>In the context of the PTNSR, it is not clear why one has to characterize material to determine if it is subject to the Nuclear Substances and Radiation Devices Regulations (NSRDR).</p> <p>The terminology “licensable quantity” is confusing in the context of the PTNSR.” Note it is also used in the same context in 3(3), 3(4) and 3(5). It is not clear why one would need to know if the material is licensable or not. The normal meaning of “licensable quantity” is that someone would need a licence to possess or handle this amount of nuclear substance. However, this does not appear to be the intent in this case. Perhaps “licensable quantity” was intended to mean a “non-exempt quantity”; i.e. the PTNSR apply to the packaging and transport of that material.</p>	<p>Delete “and the Nuclear Substances and Radiation Devices Regulations (NSRDR)” from 3.(1). If there are exemptions from the PTNSR that are identical to those in the NSRDR these should either be explicitly listed or the sections of the NSRDR referenced in section 2. (2) of the PTNSR.</p> <p>Replace “Licensable Quantity” and 3. (2) (a) & (b) with:</p> <p>“3. (2) For the purposes of section (3) of the PTNSR the PTNSR apply if there is no exemption from licensing under section 2. (2) of these Regulations.”</p> <p>Replace 3. (3) (c) with:</p> <p>“(c) immediately notify the Commission if the source of radioactivity in the load is</p>	Major Comment	

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			<p>not exempt from the requirements of the PTNSR.”</p> <p>Replace 3. (4) (b) (i) and (ii) with:</p> <p>“(i) immediately, if the source of radioactivity in the load is not exempt from the requirements of the PTNSR, or</p> <p>(ii) within 21 days, if the nuclear substance in the load is determined to be exempt from the requirements of the PTNSR, with...and confirmation that it is exempt from the PTNSR.”</p> <p>Replace 3. (5) (d) (i) and (ii) with:</p> <p>“(i) immediately, if the source of radioactivity in the load is not exempt from the requirements of the PTNSR, or</p> <p>(ii) within 21 days, if the nuclear substance in the load is determined to be exempt from the requirements of the PTNSR, with...and confirmation that it is exempt from the PTNSR.”</p>		
8.	Regulatory Impact Analysis Statement, Issues Item# 5, and last para of Description/Improvement of PTNSR	<p>It sounds like in the preamble (Background and Description) of the PTNSR, 2014 that the Canadian consignor will not need to include the Consignor’s Declaration on the shipping document. However, Section 29 instructs the user to follow the particulars of consignment under the IAEA Regulations which can include the declaration.</p> <p>PTNSR, 2014 Section 25(2) (a) indicates</p>	Clearly state if a consignor’s declaration is required.	Request for Clarification	

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	under Transport Documents Section 29 PTNSR, 2014	to follow Provision of Information for Carriers, which include IAEA Paragraph 555, which in turn refers to the Paragraph 547 the consignor's declaration.			
9.	29	<p>The wording in IAEA Paragraph 547 does not match the wording in TDG 3.6.1(1)(a), and the IAEA Regulations are not listed as a valid certification in 3.6.1(1)(b)-(e), although the wording in IAEA Paragraph 547 may match the wording in one of the acceptable alternatives listed in TDG Regulations. Therefore, if a consignor's declaration is required, how to achieve compliance with both the PTNSR and the TDG Regulations is unclear.</p> <p>The TDG Regulations were recently amended, and one of the new requirements is a consignor's declaration:</p> <p>3.6.1 Consignor's Certification</p> <p>(1) Beginning on July 15, 2015, a shipping document must include, after the information required under section 3.5, one of the following certifications:</p> <p>(a) "I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, are properly classified and packaged, have dangerous goods safety marks properly affixed or displayed on them, and are in all respects in proper condition for transport according to the TDG Regulations";</p>	Specify clearly the requirement for a consignor's certification.	Major Comment	If a consignor's declaration is required, it would be difficult to achieve compliance with both the PTNSR and the TDG Regulations.

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		<p>(b) the certification set out in section 172.204 of 49 CFR;</p> <p>(c) the certification set out in section 5.4.1.6 of the ICAO Technical Instructions;</p> <p>(d) the certification set out in section 5.4.1.6 of the IMDG Code; or</p> <p>(e) the certification set out in section 5.4.1.6 of the UN Recommendations.</p> <p>IAEA Paragraph 547 specifies the wording listed in that paragraph is required: “The consignor shall include in the transport documents a certification or declaration in the following terms.”</p>			
10.	5.(2)(a)	Does “water” include “heavy water”? The current and proposed regulations are ambiguous on this point.	Add a definition for “water” or revise 5.(2)(a) to state “...less than 225 L of water or heavy water...”	Request for Clarification	
11.	5.(2)(b)	Does the “10-5 A2/g limit for liquids” include tritiated water and tritiated heavy water? It is ambiguous whether a volume of 225 L or greater of tritiated water can be classified under 5.2(b) as LSA-II, or whether 5.2(a) means that only volumes of less than 225 L of tritiated water may be classified as LSA-II regardless of the tritium concentration.	Clarify volume and activity limits for tritiated water and tritiated heavy water.	Request for Clarification	

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12.	6.1	<p>This section is entitled "Exemptions" but it is actually listing the types of licences by using a double negative to define the conditions that are <u>not</u> exempt from licensing.</p> <p>This Section is easily misunderstood due to the use of a double negative phrase ("without a licence" and "except").</p>	Revise the section to avoid double negative phrases.	Major Comment	There is a risk of inadvertent non-compliance with the Regulations due to overly complex and confusing wording.
13.	6.(1)(c)	Is a licence required to transport large objects that meet the IAEA requirements for transport as unpackaged SCO-I?	Revise 6. (1)(c) as "the nuclear substance is contained in a large object unless it is transported as unpackaged SCO-I in accordance with the IAEA Regulations."	Major Comment	Without this change, any large object that is contaminated above the exempt limits but falls within the classification of SCO-I would require a licence. Material that meets the requirements to transport as SCO-I unpackaged according to the IAEA regulations should be exempt from the large object licensing requirements regardless of whether it could or could not fit inside of a package.
14.	6.(2)	Under the current Regulations, a person may "service" packages, special form radioactive material, or low dispersible radioactive material (6.(2)) without a licence. The suggested revision does not specify that a package may be serviced	Revise 6.(2) to include servicing of packages.	Request for Clarification	
15.	6.(3)	The requirement only indicates that a person may package a nuclear substance without a licence. Unpackaging is not mentioned. The implication is that a licence is required for unpackaging.	Revise 6.(3) for clarity to state that "A person may package or unpackage a nuclear substance..."	Major Comment	As written, once the nuclear substance is packaged, the resulting package is "prescribed equipment" by definition, and it is unclear whether "use" in 6.(2) would include unpackaging, which would change the prescribed equipment into non-prescribed equipment.

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16.	7.(e)(i)(D)	The requirement refers to "negligible liquid content" but "negligible" is not defined and is subject to interpretation.	Clearly define "negligible" in each instance and context.	Major comment	Subjective wording such as "negligible" leads to difficulties with compliance.
17.	7(e)	It is not apparent why the nuclear substance contained in a large object is restricted to SCO-I or SCO-II. A large object is inherently safe to transport if: its size, mass and robust construction makes it highly resistant (without packaging) to credible accident scenarios; and the nuclear substance inside the large object is in a form that would prevent it from being significantly harmful if it were released from the large object.	The limits for the nuclear substance in a large object should include excepted package contents, SCO-I or SCO-II or LSA.	Major Comment	The proposed change will allow a greater variety of large decommissioned components to be shipped as large objects in compliance with the Regulations.
18.	7.(e)(ii)(C)	It is not clear if the 4 Bq/cm ² includes alpha contamination other than low-toxicity alpha contamination.		Request for Clarification	
19.	8.(a)	"they must be designed and maintained to...standards other than...provided that an equivalent level of safety is maintained" is awkward wording. The proposed sentence reads as though the named standard cannot be used (must use another standard) if equivalent levels of safety are maintained.	Consider revising 8.(a) to "they must maintain an equivalent level of safety if they are designed and maintained to...". This maintains the sentence structure of the remainder of 8 while clarifying the meaning.	Request for Clarification	
20.	10(2)(d)	It is not clear where the 2.0 grams per package in 10(2)(d) comes from as the references for the fissile requirements were not stated.	Provide the reference for the fissile requirement.	Request for Clarification	

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21.	10(3)(a)	The basic radionuclide values for mixtures are not specifically listed in the IAEA Regulations, but they are calculated based on the direction and formulas in the IAEA Regulations. It is not clear if the Commission or a designated officer is required to certify calculations of mixtures (even when each of the radionuclides in the mixture has basic radionuclide values listed in the IAEA Regulations).	Specify that the calculations of basic radionuclides values for mixtures that contain only radionuclides listed in the IAEA Regulations do not require certification.	Request for Clarification	
22.	11.(3)(c)	11.(3)(c) is a duplicate of section 11.(3)(a).	Delete 11.(3)(c) as it covered by 11.(3)(a)	Major Comment	Will lead to inconsistencies in compliance. As written, “instructions” could not be modified in minor ways once a design has been certified, whereas “procedures” could be modified.
23.	11(3)(g)	It may not be practical for a Canadian applicant to know all users of a foreign design. Therefore the requirement should only address Canadian users.	Revise to “a list of the known users in Canada of the latest certified design”.	Major Comment	A list of all users of a design would be particularly problematic for foreign designs.
24.	14.(2)	The process for recertifying a design to incorporate modifications is described in a negative and reactive manner, and it is not consistent with best industry practices (i.e. applicants seek approval for a design change and a certificate amendment prior to implementation of the modification so the certificate is never void). The text “a new application for certificate must be made” could be interpreted to mean that a completely new certificate must be issued for a modified design when CNSC practice has been to issue a revision of the preceding (pre-modification) certificate.	Revising 14.(2) to “Recertification of a previously certified design or calculation is required for modifications that affect the safety of the types of prescribed equipment referred to in section 10; otherwise the modification will void the certificate. The application for recertification shall provide the information necessary to demonstrate that the modified design or calculation meets the requirements of these Regulations.”	Major Comment	The description of the modification approval process should be consistent with industry best practices (i.e. approval before implementation).

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25.	20(2) & 21(2)	Confirm whether a special form radioactive material or low dispersible radioactive material can be transported as though it were not special form or low dispersible material. For example, could a consignor treat a sealed source, for which no certificate is available, as though it were non-special form, classify it according to the A2 value rather than the A1 value, and transport it based on that classification?	Add to Section 20(2) and 21(2) "where a valid certificate cannot be produced for material previously classified as special form or low dispersible radioactive material, the material may be transported if it is classified in accordance with its A2 value".	Request for Clarification	
26.	22(2)	Confirm whether an instrument or article with an approved alternative activity limit can be transported using the activity limit specified in the IAEA Regulations. For example, if the activity in the instrument has decayed such that the approved alternative activity limit is not required.	Add to Section 22(2) "where a valid certificate cannot be produced for an instrument or article that previously had an approved alternative activity limit, the material may be transported if it is classified in accordance with its A2 value".	Request for Clarification	
27.	27(3)(a)	Clarify whether "passengers" include supervisors, assistants, and trainees	Add definition of "passenger" to 1.(1) by referencing the definition of "passenger" in the TDG Regulations.	Request for Clarification	
28.	28(2)(a)(ii) and 28(2)(c)(iii)	The wording of these sections and Section 4.14(1) of the TDG Regulations could be misinterpreted as a circular reference (i.e. it appears that the two regulations(TDG and PTNS) point to each other without specifying the detailed requirements for labelling.)	Revise the section to clarify the purpose of the reference to the TDG Regulations as follows: " 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. The appearance of each placard shall be consistent with the illustrations provided in the Appendix to Part 4 of the TDG Regulations. The placard category and the information to be marked on the placard shall be determined in accordance with the IAEA Regulations."	Major Comment	Continued confusion on placarding class 7 material which can lead to non-compliance, or over placarding.

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29.	35(1)	The definition of a “dangerous occurrence” remains subjective, and may include occurrences that have no health, safety, environmental impact, or national security impact. The public expectation will be that an event labeled a “dangerous occurrence” has, or could have, injurious consequences.	Amend the definition by moving the phrase from 35.1(g) “that may reasonably expectedeffected “ to before the colon in 35(1).	Major Comment	<p>It is necessary to have a test or threshold for identifying an event as a “dangerous occurrence” to prevent reporting of non-compliances as dangerous when it is there is minimal potential for the environment, the health and safety of persons or national security to be adversely affected. Classifying all non-compliances as “dangerous occurrences” will create unnecessary administrative burden for licencees and the CNSC, and will be misleading and alarming to the public.</p> <p>This change will ensure that a test of reasonableness is applied when any noncompliance is assessed to determine if it is a genuine and reportable "dangerous occurrence". By this test apparently minor non-compliances would be reportable if it is reasonable to conclude that they indicate a flawed or deteriorating quality management system heading towards a breakthrough event.</p>

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30.	35.(5)	The requirement that “...any other person who controls any area affected by it” should address a dangerous occurrence is too broad, and implies that the members of the public may be required to clean up a spill.	Change “...any other person...” to “...any licensee...”	Major Comment	As worded, if a shipment of radioactive material went off the road and crashed on the property of a member of the general public, that person would be required to limit the spread of radioactive material, place barriers, etc. A licensee might reasonably be expected to have sufficient expertise to perform the duties specified in 35. (5) on their property, but “any other person” is too broad.
31.	37.(3)-(5)	The information required in the preliminary report will not likely be available to the person required to make the report.	Revise “...on how and where the condition occurred...” to “...on how and where the condition occurred or was discovered...”	Major Comment	37.(3) requires the person receiving or opening the package to determine if there is a problem, 37.(4) requires them to report, but as written, 37.(5) requires them to report information that likely occurred before the material was in their control or possession. The receiver can reliably report where the problem was identified, but may not have any information on how the problem occurred when it was under the control of the Consignor or Carrier.