UNRESTRICTED

2015 May 29

Mr. Brian Torrie
Director General, Regulatory Policy Directorate
Canadian Nuclear Safety Commission
280 Slater Street
P.O. Box 1046, Station B
OTTAWA, Ontario K1P 5S9

COMPLIANCE
Regulatory Affairs
145-CNNO-15-0012-L

Dear Mr. Torrie:

Answers to Questions Posed in Discussion Paper DIS-14-02:
Modernizing the CNSC Regulations

Canadian Nuclear Laboratories has reviewed the Discussion Paper DIS-14-02 "Modernizing the CNSC Regulations" and has met with industry partners, Ontario Power Generation, Bruce Power, and New Brunswick Power and the Canadian Nuclear Association to produce a set of consolidated answers to the questions posed. The consolidated answers are contained in Attachment A.

Canadian Nuclear Laboratories believes that the industry suggestions for change will improve the Canadian Nuclear Safety Commission regulations and supporting REGDOCS for the benefit of all stakeholders. We look forward to working with Canadian Nuclear Safety Commission staff to ensure these benefits are achieved.

If you require further information or have any questions regarding this submission, please contact me as below.

Yours sincerely,

T. Arthur, Manager
Regulatory Affairs
Phone: 613-584-8021
Fax: 613-584-8031
Email: Terry.Arthur@cnl.ca
TA/mj
Attachment (1)

c C. Carrier (CNSC)
S.K. Cotnam
S. Mistry
R. Walker

Consultations (CNSC)
J.D. Garrick
S. Needham
>CR CNSC Site Office

H. Khartabil
K.L. Smith
>CR Licensing

R.M. Lesco
C.E. Taylor
>SRC

Canadian Nuclear Laboratories

Chalk River Laboratories
286 Plant Road
Chalk River, Ontario
Canada K0J 1J0
Telephone: 613-584-3311
Toll Free: 1-866-513-2325

Laboratoires Nucléaires Canadiens

Laboratoires de Chalk River
286, rue Plant
Chalk River (Ontario)
Canada K0J 1J0
Téléphone: 613-584-3311
Sans frais: 1-866-513-2325

Attachment A
Industry Response to Questions Posed in Discussion Paper DIS-14-02: Modernizing the CNSC Regulations.

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
1.	The CNSC has a body of regulations intended to regulate all nuclear activity in Canada. The CNSC is interested in learning if stakeholders see certain sections of its regulations as unclear, inconsistent or otherwise in need of improvement. Perspectives drawn from experience with regulations in other countries or jurisdictions may also be relevant. **Could the CNSC's regulations be changed to make them more efficient and effective in ensuring protection of the health, safety, security and the environment? How?**	**Yes, the CNSC regulations can be changed or adjusted to be more efficient and effective in ensuring HSSE or the workers and the public. As noted in industry response to Question 2, Regulations should be "outcome" focused.**	
		Regulations do not recognize the widely varying conditions, or capabilities between licensees, resulting in requirements that can be confusing or difficult to apply in some cases. Regulations should explicitly provide for flexibility of implementation between different licensees, even within the same class of licence. Improved consistency between the General Nuclear Safety and	The following are examples only .Radiation Protection Regulations examples include requirements around posting of radiation hazards (general vs. radiography), use of survey meters, labeling of containers of radioactive materials, etc that are not always clear depending on application. Requirements may need to differentiate (e.g., should same requirements exist in a university teaching lab vs. a nuclear power plant), or be clarified. • Compliance with requirements around frivolous posting of signs may not be practical in some specific situations, with inconsistencies as to when a sign is considered to be posted (RPR 23). Frivolous Postings of Sign requirements are impractical for areas approved to possess, handle or store radioactive materials in quantities exceeding 100 times the Exemption Quantities, where the amount of material may fluctuate below and above this value depending on operational needs. Continually removing and then re-posting presents the error likely situation of a sign not being re-posted when required. One practice has been to permanently post such areas that are approved to

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
		Control Regulations (GNSCR) and other Regulations would improve the licence application process for organizations holding multiple licences.	possess such quantities, but this could be challenged with the current wording "*No person shall post or keep posted a sign that indicates the presence of radiation, a nuclear substance or prescribed equipment at a place where the radiation, a nuclear substance or prescribed equipment indicated on the sign is not present*." • Clarity is required around term "posting", recognizing the varied activities that must be managed: One industry member had one circumstance where a sign was placed onto a board and the board leaned against the entrance to the facility. During a site inspection, the CNSC staff member did not consider this to be posted and an Action Notice was issued. On another occasion, a sign that was just made was leaning up against the wall in a sign shop. During the site inspection, the CNSC staff member considered the sign to be posted and a Directive was issued for frivolous posting of signs. Current requirements in the Nuclear Substance and Radiation Devices Regulations (NSRDR) are not sufficient for licensees decommissioning larger sites, and would be improved by consideration of international experience. • Lack of surface clearance criteria that can be applied uniformly and consistently across licensees (NSRDR 1, 5 (1)). Unconditional clearance levels and conditional clearance levels defined in the NSRDR apply to volumetric contaminated material, not surface contaminated material. When the NSRDR was revised in 2006, CNSC staff decided to not include surface contamination clearance criteria, concluding that current licence conditions in both facility and nuclear substances and radiation device licences are adequate to meet CNSC expectations. However, with many sites now undergoing decommissioning activities, CNSC staff has been challenging the use of licence-defined surface contamination clearance levels, requesting licensees to demonstrate that surface contamination criteria in use meet the dose acceptance criteria for conditional clearance levels for volumetric bulk material. This has resulted in inconsistency in the application of surface contamination clearance criteria and inconsistencies with CNSC staff interpretations and expectation. Other countries' regulations define surface contamination clearance levels and provide guidelines on their application. Canada would benefit from this. • Lack of clear dose acceptance criteria for release of buildings and lands for purpose of de-licensing (NSRDR 5). With Canada now getting involved in more large scale

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			decommissioning and land remediation, better defined requirements and guidelines are required for deriving release criteria to allow release from regulatory control of buildings and lands. Buildings and lands and release criteria are different from the NSRDR unconditional and conditional clearance criteria for the release of volumetric bulk material, and licensee's defined surface contamination clearance criteria. The latter are intended to apply to materials which will be removed and released from the licensed site for disposal, re-use or recycling. The volumetric contamination clearance levels are derived based on a source related dose constraint that will ensure a member of the public is unlikely to receive an annual dose exceeding 0.01 mSv in a year from the release of material. The source related dose constraint is set to be sufficiently low to ensure members of the public are adequately protected using the conservative assumption that a person may receive an accumulated dose as a result of exposure to various disposition pathways of materials released from a licensed site or various licensed sites or facilities. Individual dose constraints are more suitable for deriving criteria for the release of buildings or lands from regulatory control. These are commonly referred to as Derived Concentration Guidelines Levels (DCGLs), and are based on dose criteria in the range of 0.1 to 0.3 mSv in a year. Such a concept is not written or recognized in the Regulations and often the unconditional clearance levels are interpreted as being the land release criteria. These may not be suitable for the application, and may result in considerable costs for remediation and demonstrating criteria are met, with no reasonable reduction in dose or risk to the public. The *Nuclear Non-proliferation Import and Export Control Regulations* (NNIECR) licensing requirements are limited to the import and export of controlled nuclear information as defined in s1 (1) of the NNIECR. As the NNIECR does not cover all potential import/export situations, conflict or confusion over requirements may arise. • S. 26(a) of the *Nuclear Safety and Control Act* establishes the following: "26. *Subject to the regulations, no person shall, except in accordance with a licence, (a) possess, transfer, import, export, use or abandon a nuclear substance, prescribed equipment or prescribed information.*" The import and export of prescribed information related to a Class IA nuclear facility was not subject to the security measures and requirements of the *Nuclear Non-proliferation Import and Export Control Regulations* (NNIECR). Consequently the licence application requirements for these import and export licenses defaulted to the requirements of GNSCR s.3, which are inconsistent with the

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			information required by NNIECR s.3, which the licensee understood was needed by the CNSC to process the applications. • Cases have been experienced where the import and export of nuclear substances that exceeded the exemptions established in s.5(1) of the NSRDR and where the requirements of the NNIECR and INFO-0791 *Control of the Export and Import of Risk-Significant Radioactive Sources*, did not apply. Consequently the licence application requirements for these import and export licenses defaulted to the requirements of GNSCR s.3 and NSRD s.3. GNSCR s.3 and NSRDR s.3 do not establish requirements consistent with the information required by NNIECR s.3, which the CNSC requires to be able to process the applications. The scope of the NNIECRs should be updated to include the import and export of all prescribed information under the NSCA and of all nuclear substances for which there are no exemptions available under NSRD s.5 and that the NNIECR licence application requirements be updated accordingly. Alternatively, the other applicable Regulations could be updated to include the additional information required by the CNSC in respect of applications involving the import or export of these items. In some cases, Regulations may lack clarity within the single document, which can result in confusion or compliance concerns for some licensees. For example: • The Packaging and Transport of Nuclear Substances Regulations (PTNSR) defines LSA-II material as: (a) Less than 225 litres of water with a tritium concentration not greater than 0.8 TBq/L; or (b) Material in which the activity is distributed throughout and the estimated average specific activity does not exceed 10^{-4} A_2/g for solids and gases, and 10^{-5} A_2/g for liquids. Requirements for volumes of tritiated water greater than the volume limit in (a) are lower than the concentration limit in (b) not clear (e.g. 225 L at 0.4 TBq/kg). It appears that the requirements of (b) could be used, but historic interpretation has been that (b) cannot be used for tritiated water, since clause addresses tritiated water. The definition should be revised so that either (b) reads as “material <u>other than tritiated water</u> in which the activity is distributed...”, or, clarify that (a) is intended as an

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			alternative to (b) for tritiated water with a higher activity concentration than would otherwise be allowed by (b), provided it is shipped in limited volumes A number of Class I nuclear facilities are also in possession of nuclear substances and radiation devices licenses. Already being subject to the *General Nuclear Safety and Control Regulations*, these facilities should be well positioned to comply with the licensing requirements of the *Nuclear Substances and Radiation Devices Regulations* (NSRDR). Unfortunately, there are a number of inconsistencies between the GNSCR and the NSRDR and the regulatory documents that support them. Examples: • There are three cases where regulatory documents are used to establish required terms/titles with specified roles and responsibilities for which there is no regulatory basis. These requirements make assumptions about a licensee's organizational structure, roles and responsibilities. Furthermore, the terms are not used universally within CNSC regulatory documents for different licence types, which is problematic for holders of multiple licenses. The following inconsistencies should be corrected: ○ The term "Applicant Authority" is not defined in the GNSCR or the NSRDR. One interpretation is that the "Applicant Authority" corresponds to GNSCR s.15(b), but CNSC regulatory document RD/GD-371 does not specifically cite GNSCR s.15(b) as the basis for the term/role. Similarly, the term "Signing Authority" discussed in RD/GD-371 is not defined in the GNSCR or the NSRDR. RD/GD-371 does not specifically cite GNSCR s.15(a) as the basis for the term/role. ○ The "Radiation Safety Officer" (RSO) designation that is described in RD/GD-371 is not defined in the GNSCR, NSRDR or the *Radiation Protection Regulations*. However, RD/GD-371 does discuss the required organizational authority of the RSO. ○ The NSRDR should be revised in a similar manner to the recent changes to the *Class II Nuclear Facilities Regulations* if the CNSC believes it is necessary for licensees to have an RSO with defined responsibilities. If this recommendation is adopted, the NSRDR should also permit individuals certified by the CNSC as Senior Health Physicists per RD-204 to perform the duties of the RSO without the need

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			for additional certification (consistent with s.15.12 of the *Class II Nuclear Facilities Regulations*). • Requirement for a 15 day dosimeter period for operators of exposure devices (NSRDR 31(2)).The NSRDR imposes the requirement for dosimeters worn by exposure device operator to be removed for processing every 15 days. Major licensees have a dosimetry period that is considerably longer than 15 days (30 to 60 days), and utilize electronic personal dosimeters (EPDs) to track daily and accumulated doses to operators during the dosimetry period. The use of EPDs have not been recognized by CNSC staff to meet the 15 day dosimetry period requirement. We have been required to establish a separate dosimetry period of our operators of exposure devices. This has caused additional administrative costs with no improvement in protection. It seems this 15 day period is a carryover from the 1990s when the typical dosimetry period was 15 days for most licensees, before the use of EPDs became a recognized means for daily and task dose control, which have subsequently allowed dosimetry periods to be extended to longer periods for compliance monitoring, rather than dose control. • CNSC INFO-0791, Control of the Export and Import of Risk-Significant Radioactive Sources, establishes requirements for licence applications that are inconsistent with and/or exceed the requirements of GNSCR s.3, NSRD s.3, and are beyond the scope of the NNIECR. It is inappropriate for CNSC INFO documents to establish *requirements*, particularly those that are inconsistent with or go beyond the Regulations. Per NSCA s.26 (a) "26. Subject to the regulations, no person shall, except in accordance with a licence, (a) possess, transfer, import, export, use or abandon a nuclear substance, prescribed equipment or prescribed information." The scope of the NNIECR should be amended to include the import and export of risk-significant radioactive sources, and that the licence application requirements in the NNIECR be updated accordingly. Alternatively, the NSRDR could be updated to include the additional information required by the CNSC in respect of applications involving the import or export of risk-significant radioactive sources (i.e., non-exempt nuclear substances) that are not subject to the NNIECRs. • The GNSCR or the NSRDR should also be revised to provide a clearer path for the application for a licence to export a nuclear substance. There is currently no clear path for a one-off licence to export nuclear substances.

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			• The *Radiation Protection Regulations* include a requirement to post signs in areas that have a radiation dose rate of 0.025mSv/h, whereas the NSRDR require posting at 0.1mSv/h for the use of an exposure device. This inconsistency makes the requirements difficult to apply in Nuclear Power Plants (NPPs) where there are changing conditions in areas that are known to have radiation dose rates. There is currently a 2 tier system for posting: the first tier requires posting dose rates of 0.025mSv/h in normal radiation areas; and the second tier requires posting dose rates of 0.1mSv/h in areas of exposure device operation (radiography). Industry members have had inconsistencies in the past with CNSC staff communicating individual expectations. For example, CNSC has challenged why the boundary of local areas with dose rates exceeding 0.025 mSv/h are not barricaded or ribboned off, though there is no regulatory requirement and the areas is clearly posted and is a low occupancy area. A more consistent approach would be appropriate for facilities like the NPPs, which would allow the posting of a 0.1mSv/h dose rate. This should have no impact on worker safety as the NPPs have controlled access and only suitably trained and qualified workers can access the NPP. This would not impact the Radiation Protection Programs and would prevent frivolous reporting of low-level dose rates that exceed dose rates that were posted due to changing conditions in radiation areas. It would also prevent non-compliances with the Regulations that are of no consequence to worker safety and are potentially subject to Administrative Monetary Penalties. Different licensees must work in different legislative frameworks, and have varying infrastructures, even within licensee classes. This can mean that what appears “simple” for one licensee is complex for another, or results in conflicting legal requirements. Recent staff direction to re-combine radiation devices / servicing licences for one licensee adds administrative burden with no safety benefit, and is not off-set by gains elsewhere. This re-alignment from current practices does not appear to be required under the existing Regulations.
		Some Regulations need to be updated to reflect modern technology / understanding, where possible allowing for future foreseeable changes.	The current Nuclear Non-proliferation Import and Export Control Regulations and General Nuclear Safety and Control Regulations currently do not recognize electronic transmission and storage media. This poses challenges to industry as many vendors of materials, services etc. are internationally based. Industry recognizes and supports efforts to address this challenging issue.

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			The Radiation Protection Regulations refer to old ICRP weighting factors. This should be updated. Where numerical limits, values may be subject to change, Industry suggests that these be removed from the Regulation and captured elsewhere. One suggestion is creation of a new regulatory reference document to capture some of these "changing" targets (i.e. documents that are easier to revise).

		Requirements for similar activities should be combined into 1 place, to facilitate use and compliance.	Similar requirements may be contained in multiple Regulations or obscurely placed in a single Regulation. This can make it difficult to ensure relevant regulatory requirements are identified for compliance. Where requirements appear to be similar but are not identical, this may lead to confusion as to the actual requirements.
			The following are specific examples:
			• Posting of radiation signs. Requirements are included in both the Nuclear Substances and Radiation Devices Regulations (NRDR) and Radiation Protection Regulations (RPR):
			  • RPR 20(1): Labelling of containers and devices
			  • NSRDR 22: Labelling of exposure devices for field operations
			  • RPR 20 (21): Posting of signs at boundaries and point of access
			  • NSRDR 23: Posting of signs
			  • NSRDR 31(k): Posting radiation hazard sign for dose rate rates > 0.1 mSv/h for possession and use of exposure device (unclear whether 0.025 mSv/h hazard posting requirement also applies)
			• Radiation protection related reporting requirements are peppered through various regulations:
			  • GNSCR 29(1) : reporting if a dose limit is exceeded
			  • RPR: actions to take if a dose limit is exceeded
			  • GNSCR 3(1): developing action levels
			  • RPR 6(2): actions to take if action level exceeded
			  • NSRDR 30(2): reporting of the loss, theft or damage to an exposure device
			  • NSRDR 38(1) a ,b ,c ,d and 38(2) : reporting and actions to be taken if lost or theft of

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			a nuclear substance device or damage to a radiation device • NSRDR 38(1) e) and 38(2): reporting and actions to be taken if radioactive spill in work place • NCSA 45 and GNSCR 24 and 26: Reporting and actions to take if contaminated material sent off of the licensee's site • Packaging and Transport of RAM 19: reporting and actions to be taken for dangerous occurrence associated with the road transport of radioactive material (including lost or stolen material, contaminated packages). • Packaging and Transport of RAM 21 (4) (5)(6): reporting and actions to be taken if received radioactive package found damaged, tampered or leaking contents. One option would be include like requirements in 1 place, and to reference in other Regulations. Requirements should not be duplicated in multiple Regulations. If one requirement is intended apply to a specific condition, the more general requirement should be clear on the exception.
2.	Recent modernization exercises undertaken by other Canadian regulators have placed an emphasis on the development of performance-based regulations. Performance-based requirements state an end goal or a safety objective, but allow flexibility for regulated parties to propose how they will meet the objective. However, performance-based regulation can also pose challenges for parties that lack capacity to develop their own systems and processes to ensure requirements are met. In some cases, a prescriptive approach may be	Industry is supportive of a performance-based approach that allows licensees to demonstrate how they meet health, safety, security, and environmental objectives. There are, however, instances where performance-based objectives have resulted in a lack of clarity regarding what is required. Industry also acknowledges the need for prescriptive requirements or hard limits under certain circumstances. That said, there are instances where the regulations are too prescriptive, or prescriptive in a	• Performance based requirements must be clear and unambiguous. For Example, our security experience with regulatory performance testing programs suggests that performance objectives demand more robust mitigation than is typical of prescriptive requirements. Criteria are excellent when they define what action the licensee must take. When criteria are outcome based it is not always clear what criteria need to be met. • GNSCR s.18 requires the licensee to present the import or export licence to a customs officer when importing or exporting a nuclear substance, prescribed equipment or prescribed information. For electronic transactions involving prescribed information, this requirement is currently being met (with CNSC agreement) by submitting a copy of the licence to the Canada Border Services Agency in advance of the first import or export transaction, but not for each transaction under the licence. Industry recommends that s.18 be amended to be less prescriptive in how these communications are carried out or to exempt all electronic transactions involving

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
	preferred. The CNSC currently uses a combination of performance-based and prescriptive regulations. ***Is the CNSC striking the right balance between performance-based regulation and prescriptive requirements? Are there specific regulatory requirements that do not seem to have the correct approach?***	manner that does not benefit health, safety, security, or the environment. Where a specific requirement is necessary, regulations should be developed or amended, and where objectives are appropriate, guidance should be provided in the form of a REGDOC	prescribed information from the requirement. For example, GNSCR s. 18 could be revised to exempt electronic import and export transactions involving controlled nuclear information under the NNIECRs and other prescribed information under the NSCA. • The NSRDR were amended in 2008 to add s.5.1 "Abandonment or Disposal". S.5.1(2)(b)(i) specifies that the exemptions established by s.5.1(1) do not apply to discharges of effluents from Class I nuclear facilities that contain nuclear substances. This implies that a licence is required for the discharge of effluents from Class I nuclear facilities, but Bruce Power's PROLs do not include abandonment or disposal as a licensed activity. This gap would not affect our operations, as we clearly document discharges to the environment within PROL applications and regulatory oversight is currently being provided by the province under the Municipal Industrial Strategy for Abatement (MISA). However, it is unclear why the NSRDR were amended to include this language if the corresponding changes were not made to the Class I Nuclear Facilities Regulations or the licenses issued under those regulations. (Also see comment regarding discharges under Question 3.) • The *CNSC Rules of Procedure* are reflective of the quasi-judicial nature of the Commission Tribunal. Nevertheless, we believe that they would benefit from some additional rigour. For example, additional clarification could be provided regarding who is "a person who has an interest in the matter being heard" and why a person's interest justifies their intervenor status. • Similarly, there needs to be a mechanism for validating the evidence brought before the Commission. Individuals who make oral presentations and written submissions could be called upon to verify their information at the request of the Commission through affidavit or other means. Those making submissions to the Commission should be required to attest to the accuracy of the information presented. • The hearing process would also benefit from a mechanism by which matters that have been previously settled can be closed out rather than revisited year after year. There

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			may also be some benefit to the establishment of a process for the filing of complaints regarding conduct and other considerations. • The CNSC has been receptive and open to implementing performance based regulations, but on a limited basis. More consideration could be given to allowing performance based analysis and models, using a defined methodology, are preferred to strike a balance. The focus on performance based requirements, which state the end goal should be the standard for all regulations. • Where performance requirements are not clearly specified, staff are providing more detailed direction through REGDOCs, eroding the licensee accountability for safety. In some cases, this is becoming excessively prescriptive. One potential solution may be the use of industry working groups, which may be able to bring practical experience to the table and better define "what does good look like" and thus, help set performance-based requirements.
3.	Current government policies under the Red Tape Reduction Action Plan require increases in administrative burden resulting from regulatory changes to be offset by reductions in other administrative burden. The government considers information requirements such as filing applications for permission to conduct activities, filing reports and keeping records to be administrative burden. The CNSC is interested in stakeholder perspectives on whether areas of its regulations could be amended to reduce administrative burden without compromising safety.	A key consideration in achieving the right balance between performance-based regulation and prescriptive requirements is the avoidance of duplication. Where prescriptive requirements already exist in other jurisdictions, equivalency and authorizing regulations should be pursued, as opposed to new regulatory requirements or duplicating regulatory requirements. Reducing duplication would also reduce the administrative burden introduced by overlaps with other jurisdictions, such as	• The environment is one area where regulatory requirements are understandably prescriptive. It is also an area where there is a high potential for overlap and duplication. For example, Environment Canada has yet to develop authorizing regulations with limits for discharges from many industrial facilities. Class IA licensees are, however, subject to provincial limits under the MISA Effluent Monitoring and Effluent Limits regulations. As such, there is no need to establish any additional prescriptive limits. In fact, there are new regulations under the Fisheries Act that allows the Minister to issue an authorizing regulation where discharges are already subject to adequate federal or provincial guidelines. • DIS 15-01, Proposal to Amend the Nuclear Non-proliferation Import and Export Control Regulations (NNIECR) completely overlaps the Group 3: Nuclear Non-Proliferation List and Group 4: Nuclear-Related Dual-Use List in the Export Control List under the authority of the Export and Import Permits Act. This is an example where there will be duplicated regulatory activities, although the end-user may not experience much added administrative burden. Exports of items in the schedules under the NNIECR need to include both the export permit number from DFATD and the export licence number from the CNSC. Annual reports by the licensee are only made to the CNSC

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
	Are you aware of opportunities for the CNSC to reduce administrative burden, without compromising safety?	with the Ministry of the Environment, Fisheries and Oceans Canada, Environment Canada, Ministry of Labour, Employment and Social Development Canada, etc. without compromising safety. Where there are appropriate provincial or federal requirements in place, the CNSC should accept those regulations as equivalent, rather than duplicating the requirements. Along these same lines, industry would see a benefit to improving the consistency of approach among the various CNSC licensing divisions. This could be taken a step further by allowing for the consolidation of multiple licences that a single organization holds.	under the export licence. Imports of items under the NNIECR need to include both the import licence number from the CNSC and the import permit number from DFATD, where an import permit is required. • There also needs to be a clear distinction between the CNSC and other regulatory jurisdictions pertaining to Occupational safety and Health. We believe that there is an opportunity to more clearly distinguish between the CNSC standards and other regulatory bodies' standards pertaining to Occupational Safety and Health (i.e., Canada Labour Code versus NSCA) and to clarify which regulator has oversight (CNSC, ESDC, MOL) for strictly conventional safety issues. For example, Canada Occupational Health and Safety regulations (ESDC) makes the distinction in regards to ionizing radiation where CNSC standards are referenced: (3) If an employee works on or near a device that may emit nuclear energy, the employer shall ensure that the exposure of the employee to nuclear energy does not exceed the radiation dose limits set out in the Radiation Protection Regulations; and (4) No employee, other than a nuclear energy worker as defined in section 2 of the Nuclear Safety and Control Act, shall be exposed in the course of any year to a concentration of radon that on average, over the year, is higher than 800 Bq/m^3. • CNSC staff are interpreting "should" statements as requirements. For example, they sometimes require a written justification for not following the 'guidance' in REGDOCS. Specific examples include the following: In REGDOC 2.3.2, Accident Management the Preface states "…Guidance contained in this document …Licensees are expected to review and consider guidance; should they choose not to follow it, they should explain how their chosen alternate approach meets regulatory requirements". It also states "While there are potential limitations to the use of simulators for BDBA, the licensee should use simulator training...", which the licensee would then need to justify. REGDOC 2.10.1 Emergency Preparedness and REGDOC 2.2.6 Emergency response facilities and equipment … states "4. have an emergency response facility (ERF) located onsite, but outside of the protected area; if this cannot be achieved… 5. have an emergency response facility located offsite and outside of the plume exposure planning zone". Locations are part of "how" the licensee would meet the requirement. There are

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			portable ERFs, virtual ERFs, etc. The licensee would again need to justify an alternative way of meeting the intent of the guidance. • RD-336 section 5.2 states “Individual weights shall not be rounded” but in GD-336 section 3.2 states “For this reason, individual weights should not be rounded.” Section 5.4 (RD) “Reporting a correction to a previously submitted report shall be done as soon as the error is realized by the licensee.” And the GD (Section 3.4) states “Reporting a correction to a previously submitted report should be done as soon as the error is realized by the licensee”. • RD-327, Section 23.2.1 “Management shall clearly establish responsibility for nuclear criticality safety. Supervisors should be made as responsible for nuclear criticality safety as they are for production, development, research, or other functions.” Section 2.3.2.3 “The procedures shall specify all parameters that they are intended to control. They should be such that no single, inadvertent departure from a procedure can cause a criticality accident.” Section 2.3.3.2 “The following principles shall be incorporated as appropriate to attain the required availability and reliability of engineered nuclear criticality safety controls [2]. Double contingency principle Process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.” • Licensees are required to demonstrate how they meet the requirements of the regulations every time their licence is renewed but inconsistencies between the regulations limit the licensees ability to apply previous licensing experience to a licence renewal or a license application. Licensees are required to demonstrate compliance on an ongoing basis throughout the licence period. The regulations could be revised to streamline the licence renewal requirements for licensed facilities. Specifically, the GNSCR and *Class I Nuclear Facilities Regulations* could be revised to streamline licence renewal requirements for existing facilities. Existing Licensees are required to demonstrate how they meet all of the requirements of these regulations every time their licence is renewed. • The CNSC has adopted the policy that all documents related to a Commission or Designated Officer decision must be made available to the public. This policy has the potential to create a significant burden on licensees, as they will need to redact (e.g., proprietary and security related information) sections of the documents so that

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			they may be shared with the public. We submit that while there is a need to be transparent, the CNSC as the regulator is not required to release all of the technical documents that they receive. • S.9(3) of the *Class 1 Nuclear Facilities Regulations* states that: "The Commission or a designated officer authorized under paragraph 37(2)(b) of the Act may renew a certification after receiving from a licensee an application stating that the certified person (a) has safely and competently performed the duties of the position for which the person was certified; (b) continues to receive the applicable training referred to in the licence;" (c) has successfully completed the applicable requalification tests referred to in the licence for renewing the certification; and (d) is capable, in the opinion of the licensee, of performing the duties of the position." While this requirement seems clear and straight forward, CNSC staff has repeatedly requested that the NPP licensees provide additional <u>detailed</u> information. These requests increase administrative burden, and have zero impact on safety, as this is an area addressed extensively through regulatory oversight. • There should be a mechanism for consolidating licenses to meet the business needs of the licensees the efforts that are required for preparation of licence amendment requests are strictly an administrative exercise that does not offer any value to the overall safety of the Class II facility. Licensees need the flexibility to combine licenses to align with their business needs as follows: 1. In 2014, OPG renewed its Class II Licence to Operate. Although the renewed licence had not changed significantly from the previous version, there were considerably more documents listed in the Appendix: Licence Documents. The renewed licence now lists numerous other documents which include low-level, uncontrolled documents that were submitted as supplementary information during the relicensing process. The administrative burden of licence amendments for each document associated with these licences is not practical, efficient, or in the interest of safety. In addition, the CNSC already cannot keep up with requests for licence amendments, so they should also be in favour of this request. However, this does not appear to be the case: 2. Licence Condition 2920-6 *Inaccuracies Notification* requires inaccuracies or incompleteness in the licence documents such as document revisions. This was

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			previously interpreted to mean that OPG could send written notification to the CNSC of the change. However, the CNSC staff has informed OPG that it is not acceptable to only provide written notification, but must also request an amendment to the licence. This interpretation was provided after OPG notified the CNSC of the change in Applicant Authority and was told an amendment must be requested. Based on this interpretation, personnel changes and document revisions will require frequent licence amendments. 3. In preparation for the renewal of the Class II Licence to Service 12861-13 in 2015, OPG benchmarked with other Class II licensees to understand how they managed their administrative work associated with licence documents. OPG learned that other licensees had experienced similar challenges and had created a new document, similar to an LCH that summarized the information related to their Class II facility as required for the licence application. This approach was followed and a new program manual (N-MAN-09071-10000) was created and submitted with the renewal application for the Licence to Service. The CNSC has responded that this manual is not an acceptable replacement for the licence documents and OPG must also submit each of the procedures referenced by the manual. • Removal or up to 3 y leak test requirements for sealed sources (NSRDR S.18) that are either located in an already contaminated environment or located in an area that is not typically accessible (e.g. unit on-power, Fuel Bays). There are no safety implications in either case that are not already addressed, either by controls for surrounding contaminates or no access to the area. • Provide an exemption for NSRD Section 30(3) (e) (ii) for CEDOs working in Class I facilities (i.e. the requirement to have an EPD with alarm set points of 500 mrem/h and dose limits of 200 mrem). There is no need for these limits in cases where a radiographer may need to get into dose rates >500 mrem/h due to working in a Class I facility. Exceedance of 200 mrem is already captured by the Action Level documents associated with the licences The CNSC is increasingly using Regulatory Documents (REGDOCs) to place new regulatory requirements on licensees. This bypasses the proper process for setting regulatory requirements through the development of regulations. It also creates a significant burden on the licensee. If an issue that arises that warrants placing new requirements on licensees then it should be implemented through the development of a regulation, rather than through a REGDOC. REGDOCs

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			should be used to provide guidance on how to meet the specific requirements that are outlined in the regulations. • In the case of regulations, a Regulatory Impact Analysis Statement (RIAS) explains what the regulatory proposal is intended to address, what it is intended to achieve, and what the benefits and costs are. To our knowledge, no such assessment is undertaken in the development of new REGDOCs. We would argue that there should be a demonstrable benefit to health, safety, security, or the environment before any regulatory measure is developed. The relationship between the added safety, or other value and the implementation costs should be clear. • The CNSC acknowledges the need to consider cost-benefit information in support of decision-making on regulatory proposals other than new regulations, some of which cost tens of millions of dollars to implement. However, there appears to be a reliance on external parties for the submission of cost-benefit information through public Commission proceedings. We would recommend that the CNSC develop a cost-benefit analysis methodology in partnership with industry and other key stakeholders.
4.	One of the ways the CNSC maintains an efficient regulatory framework is by making appropriate use of existing standards. Some CNSC regulations incorporate standards such as those of the International Atomic Energy Agency, the CSA Group or other standards-setting bodies. ***Is the CNSC making effective use of existing standards?*** ***Are there additional opportunities for the CNSC to reference standards in its regulations?***	Referencing Standards such as IAEA Standards in Regulations may be appropriate in some cases. However, caution must be applied. Regulations are very time consuming to revise, and thus may not be appropriate for codes and Standards which may be updated more frequently. Standards such as CSA Standards are readily included in licences (or Licence Conditions Handbooks). As new Standards are introduced or updated, the licence / LCH process is flexible enough to capture.	Industry notes that IAEA Standards are being effectively used in Regulations. However, incorporating the CSA and similar series of Standards into Regulations would complicate the practice of systematically updating and continuously improving the referenced Standards, as well as making it more difficult to implement any improvements that have been made to the updated Standards. In addition, Standards may not exist for all facility types, which can result in unclear requirements in the Regulations. The current practice of referencing CSA Standards in the Licence Conditions Handbook where available, or into the licence conditions where it is not, should be continued rather than incorporating into Regulations. CNSC staff participates in the development of CSA Standards, so has an opportunity to influence their development. As Standards are also open to public review (including links on the CNSC website), industry recommends that where an appropriate Standard exists, other regulatory instruments not be developed, and appropriate Standards be included in the licensing process. The following are a small sample of examples of overlapping and potentially conflicting requirements, including overlapping requirements between CSA Standards and Regulatory

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
		Although the CNSC has improved in the referencing of other standards in lower tier documents such as CNSC REGDOCs or licences/LCHs, there is still a tendency to "repeat" those requirements. REGDOCS should reference the appropriate Standard, and then identify within the CNSC RegDoc or licence only the differences in requirements that must be applied (increased or decreased).	Documents: • REGDOC 2.10.1 Section 2.2.6 "Emergency response facilities and equipment" and CSA N1600 clause 4.5.9.2 "Critical facilities" both contain similarly worded requirements. Inclusion into Regulations will likely create more issues. • In the revised Packaging and Transport of Nuclear Substances Regulations (once they are issued) – the CNSC has adopted the IAEA standards with only a few exceptions. However, some additional work needs to be done to eliminate confusing (and perhaps contradictory) overlapping areas in the Transportation of Dangerous Goods Regulations (i.e. Proof of Classification and declaration for Dangerous Goods) • RD 327 Nuclear Criticality Safety (and the associated GD are essentially repetition of the ANS-8 standards from 2010). GD-327 Nuclear Criticality Safety has everything that RD-327 has, plus guidance/examples.
5.	CNSC licensees must comply with the requirements set out in the NSCA and its regulations as well as the requirements established in their licenses. Over the last decade, several standard licensing conditions – aligned with the CNSC's safety and control areas – evolved for major facilities. For example, two standard conditions state that "the licensee shall implement and maintain a waste management program" and that "the licensee shall implement and maintain a radiation protection program." ***Is the relationship between CNSC regulations and the obligations set forth in licenses clear and straightforward? Would it be***	It would not be beneficial to prescribe more standard licence conditions in the Regulations as they are currently repeated in the licences. Instead the industry sees many opportunities to streamline the Class I Nuclear facility Operating Licences and to provide greater clarity in the associated Licence Condition Handbooks. Furthermore the inclusion of more licence conditions in Regulations would be problematic as it would be much more difficult and time consuming to make necessary changes to Regulations than the licence/LCH. This would inhibit	The structure of the Class I Nuclear Facility Operating licences is based on the CNSC Safety and Control Areas and as a result they contain numerous redundant licence conditions. Licence conditions that do not contain specific requirements beyond what is already stated in the regulations do not need to be restated, as a licence cannot be issued without meeting these requirements. Examples of areas where the licence conditions duplicate the regulations include the following: • measures to ensure compliance with the Radiation Protection Regulations and the Nuclear Security Regulations; (GNSCR 3(1)(e)) • proposed action levels for the purpose of section6 of the Radiation Protection Regulations (GNSCR 3(1)(f)) • security measures (GNSCR 3(1)(g) & (h)) (Class I 6(l)) • waste handling information(GNSCR 3(1)(j)) • financial guarantees (GNSCR 3(1)(l)) • quality assurance program for the activity to be licensed; (Class I 3(d)) • proposed worker health and safety policies and procedures; (Class I 3(f))

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
	clearer to prescribe some standard licence conditions in regulations rather than in licenses? If so, which ones?	change and introduction of learning. It would also not allow for any flexibility for different licensees. Licence conditions for large corporations with multiple licence types may be different from those of smaller licensees, but embedding conditions in the Regulations removes flexibility from staff (and licensee), potentially forcing more administrative burden on one or the other. The Nuclear Security Regulations as well as a number of related federal regulations continue to be out of step with the expected operating security regime for nuclear power plant security. Industry suggests that a workshop be set up to discuss the changes required in the Nuclear Security Regulations, to ensure these gaps are properly addressed.	• environmental protection requirements; (Class I 3(g)&(h)and 6 (i)&(j)) • public information program ; (Class I 3(j)) • decommissioning plans ; (Class I 3(k)) • measures, policies, methods and procedures for operating and maintaining the nuclear facility (Class I 6(d)) • procedures for handling, storing, loading and transporting nuclear substances and hazardous substances (Class I 6(e) and PTNSR) • measures to facilitate Canada's compliance with any applicable safeguards agreement (Class I 6(f)) • emergency management (Class I 6(k)) • training (Class I 6(m)&(n)) The Nuclear Security Regulations as well as a number of related federal regulations continue to be out of step with the expected operating security regime for nuclear power plant security despite the considerable time that has passed since the events of 2001. Nuclear operators responded quickly to the increased security requirements, but a number of required authorities and clarifications on the limit of those authorities remain outstanding despite repeated requests for clarification. This work should be given high priority. Industry suggests that a workshop be set up to discuss the changes required in the Nuclear Security Regulations, to ensure these gaps are properly addressed. There are a number of areas where the Nuclear Security Regulations could be more prescriptive, or specific in how they define terminology. Terms such as ‘property’ and ‘controlled area’ are not clearly defined in the Regulations, even though they dictate where Nuclear Security Officers (NSOs) have the legal authority to protect against death or bodily harm. These terms need to be defined clearly and broadly enough to ensure that NSOs have sufficient authorization to protect themselves and others on any of Licensees’s properties. Similarly, ‘effective intervention’ is not defined clearly enough to communicate what is intended with respect to the protection of oneself and others against death or bodily harm. As a consequence, it is unclear who should be protected, how they should be protected and where they should be offered that protection. Further, NSOs should also be clearly

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			authorized to respond to such circumstances with an appropriate amount of force. This lack of clarity carries over to the definition of 'potential adversary', which should include anyone who could threaten, or attempt to cause death or bodily harm to themselves and others on licensees's properties. The activities that a potential adversary could undertake should also be expanded. They should be expanded to include the potential for sabotage and to include all of Licensees' properties. With respect to preparing for these circumstances, it is important that preparations such as design basis threat analyses and threat risk assessment activities be commensurate with the level of risk (e.g., appropriate for a high-security site). Not only should design basis threat analyses and threat risk assessments should be commensurate with the risk, they should be revisited only when that risk has, or is expected to change. Finally, there is an administrative burden associated with the revocation of authorizations under s. 21 of the Regulations, which could be more easily addressed through means other than written correspondence (e.g., by disabling a persons protected area access card). We note that this was a recent administrative change based on minimal consultation with the industry and as a result caught the industry by surprise. This administrative change, which changed the word 'may' to 'shall' creates a significant administrative burden on the industry and the outside agencies which support the industry in the authorization process. This demonstrates the importance of ensuring that the wording in the Regulations is correct so that there are no unintended implications.
6.	Through the Red Tape Reduction Action Plan, the Government of Canada is committed to making it easier for regulated parties to understand what they must do in order to comply with regulations. The CNSC does this by inviting comments on drafts of new or revised regulatory documents for stakeholder review and comment, helping to ensure these documents are clear. CNSC staff also	The industry has previously expressed concerns with the regulatory framework process for deciding on the creation of and revision to REGDOCS, CSA standards, or changes to Regulations. The industry would advocate for a more robust process to include: 1. Engagement with the	The industry recommends that the regulatory process have a quorum to discuss possible interpretations, to clarify any new requirements and to determine what exactly the change will look like. Having an end goal and consistent approach amongst the industry will permit better change management and further dialogue on feasibility (i.e., mmeetings to ensure consistency in the application of new requirements). This would include a decision stage to decide which regulatory vehicle is appropriate (REGDOC, CSA Standard, regulation change) or no change. The industry would appreciate more proactive discussions on the development of exactly what constitutes new requirements. There has been a significant increase in the development of regulatory requirements at a time when the industry is challenged. Industry feels the need for greater trade off as to the need for such a broad and resource related introduction of new requirements and the need to reduce "regulatory burden" in

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
	participates in outreach sessions, workshops, conferences, and meetings, allowing them to clarify requirements and respond to issues. ***Are there opportunities where the CNSC can provide greater assistance to applicants and licensees understand what they must do to comply with the CNSC's regulatory requirements?***	industry and other stakeholders for determining the need for a REGDOC CSA standard , or changes to Regulations; 2. A cost-benefit analysis to support new requirements in REGDOCS, CSA standards, or changes to Regulations; 3. Initial engagement of industry experts and other stakeholders as a part of fact finding support for new /revised REGDOCS CSA standards, or changes to Regulations. This more robust process would ensure a better understanding of the CNSC's regulatory requirements.	other areas. The Federal Government has introduced policy to this effect that may be of assistance: Cabinet Directive on Regulatory Management, Red Tape Reduction Action Plan, Annual Scorecard Reports and One on One Rule The engagement process for regulatory documents under development/revision requires further improvement. Licensees do appreciate the opportunity to provide input during the development of regulatory documents. However, the licensees believe that the current REGDOC development process adds undue administrative burden (red tape) in order to finally develop REGDOCs that can be effectively implemented. Examples of this are REGDOC 2.3.2, REGDOC 3.1.1. An example of early and effective engagement is REGDOC 2.3.3. Early and effective engagement lead to a REGDOC that could be readily Implemented Note that in addition to effective initial engagement of industry, the use of discussion papers can be a useful mechanism to reduce rework and administrative burden in the production of REGDOCS. This process provides better understanding by all parties. Ultimately, we attain a more meaningful licensing basis and ease our transition to compliance The industry would appreciate more proactive discussions on the development of exactly what constitutes new requirements. There has been a significant increase in the development of regulatory requirements at a time when the industry is challenged. Industry feels the need for greater trade off as to the need for such a broad and resource related introduction of new requirements and the need to reduce "regulatory burden" in other areas. The Federal Government has introduced policy to this effect that may be of assistance: Cabinet Directive on Regulatory Management, Red Tape Reduction Action Plan, Annual Scorecard Reports and One on One Rule. Recommendations to assist with industry engagement and understanding of requirements: • Introduce a process similar or equivalent to the Regulatory Impact Analysis Statement into the CNSC regulatory document development process to ensure it is clear what the regulatory document is intended to address, what it is intended to achieve, and what are the benefits and costs. • Require a period early in the process before decisions to proceed are made, especially for significant documents, where directly affected stakeholders can discuss the benefits and cost implications of the planned document as an input to the process.

Question	CNSC QUESTION	SUMMARY ANSWER	DETAILED SUPORTING INFORMATION
			• Assess the potential impacts to health and safety, security, the environment, and the social and economic well-being of Canadians when reviewing regulatory documents for final approval by requiring the presentation of information that clearly quantifies all new requirements and the potential positive and negative impacts of the regulatory document. • In this process, consider the relative priority and benefits of new regulatory document requirements alongside other improvement initiatives, however initiated, and develop plans and schedules for implementation that take account of these relative benefits. In addition, the process should acknowledge that some proposals may in fact not make the cut to be implemented at all.