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19.M29.3

Interim Report

Rapport sur le secteur nucléaire

**Regulatory Oversight on
the Use of Nuclear
Substances in Canada:
2018**

**Rapport de surveillance
réglementaire sur
l'utilisation des
substances nucléaires au
Canada : 2018**

Public Meeting

Réunion publique

Scheduled for:

Prévue pour :

07 November 2019

07 novembre 2019

Submitted by:

Soumise par :

CNSC Staff

Le personnel de la CCSN

Summary

- CMD 19-M29, Regulatory Oversight Report on the Use of Nuclear Substances in Canada: 2018 was released for public comment from September 6, 2019 to October 7, 2019. Three written interventions were received.
- This Commission member document provides CNSC staff's disposition of the comments received.

There are no actions requested of the Commission. This CMD is for information only

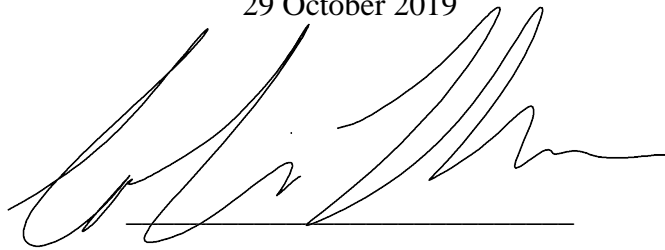
Résumé

- CMD 19-M29, Rapport de surveillance réglementaire sur l'utilisation des substances nucléaires au Canada : 2018 a été publié pour fin de commentaire du 6 septembre 2019 au 7 octobre 2019. Trois interventions écrites ont été reçu.
- Ce document à l'intention des commissaires (CMD) présente la disposition, par le personnel de la CCSN, des commentaires reçu.

Aucune mesure n'est requise de la Commission. Ce CMD est fourni à titre d'information seulement.

Signed/signé le

29 October 2019

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end, positioned above a solid horizontal line.

Colin Moses

Director General

Directorate of Nuclear Substance Regulation

Directeur général

Direction de la réglementation des substances nucléaires

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EXECUTIVE SUMMARY

The Regulatory Oversight Report on the Use of Nuclear Substances in Canada: 2018 was published for a public consultation period from September 6 to October 7, 2019. Comments were received from Benoit R. Poulet, the Canadian Radiation Protection Association (CRPA), and the Canadian Environmental Law Association (CELA). Benoit R. Poulet and CELA were awarded participant funding through the Participant Funding Program.

This CMD outlines CNSC staff's response to comments received on the report.

Referenced documents in this CMD are available to the public upon request.

Comments received from public consultation

Comments received:

- September 6 to October 7, 2019: 43 comments from three reviewers

Table A: Comments received on the draft document

	Intervenor	Section or Para. #	Intervenor's Comment and Proposed Change	Response
1	B. Poulet (19-M29.1)	Section 6.4	Consideration should be given to including a statement in future RORs to clarify the INES ratings being presented are strictly those of the CNSC staff	Accepted by staff. Clarification to that effect will be included in future Regulatory Oversight Reports.
2	B. Poulet (19-M29.1)	Section 3	The implementation of a more rigorous regulatory framework for the licensing of organizations, the designation of RSOs, and the certification of EDOs, should be considered as a means of improving the safety performance of CNSC licensees and minimize the number of events resulting from weaknesses in the licensee management programs or workplace conduct issues. Any CNSC improvement initiatives undertaken in this area should be presented in future RORs.	The regulatory oversight for the use of nuclear substances and prescribed equipment integrates licensing, certification of personnel, certification of packages and prescribed equipment, and compliance verification. CNSC staff monitor performance and analyze performance results. When trends are identified, improved guidance or, if warranted, new requirements are implemented. The licence application guides are examples of cases where CNSC staff increased the guidance for applicants. For a specific use, when CNSC staff had concerns about the performance in the industrial radiography subsector, they worked with the CSA group to set up the PCP-09 scheme committee which led to the development of CSA Group document CSA PCP-09, <i>Certified Exposure Device Operator Personnel Certification Guide</i> and introduced new requirements for exposure device operator certification, including the requirement to renew the certification every five years. Another example where CNSC staff implemented additional requirements based on concerns around performance was the revision of the licence condition for vessel or hopper entry applicable to fixed gauges. CNSC staff revised the condition to be more prescriptive on the steps licensees must follow prior entering a vessel or hopper to which a fixed gauge is mounted. The examples provided above show that CNSC staff monitor performance of licensees and when merited will introduce new expectations.
3	B. Poulet (19-M29.1)	Section 2	Including relevant program, licensing, and compliance verification information on SCAs which are currently not covered in the ROR should be considered in future RORs	The four safety and control areas used as indicators of licensee safety performance in this report - management systems, operating performance, radiation protection and security - were chosen because they apply to all licensees covered by this Regulatory Oversight Report and provide a holistic view of performance of the licensees covered by this report. While only four safety and control areas are reported in the Regulatory Oversight Report, all relevant safety and control areas are assessed during licensing activities and are reviewed during compliance verification activities.
4	B. Poulet (19-M29.1)	Section 3.2	The ROR does not provide information on the scope of the questions that would be posed during the pre-licensing visit nor whether the interview results are documented and kept. Are the pre-licensing interview questions, answers, and assessments standard and fully documented? Are the pre-licensing interview results documented and kept?	The pre-licensing visit questions are based on the relevant SCAs for the licensed activity. The questions are catered to the use type (e.g., emergency procedures for source retrieval in radiography vs. fishing in well logging). Interviews are documented and summarized. That summary is provided to the Designated Officer when making a decision on the licence.

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5	B. Poulet (19-M29.1)	Section 6.1	Doses to workers: Could CNSC staff confirm the data in Figures 10, 11, 25, 26, and 28?	The discrepancies will be corrected and included in the presentation to the Commission, and will be corrected prior to publication of the final version of the ROR.
6	B. Poulet (19-M29.1)	Section 6.1	The current 5 year dosimetry period will end on December 31, 2020. Did any of the Canadian NEWs exceed the 5 year effective dose limit of 100mSv in 2018?	No Canadian NEWs exceeded the 5-year effective dose limit in 2018. In addition – the National Dose Registry sends an automated notification when a regulatory dose limit has been exceeded.
7	B. Poulet (19-M29.1)	Section 6.1	What happens to the workers once they have exceeded these effective dose limits (>50 mSv for one year or >100mSv for a 5 year period)? Are they the subject of a special follow-up w.r.t. health or employment activity?	The dose limits in the <i>Radiation Protection Regulations</i> are set at safe levels, below any deterministic effect thresholds. So in all but the most extreme cases of a dose limit exceedance, health follow-up would not be warranted. Regardless of how the dose was received, the individual is removed from radiation duties until a return to work is authorized by the Director of the Radiation Protection Division of the CNSC. Conditions of return may be subject to prorated dose limits.
8	B. Poulet (19-M29.1)	Section 6.2	Presentation of the compliance verification data in the ROR is both relevant to this sector of the nuclear industry and helpful to the reader. The practice should be maintained in future RORs. In cases, where the compliance verification data being provided shows potential gaps in the safety performance of the licensees, the ROR should include an explanation of the safety significance of the data, a description of any additional measures being taken by the licensee(s) to ensure safety, and a description of any regulatory follow-up being taken.	CNSC staff are in agreement on the value of presenting compliance verification data. Over the past few years, the information in the Regulatory Oversight Report has focused on the most common areas of non-compliance in each safety and control area in the report, as well as cases that were significant enough to warrant issuing enforcement actions. In 2018, case studies were added to the report to provide specific examples of how CNSC staff monitor performance of licensees and implement regulatory oversight strategies to address the concerns.
9	CRPA (19-M29.2)	General	The 2018 ROR does not seem to have been explicitly posted on the CNSC website rather it was located as a Commission Member Document in the 'meeting downloads' section.	The posting of the Regulatory Oversight Report followed the Commission's process for publishing material associated with Commission proceedings. The final version of the Regulatory Oversight Report will be published on the CNSC website as a publication along with previous year's reports.
10	CRPA (19-M29.2)	Section 2.2	The fifth paragraph states that performance in the packaging and transport SCA is not explicitly covered – we still believe that there are compliance concerns with Class 7 TDG and that this SCA should be explicitly addressed (same comment last year). Three of five common non-compliances for portable gauge licensees (ROR page 22) are transport related so we are really mystified why the Packaging and Transport SCA seems to get short shrift.	To build on the response #3 above, CNSC staff assess all relevant safety and control areas during licensing and compliance activities, and report on significant trends. For the packaging and transport safety and control area, most of the items of non-compliance identified during inspections are administrative in nature (eg. PTNSR (2015) 29(1) – particulars on the transport document for consignment). The events related to packaging and transport provide information into licensees' and other transporter's performance in this area. Where appropriate, CNSC staff make use of other vehicles outside the Regulatory Oversight Report, to disseminate information to specific groups. For example, the "Working Safely with Portable Gauges" booklet (updated in 2018) and the "Stay safe working with Portable Gauges" video for portable gauge users both addressed the common problems seen with transportation of portable gauges. As CNSC staff explore new avenues for presenting information in a manner that is useful to readers, we will consider how we can highlight performance trends where appropriate.
11	CRPA (19-M29.2)	Section 4.4	We remain hopeful that REGDOC-1.6.2 will have a positive effect on the performance of licensees.	CNSC staff look forward to receiving feedback on the draft REGDOC-1.6.2 when it is posted for public comment.

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12	CRPA (19-M29.2)	Section 5.2	We are taken aback by Figure 9 on page 24, not that it is incorrect but by the visual impact it has on displaying worsening performance in nuclear medicine. The CRPA members of the CRPA-CNSC Working Group are most willing to consider how they can assist CNSC staff in this area. Perhaps consideration should be given to CNSC staff offering additional outreach sessions to medical RSOs.	CNSC staff recognize CRPA's active engagement in the industry through their annual conference, and participation in consultations, the RSO evaluation and the CRPA-CNSC working group. Based on the recommendations of the evaluation on the role of the RSO, CNSC staff are reviewing their outreach activities and tools available to help licensees with an eye to focusing efforts where they will result in the most impact to safety. CNSC staff look forward to continued engagement with the CRPA as they work on strategies targeting performance in the nuclear medicine subsector.
13	CRPA (19-M29.2)	Section 5.2	If non-compliances are being corrected during CNSC inspections are they recurring during the next inspection or being observed with other discrete licensees? It might aid in understanding if the most common non-compliances were highlighted.	<p>There are two aspects to this issue: (A) repetitive non-compliance by a licensee and (B) the most common items of non-compliance across a sector or across the industry as a whole. The two aspects are dealt with separately in the response below.</p> <p>A) Before conducting a planned inspection of a licensee, CNSC staff will review past inspection reports. If, during the course of the inspection, recurrent non-compliances are observed, this will influence the approach the inspector may take, particularly it may impact the decision on whether to issue enforcement actions and which enforcement tool to choose</p> <p>B) As part of monitoring performance, CNSC staff look at the most common items of non-compliances in a given safety and control area, and for particular groups of licensees, as these indicate specific challenges for licensees. These areas of non-compliance become targets for information dissemination and outreach using, for example targeted communications to particular groups of licensees, safety bulletins, or the DNSR Newsletter. Sometimes, these items of non-compliance are an indication of a lack of clarity around the specific requirement and will prompt CNSC staff to develop additional guidance for licensees. For example, CNSC staff revised REGDOC-2.12.3, <i>Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material, Version 2</i> to improve the guidance on the security of sealed sources based on some challenges licensees faced during the early implementation of the REGDOC. Another example are the various safety posters developed for nuclear substance and radiation devices licences.</p>
14	CRPA (19-M29.2)	Section 6.1	With regard to skin doses we do not see any information on possible internal intake of nuclear substances, nor have we seen such information in the past few reports that have highlighted significant skin contamination incidents. Where are the Internal Dose Assessments? For the I-131 skin contamination incidents are we to assume that Thyroid Screening was performed and was negative?	<p>The need for internal assessments is dependant on the radiation protection program of the licensee as well the dose in question.</p> <p>For skin contamination events, unless the radioactive material is in liquid form at room temperature (e.g. radio-iodine), or there is a break in the skin, there is no reason for the radioactive material to penetrate into the body. In most skin contamination events, the radioactive material is a solid dissolved in a liquid, which should not penetrate beyond the epidermis.</p>
15	CRPA (19-M29.2)	Section 6.3	With performance worsening in the medical sector it is interesting that the industrial sector seems to be most subject to enforcement actions. Outsiders might develop the perception that CNSC is "soft" on medical sector licensees (two of the three CRPA members on the CRPA-CNSC Working Group are medical RSOs and would dispute	CNSC staff have many tools at their disposal to address items of non-compliance and bring licensees back into compliance. These tools include, but are not limited to, discussions with the Radiation Safety Officer or Applicant Authority, increased regulatory scrutiny (for example additional inspections, or increased reporting requirements), licensing restrictions, orders, and AMPs. When selecting the most appropriate tool CNSC staff make the decision based on the individual circumstances of the case.

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			that perception, DNSR staff are certainly not "soft" on our organizations). This misperception can fester and corrections to it could become very difficult to ameliorate.	<p>Orders are only issued in situations where there is an immediate risk to health, safety, or security. It is important to note that finding an item of non-compliance does not necessarily equate to an immediate risk to health, safety, or security.</p> <p>There are generally fundamental differences in the operations of an industrial licensee and a medical licensee, which may influence the choice of approach when items of non-compliance are detected. The goal is always to return the licensee to compliance as quickly as possible. CNSC staff have found that a direct conversation with the senior management of medical facilities is often a very effective tool in bringing these licensees back into compliance, and so, additional action is not usually required.</p>
16	CRPA (19-M29.2)	Section 6.4	While the summary of reported events in Appendix E of the ROR is helpful, along with INES classification, Radiation Safety professionals in Canada would find on-line, CNSC published "NRC-style" event reports to be even more helpful as noted in our comments on the 2016 and 2017 RORs .	Every event that is reported to the CNSC is assessed by CNSC staff. CNSC staff also look at trends in reported events to identify possible areas of concern, or particular events that should be shared as operating experience with particular segments of the industry. Depending on the particular circumstances, CNSC staff leverage a variety of communication tools, including: special mailouts, the DNSR newsletter, or existing working groups. When trends in events are observed, CNSC staff will examine the requirements to see if additional requirements or guidance are needed to prevent similar events from occurring.
17	CRPA (19-M29.2)	Section 7	<p>As stated in our comments to the 2017 ROR, CRPA members continue to find CNSC outreach sessions very worthwhile and CNSC presentations and participation at our annual conference priceless.</p> <p>The <i>DNSR Newsletter</i> is another good tool for maintaining stakeholder engagement, and as noted in our comments to the 2016 and 2017 RORs, increasing publication frequency is desirable.</p> <p><i>WebEx</i> is a tool that has allowed collaboration in several sessions such as those dealing with Dose to Lens of the Eye, that collaboration has been between Health Canada, CNSC and CRPA and has allowed interested practitioners to participate remotely, those sessions were in 2018, 2019 with another one tentatively planned for 2020.</p>	As noted in the Regulatory Oversight Report and in the presentation, CNSC staff are examining the tools and strategies used for engagement with the goal of bringing together a set of tools that are specifically designed to assist licensees that may be struggling to meet performance expectations. CNSC staff appreciate the active and constructive engagement of the CRPA.
18	CRPA (19-M29.2)	Section 8.9	The 6th bullet point in this section lists regulatory documents that were published for public comment on 2018, the 2nd sub-bullet identifies REGDOC-2.5.6 <i>Design of Nuclear Substance Laboratories and Nuclear Medicine Rooms</i> as one of the REGDOCS posted for public comment in 2018 but in the "Regulatory Documents" portion of the CNSC website, as of 10 SEP 2019, REGDOC-2.5.6 is identified as not yet developed, see	This was an error in the Regulatory Oversight Report. The correction is addressed in the presentation to the Commission and will be corrected prior to publishing the final version of the Regulatory Oversight Report.

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			http://www.cnscc.gc.ca/eng/acts-and-regulations/regulatory-documents/index.cfm . This was communicated to DNSR staff 11 SEP.	
19	CELA (19-M29.3)	General	Given the reduced length of this year's ROR, information should be provided at the ROR meeting in November 2019 explaining the rationale for this reduction in size/scope, including a summary of the information that will no longer be provided or will only appear in an even more abbreviated form.	<p>CNSC staff are committed to providing clear and accessible information to the Commission and our stakeholders. In 2018, we undertook a holistic review of the Regulatory Oversight Report to identify opportunities to focus the report on critical information on performance trends. The focus was to highlight factors that are relevant to the effectiveness of our regulatory program and give useful information to licensees and the public on areas that warrant attention in order to continuously improve.</p> <p>Page count is not a relevant comparison of the quality and effectiveness of the report, in particular because the ROR is not the only vehicle that CNSC staff use to communicate with stakeholders. Changes to the 2018 report include: restructuring the report to allow removal of duplicate information, using hyperlinks to point to information that is already available on CNSC's website, presenting the detailed performance of subsectors as an annex and table format rather than graphs, removing the duplicate summaries of the different types events from the body of the report, and moving the waste nuclear substance licences to a subsector of the commercial sector rather than their own sector.</p>
20	CELA (19-M29.3)	General	The ROR would be more effective if the CNSC canvassed a list of issues and topics to inform the scope of the ROR. Given the trend to longer, ten-year licences, soliciting public comment on the scope of issues addressed in ROR would provide a starting point for public engagement.	The CNSC recognizes that there are opportunities to engage with members of the public and Indigenous groups in new and different ways that could help strengthen public trust and align with the practices of government and other quasi-judicial modern engagement. In particular, the CNSC is piloting a new forum with civil society organizations in the upcoming months. During this meeting, CNSC would welcome a discussion on opportunities for new ways to engage with civil society organizations including CELA on issues and topics of interest to stakeholders.
21	CELA (19-M29.3)	p. 103	CELA remains of the opinion that the CNSC's previous rating levels were easier to understand and more detailed than the current scale presented in the ROR. We reiterate our recommendation made in the past ...to reconsider the shift in terminology...	The <i>Regulatory Oversight Report on the Use of Nuclear Substances: 2018</i> makes use of the terminology that is standard across the CNSC for describing licensee performance and provides a consistent frame of reference year-over-year.
22	CELA (19-M29.3)	p. 8	...(T)he ROR sets out a list of activities undertaken to encourage licensee compliance (ie. discussions with licensee, sanctions, monetary penalties, etc). However, what is not clear is the frequency with which each of these tools are used. This would be a helpful comparison to make in the report as it would illustrate whether the CNSC, in its licence verification activities, is using the gamut of powers available to it or prioritizing 'softer' mechanisms, for instance.	When CNSC staff encounter items of non-compliance, they will use the tool that is most likely to effect the desired change in behaviour. The selection of enforcement tools is dependent on the specific situation. CNSC staff's intent is to bring or drive licensees back into compliance, and mitigate future non-compliance. The enforcement reporting included in the Regulatory Oversight Report on an annual basis demonstrates that the CNSC use the full range of tools to meet this objective.
23	CELA (19-M29.3)	p. 6-7	Compliance percentages for all Safety and Control Areas should be included in the ROR to allow the public to gain better insight into the overall performance of licensees.	Please refer to comment #3 in this table as it addresses the same issue.
24	CELA	Section 6	Any licensee that receives a below expectation rating should be	The objective of the Regulatory Oversight Report on the Use of Nuclear Substances is to provide

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	(19-M29.3)		profiled in the ROR, even if it's in regards to an SCA not described in the report.	performance information and trending to the Commission and stakeholders. The report considers performance at a sector level, not an individual licensee level. Therefore trends, performance, and regulatory approaches are more relevant when presented at a sector level. Notwithstanding, the report highlights common areas of non-compliance and identifies all licensees that received unacceptable ratings resulting in orders or administrative monetary penalties.
25	CELA (19-M29.3)	Appendix C.4	Appendix C4 should be updated to include data which led to the positive performance rating for licensees under the Environmental Protection SCA.	The overall compliance rating for environmental protection in the waste nuclear substance sector was 100% in 2018 (5 out of 5 inspections were rated fully satisfactory or satisfactory). No licensees received below expectations or unacceptable ratings in this SCA. The licensees continue to manage and monitor environmental releases as a result of licensed activities. Any releases to the environment are kept well below regulatory limits. There were no unplanned releases to the environment as a result of licensed activities. If any unplanned releases were to occur they would be included in the Regulatory Oversight Report as a reported event.
26	CELA (19-M29.3)	p. 7	The upcoming ROR meeting and the ROR should be updated by way of addendum, to set out how the environmental protection threshold per REGDOC 2.9.1 is fulfilled.	As noted in the Regulatory Oversight Report and the introductory sections of REGDOC-2.9.1, the majority of nuclear substances and radiation device licensees are authorized for the possession and use of sealed sources or radiation devices. These nuclear substances have no potential for release to the environment. Protection of the environment is inherent in their design. Licensees are required to verify the source by performing leak tests at frequencies defined in the regulations. CNSC inspectors verify the leak tests were performed and the results of the leak tests show no leaks. Unsealed nuclear substances are generally used inside controlled rooms or laboratories designed in accordance with regulatory requirements, including work practices, which prevent the release or uncontrolled release to the environment. These measures are incorporated into the licensing basis for the CNSC licence issued. CNSC staff verify these measures through compliance activities.
27	CELA (19-M29.3)	p. 45	Information should be provided in the ROR which describes the motivation to change oversight for larger and more complex licensees. This information should be presented at the upcoming ROR meeting.	CNSC staff monitor trends in order to ensure readiness to regulate new technologies or adapt regulatory programs. One significant trend in the medical sector, for example, is the trend towards amalgamation of health facilities by provincial ministries, and consolidation or acquisition of smaller companies as a result of economic factors. As licensees evolve, CNSC staff review our regulatory oversight strategies to make sure it is effective and efficient. Traditionally, compliance of large licensees was focused on location-specific verifications which were used to judge overall program performance. Since 2016, recognizing the need for a broader programmatic perspective, the use of Type I inspections in the nuclear substance and radiation device compliance program has been increasing. CNSC staff have seen the advantages of this programmatic approach to compliance verification for complex licensees or unique applications. Therefore, CNSC staff are examining the licensing and compliance strategies for these licensees to embed a programmatic lens and/or to adapt to unique licensee risk profiles.
28	CELA (19-M29.3)	p. 11	A description of what is intended by the phrase "CNSC staff optimized their process" should be provided at the ROR meeting.	CNSC staff involved in the certification of exposure device operators optimized their process in a couple of ways. First, they improved the forms used by applicants. Use of the new forms has reduced the back-and-forth between CNSC staff and applicants that occurred due to incomplete application

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				forms or incorrectly filled out forms. Thus, the process is more streamlined. Second, CNSC staff improved the way they are coding their time in items related to certification such that only direct certification work is captured whereas, in previous years, all work done by these staff were allocated to one time code so general program work and direct certification work were in the same time code bucket.
29	CELA (19-M29.3)	Section 3.7	<p>1. As other parts of the ROR allude to higher performance rates within the SCAs as a result of increased inspections, this begs the question whether this decrease in time spent on compliance verification may have led to fewer compliance issues being discovered. Therefore, CELA requests the Commission direct CNSC Staff to provide further information on whether this might be the case, and if not to provide an analysis of why this is not so.</p> <p>2. Given that the ROR does not provide a clear answer regarding the allocation of inspection resources, CELA requests information as to what, if any, inspection areas or activities have been given lower priority to allow for the increased focus on medium risk-licensees in 2019.</p>	The nuclear substances and prescribed equipment regulatory program is based on a mature, risk-informed regulatory approach, which ensures effective and risk-appropriate regulatory oversight of nuclear substances and prescribed equipment licensees. A risk-informed regulatory approach is taken when prioritizing inspections for annual inspection plans. Periodically, CNSC staff analyze performance data in detail to review our compliance approach for each subsector and adjust to respond to trends. In 2019, we are completing this review which brings in new factors like programmatic oversight of complex or unique licensees and documenting factors that should trigger increased oversight. The case studies highlighted in the Regulatory Oversight Report are examples of how CNSC staff identify issues and adjusts oversight strategies accordingly.
30	CELA (19-M29.3)	Appendix C.2	Within the industrial sector, a persistent problem with compliance can be observed in the fixed gauge subsector, with ratings dropping to rather disappointing levels...Therefore, CELA requests the Commission require CNSC Staff to provide information on the possible causes of these decreasing ratings and proposals for how it may be reversed.	<p>This has been discussed in previous Regulatory Oversight Reports. Please see the Regulatory Oversight Report on the Use of Nuclear Substances in Canada: 2017.</p> <p>In recent years, the CNSC has introduced new requirements – for example - for security of sealed sources with REGDOC-2.12.3, Security of Nuclear Substances: Sealed Sources, which came into force on May 31, 2018 for Category 3, 4 and 5 sealed sources as well as new requirements for vessel and hopper entries. These were accompanied by targeted inspections that identified areas where fixed gauge licensees needed to adapt their programs to these new expectations.</p>
31	CELA (19-M29.3)	p. 22 and Section 3.6	<p>1. Given the shift from performance-based inspections to records-based inspections, CELA requests information on how many of these inspections were performance-based and how many were records-based. CELA also requests information regarding the share of performance-based inspections vs. records-based inspections in past years, in order to gain a better understanding of how many performance-based inspections were carried out in past years compared to 2018</p> <p>2. The Commission should require greater field-based rather than desk-top inspections of licensee compliance in the nuclear substance sectors beyond those noted in the ROR, of portable gauges, nuclear</p>	<p>Every inspection includes a mix of records and performance verification. Inspection worksheets have been retooled to include performance information so that performance-based verification is embedded in all inspections in some form. It is therefore artificial to distinguish between the two (records-based vs performance-based) when reporting on inspection activities.</p> <p>CNSC staff recognized the benefits of including performance-based verification and integrated this layer of oversight into our inspection practices. CNSC staff also agrees that the portable gauge, nuclear medicine and industrial radiography subsectors in particular have benefited from CNSC staff's inclusion of performance-based inspections in our regulatory program.</p>

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			medicine and industrial radiography.	
32	CELA (19-M29.3)	p. 12	The ROR should list and reference key international standards as well as obligations guiding licensing requirements and discuss how international obligations are communicated to licensees.	<p>In terms of international standards, a recent IRRS mission to Canada "... recognizes Canada's ongoing commitment to continuous improvement and the implementation of the IAEA safety standards, which serve as the recognized international basis for nuclear and radiation safety."</p> <p>With respect to international obligations, in addition to general requirements in the regulations, requirements are set in the licence. For example, where relevant, licensees are required to track and report safeguarded materials. Among the licensees covered in this report, the quantities of safeguarded materials are generally minimal and include, for example, depleted uranium that is used as shielding in devices must be reported as safeguarded material.</p>
33	CELA (19-M29.3)	Section 3.2	For both of these instances, CELA recommends including more detailed information regarding the decision to carry out secondary pre-licensing visits.	Pre-licensing visits are used by CNSC staff to assess the readiness of an applicant to conduct licensed activities. In the two instances cited in the report and in the intervenor's comment, CNSC staff determined that the applicant was not ready to conduct licensed activities. The second pre-licensing visits were carried out assess if the applicant had made the changes necessary to meet the requirements such that CNSC staff were comfortable to make the recommendation to issue a licence. Additional details about pre-licensing visits were provided in the response to item #4 of this table.
34	CELA (19-M29.3)	General	A public registry should be established for the 2000+ nuclear substances so that the licences are viewable and amendments or decisions from the Commission specific to the licence are traceable.	The CNSC currently maintains a full list of licensees on its website, which provides various search capabilities. However, the current systems used by the CNSC do not allow for reporting at this level of detail. The CNSC continues to evolve and modernize its digital systems which may provide the foundation to explore a stronger e-business approach to interactions between the CNSC and licensees, and additional public reporting capabilities.
35	CELA (19-M29.3)	Section 6.1	Further information should be provided about the potential long-term health risks to exposed nuclear energy workers and how their long-term health will be monitored and evaluated.	<p>The purpose of both the extremity and skin dose limits for NEWs is to protect against deterministic (short term) effects, while the purpose of the effective dose limits for NEWs is to protect against stochastic effects (long-term effects). Protecting the skin as an organ from long term effects is built into the effective dose limits. In these two skin contamination incidents, the dose was based on calculations that included conservative assumptions. Although they were above the dose limits, these limits are set far below deterministic health effects (such as skin erythema), and no deterministic effects were observed in the affected individuals. The long term risk to the exposed skin must be weighed against the very small surface area that was exposed, relative to the skin surface area over the entire body. As such, long-term health monitoring is not required. The resulting effective dose from the skin dose due to contamination can be ascertained to provide an idea of overall health detriment, but because the calculation involves multiplying the dose by both the tissue weighing factor of 0.01, and the ratio of exposed skin relative to the total surface area of skin on the body, the resulting effective dose would on the order of a few micro Sieverts which is insignificant and not generally reported.</p> <p>CNSC have regulatory requirements in place following a suspected overexposure and authorizing a worker's subsequent return to work. The considerations as to whether a worker is allowed to return to work would include whether threshold doses for tissue effects were exceeded and there were any</p>

	Intervenor	Section or Para. #	Intervenor's Comment and Proposed Change	Response
				observed deterministic effects, as examples. These cases would need to be considered on a case-by-case basis and may result in work restrictions and careful analysis of the health consequences to the individual from returning to routine occupational exposures to radiation
36	CELA (19-M29.3)		The ROR should explain what ALARA constitutes in each of the nuclear substance sectors reviewed and how, in light of greater or lesser risk to the worker or the environment, licensing requirements and inspections are either more/less responsive.	Information about ALARA can be found in REGDOC G-129, <i>Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)"</i> . A new REGDOC, REGDOC-2.7.1, Radiation Protection , recently out for consultation will incorporate the information from several existing radiation protection REGDOCs including G-129.
37	CELA (19-M29.3)	Section 6.1	In response to a negative trend in Nuclear Medicine compliance ratings for at least the past 5 years, a more in-depth explanation and analysis of this trend, including possible causes and solutions should be provided to the Commission at the upcoming ROR meeting in November 2019.	The performance trend and plan for action for the nuclear medicine subsector is discussed in detail in the report, and also in the presentation. CNSC staff began discussion of a strategy for improving performance in the medical sector in 2017 and presented to the Commission in CMD 17-M44 . The results of the evaluation that was conducted as a result of the plan presented in CMD 17-M44 is posted on CNSC's public web page.
38	CELA (19-M29.3)	p. 55	CELA requests the CNSC detail what steps have been taken to alleviate the administrative burden in this subsector, while still retaining a sufficient level of protection. We request the CNSC clearly set out how they intend to ensure hospital staff are not being tasked with burdensome requirements that, while of benefit to the CNSC, may fit poorly within the workflow at hospitals. In light of this potential burden, CELA requests the CNSC provide information on how it aims to increase capacity. Ultimately, if unrealistic reporting expectations are placed on hospital staff, it will limit the value and potential of the CNSC's oversight.	The evaluation on the role of the radiation safety officer found that some RSOs in the medical sector note a lack of time as a challenge for them to meet all of their duties associated with being an RSO. As discussed in the report and the presentation, CNSC staff are working towards meeting the recommendations of the evaluation. Separate from the evaluation, in 2019 CNSC staff have been working to update the ACR forms to make them more streamlined. CNSC staff have a commitment not to impact patient treatment. For example, when inspecting radiation therapy licensees, CNSC staff will observe the QA testing of the equipment first thing in the morning, when it is performed for the hospital's needs, and they will perform any radiation surveys of the facility once the hospital treatment schedule is done for the day.
39	CELA (19-M29.3)	Section 6.2	Discrepancies in order number 1206 and the order not numbered, but dated December 19, should be remedied. CELA recommends including a brief description of the issues in question, in a manner similar to that provided for all of the closed orders.	<p>Issued orders and a description of the orders including the two in question are posted on the CNSC external website.</p> <p>The order dated December 19 is a designated officer order, and designated officer orders do not have order numbers associated with them. In relation to this order, the licensee is complying with it and the concerns have been resolved as it relates to the production of diagnostic iodine-131 (I-131) capsules (June 2019). All applicable terms and conditions of the order remain in effect for the processing of I-131 therapeutic capsules. CNSC staff have been receiving periodic updates from the licensee and is monitoring progress.</p> <p>Order 1206 requires the licensee to place all radioactive materials in secure storage and is prohibited from acquiring any radioactive materials until such time it can demonstrate, to the satisfaction of the CNSC, that the licensee has implemented an effective radiation protection program with management control over work practices. Currently, all sealed sources are in secure storage and will not be used until such time the order is complied with and closed. CNSC staff continue to monitor the licensee's compliance with the order.</p>

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40	CELA (19-M29.3)	p. 17	The acronym DNSR should be described and spelled out in full	DNSR: Directorate of Nuclear Substance Regulation
41	CELA (19-M29.3)	p. 20	The amounts of contaminated materials received from 'other types of nuclear facilities', the characterization of these materials' contamination, and a clearer identification of what constitutes 'other types of nuclear facilities' should be provided to the Commission and included in next year's ROR.	The licensees are limited to a resident inventory of 10^{15} Bq. Each licensee is required to maintain records of the waste that they have onsite, including its origin and characterization information. CNSC staff verify that licensees maintain these records through regular compliance verification. The licensees manage waste from research laboratories (e.g., gloves, paper towels, liquid scintillation vials), as well as contaminated metals, laundry, tooling and equipment from other types of nuclear facilities (e.g., nuclear power plants and fuel cycle facilities).
42	CELA (19-M29.3)	Section 7	In response to stakeholder engagement, CNSC Staff should provide information to the Commission regarding the location of "licensee communities" and detail which communities have been visited in the year in focus.	"Licensee communities" refers to communities of practice of the different uses of nuclear substances and prescribed equipment, rather than physical locations or communities. CNSC staff will clarify language in future Regulatory Oversight Reports. The location of inspections conducted in 2018 is included in Appendix H of the report.
43	CELA (19-M29.3)	Section 8	Lastly, the ROR reviews a number of REGDOCs which either came into force during the year in review or will soon be available in draft form, and public comments solicited. In each instance, CELA requests the CNSC whether the coming into force of a REGDOC will be retroactive and made a licence compliance document for each licensee. Should this not occur, CELA requests an explanation as to why.	Because of the diversity of activities of licensees covered by this Regulatory Oversight Report, the main focus for REGDOCs that touch these licensees is on licence application guidance to ensure that licensees will have in place programs that address all relevant safety areas. When introducing new requirements, the Commission can, and has, amended all impacted licences on its own motion. This was done when REGDOC-2.12.3, <i>Security of Nuclear Substances: Sealed Sources</i> was introduced and also with the introduction of financial guarantees for the nuclear substance and prescribed equipment licensees.