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**Written submission from the
Radiation Safety Institute of
Canada**

**Mémoire de l'Institut de
radioprotection du Canada**

**Regulatory Oversight Report on the
Use of Nuclear Substances in
Canada: 2023**

**Rapport de surveillance réglementaire
sur l'utilisation des substances
nucléaires au Canada : 2023**

Commission Meeting

Réunion de la Commission

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Review of the` CNSC Regulatory Oversight Report on the Use of Nuclear Substances in Canada: 2023

for

Canadian Nuclear Safety Commission
(Reference: Form number: *PFP 2024 DNSR ROR*)

by

Radiation Safety Institute of Canada



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1 Introduction

1.1 About the Radiation Safety Institute of Canada

Founded in 1980, the Radiation Safety Institute of Canada (RSIC) is an independent, national organization dedicated to promoting and advancing radiation safety in the workplace, in the environment, and in the community. Our commitment to the principle of “good science in plain language”[®] underpins everything we do. The Radiation Safety Institute of Canada is incorporated under federal statute as a not-for-profit corporation and is also a registered charity (number: 106861511RR001).

The Radiation Safety Institute of Canada offers a broad range of educational, technical, and scientific services to businesses, government organizations, health care providers, communities, and individuals across Canada and around the world. The Institute is known for the high quality and scientific integrity of its work, and the practical and helpful assistance of its staff. The Institute’s independent information service receives hundreds of calls and e-mails every year, for information and assistance on workplace radiation questions.

1.2 Project

The Radiation Safety Institute of Canada (Institute) applied for and was approved to receive funding through CNSC’s Participant Funding Program (PFP). This funding is intended to assist in the review of the CNSC’s “Regulatory Oversight Report on the Use of Nuclear Substances in Canada: 2023”. The Institute agreed to a review of the document, and participation in the public Commission hearing if required.

1.3 Background:

The CNSC’s “*Regulatory Oversight Report on the Use of Nuclear Substances in Canada: 2023*” (referred to as the ROR throughout the rest of this document) provides a review on licensee use of nuclear substances and prescribed equipment in the medical, industrial, academic and research, and commercial sectors. Most of these licensees are regulated by the CNSC’s Directorate of Nuclear Substance Regulation. The report also includes waste nuclear substance licensees that are not reported on in other Regulatory Oversight Reports (regulated by the Directorate of Nuclear Cycle and Facilities Regulation).

2 Review of Documentation Related to Licence Application

The Institute was provided with copies of the CNSC’s ROR as (1) e-Doc 7337221 (English version) which was reviewed, and (2) e-Doc 7337204 (French version) which was not reviewed. Of note in this document were the following items.

2.1 General

In Canada in 2023, there were 1,457 licensees holding 2,058 licences. Of these, 2005 licences were held by 1,411 Canadian licensees and the remaining 58 licenses were held by countries headquartered outside of Canada.

The number of licensees in Canada has remained fairly stable over the past 5 years, with the CNSC providing the following data:

Table 1: Reproduction of ROR Table 2 – Number of CNSC Licences per Sector

Sector	2019	2020	2021	2022	2023
Medical	438	445	440	443	449
Industrial	1,228	1,207	1,221	1,205	1,180
Academic and research	187	189	187	185	185
Commercial	237	238	249	247	244
Total	2,090	2,079	2,097	2,080	2,058

In 2023, the CNSC performed 815 inspections (747 in person, 31 remote, 37 hybrid) which is 159 more than in 2022 and was 14 more than originally planned. 815 inspections is approximately 39.5% of licensees (although it is recognized that more than one inspection can occur per licensee in a year, so that such is not an exact comparison). The CNSC noted that it is continuing to address an inspection backlog due to pandemic restrictions and that it cannot predict when it will return to the baseline inspection frequency.

2.2 Inspections by SCA

Inspections are performed using a Safety and Control Area (SCA) framework, and the CNSC report focuses on SCAs that the CNSC believes “are most effective in providing an overall indication of the safety performance of the licensees covered in this report” being the

management system, operating performance, radiation protection, and security SCAs. Overall, as a result of CNSC inspections, there were 7 unacceptable ratings issued to 7 different licensees, and all such unacceptable ratings resulted in an Order being issued: 4 related to the Radiation Protection SCA, 2 for the Operating Performance SCA, and 1 for the Security SCA.

A summary of the findings by the “main” SCAs is as follows:

Table 2: Summary of 2023 CNSC Inspections and Findings by Safety and Control Area (SCA)

SCA	Number of Inspections	% Satisfactory	Comparison to 5-year Average	Number of Unacceptable Ratings
Management Performance	727	97.4%	Similar	0
Operating Performance	746	84%	Similar	2
Radiation Protection	763	77%	Slightly Lower	4
Security	714	92%	Similar	1
Conventional Health & Safety (WNSLs only)	3	100%	Similar	0
Environmental Protection (WNSLs only)	3	100%	Similar	0

There were two items of note in the Operating Performance SCA. The first is that the medical subsector decreased substantially in the number of satisfactory inspections, but it was noted that only 5 inspections were performed (10% of such licensees) and therefore the findings may not reflect the industry as a whole. The second is that the industry fixed gauge subsector improved by 7%, which is a change from a downward trend over the previous several years, even with an increase in the number of inspections.

Of note in the Radiation Protection SCA is a somewhat lower satisfactory value overall (77% satisfactory compared to the 5-year average of 80%). In addition, the commercial sector decreased to 79% satisfactory (from 91% in 2022) and the medical sector as a whole was only at 59% satisfactory (down from 68% in 2022 and continuing an observed downward trend from 78% observed in 2021). The nuclear medicine subsector itself had only 54% satisfactory assessments, down from 63% in 2022 and from 75% in 2021. The report indicates that as far back as 2017, while “there was no systemic safety concern identified, the trending indicated that opportunities existed to strengthen licensee radiation protection programs and improve

regulatory compliance by enhancing guidance provided to licensees.” Although this downward trend is obvious, in 2023 no unacceptable ratings were issued in the medical sector, and there were no Orders or Administrative Monetary Penalties (AMPs) issued in the medical sector.

2.3 Enforcement

On the enforcement side of things, the CNSC issued a total of 9 orders (all as a result of inspections) and 3 AMPs (1 as a result of CNSC inspection and 2 as a result of events reported to the CNSC). This is an increased total number of Orders/AMPs compared to 2022, but is still low (1.5%) compared to the # of inspections (815). The CNSC indicated in the report that all orders are now closed (all actions required to be taken by the licensee have been satisfactorily taken) and all AMPs have been paid.

CNSC received 222 notifications of potential events related to nuclear substances and prescribed equipment, in 2023, of which CNSC staff considered 184 to be reportable. 183 of these were considered level 0 (no safety significance) on the International Nuclear and Radiological Event Scale (INES), and 1 was considered level 1 (anomaly). Events were tabulated by sector and by type of event.

2.4 Effective Doses to Workers

The ROR indicates that in 2023, licensees reported doses for 52,550 workers in the 4 sectors. Of those workers, 21,917 were nuclear energy workers (NEWs), and the remaining 30,633 are referred to as non-NEWs in the report. Never-the-less, doses appear to be low for Non-NEWs and NEWs alike, as can be seen in Figure 1 and Figure 2.

Figure 1: Reproduction of ROR Figure 17 – 2023 Annual Effective Doses to Non-NEWs reported by Licensees

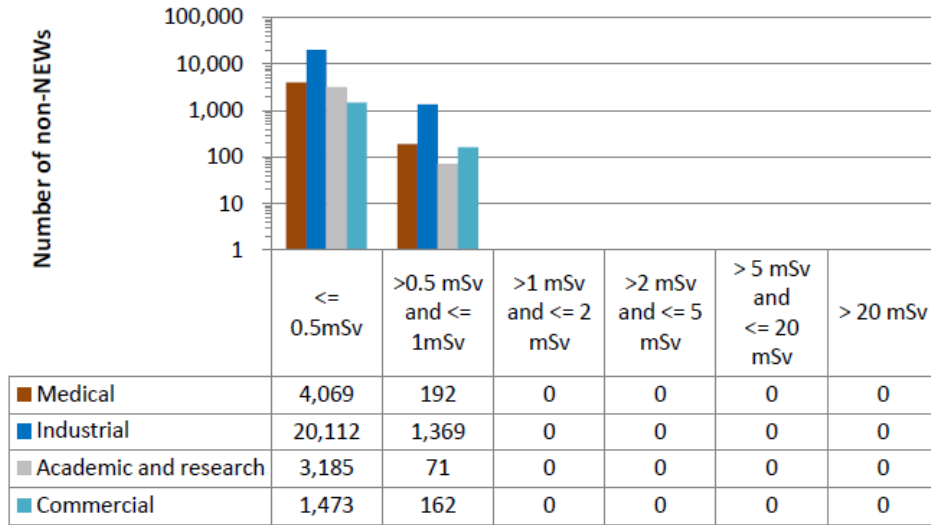
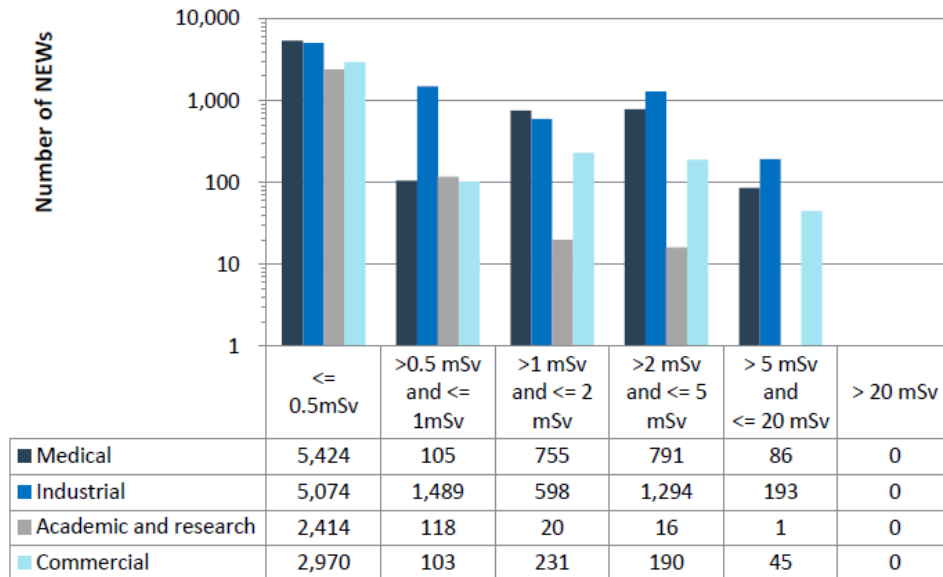


Figure 2: Reproduction of ROR Figure 18 – 2023 Annual Effective Doses to NEWs reported by Licensees



3 Discussion

3.1 General

This ROR focuses on SCAs that the CNSC believes “are most effective in providing an overall indication of the safety performance of the licensees covered in this report” being the management system, operating performance, radiation protection, and security SCAs. However, there are several other SCAs as noted in the CNSC website¹, including

- Management
 - Human performance management
- Facility and equipment SCAs:
 - Safety analysis
 - Physical design
 - Fitness for service
- Core Controls and Processes
 - Emergency management and fire protection
 - Waste management
 - Safeguards and non-proliferation
 - Packaging and transport

Although these SCAs may not play as large a role for small licensees as they do for Class I or II facilities, the performance in these areas is still important. It is recommended that the CNSC include the statistics on performance for all SCAs, not just the four provided in this ROR.

3.2 Radiation Protection SCA

Although 7 unacceptable ratings/orders out of 815 inspections is a very low percentage (0.86%), the report has some data that is concerning, particularly in the Radiation Protection SCA. The CNSC briefly mentioned that 2023 status is lower than before, but didn't go into detail. The graph in the appendix (reproduced below as Figure 3) shows an overall general downwards trend since 2020. No sectors have had satisfactory results above approximately 90% since 2020 and in 2023 the highest satisfactory level is approximately 85%. In addition, in 2023, ALL sectors are down in the number of satisfactory Radiation Protection SCA ratings (see Figure 4) as compared to the 5-year average. This was not discussed in much detail in the report. The report states the following:

¹ <https://www.cnsccsn.gc.ca/eng/resources/publications/reports/powerindustry/safety-and-control-areas/>

“There has been a drop in performance in the radiation protection SCA. The most common non-compliances included issues related to ascertainment and recording of doses, posting of signs, and radiation monitoring equipment.”

That is all the discussion on this topic. It is of concern if ALL sectors are trending downward in the Radiation Protection Safety and Control Area as this area is fundamental for the protection of workers. The ROR listed many actions that have been taken by the CNSC to try to address some of the compliance issues noted for the Radiation Protection SCA in the medical sector. This included outreach such as using the DNSR Digest to provide information on updated and new requirements and how to prepare for an inspection, along with emails, a webinar on instrumentation, and developing working groups with the CRPA (Canadian Radiation Protection Association) and the CAMRT (Canadian Association of Medical Radiation Technologists). It is recommended that the CNSC consider whether more outreach to all sectors for the Radiation Protection SCA is required, to try to address this downward trend before it becomes more significant.

Figure 3: Reproduction of ROR Figure 10 – Inspection Ratings for Radiation Protection SCA

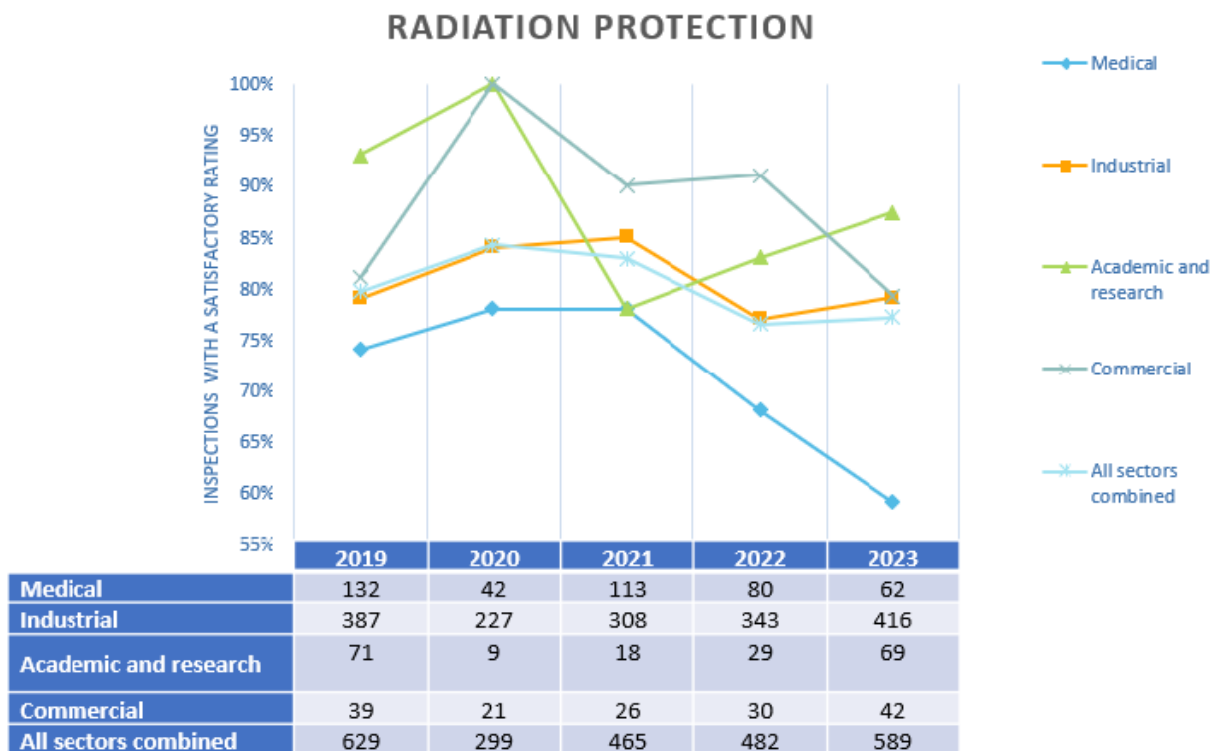
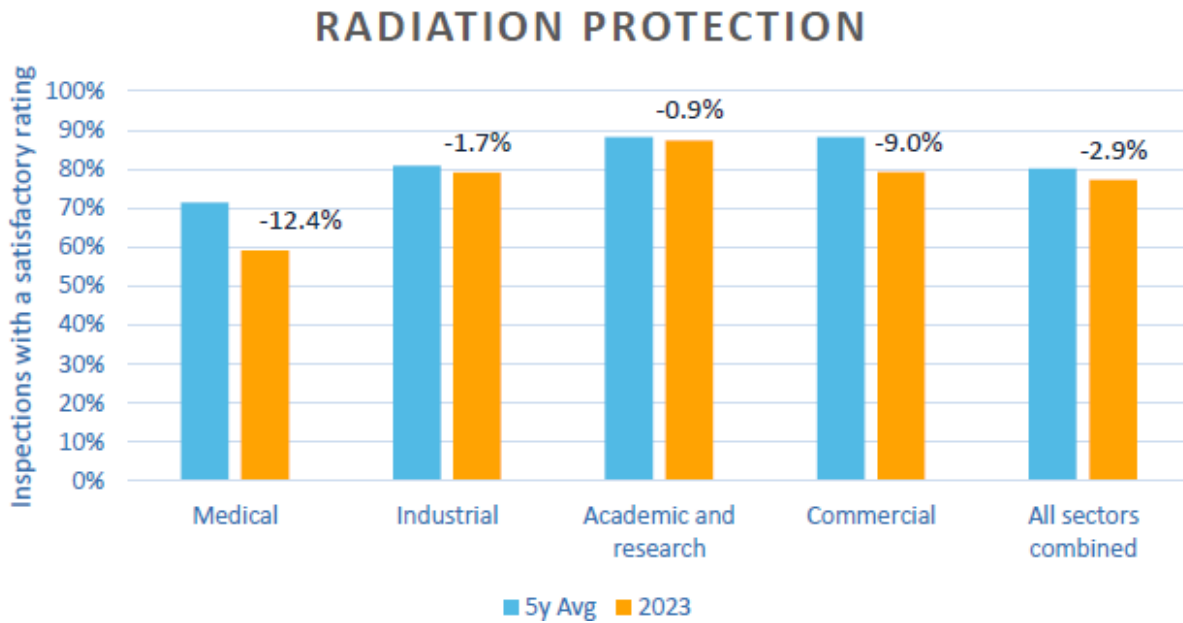


Figure 4: Reproduction of ROR Figure 11 – Sector Comparison for Satisfactory Ratings in the Radiation Protection SCA



3.3 Management System SCA

In the discussion around the lower performance in the Radiation Protection RCA, by the nuclear medicine subsector, the report says the following:

“The nuclear medicine subsector demonstrated lower performance in the radiation protection SCA once again in comparison to previous years, although ratings have been consistently low over the last 5 years. The most frequent items of non-compliance in 2023 included the ascertainment and recording of doses (specifically related to new requirements in the Radiation Protection Regulations for extremity dosimetry), those related to radiation detection equipment and those related to thyroid monitoring requirements. These items are related to inadequate management oversight in the implementation of the radiation protection program”

However, the assessment of the Management System SCA indicated that “97% of the licenses inspected demonstrated that adequate processes and programs were in place to achieve their safety objectives and therefore received satisfactory ratings” and that there were no unacceptable ratings in this SCA. In the detailed chart of the ROR’s Figure 5, 87% of the Medical sector has acceptable ratings in the Management System SCA.

This discontinuity in the report is confusing. Is the problem with the Radiation Protection SCA really a management issue, if the assessment of the Management System SCA showed no

issue? It is easy to “blame” management oversight. Perhaps a deeper dive into the root causes would be of assistance to determine why the poor performance in the Radiation Protection SCA exists, and if it is indeed due to Management.

3.4 Doses to Workers

The 2023 ROR only reports doses for workers in 2023, and did not include data on past year doses. Instead it states that effective doses overall are low and that previous “year-over-year trending showed this was consistent across the years.” The report stated that

“To further increase the granularity of dose reporting, CNSC staff have updated the annual compliance report forms to subdivide the 1–5 mSv effective dose category into 1–2 mSv and 2–5 mSv categories. In the past, we have included a graph showing the annual effective doses to NEWs, over 5 years, but due to this change, we no longer have the same data to compare.”

We completely disagree with this statement and strongly suggest that a trend graph should continue to be provided. It is simple math to use the 2023 data presented in this report, to create data in the same dose ranges as for past data: adding the 2023 data from the “1-2 mSv category” to the “2-5 mSv category” will give the required 2023 data for doses in the “1-5 mSv category”. This would allow the data to be presented as a trend with past data as was done in 2022 (see Figure 5 which has the 2022 trend graph). This trend graph can be continued with the previous dose ranges until ALL years have the more granular data ranges. A graph trending dose over time is important to provide and review.

The RSIC has taken the data from the 2022 and 2023 reports and created such a dose trend comparison. It is provided in Figure 6. The logarithmic scale (to continue the same format used as the CNSC) makes it somewhat difficult to see small changes in the data in each section, but overall doses appear to be fairly consistent over the timeframe from 2018 to 2023. 2023 does show some shift of doses from the 0.5-1 mSv category into higher categories of 1-5 mSv and 5-20 mSv. A continued presentation of trend data is required in order to evaluate if the trend continues or is just an anomaly for 2023.

Figure 5: Reproduction of Figure 15 from the “Regulatory Oversight on the Use of Nuclear Substances in Canada: 2022” – Annual Effective Doses to NEWs, 2018 to 2022, all Sectors Combined

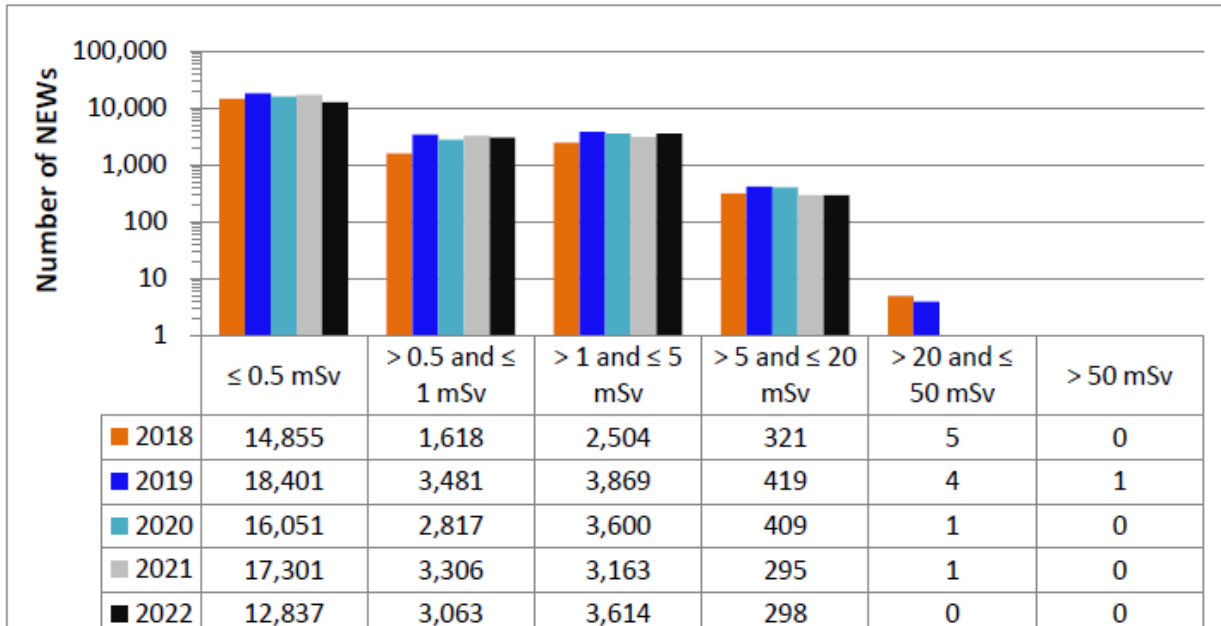
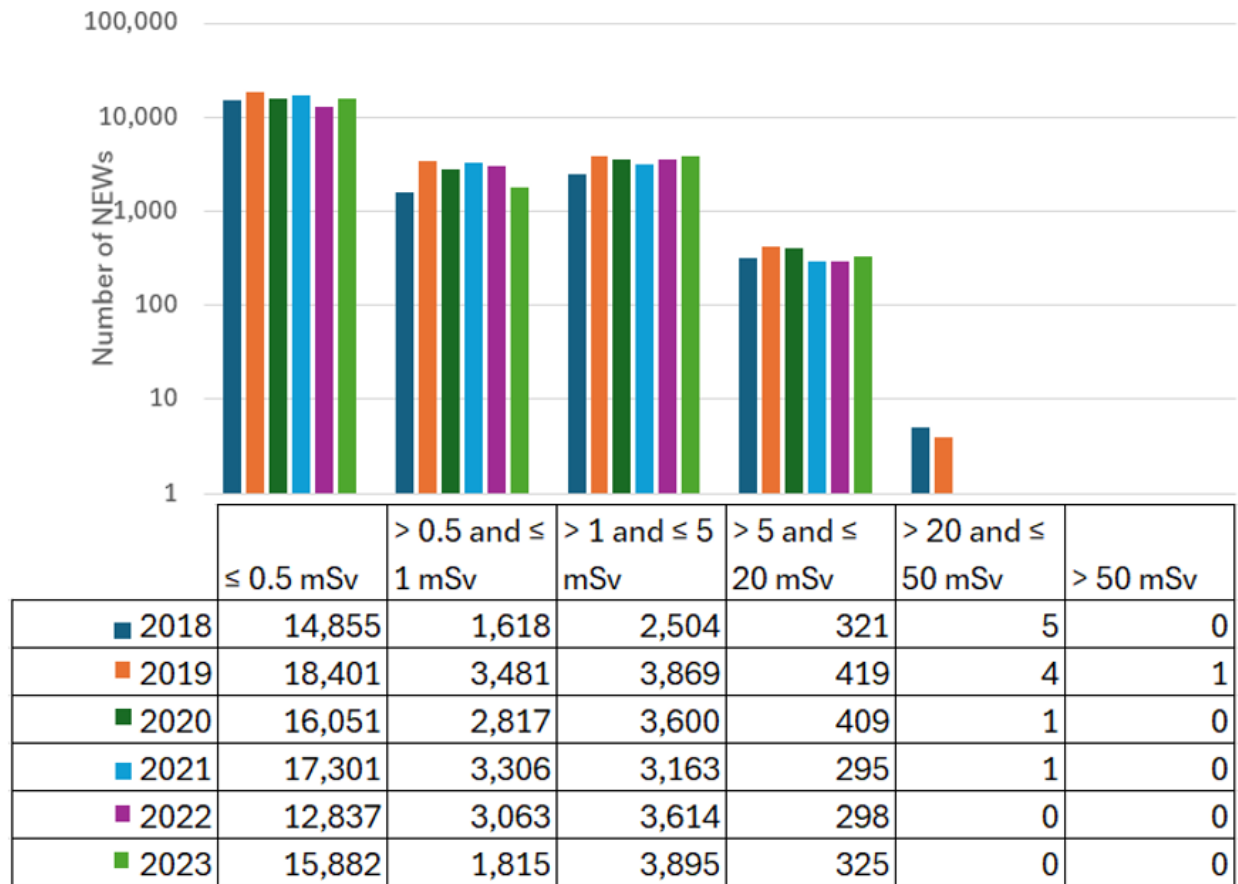


Figure 6: RSIC Created – Annual Effective Doses to NEWs, 2018 to 2023, all Sectors Combined, based on data in CNSC’s 2022 and 2023 RORs



We note that this ROR provides the effective doses to workers but does not provide any data on equivalent doses. The Radiation Protection Regulations require Licensees to track equivalent doses as well as effective doses. Recent changes to the regulations have added a requirement for a licensed dosimetry service provider to be used if workers have a reasonable probability of receiving an equivalent dose to the skin or the hands and feet doses above 50 mSv. As such, licensees should be reporting doses to the CNSC, and such data should be included in the ROR. Although effective dose is a good measure of the overall risk to workers, an assessment of dose to the skin and/or dose to the extremities will also give a good measure of licensees control over their radiation protection programs.

3.5 Enforcement

No obvious trends are noted over time, and the events are spread out over different types of events, with no single event type standing out as particularly more common than others.

3.6 Reportable Events

The reviewer did not find the Section or the Appendix on Reportable Events to be particularly helpful. The table(s) categorizing events by type and by sector provides some limited information, but doesn't help to provide information as to the causes of the events or if there are commonalities that can be considered by licensees in order to prevent events from occurring. The listing of individual events (ROR Table 26) was also not found to be particularly useful. This table is 54 pages long and doesn't contain more than date, type, sector, and a brief event description.

More of an analysis of events is recommended. Such could include more details as to types of events. For example, some drill down information could be organized along the following original types:

- Malfunctioning or damaged devices
 - Exposure device source issues (failed to return to shielding, disconnect)
 - Gauge shutter failed open
 - Gauge exposed to hazardous materials causing malfunction
 - Device impact (vehicle, heavy equipment) causing damage
- Spills, contamination or release
 - Spills < 100 EQ
 - Spills > 100 EQ
 - Personal contamination events
- Lost, stolen, found or abandoned nuclear substances
 - Lost substances/devices
 - Stolen substances/devices
 - Abandoned substances/devices
- Packaging and transport
 - Incorrect packaging
 - Damaged packaging
 - Minor motor vehicle collisions
 - Serious motor vehicle collisions
- Breach of security
- Unplanned exposure

- Unmonitored dose
- Action level exceedance
- Regulatory level exceedance

For example, a quick perusal of the first 15 pages of the 54-page table finds that in 2023 there were

- 8 events where a fixed or portable gauge shutter was stuck or found in the open position unexpectedly
- 3 events where a portable gauge was damaged by impact from a vehicle or from heavy equipment or by falling/dropping
- 5 events involving a collision during transportation of substances/devices

Information as to the causal factors for events would also be of great benefit to the industry as a whole. It is recommended to provide a summary indicating common root causes and contributing factors and indicate, for the 2023 events, how many were related to each cause/factor (understanding that events often have more than one causal factor and therefore events may be tallied in several).

4 Conclusion

The RSIC appreciates the opportunity to review the CNSC's Regulatory Oversight Report on the Use of Nuclear Substances in 2023 and be a part of the public review process. We have observed certain trends that in our opinion deserve the regulator's attention, and we have outlined a few items on which we would appreciate more information.

We look forward to continuing this conversation both with the Commission and with the public.