Directorate of Nuclear Substance Regulation Regulatory Oversight Reports: Part I: Use of Nuclear Substances in Canada: 2019 Part II: Class IB Accelerators in Canada: 2018-2019

CNSC Staff Presentation
Commission Meeting
November 5, 2020
CMD 20-M23.A

e-Doc 6305112 (PPTX)
e-Doc 6411025 (PDF)

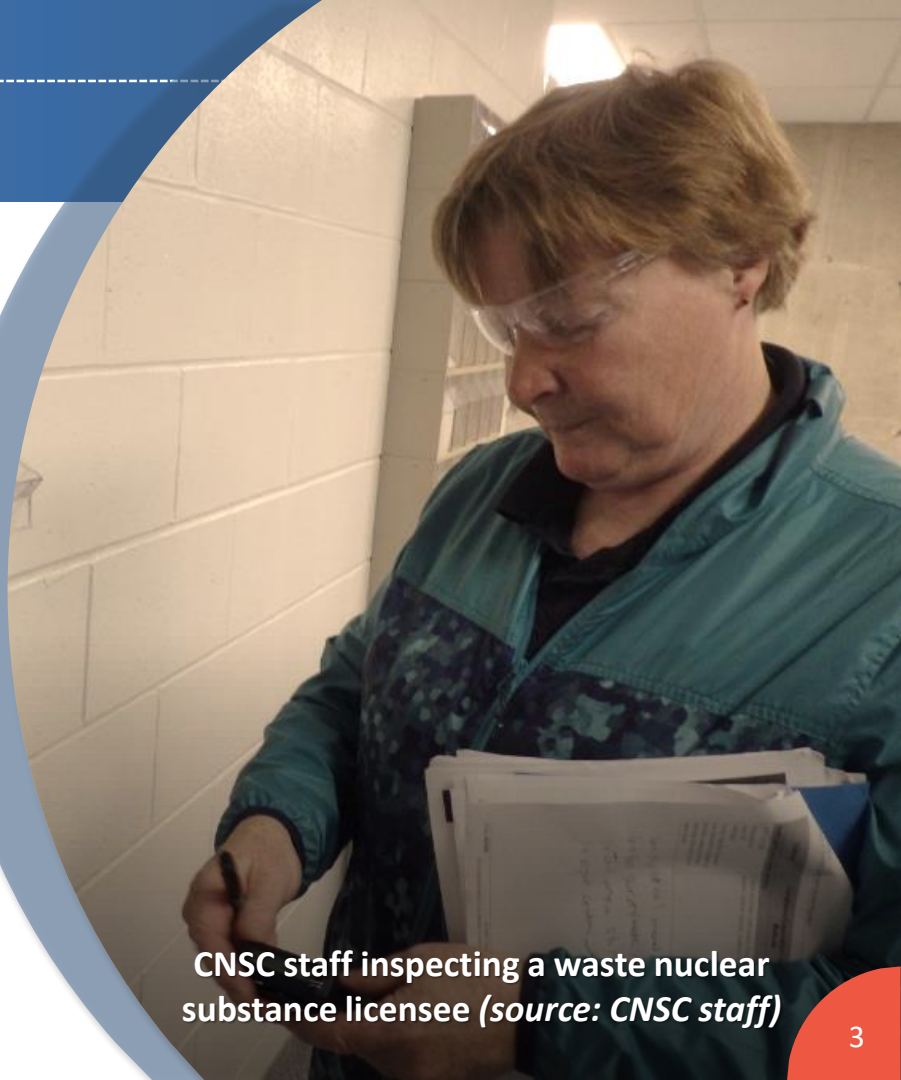
CNSC Regulatory Oversight Reports

November 5, 2020:
Directorate of Nuclear Substance Regulation Regulatory Oversight Reports:
Part I: Use of Nuclear Substances in Canada: 2019
Part II: Class IB Accelerators in Canada: 2018-2019

December 8, 2020:
Canadian Nuclear Power Generating Stations
Canadian Nuclear Laboratories Facilities
Uranium Processing and Nuclear Substance Processing Facilities
Uranium Mines and Mills

Overview

- Covid-19 Update
- Introduction
- Part I: Use of Nuclear Substances in Canada: 2019
- Case studies
- Part II: Class IB Accelerators in Canada: 2018-2019
- Interventions
- Concluding remarks



CNSC staff inspecting a waste nuclear substance licensee *(source: CNSC staff)*

CNSC RESPONSE TO COVID-19

Directorate of Nuclear Substance Regulation Regulatory Oversight Reports

Measures Implemented

Impacts from the COVID-19 Pandemic and Measures Taken:

Initial Impact

Activation of the Business Continuity Plan and Implementation of Health and Safety Controls:

- Restricted access to CNSC systems
- Suspension of non-critical oversight activities, including routine on-site inspections

Immediate Measures Implemented

Ensure critical services:

- Immediate readiness to respond to unplanned events or situations
- Reallocated resources to ensure licensing and certification activities continued to be performed
- Conducted outreach activities to ascertain licensees' operating environment

Revised Approach for Regulatory Oversight

Ensure capability in performing regulatory functions:

- Developed alternative oversight process for remote inspections
- Developed revised regulatory oversight plans
- Developed health and safety protocols for performing on-site inspections safely

Revised Regulatory Oversight Plans

Revised Regulatory Oversight Plans for FY20/21:

- Leverages the use of alternate performance verification activities
  - Inspections can be performed remotely or on-site
  - Only few planned inspections require on-site presence
- Prioritizes the health and safety of CNSC staff, licensees, inspectees and the public
  - Type of compliance verification activity is determined on a monthly basis and chosen based on the current climate of the pandemic
  - At the time of writing this presentation, CNSC staff demonstrated healthy safety culture by deciding to pause on-site inspections while COVID numbers are on the rise
- Ensures completion of high priority inspections
  - By finding alternative ways to obtain compliance information from lower priority inspections

There are no expected impacts on safety due to revised regulatory oversight plans

INTRODUCTION

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Licensees' Safety and Responsibilities

- In 2019, Licensees had appropriate programs to protect health, safety, security and the environment
- Licensees continued to maintain adequate measures to implement Canada's international obligations
- In 2019, one worker exceeded the whole body regulatory dose limit for non-NEWs and one worker exceeded the whole body regulatory dose limit for a NEW. No impact on health of workers

The use of nuclear substances in Canada is safe

CNSC inspectors survey a licensee's inventory *(source: CNSC staff)*

PART I: USE OF NUCLEAR SUBSTANCES IN CANADA: 2019 OVERSIGHT ACTIVITIES IN 2019

Directorate of Nuclear Substance Regulation Regulatory Oversight Reports

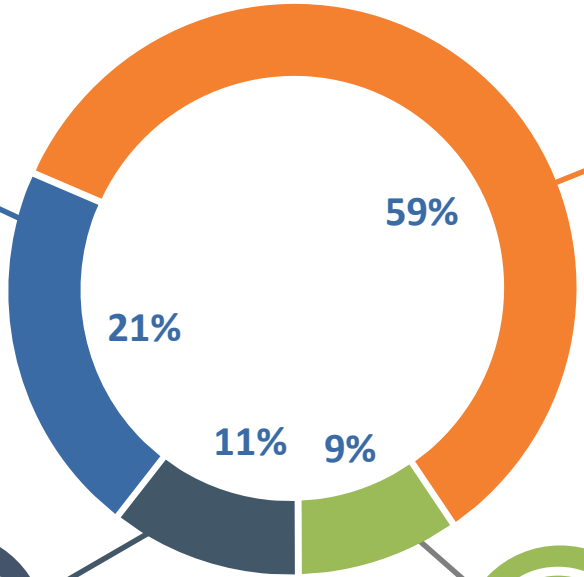
Diverse Uses Of Nuclear Substances

MEDICAL
438
licences

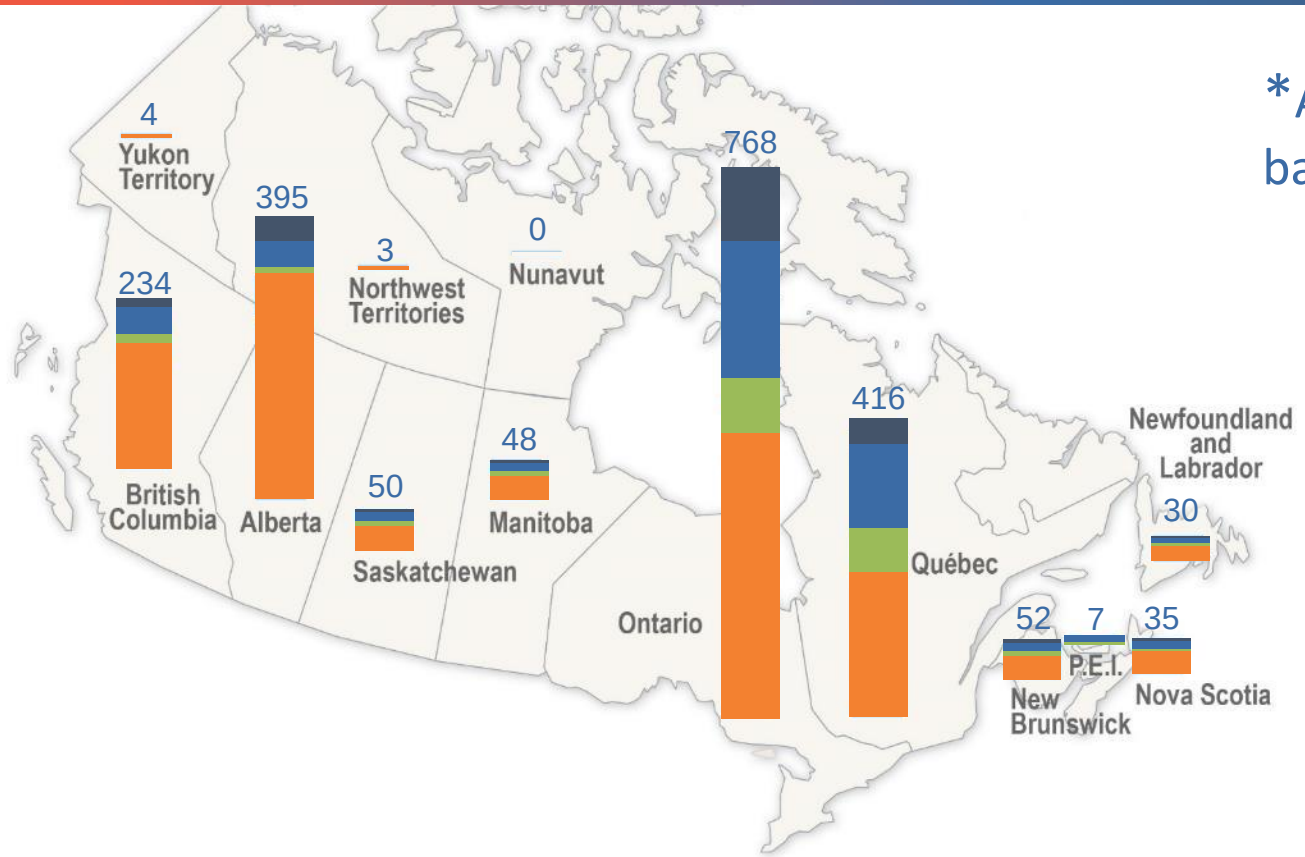
INDUSTRIAL
1,228
licences

COMMERCIAL
237
licences

ACADEMIC & RESEARCH
187
licences



2,042 Licences across Canada*



*Additional 48 licensees based outside Canada

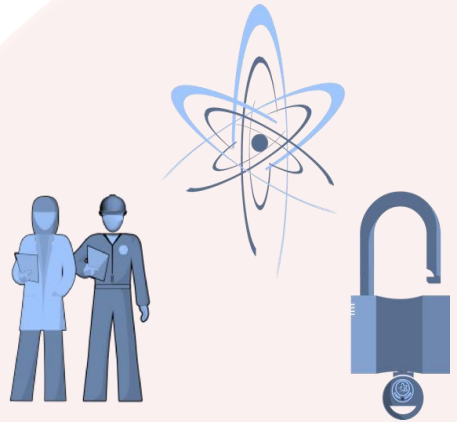
Legend

- Commercial
- Medical
- Academic & Research
- Industrial

Risk-informed Regulatory Program

The risk-informed regulatory program provides:

- A risk-ranking that recognizes potential safety impact of the licensed activity
- Effective and informed allocation of effort
- Effective, transparent, consistent oversight



Regulatory oversight is commensurate with risk of activity

Licensing and Certification

CNSC staff review applications and conduct technical assessments to determine if:

- All CNSC regulatory requirements are met
- Adequate measures are in place to protect health, safety, security and the environment

Application Guides to assist applicants

- **REGDOC-1.4.1**, *Licence Application Guide: Class II Nuclear Facilities and Prescribed Equipment*
- **REGDOC-1.5.1**, *Application Guide: Certification of Radiation Devices or Class II Prescribed Equipment*
- **REGDOC-1.6.1**, *Licence Application Guide: Nuclear Substances and Radiation Devices, version 2*

Compliance Verification

- CNSC staff conduct compliance activities
  - Field inspections
  - Desktop reviews
- Results of compliance activities are documented
- Items of non-compliance are tracked until addressed by the licensee to the satisfaction of CNSC

CNSC staff observe a worker operating a portable gauge *(source: CNSC staff)*

Evolution in Inspection Planning

- Planning is based on risk-informed inspection frequencies and performance history
- Continuing to focus on performance-based inspections
- Historically, priority of inspections was high risk licensees
  - Performance of these licensees has been strong for a number of years
- The 2019 inspection plan dedicated more effort to medium risk licensees
  - In response to declining performance

Continuous improvement,
responding to performance trends

Enforcement

- Graduated approach to enforcement
- Range of tools available, including:
  - Orders
  - Administrative Monetary Penalties (AMPs)
  - Licensing actions
  - Increased regulatory oversight
- Enforcement action is selected and applied using risk-informed decision making

Orders and AMPs

Thirteen enforcement actions in 2019

All thirteen enforcement actions were orders

Three remain open

Sector	2015	2016	2017	2018	2019
Medical	2	1	0	1	0
Industrial	14	18	23	14	9
Academic	1	0	0	0	0
Commercial	6	3	1	1	4
ALL	23	22	24	16	13

Orders are closed only when all conditions are satisfied

OVERALL SAFETY PERFORMANCE IN 2019

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Measures of Safety Performance

- Doses to workers
- SCA performance results
- Reported events

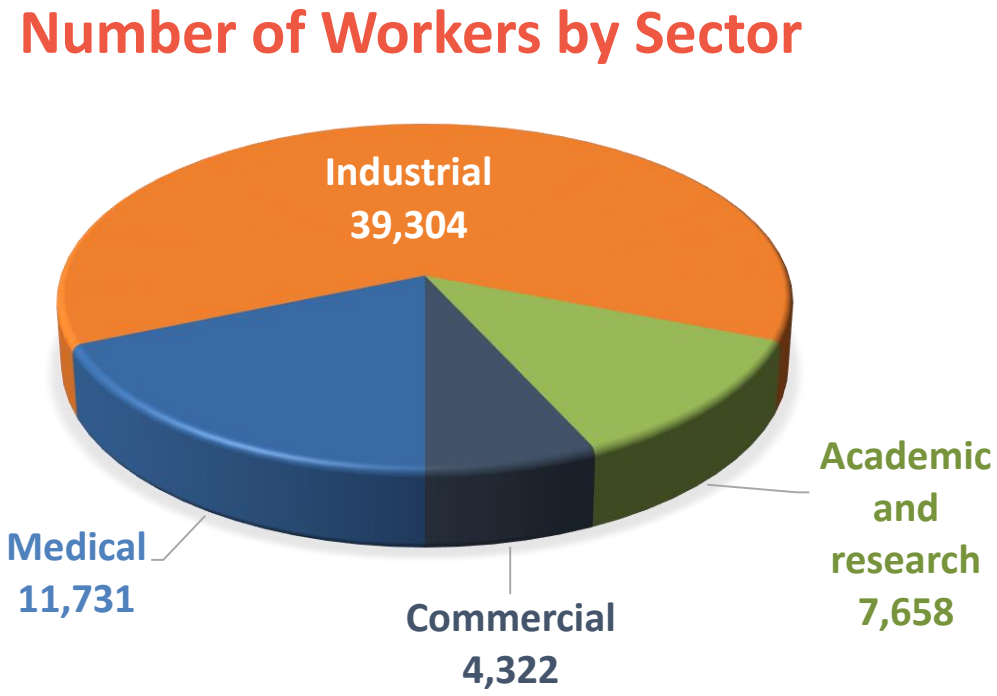
CNSC staff inspecting a licensee from the commercial sector (source: CNSC staff)

Doses to Workers

Licensees are required to implement radiation protection programs to protect workers

CNSC staff conducting inspection of licensee with Class II prescribed equipment*(source: CNSC staff)*

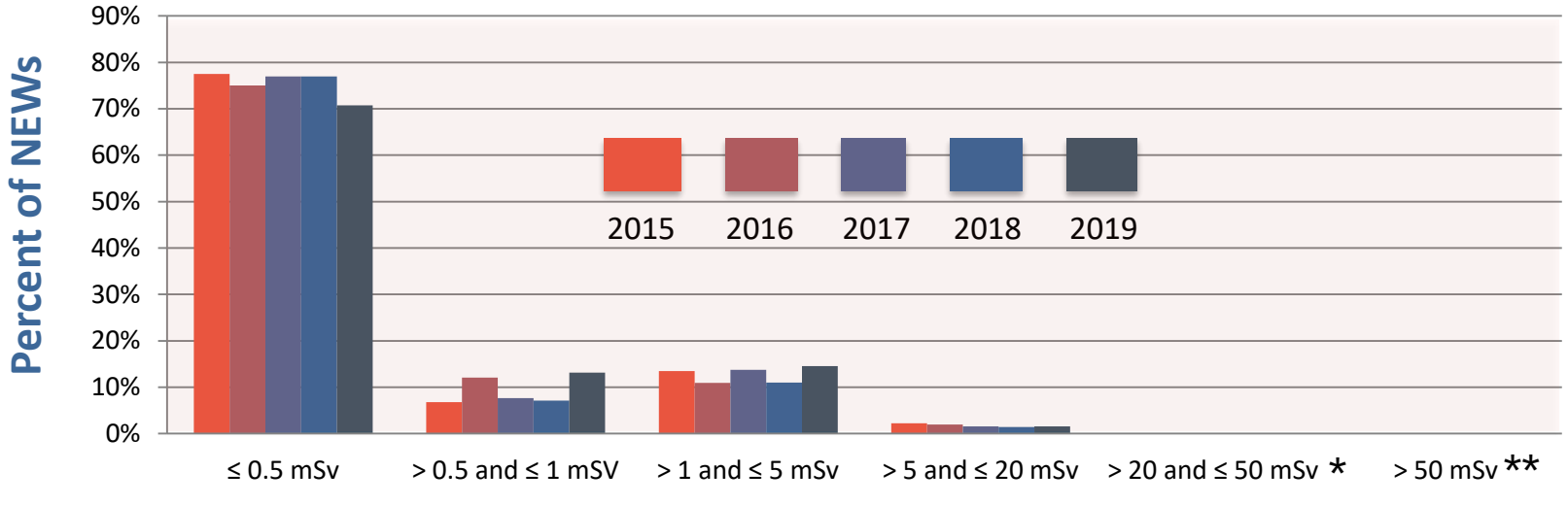
Number of Workers by Sector in 2019



63,015 workers in the four sectors monitored for occupational doses

- **26,539** Nuclear Energy Workers (NEWs)
- **36,476** non-NEWs

Annual Effective Dose



Annual whole body dose

The annual effective dose limit for NEWs is 50 mSv

2019: Four workers had a dose > 20mSv and ≤ 50 mSv *, one worker > 50 mSv **

Doses to workers remain low

Performance Results

Results shown at the sector level

A licensee setting up for industrial radiography operations *(source: CNSC staff)*

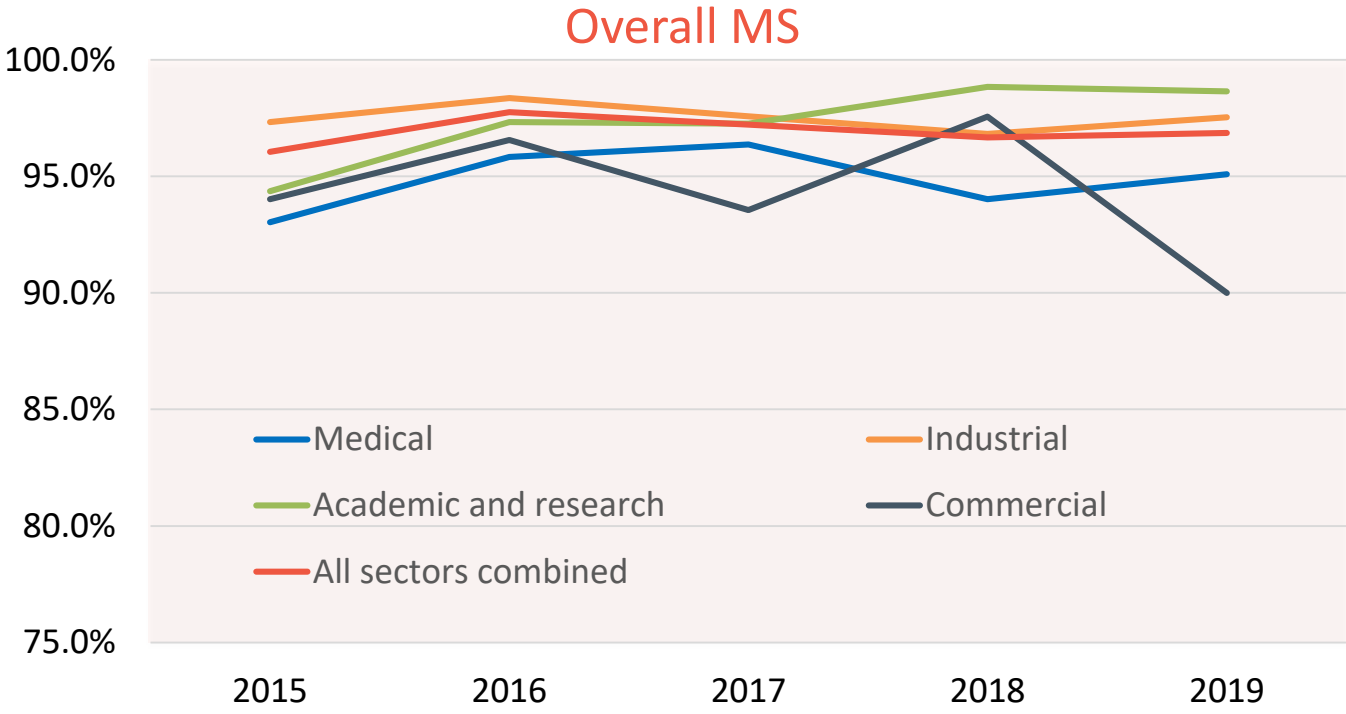
Safety and Control Areas

SCAs presented in the 2019 ROR:

- **Management systems** – processes and programs in place to achieve safety objectives and to foster a healthy safety culture
- **Operating performance** – provisions for the health, safety and security of persons, and protection of the environment
- **Radiation protection** – processes and programs in place to maintain radiation exposure to workers and the public as low as reasonably achievable (ALARA)
- **Security** – provisions in place to prevent the loss, sabotage and illegal use, possession or removal of nuclear substances

Although not incorporated into Part I, all relevant SCAs are assessed during compliance inspections and reviews of licensees' documents, and a compliance rating is assigned for each SCA

Evaluation of Management Systems (MS)



97% of inspections met expectations

Three Unacceptable ratings in MS

Unacceptable Rating In Management Systems (1 of 3)

Type of Licensee

Nuclear Medicine Licensee

CNSC Action

Corrective actions were tracked through the Type I inspection process for the Nuclear Medicine Licence

Reasons for UA ratings

Inadequate management control over the Radiation Protection Program

Licensee Response

For the Nuclear Medicine licence, CNSC staff are monitoring licensee's progress for correcting the findings from the inspection.

Procedural updates required, negligible impacts on health and safety

Unacceptable Rating In Management Systems (2 of 3)

Type of Licensee

X-Ray Fluorescence Licence

CNSC Action

Order was issued

Reasons for UA ratings

Inadequate management control over the Radiation Protection Program

Licensee Response

CNSC staff are monitoring licensee's progress for implementing corrective measures to meet the terms and conditions of the order

Low risk device, negligible impacts on health and safety

Unacceptable Rating In Management Systems (3 of 3)

Type of Licensee

Isotope Production Accelerator Facility

CNSC Action

- Multiple action notices were issued by the CNSC inspector to correct all deficiencies.
- Follow-up inspection scheduled for 2021

Reasons for UA ratings

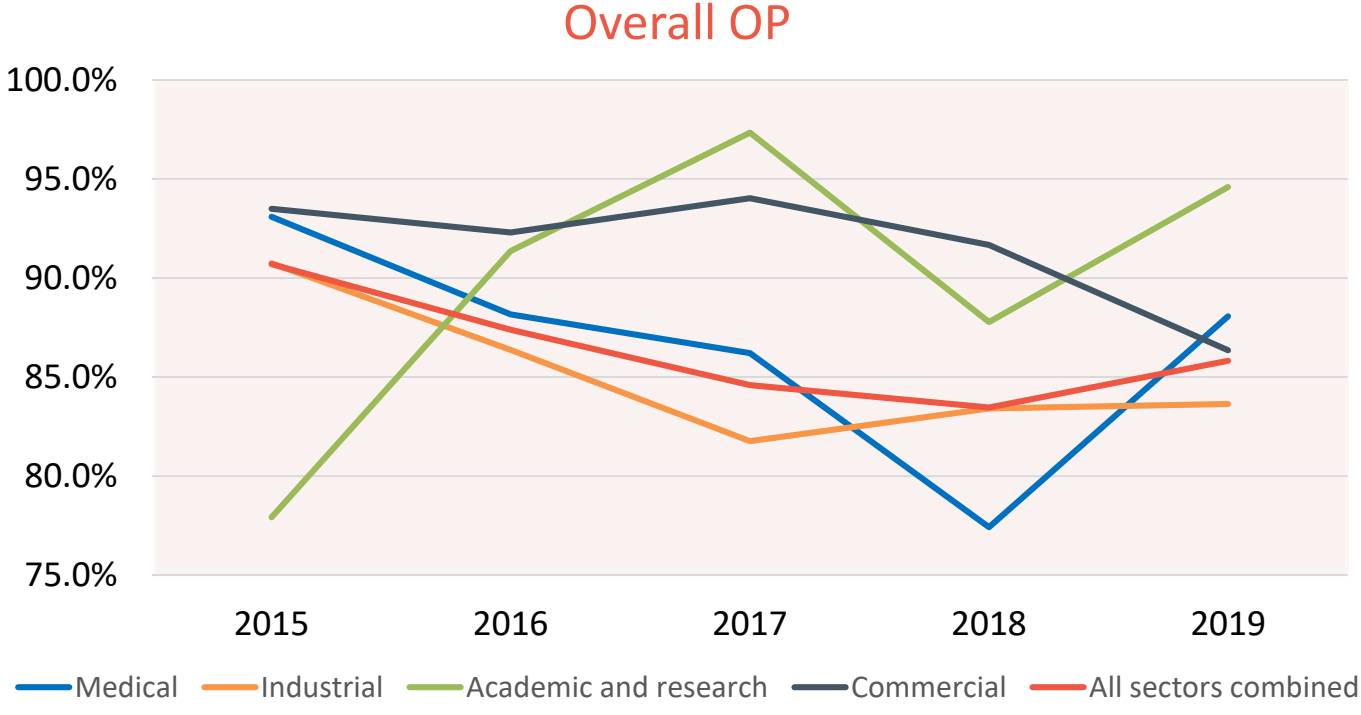
Inadequate support from Senior Management over the Radiation Protection Program

Licensee Response

Licensee has addressed all items of non-compliance

Non compliances addressed and inspection scheduled for 2021

Evaluation of Operating Performance (OP)



86% of inspections met expectations

Two inspections with a rating of Unacceptable.

An order was issued to one licensee with an unacceptable rating

Unacceptable Rating In Operating Performance (1 of 2)

Type of Licensee

Fixed Gauge Licensee

Reasons for UA ratings

Vessel entries contrary to licence condition

CNSC Action

Order was issued

Licensee Response

- Developed appropriate training for workers entering vessels fitted with radiation devices
- A system was put in place to ensure that all workers entering such vessels have received the required training
- Updated vessel entry-related procedures and documentation to meet the requirements of the vessel entry licence condition

Corrective measures implemented to prevent re-occurrence

Unacceptable Rating In Operating Performance (2 of 2)

Type of Licensee

Research Particle Accelerator

CNSC Action

Multiple action notices were issued by the CNSC inspector to correct all of the deficiencies.

Reasons for UA ratings

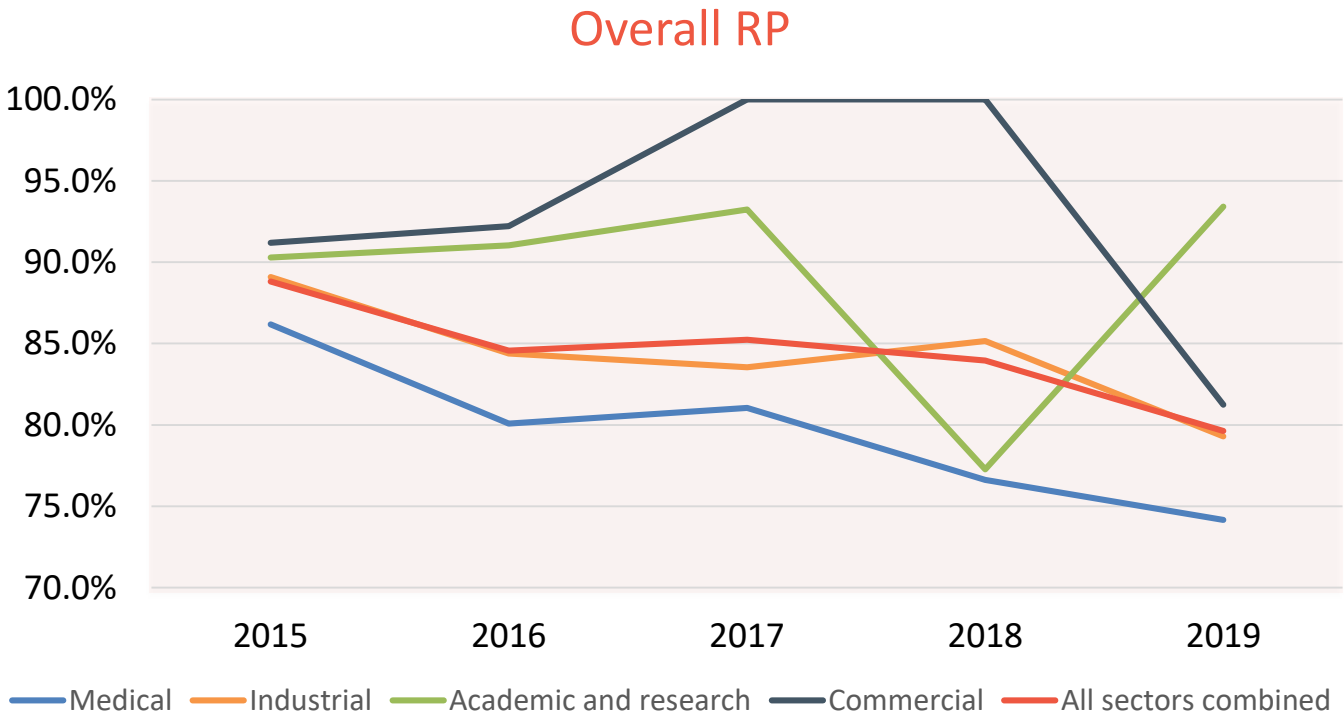
Inadequate control over the safety systems

Licensee Response

Licensee implemented satisfactory corrective measures

Corrective measures implemented to address deficiencies

Evaluation of Radiation Protection (RP)



80% of inspections met expectations

One inspection with a rating of Unacceptable.

Order issued

One Unacceptable Rating In Radiation Protection

Type of Licensee

Portable gauge licensees

Reasons for UA ratings

Insufficient management oversight of RP programs

CNSC Action

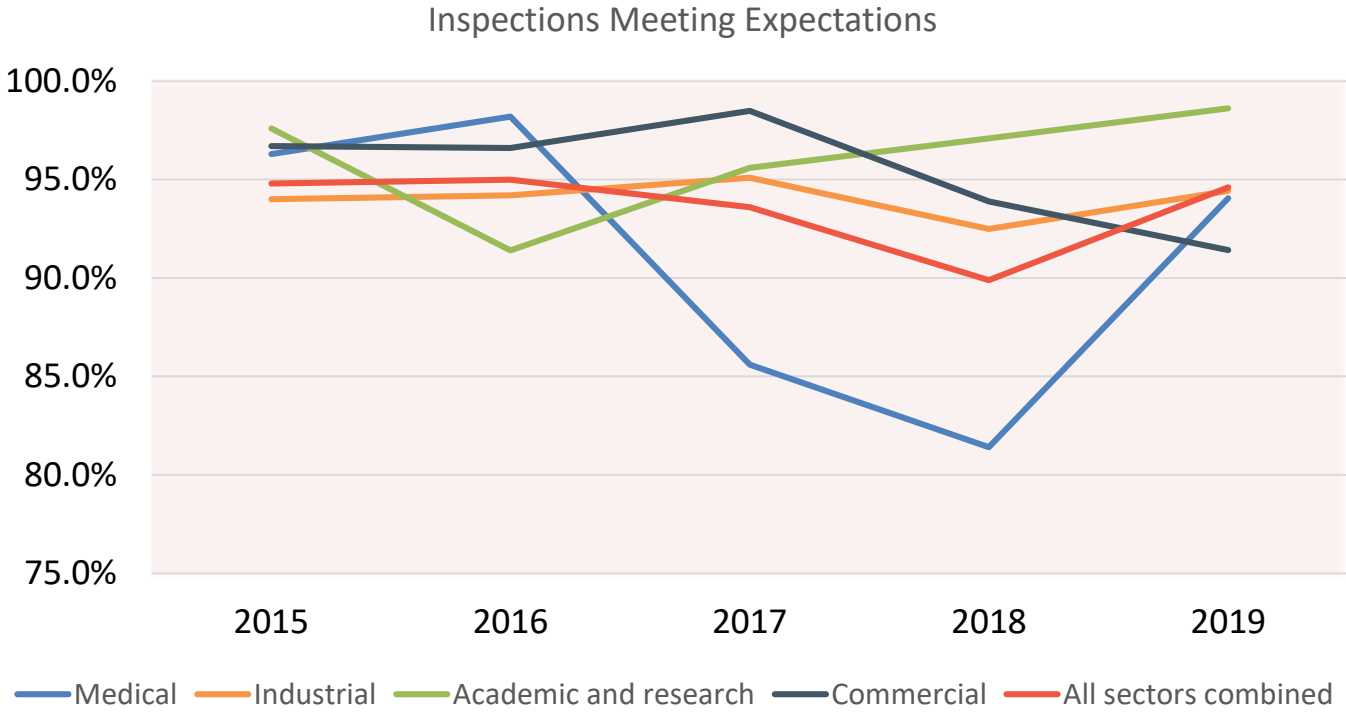
Order was issued to the licensee

Licensee Response

- Revised its radiation safety manual
- Improved its internal audit program
- Conducted an internal review of its radiation protection program and corrected any deficiencies
- Completed RSO training
- Radiation safety and TDG training were provided for their workers
- Corrected all items of non-compliances identified in the inspection reports for the inspections

The licensees addressed the items of non-compliance

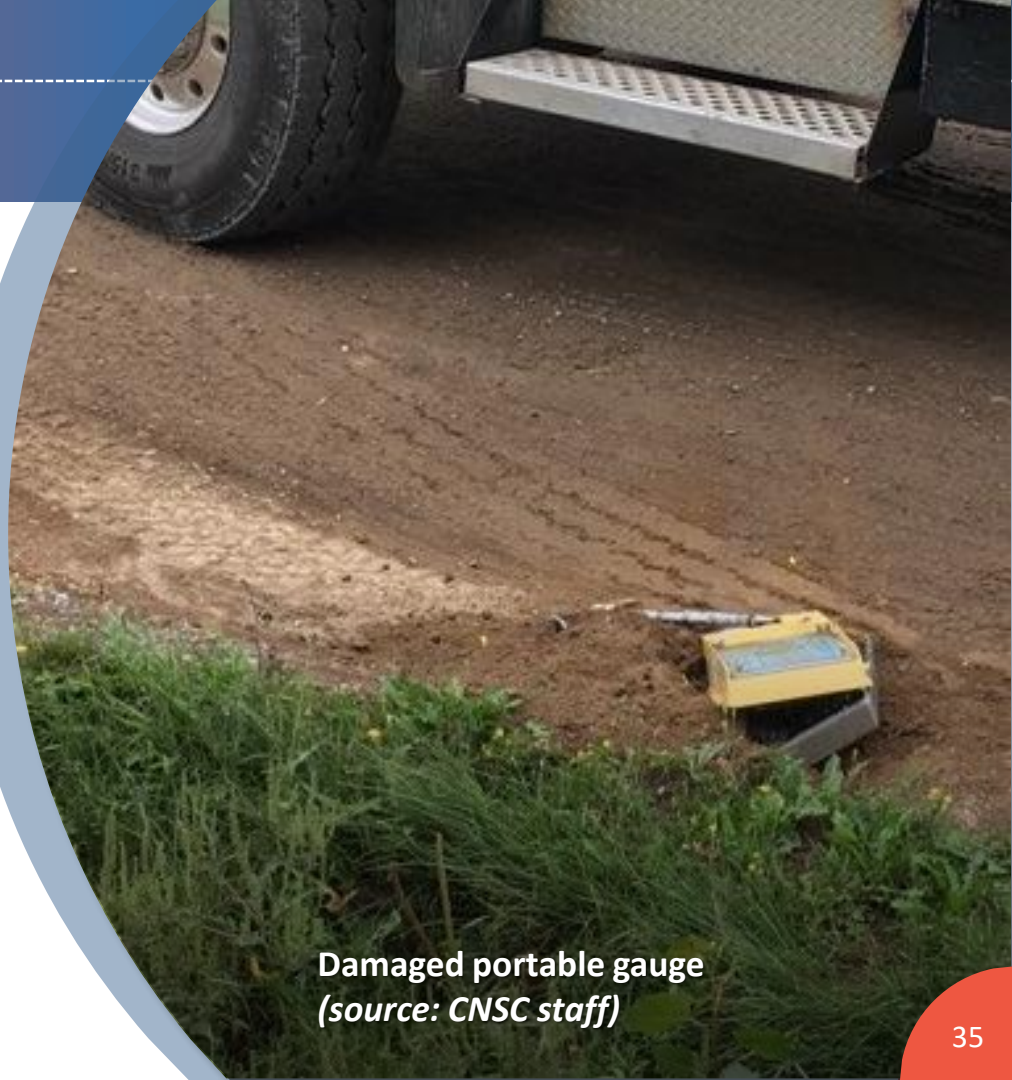
Security



95% of inspections met expectations

Event Reporting

Licensees are required to have programs for the management of unplanned events and accidents



Damaged portable gauge
(source: CNSC staff)

INES Scale for Radiological Events

The International Nuclear and Radiological Event Scale (INES) provides an applied means of reporting the safety significance of a radiological event.

Events are classified on a scale that includes 7 levels.

Level 0

Events are below scale, have no safety significance

Level 1

Events could include:

- Overexposure of a member of the public in excess of the public dose limit
- Loss/theft of Category 2, 3 or 4 sealed source with safety provisions in place

Level 2

Events could include:

- Exposure to a member of the public in excess of 10 mSv, or exposure of a NEW in excess of limits
- Loss/theft of Category 2, 3 or 4 sealed source with unknown safety provisions in place

Level 3

Events could include:

- Exposure in excess of ten times the annual limit for a NEW
- Loss/theft of a Category 1 sealed source with unknown safety provisions in place

Events Reported in 2019

186

Level 0
No significance

All events were assessed by staff

1

Level 1
Anomalies

1

Level 2
Incidents

0

Level 3
Serious incident

INES Level 1 Event

Non-NEW Worker Exceeded the Regulatory Limit of 1 mSv

The dose to the non-NEW was 1.85 mSv. The licensee was unable to determine the cause.

CNSC Actions

CNSC Designated Officer approved the return to work authorization. Event Initial Report was presented to the Commission in CMD 19-M41 in November 2019.

Corrective Actions

The employee was allowed to return to work granted that there was increased monitoring with a direct reading dosimeter. All doses recorded during the 6 month period after the event were normal.

INES Level 2 Event

Nuclear Energy Worker with dose over limit

The licensee reported a dose to a NEW of 57 mSv exceeding the annual limit of 50 mSv.

CNSC Actions:

- Reported to the Commission as an Event Initial Report (CMD 20-M17) in June 2020
- CNSC staff reviewed the event report and dose estimates
- CNSC return to work authorization was issued on December 20, 2019.

Corrective Actions:

- Worker immediately assigned to other duties to prevent further dose
- The investigation did not reveal any incident or abnormal work practices that may have caused the dose and it is possible that this is a non-personal dose
- During the Commission meeting for the EIR, it was recommended that the licensee apply for a dose change request

STAKEHOLDER ENGAGEMENT

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Stakeholder Engagement

- Keeping licensees and public informed is important
- Staff are reviewing tools and strategies for communicating with licensees
- Focus on identifying tools that will help licensees succeed in operating safely

CNSC staff participate in outreach activity
(source: CNSC)

CASE STUDIES IN REGULATORY INTERVENTIONS

Directorate of Nuclear Substance Regulation Regulatory Oversight Reports

CASE STUDY: I-131 RADIOISOTOPE PRODUCTION FACILITY

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Background

- In 2018, Isologic Innovative Radiopharmaceuticals Ltd. reported an extremity dose limit exceedance (1.7Sv) and atmospheric release of I-131 above their action level
- CNSC staff presented the reported events to the Commission in CMD 18-M65 as an Event Initial Report on December 13, 2018
- Following this meeting a Designated Officer order was issued to the licensee
- CNSC staff took a collaborative approach in working with the licensee to return them to compliance
- Diverse team of CNSC specialists performed detailed reviews of the monthly updates and standard operating procedures submitted
- The terms and conditions of the order were met in January 2020 and the licensee was granted authorization for routine operation of their new I-131 facility in April 2020

Current Status

At present, the licensee:

- Has appropriate measures for workers support and training as well as improved management oversight practices
- Is fully compliant at this time and reported monthly releases to the environment remain low
- Is motivated to continuing best practice and is looking to implement improvements in other aspects of their operations

Regulatory Lessons Learned

- Standard CNSC approach to regulatory oversight for licensees using nuclear substances focuses on regulating similar activities across multiple licensees
- However, CNSC staff recognized that Isologic Innovative Radiopharmaceuticals Ltd. required a tailored regulatory oversight strategy, using a Facility Assessment and Compliance Team approach
- Regular meetings with the licensee foster an environment for sharing regulatory knowledge and operational experience

A collaborative regulatory approach results in fully compliant operations

CASE STUDY: MEDICAL ISOTOPE PRODUCTION CYCLOTRON FACILITY

Directorate of Nuclear Substance Regulation Regulatory Oversight Reports

Background

- MNI produces and processes medical isotopes mainly for R&D of novel radiotracers
- Processing steps may involve some direct handling of radioactive materials
- Repeated Action Level exceedances for extremity doses in 2017 and 2018
- Worst dose performance in the industry category (Comparative study IPA Report Card)

CNSC Staff Response

- Enhanced CNSC compliance monitoring and enforcement using a variety of tools
  - Increased inspection frequency
  - Augmented inspections
  - Required ALARA comprehensive evaluation
  - Required monthly reporting on more detailed performance parameters
  - Discussed and followed up improvement action plan
- When all the previous steps didn't work, issued an Order
  - Imposed temporary restriction on maximum handled activity
- Licensee decided to incorporate the imposed limit as part of its permanent revised work procedure

Regulatory Lessons Learned

- CNSC staff continue to apply enhanced oversight until satisfied that the licensee's program has improved
- Undertaking comparative studies of groups of licensees can help CNSC staff identify licensees with performance below industry standard and then take necessary regulatory action

PART II: CLASS IB ACCELERATORS IN CANADA: 2018-2019

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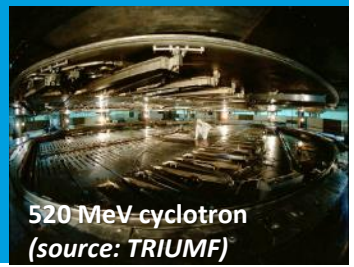
Class IB Accelerators

Two Class IB Accelerator Facilities in Canada

TRI University Meson Facility (TRIUMF)

- 520 MeV cyclotron facility
- Nuclear and particle physics research and radioisotope production
- U. of British Columbia Campus
- In operation since 1975



520 MeV cyclotron
(source: TRIUMF)

Canadian Light Source Inc. (CLSI)

- 2.9 GeV synchrotron facility
- Synchrotron radiation used as light source for experiments
- U. of Saskatchewan Campus
- In operation since 2005

Synchrotron Hall
(source: CLSI)

CNSC Regulatory Oversight

Facility	2018			2019		
	Number of Inspections	Compliance (person-days)	Licensing (person-days)	Number of Inspections	Compliance (person-days)	Licensing (person-days)
TRIUMF	1	115	6	2	133	4
CLSI	2	63	8	1	134	5
Totals	**3**	**178**	**14**	**3**	**267**	**9**

Increased assessment efforts in 2018 and 2019 due to implementation of CSA Standard N286-12, *Management System Requirements for Nuclear Facilities*

2018-2019 Safety and Control Area Ratings

2018-2019 TRIUMF Ratings

2015-2017 ratings provided for trending

Safety and control area	2015	2016	2017	2018	2019
Management system	SA	SA	SA	BE	BE
Human performance management	SA	SA	SA	SA	SA
Operating performance	SA	SA	SA	SA	SA
Safety analysis	SA	SA	SA	SA	SA
Physical design	SA	SA	SA	SA	SA
Fitness for service	SA	SA	SA	SA	SA
Radiation protection	FS	SA	SA	SA	SA
Conventional health and safety	SA	SA	SA	SA	SA
Environmental protection	SA	SA	SA	SA	SA
Emergency management and fire protection	SA	SA	SA	SA	SA
Waste management	SA	BE	SA	SA	SA
Security	SA	SA	SA	SA	SA
Safeguards and non-proliferation	FS	FS	FS	FS	FS
Packaging and transport	SA	SA	SA	SA	SA

Legend

FS: Fully satisfactory

SA: Satisfactory

BE: Below expectation

2018-2019 Safety and Control Area Ratings

2018-2019 CLSI Ratings

2015-2017 ratings provided for trending

Safety and control area	2015	2016	2017	2018	2019
Management system	SA	BE	SA	SA	BE
Human performance management	BE	SA	SA	SA	SA
Operating performance	SA	SA	SA	FS	FS
Safety analysis	SA	SA	SA	SA	SA
Physical design	FS	FS	FS	FS	FS
Fitness for service	SA	FS	FS	FS	FS
Radiation protection	FS	FS	FS	FS	FS
Conventional health and safety	SA	SA	FS	FS	FS
Environmental protection	SA	SA	FS	FS	FS
Emergency management and fire protection	SA	SA	SA	SA	SA
Waste management	FS	FS	FS	SA	SA
Security	FS	FS	FS	SA	SA
Safeguards and non-proliferation	N/A	N/A	N/A	N/A	N/A
Packaging and transport	FS	FS	FS	FS	FS

Legend

FS: Fully satisfactory

SA: Satisfactory

BE: Below expectation

Compliance Performance

DNSR ROR: Part II focus is on the following Safety and Control Areas (SCA)

Management system

- Important key performance indicator of the safety of a facility
- Implementation of CSA Standard N286-12
- Only SCA with a below expectation rating for this ROR period

Radiation Protection

- Radiation exposure is a principal hazard at accelerator facilities
- Both facilities invest important resources to maintain an effective radiation protection program
- Application of ALARA Principle

Conventional health and safety

- Industrial hazards is another principal hazard
- Based on CNSC's risk-informed analysis, this SCA is the only SCA rated high for both the probability and the impact of an accident

Compliance Performance: Management System

In 2016, both facilities agreed with CNSC Staff to comply by January 2018 to CSA Standard N286-12, *Management System Requirements for Nuclear Facilities*

TRIUMF

- Initial delay in performing gap analysis
- Gap analysis further delayed while staffing Quality Manager
- New Quality Manager hired in November 2019
- Gap analysis submitted in March 2020
- On track to meet N286-12 requirements by December 2020

Below Expectation MS Rating for both 2018 and 2019

CLSI

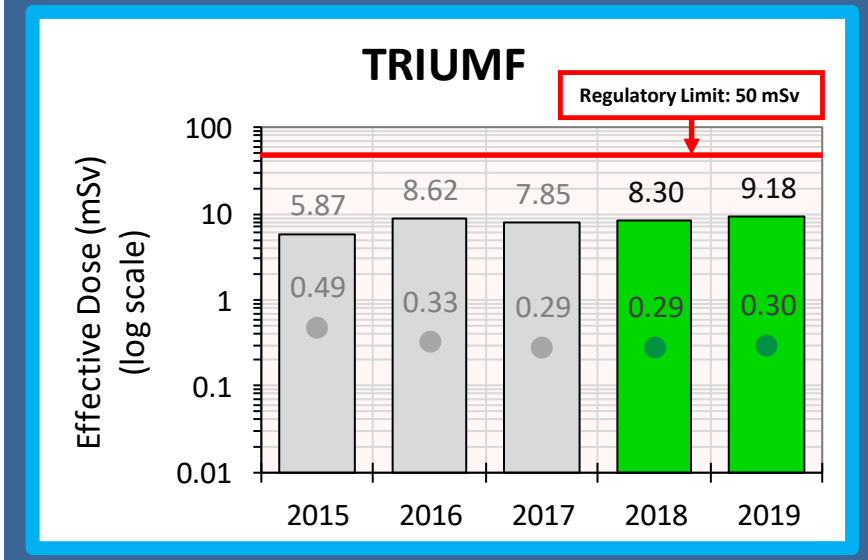
- Gap analysis performed and procedures updated to meet the January 2018 compliance date
- Initial CNSC staff assessment determined that CLSI was compliant
- Inspection in July 2019 found that CLSI was non-compliant to N286-12
- Follow-up inspection performed in October 2020

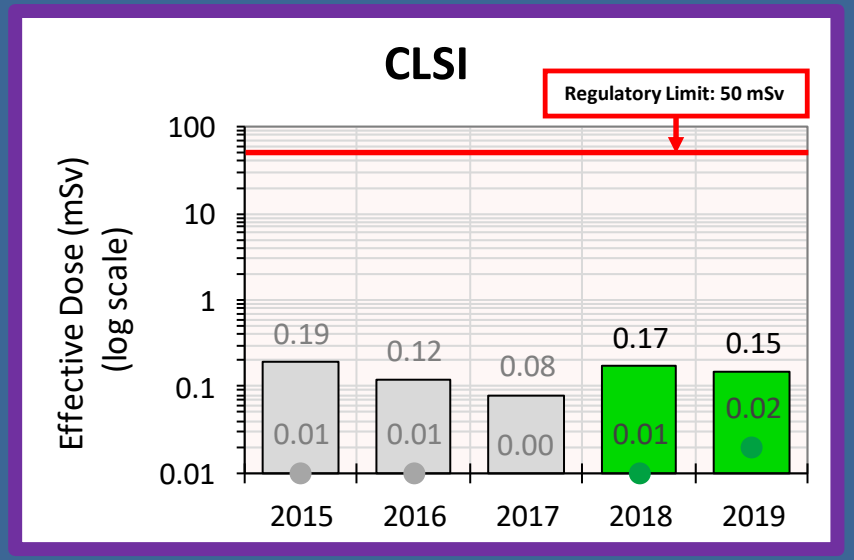
Below Expectation MS Rating for 2019

Below Expectation ratings do not introduce safety concerns

Compliance Performance: Radiation protection

Maximum and Mean Annual Effective Dose to Nuclear Energy Workers (mSv)



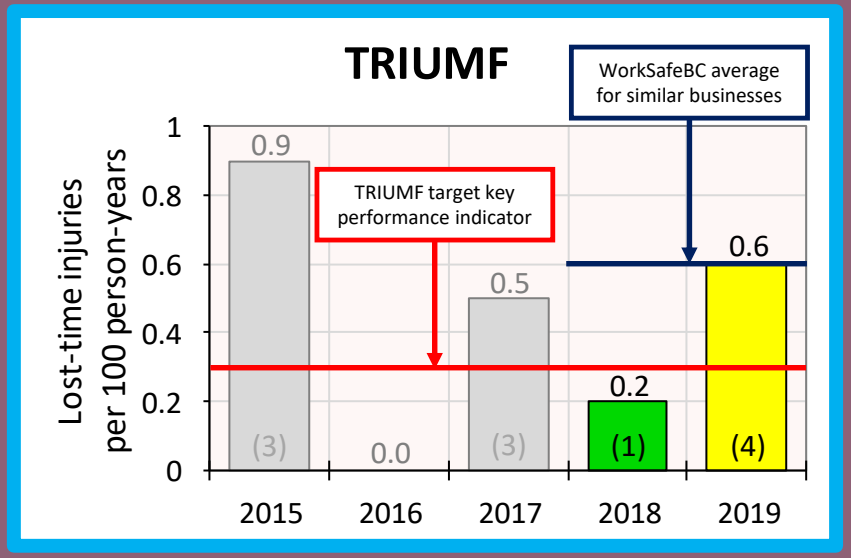


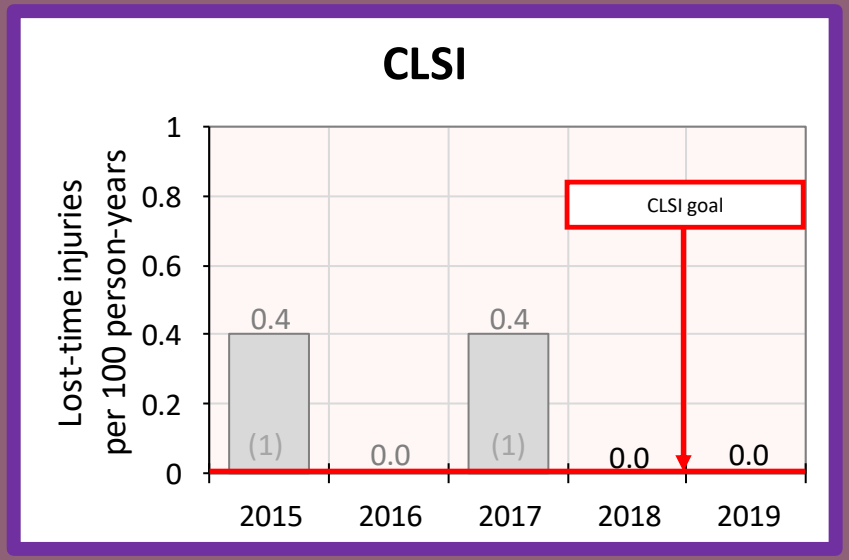
Maximum effective dose, 2018-2019
Maximum effective dose, 2015-2017
Mean effective dose, 2018-2019
Mean effective dose, 2015-2017

Doses to workers remain acceptable

Compliance Performance: Conventional health and safety

Annual lost-time injury (LTI) rates per 100 person-years





- LTI rate below TRIUMF key performance indicator
- LTI rate above TRIUMF key performance indicator
- 2015-2017 annual rates provided for trending

- Above columns: annual LTIs per 100 person-years
- In parenthesis: number of annual LTIs

Lost-time injury rates remain acceptable

Compliance Performance: Conventional health and safety

Action to CNSC staff

August 2018: Presentation of CMD 18-32, *Regulatory Oversight Report for Research Reactors and Class IB Accelerators: 2016-2017*

- Commission expressed concern with number of lost-time Injuries at TRIUMF
- Action on CNSC Staff to provide additional details regarding lost-time injuries in future ROR

CNSC staff provided detailed descriptions of the lost-time injuries in the ROR CMD

Enforcement

For 2018-2019, none of the Class IB accelerator facilities had enforcement actions beyond normal inspection follow-ups

No enforcement actions

Reported Events

- For 2018-2019, TRIUMF had 11 events and CLSI had six
- For each event reported, the licensees:
  - performed an internal investigation
  - implemented corrective actions to prevent reoccurrences
- All events were reported to CNSC as required by regulation or licence condition

CNSC staff reviewed the reports and corrective actions and found them satisfactory

Public Information and Disclosure Program (PIDP)

- CNSC staff assessed the PIDP through annual compliance reporting
- CNSC provided feedback to both facilities to ensure the program remain effective

PIDP were implemented satisfactorily

PUBLIC INTERVENTIONS

Directorate of Nuclear Substance Regulation Regulatory Oversight Reports

Public Interventions

Report was publicly available for written comments for a period of 41 days

Participant Funding was offered and $5,000 was awarded to the Canadian Environmental Law Association (CELA)

Two interventions received

Key Themes in Interventions – Positive Comments

- Broadcasting Commission hearings and meetings via webcast is effective way of communicating CNSC expectations and operating experience
- Appreciation for ongoing CNSC staff involvement with stakeholders

Key Themes in Interventions – Recommendations (1/3)

Intervener comments:

- There are a few factual errors throughout the ROR
  - Draft REGDOC-1.6.2 (posted for consultation in November 2019) was not included Appendix N
  - Typographical errors noticed in Appendix E

CNSC staff response:

- Errors identified by interveners will be corrected in the final version of the ROR

Key Themes in Interventions – Recommendations (2/3)

Intervener comments:

- Suggestion to include other SCAs in the ROR (e.g. Environmental Protection, Packaging and Transport)

CNSC staff response:

- The ROR is a summary that conveys the annual status of various industry sectors at a relatively high level and is not intended to provide detailed information on every SCA
- Similar comments have been raised in the past with similar response from CNSC staff; upcoming Discussion Paper on RORs will provide opportunity to explore this issue in more detail

Key Themes in Interventions – Recommendations (3/3)

Intervener comments:

- Interveners made a number of suggestions for improvement/modifications to scope and content of the ROR, including:
  - RORs should provide greater trend analysis
  - Greater detail, including the nature of the regulated sector and its particular use of nuclear substances, should be described in the body of the report
  - Reported Events should include root cause and a summary of corrective actions

CNSC staff response:

- Discussion paper on RORs to be published late 2020 or early 2021
- Process will be open and transparent and any topic related to the ROR is up for discussion
- Process will ensure that all interested parties have an opportunity to comment on the ROR process

CLOSING REMARKS

Directorate of Nuclear Substance Regulation Regulatory Oversight Reports

Conclusion DNSR ROR Part I: Nuclear Substances and Radiation Devices 2019

- SCA performance is satisfactory
- Doses to workers similar to past years
- Reported events reviewed and assessed by CNSC Staff
- CNSC staff maintain oversight through continued monitoring, and data analysis

Use of nuclear substances and prescribed equipment is safe

Fixed gauge measuring fill level in cans
(source: CNSC staff)

Conclusion DNSR ROR Part II: Class IB Accelerators in Canada: 2018-2019

TRIUMF and CLS made adequate provision for:

- the health and safety of workers
- the protection of the public and the environment
- Canada's international obligations

Operation of Class IB Accelerators in Canada is safe

TRIUMF Meson Hall
(source: Jonathan McRae, TRIUMF Lab)

Final Thoughts: IRRS Mission

- Integrated Regulatory Review Service (IRRS) mission to Canada was performed in September 2019.
- The purpose of the IRRS mission was to perform an international peer review of Canada's regulatory framework for nuclear and radiation safety against IAEA safety standards.

"Canada has a comprehensive and robust regulatory framework for nuclear and radiation safety covering current facilities and activities. The CNSC strives to continuously upgrade its regulatory framework to address new challenges and upcoming technologies"

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ANNEX 1
INTERVENTION COMMENTS

Directorate of Nuclear Substance Regulation Regulatory Oversight Reports

Interventions

Concerns or recommendations from the following interventions are addressed:

- CMD 20-M23.1 - Canadian Environmental Law Association (CELA)
- CMD 20-M23.2 - Canadian Radiation Protection Association

CMD 20-M23.1 - Canadian Environmental Law Association (CELA)

Comment	CNSC Disposition
RECOMMENDATION NO. 1: Greater detail, including the nature of the regulated sector and its particular use of nuclear substances, should be described in the body of the report. As nuclear substances do not undergo public licensing hearing processes, the ROR is an opportunity to provide the public with information specific to nuclear substance licensees, and the CNSC's oversight actions and findings.	**Clarification:** In the first paragraph of Part I of the 2019 ROR, there is a reference to section 4 of the 2018 ROR. This reference was added to replace the basic information on the sectors covered in the 2019 report and the uses of nuclear substances used in these sectors. Since the information on these sectors remained the same, we chose to use a reference to the previous years information to streamline the report.

CMD 20-M23.1 - Canadian Environmental Law Association (CELA)

Comment	CNSC Disposition
RECOMMENDATION NO. 2: Conclusions in the ROR specific to various safety and control areas, including that for the Environmental Protection, should be supported by information setting out on what basis the finding is made.	The ROR is a focused regulatory oversight summary that conveys the annual status of various industry sectors at a relatively high level and is not intended to provide detailed information on every SCA. That being said, any unacceptable ratings in any SCA would be included in the ROR. To address the comments on improvement and modification to the ROR, CNSC staff intend to publish a Discussion Paper by the first quarter of 2021, seeking feedback from interested parties on elements of the ROR. The process will be open and transparent and any topic of the ROR is up for discussion. The publication of the Discussion Paper will be followed by a comment period to allow submissions on potential changes to the RORs. This process will ensure that all interested parties have an opportunity to comment on the ROR process and what is covered in the RORs. We are recommending that suggestions related to changing the content or scope of the ROR be raised within the context of the Discussion Paper to allow for a holistic consideration of such suggestions.

CMD 20-M23.1 - Canadian Environmental Law Association (CELA)

Comment	CNSC Disposition
RECOMMENDATION NO. 3: RORs should provide greater trend analysis, such as reporting of inspections spanning a 5-year timeframe, to better explain decreases in inspection levels since 2015.	As this is a comment related to the content and scope of the ROR, we recommend that this be raised in the context of the upcoming ROR Discussion Paper (see response to CELA Recommendation No. 2).
RECOMMENDATION NO. 4: To add credibility to the conclusions reached in the ROR, the report should set out the objectives and scope of inspection criteria, and methods used by CNCS Staff to track and report compliance of nuclear substance licensees.	As this is a comment related to the content and scope of the ROR, we recommend that this be raised in the context of the upcoming ROR Discussion Paper (see response to CELA Recommendation No. 2).

CMD 20-M23.1 - Canadian Environmental Law Association (CELA)

Comment	CNSC Disposition
RECOMMENDATION NO. 5: For matters where CNSC Staff have committed to undertake a review or reform in the coming year, updates of the project's status should be a required component of the subsequent year's ROR.	Due to COVID-19, CNSC staff lost time in the process for developing the ROR, which led us to focus on elements of the report that we considered of higher regulatory significance. That being said, while we have in the past made reference in the ROR to interesting projects that CNSC staff are working on, this wasn't intended as a commitment to provide regular updates on ongoing internal projects. As this is a comment related to the content and scope of the ROR, we recommend that this be raised in the context of the upcoming ROR Discussion Paper (see response to CELA Recommendation No. 2).

CMD 20-M23.1 - Canadian Environmental Law Association (CELA)

Comment	CNSC Disposition
RECOMMENDATION NO. 6: The ROR should directly reference the international standards and regulatory basis (i.e. regulation or REGDOC) which supports the ROR's conclusion that licensees adequately implemented Canada's international obligations. The ROR should also set out how CNSC Staff sought to review compliance of said obligations.	The ROR is a focused regulatory oversight summary that conveys the annual status of various industry sectors at a relatively high level and is not intended to provide detailed information on every aspect of licensee compliance, including conformity to international obligations. As this is a comment related to the content and scope of the ROR, we recommend that this be raised in the context of the upcoming ROR Discussion Paper (see response to CELA Recommendation No. 2).

CMD 20-M23.1 - Canadian Environmental Law Association (CELA)

Comment	CNSC Disposition
RECOMMENDATION NO. 7: The new column displayed in Figure 11 should be explained at the upcoming ROR meeting. Specifically, why this additional column has been added, its purpose and whether it will continue in subsequent RORs.	**Clarification:** The column referred to in this comment was left out of the original 2018 ROR, in error. This error was noted during the ROR presentation last year and was subsequently corrected; the corrected version of the 2018 ROR is posted on the CNSC website. The column appears correctly in the 2019 ROR and will continue to be included in subsequent RORs.

CMD 20-M23.1 - Canadian Environmental Law Association (CELA)

Comment	CNSC Disposition
RECOMMENDATION NO. 8: Explanation should be provided describing the significant changes to effective doses received to Industrial sector NEWs from 2018 to 2019.	**Clarification:** As explained in the response to CELA Recommendation No. 7, there were errors in Table 11 from the 2018 ROR, these were subsequently corrected; the corrected values were: • In 2018, 1,093 NEWs in the Industrial sector received effective doses > 1 and ≤ 5 mSv. In 2019 it was 2,073 • In 2018, 846 NEWs in the Industrial sector received effective doses > 0.5 and ≤1 mSv. In 2019 it was 2,581 The process to collect/determine/report on the dose figures was re-evaluated and improved in 2019. Licensees submit dose information in the Annual Compliance Reports (ACRs). When ACRs are submitted near the end of the year, it was difficult to determine which year the ACR covered. CNSC staff improved its internal process to clarify the year covered by each ACR and therefore ensure that ACR information is reported in the correct year's ROR. We expect the total number of NEWs in each category to remain stable in future years. As summarized in the ROR, all doses to workers were effectively managed and were within regulatory limits, with the exception of the two exceedances described in the ROR.

CMD 20-M23.1 - Canadian Environmental Law Association (CELA)

Comment	CNSC Disposition
RECOMMENDATION NO. 9: The Commission should discuss how the ROR process meets the "public engagement" requirement set out in REGDOC-2.9.1. As drafted, the ROR does not contain a critical review or discussion of licensee environmental protection actions. Thus, without data or findings supporting how conclusions in the ROR specific to environment protection are reached, the public's ability to engage with such matters is limited.	For any licensing activities, the CNSC goes through the process as described in REGDOC-2.9.1. In all cases, the environmental assessment, the environmental protection measures and the environmental risk assessment (where required) are commensurate with the scale and complexity of the environmental risks associated with the nuclear facility or activity. Since the majority of the licensees covered in the ROR are sealed sources and have no potential for a release to the environment. However, for Class 1B accelerators and Waste Nuclear Substance Licensees (WNSLs), there would be some engagement, as per REGDOC-2.9.1. depending on the level of interests of the public and Indigenous groups. The licensees that do have releases to the environment have robust environmental protection programs. The WNSLs have environmental protection programs and their releases to the environment are below the Derived Release Limits and the estimated doses to the public are within background. For CLSI, there are no releases to the environment. CNSC staff review the annual compliance reports and confirm that estimated doses to the public are within background. For TRIUMF, CNSC staff review the annual compliance reports and confirm that releases are orders of magnitude below the Derived Release Limits and the estimated doses to the public are below background. There is environmental protection-related information for the licensees covered by this ROR on the CNSC website.

CMD 20-M23.1 - Canadian Environmental Law Association (CELA)

Comment	CNSC Disposition
RECOMMENDATION NO. 10: With the aim of remedying historical oversights, the review of licensees' decommissioning plans should be a required component of RORs. As RORs canvas topics which are of relevance to all licensees of a certain class or type, a discussion of the technically complex and challenging decommissioning actions specific to accelerators would be appropriate to review.	RORs are a summary to the Commission and interested members of the public to describe the overall safety performance of licensees within the nuclear industry over the reporting period. Inclusion of a public review of decommissioning plans is beyond the scope of Regulatory Oversight Reports. The CNSC's regulatory approach for decommissioning stems from the *Nuclear Safety and Control Act* and is articulated in regulations as well as CNSC regulatory documents, such as REGDOC 2.11.2, *Decommissioning*. In developing regulatory documents, the CNSC draws upon recommendations of the IAEA and best practices from the international and national community. Decommissioning plans submitted by licensees are assessed by the CNSC against regulatory requirements to ensure the protection of the health and safety of the public and the environment. As this is a comment related to the content and scope of the ROR, we recommend that this be raised in the context of the upcoming ROR Discussion Paper (see response to CELA Recommendation No. 2).

CMD 20-M23.1 - Canadian Environmental Law Association (CELA)

Comment	CNSC Disposition
RECOMMENDATION NO. 11: The ROR should be used as an opportunity to review decommissioning matters as plans are otherwise not accessible nor in the public domain	As noted in the response to CELA Recommendation No. 10, decommissioning plans are assessed by the CNSC against regulatory requirements to ensure the protection of the health and safety of the public and the environment. As a condition of a licence, a licensee shall maintain a decommissioning plan which is reviewed periodically or when requested by the Commission or a person authorized by the Commission. Decommissioning plans are licensee documents that may contain protected information. As such, the documents need to be requested from CNSC through the Access to Information process to ensure sensitive information is adequately safeguarded, or from the licensee.

CMD 20-M23.2- Canadian Radiation Protection Association

Comment	CNSC Disposition
863 inspections are mentioned in the Executive Summary but the inspection totals in figures 2, 4, 6 and 8 don't seem to add up to 863.	**Clarification:** The totals for figures 2, 4, 6 and 8 are less than the total number of inspections because not every SCA is inspected for each inspection. Some inspections are targeted and may only cover specific SCAs and SCAs may not apply to all licensees that are inspected.
What is the actual objective or objectives of publishing the ROR?	The ROR provides information on the safety performance of Canadian licensees who are authorized to use nuclear substances. The report evaluates licensees based on their safety procedures and adherence to regulatory policy. Key issues and emerging changes in regulation are also highlighted. This report also describes the safety performance of licensees using nuclear substances in medical, industrial and commercial applications, as well as for academic and research purposes. The report covers key safety and control areas. It also includes a summary of reported events and regulatory actions issued by the CNSC.

CMD 20-M23.2- Canadian Radiation Protection Association

Comment	CNSC Disposition
It seems that the Radiation Protection SCA for Nuclear Medicine shows a steady decline for the past five years – are there any suggestions as to why? The continued decline in this SCA is of concern to the authors and has been flagged to the CRPA Board of Directors. There is also a decline in the Radiation Protection SCA for Portable Gauges – again, any suggestions as to why?	The top three most common non-compliances for nuclear medicine related to the RP SCA observed during inspections are the following: Thyroid monitoring (licence condition 2046); contamination criteria (licence condition 2642) and Management oversight and implementation of the radiation protection program (ALARA/RP program (RP04(a))) Possible reasons/suggestions as to why: 1. Prioritized most overdue and poor performing medium risk licensees such as nuclear medicine and portable gauge licensees over good performing high risk licensees in the 2019-20 planning. As a result, in 2019, there was an increase in the number of those medium risk licensees compared to previous years. By doing so, we may be observing the following based on the downward RP SCA trend: • There seems to be a reliance on the CNSC to conduct inspections to correct or improve programs (as we are observing issues if the licensee has not been inspected for a long time). As a result, it is CNSC staff's opinion that a greater emphasis should be put on the licensee to improve their internal audit program and that having good internal auditing skills is necessary in order to manage an effective radiation protection program. • The corrective actions implemented by the previously poor performing licensees were not effective in solving the issues and, therefore, we continued to observe some findings. **(Continued on the next slide)**

CMD 20-M23.2- Canadian Radiation Protection Association

Comment	CNSC Disposition
(continued) It seems that the Radiation Protection SCA for Nuclear Medicine shows a steady decline for the past five years – are there any suggestions as to why? The continued decline in this SCA is of concern to the authors and has been flagged to the CRPA Board of Directors. There is also a decline in the Radiation Protection SCA for Portable Gauges – again, any suggestions as to why?	**(continued)** 2. Looking at the RP SCA results compared to the Operating Performance SCA results, CNSC Staff conclude that workers are conducting activities safely. The issue seems to be more related to the management of the radiation protection program itself. There needs to be improvement on how the licensees are managing their programs so that they are making sure that things are being checked daily such as performing the daily contamination checks, as an example for nuclear medicine licensees, and ensuring that doses to workers or shot counts are being tracked in the case of portable gauge licensees.

CMD 20-M23.2- Canadian Radiation Protection Association

Comment	CNSC Disposition
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 two years)	While the performance in a sub-set of safety and control areas are included in the ROR, it is important to note that all relevant Safety and Control Areas are evaluated during assessments and compliance verification activities. These four safety and control areas have been selected because they are the most indicative of overall safety, and for ease of communication; presenting all SCAs would significantly increase the size of the ROR, and every SCA is not necessarily applicable to all licensees, as is the case for the Packaging and Transport SCA. Instead, reported events are a more meaningful indicator for the Packaging and Transport SCA and a list of all events is included in the ROR. As this is a repeated intervention, CNSC staff plan on following up with the CRPA to better understand the concern.
The number of inspections is decreasing and the time per inspection is increasing – is that analysis correct?	The focus on inspecting medium risk licensees that have not been inspected in some time could have attributed to the fact that more time was spent during inspections: • Increase in the number of findings (inspections where non-compliances are observed generally take more time) • Increased time spent on outreach information during inspections • Adding a larger emphasis on how the radiation protection program is implemented and managed • Increased focus on licensees to perform effective self-audits so that they can become more self sufficient rather than relying on the next CNSC inspection to improve their programs

CMD 20-M23.2- Canadian Radiation Protection Association

Comment	CNSC Disposition
While the case studies shown may be of interest to those with either a medical production background or a medical production facility in their area of responsibility, these case studies address very specific kinds of licensees. It's too bad that another licence type wasn't selected, say from Portable Gauge users	The purpose of the case studies is to show examples from a specific sector. The intent of the cases studies are to focus on a different sector for each ROR. The sector chosen for 2019 was commercial licensees. The portable gauge subsector and nuclear medicine subsector case studies were included in the 2018 ROR.

CMD 20-M23.2- Canadian Radiation Protection Association

Comment	CNSC Disposition
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, 2017 and 2018 RORs. Root cause and summary of corrective actions are missing. A trend analysis appears to be missing. Perhaps that would be so much information as to warrant a separate publication - it is more likely that such a document would be reviewed and used by NSRD RSOs compared to a Regulatory Oversight Report.	The ROR is a focused regulatory oversight summary that conveys the annual status of various industry sectors at a relatively high level and is not intended to provide detailed information on every event. As this is a repeated intervention, CNSC staff plan on following up with the CRPA to better understand the concern. As this is a comment related to the content and scope of the ROR, we recommend that it be raised in the context of the upcoming ROR Discussion Paper (see response to CELA Recommendation No. 2).

CMD 20-M23.2- Canadian Radiation Protection Association

Comment	CNSC Disposition
Typographical errors noticed in Appendix E have already been flagged to an NSRD staff member. Appendix N – Regulatory Documents: Draft REGDOC -1.6.2 that was published 18 NOV 2019 as a consultation document does not seem to have been mentioned.	**Accepted:** Errors and omissions identified by interveners will be corrected in the final version of the ROR.