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

CNSC Staff Presentation
Commission Meeting
November 7, 2019
CMD 19-M29.A

e-Doc 6004757 (PPTX)
e-Doc 6031032 (PDF)

Corrections to CMD 19-M29

Doses to workers

- Quality check of dose data noted duplicate and data entry errors in the dose data included in the report
  - Reporting lower number of workers than original report (50,522 instead of 58,689)
  - Changes do not impact the conclusions or trends included in the report
- The corrected figures are in an Annex to this presentation

Section 8.9

REGDOC-2.5.6, *Design of Nuclear Substance Laboratories and Nuclear Medicine Rooms* was not published for public comment in 2018

CNSC Regulatory Oversight Reports

- **November 6, 2019:** Canadian Nuclear Power Generating Sites
- **November 7, 2019:** Use of Nuclear Substances in Canada
- **November 7, 2019:** Canadian Nuclear Laboratories Sites
- **December 11, 2019:** Uranium Processing and Nuclear Substance Processing Facilities
- **December 12, 2019:** Uranium Mines and Mills

Public Consultation

- Report was publicly available for written comments for a period of 30 days
- PFP was offered and awarded
- Three interventions received

Overview of the Presentation

- Introduction
- Oversight activities in 2018
- Overall safety performance in 2018
- Two case studies in regulatory interventions
- Stakeholder engagement
- Concluding remarks

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

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INTRODUCTION

Licensees' Safety and Responsibility in 2018

- Licensees have appropriate programs to protect health, safety, security and the environment
- Licensees continued to maintain adequate measures to implement Canada's international obligations
- One instance of a release to the environment above regulatory limits. No impact on environment
- Two workers exceeded regulatory dose limit for extremities. No impact on health of workers

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

The use of nuclear substances in Canada is safe

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OVERSIGHT ACTIVITIES IN 2018

Diverse Uses Of Nuclear Substances

Industrial

1,259 licences

Academic & research

192 licences

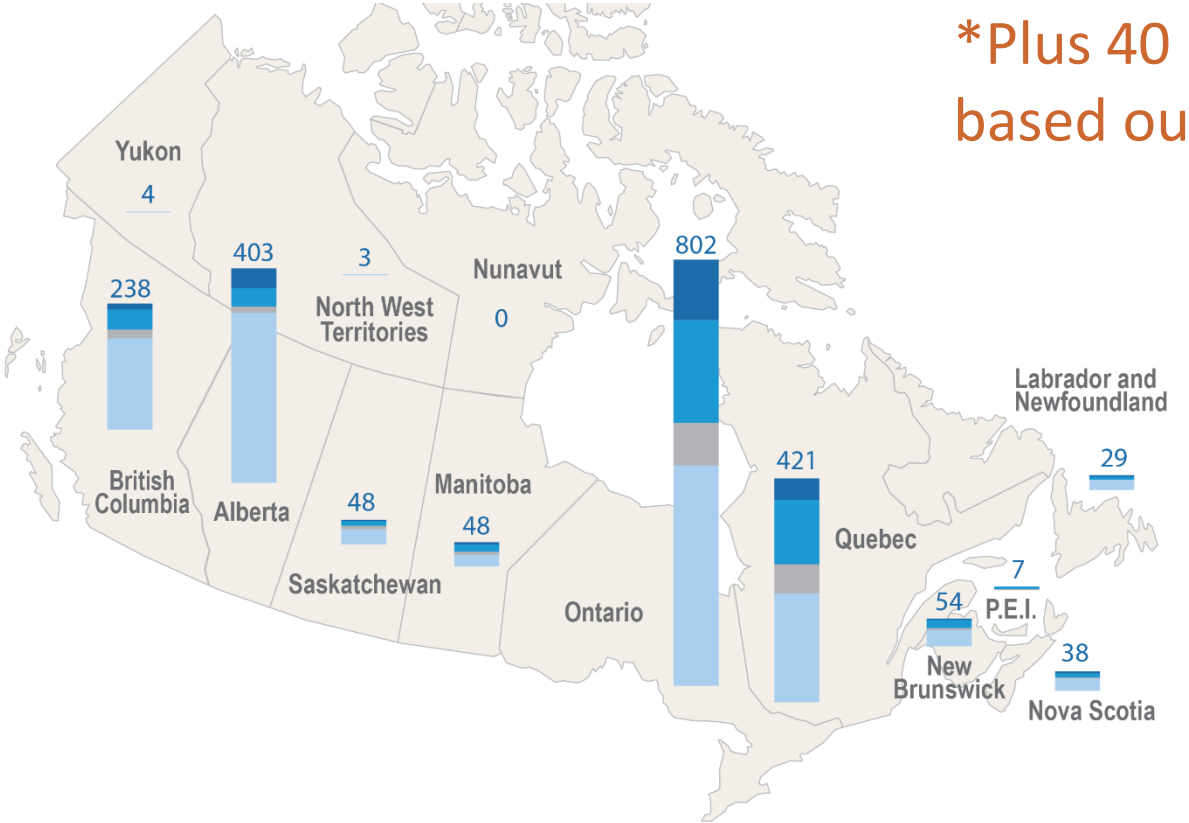
Medical

436 licences

Commercial

248 licences

2,095 Licences across Canada*



*Plus 40 licensees based outside Canada

Legend

- Commercial
- Medical
- Academic
- 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* (under development)
- **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*

Licensing and Certification Decisions

Designated Officers (DOs) made a number of licensing and certification decisions related to the use of nuclear substances.

Type of decision	2014	2015	2016	2017	2018
Licensing	2,162	2,089	2,185	1,972	1,824
Certification of prescribed equipment	98	92	143	182	93
Certification of Exposure Device Operators	156	381	455	389	488
Certification of Class II Radiation Safety Officers	13	17	22	28	19
Total	**2,429**	**2,579**	**2,805**	**2,571**	**2,424**

Compliance Verification

- CNSC staff conduct compliance activities
  - 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 compliance history
- Continuing to focus on performance-based inspections
- Historically, priority of inspections was high risk licensees
  - Performance of these licensees is strong
- Current year's inspection plan dedicated more effort to medium risk licensees
  - In response to declining or stagnating performance

Continuous improvement,
responding to performance trends

Enforcement

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

Orders and AMPs

Sixteen Enforcement Actions in 2018

Thirteen orders issued:
Two remain open

Three AMPs:
All paid

Sector	2014	2015	2016	2017	2018
Medical	0	2	1	0	1
Industrial	16	14	18	23	14
Academic	2	1	0	0	0
Commercial	1	6	3	1	1
ALL	**19**	**23**	**22**	**24**	**16**

Orders are closed only when all conditions are satisfied

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OVERALL SAFETY PERFORMANCE IN 2018

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

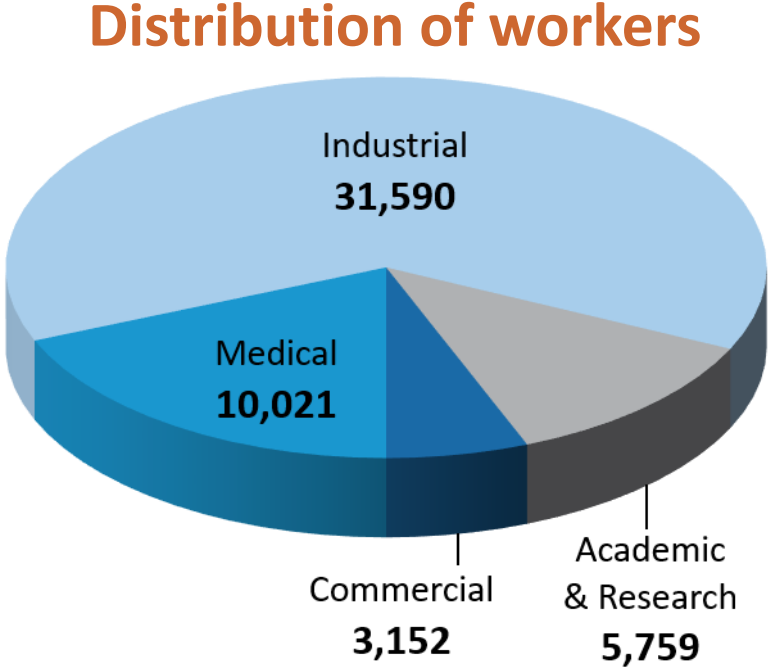
Licensees are required to implement radiation protection programs to protect workers

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

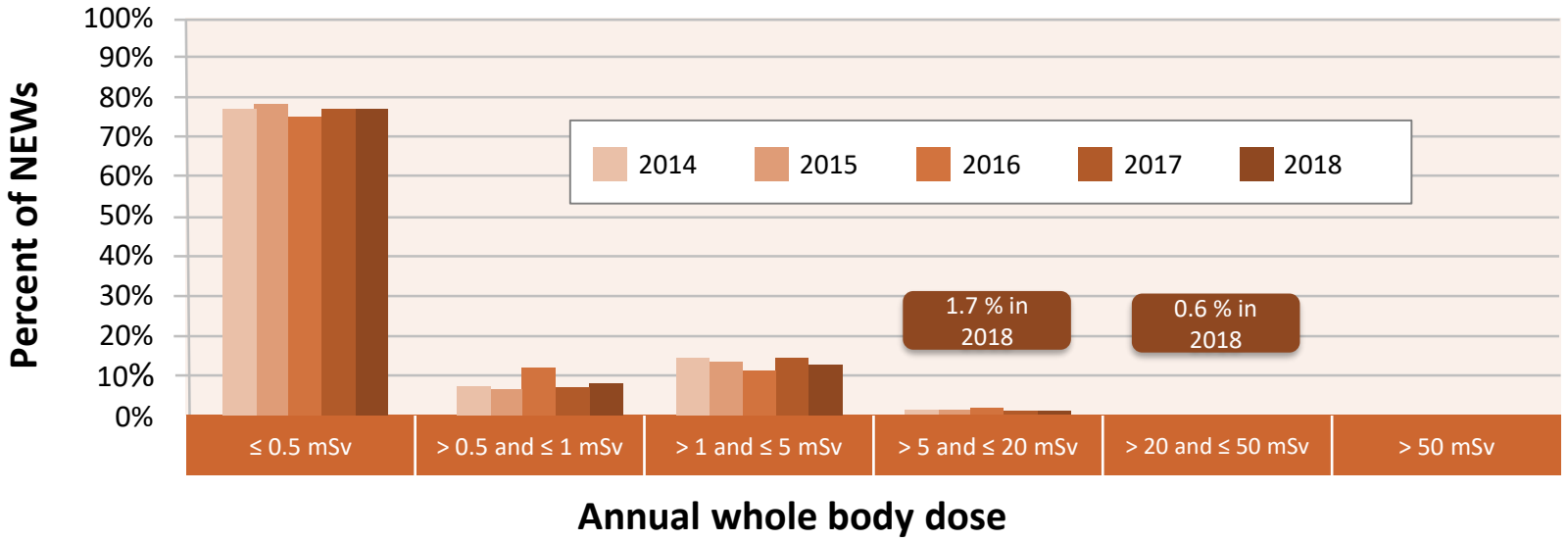
Distribution of Workers in 2018

50,522 workers in the four sectors monitored for occupational doses

- 19,303 Nuclear Energy Workers (NEWs)
- 31,219 non-NEWs



Annual Effective Dose



Doses to workers remain low

Performance Results

Results shown at the sector level only

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

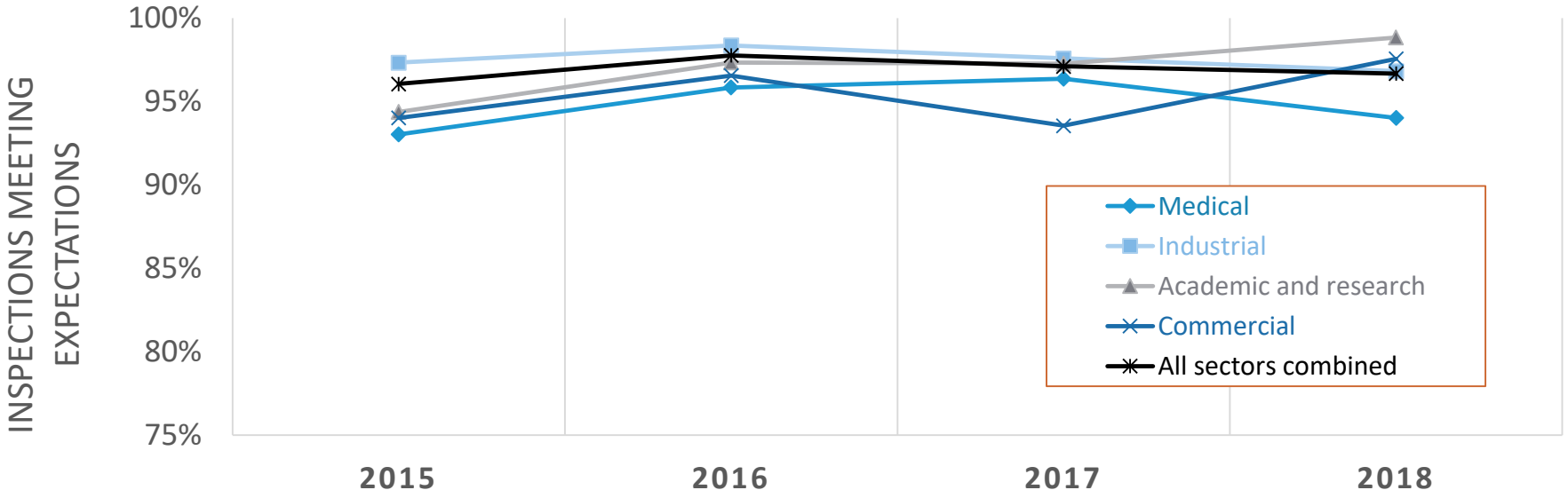
Safety Performance Areas

Licensees demonstrated satisfactory performance in the SCAs presented here:

- **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

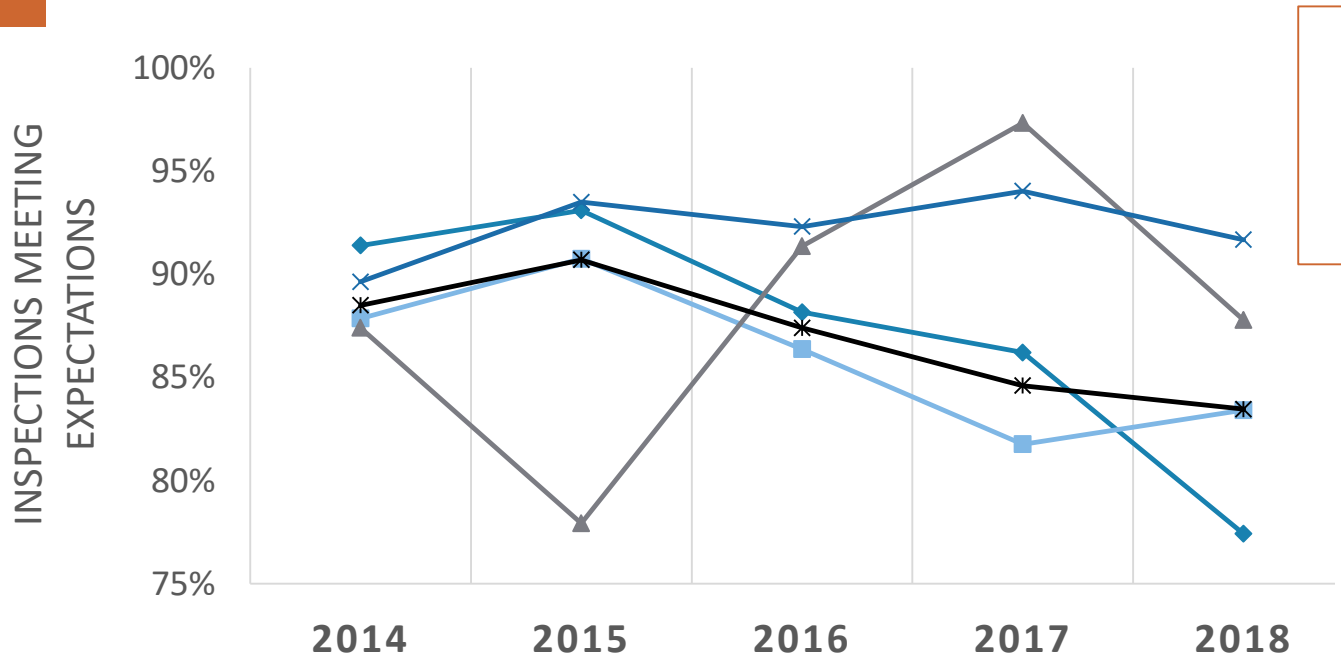
Items of non-compliance in any SCA are addressed by licensee

Evaluation of Management Systems (MS)



94% of inspections met expectations
No Unacceptable ratings in MS

Evaluation of Operating Performance (OP)



- **Four** inspections with ratings of Unacceptable
- Order issued in **three** cases
- AMP issued in **one** case

84% of inspections met expectations

Four Unacceptable Ratings In Operation Performance

Types of Licensees

- Portable Gauge Licensee
- Industrial Radiography Licensee
- Fixed Gauge Licensee
- Oil Well Logging Licensee

CNSC Action

- Orders in three cases (portable gauge, industrial radiography, fixed gauge licensees)
- AMP in one case (oil well logging licensee)
- Follow-up inspection (oil well logging licensee)

Reasons for UA ratings

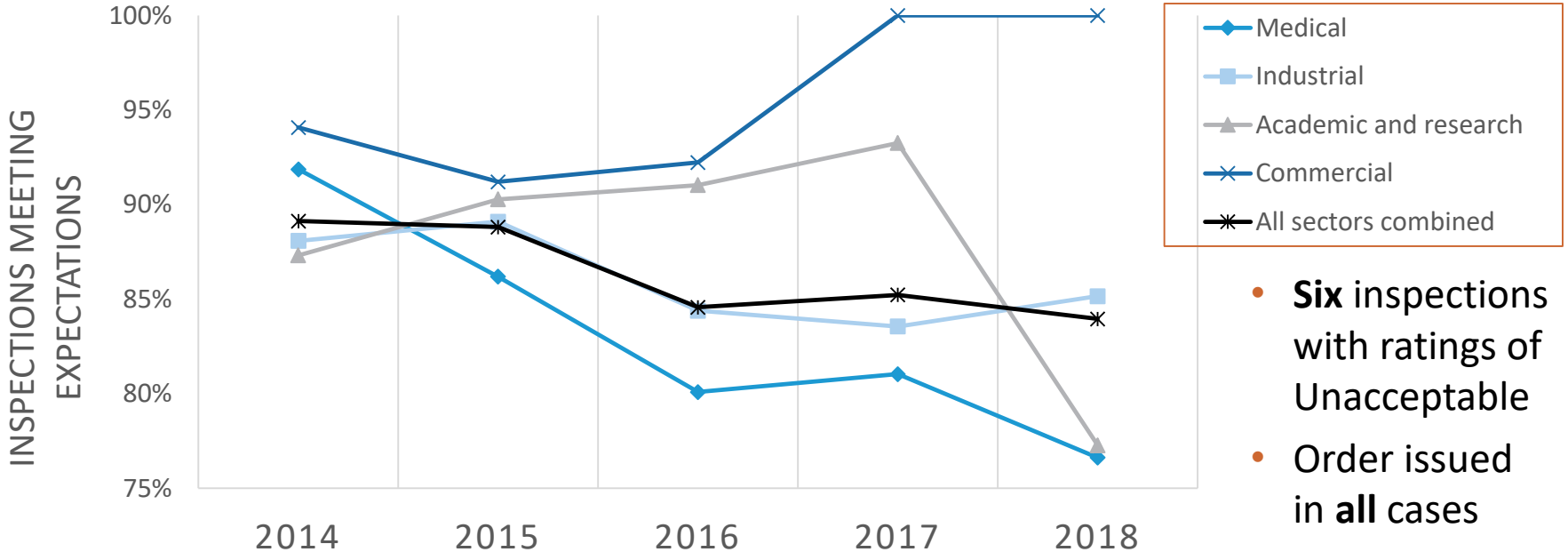
- Records of device maintenance not retained
- Failure to meet workers obligation
- Failure to follow licensee's procedures
- Vessel entries contrary to licence condition

Licensee Response

- All implemented satisfactory corrective measures
- Licensees met the terms and conditions of the orders

Orders were closed

Evaluation of Radiation Protection (RP)



- **Six** inspections with ratings of Unacceptable
- Order issued in **all** cases

84% of inspections met expectations

Six Unacceptable Ratings In Radiation Protection

Types of Licensees

- Three portable gauge licensees
- One industrial radiography licensee
- One fixed gauge licensee
- One nuclear medicine licensee

Reasons for UA ratings

- Survey meters not available or not calibrated
- Doses not recorded or not ascertained
- Storage of devices near occupied area
- Lack of RSO involvement
- Insufficient management oversight of RP programs

CNSC Action

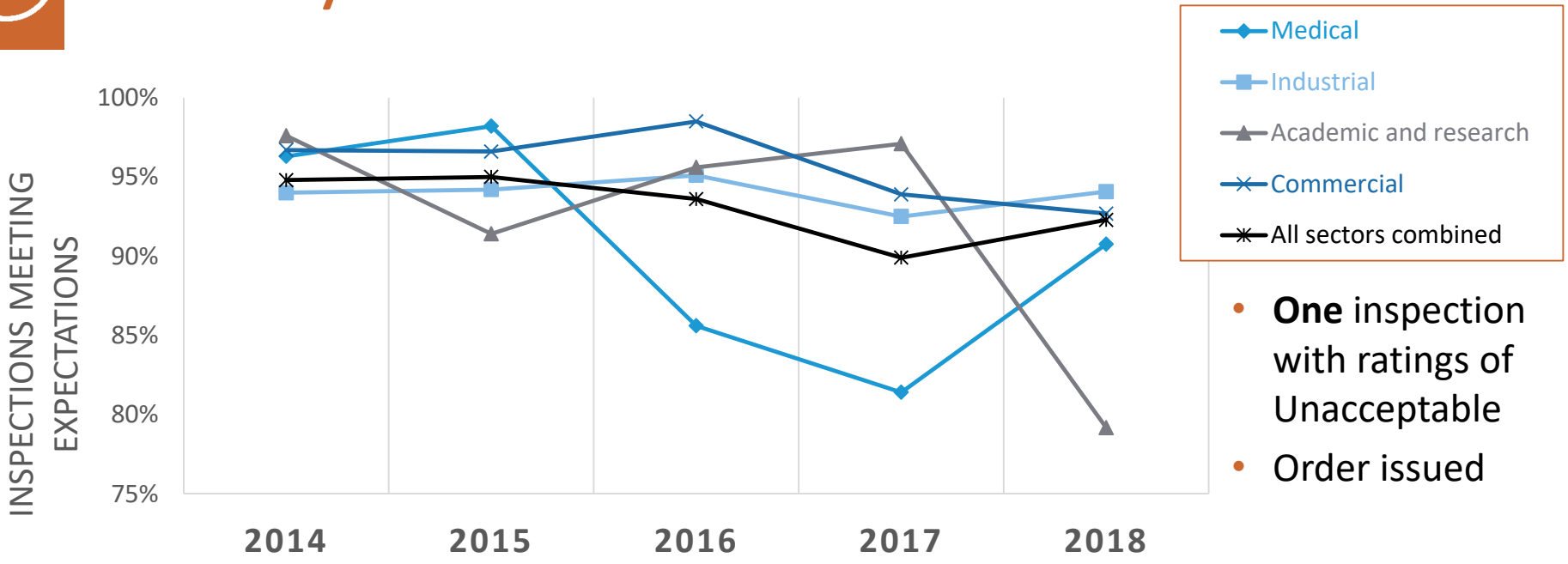
Orders issued in all cases

Licensee Response

- In five cases, licensees implemented satisfactory corrective measures and met terms and conditions of order
- In the sixth case (nuclear medicine), licensee not using nuclear substances. CNSC staff are monitoring licensee's progress to meeting terms and conditions of order

One order remains open

Security



- **One** inspection with ratings of Unacceptable
- Order issued

92% of inspections met expectations

One Unacceptable Rating In Security

Types of Licensee
Portable gauge licensee

CNSC Action
Order issued

Reasons for UA rating
Portable gauge in its transport package was left unattended at a construction site

Licensee Response
Licensee has met and condition of the order

Order is closed

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:

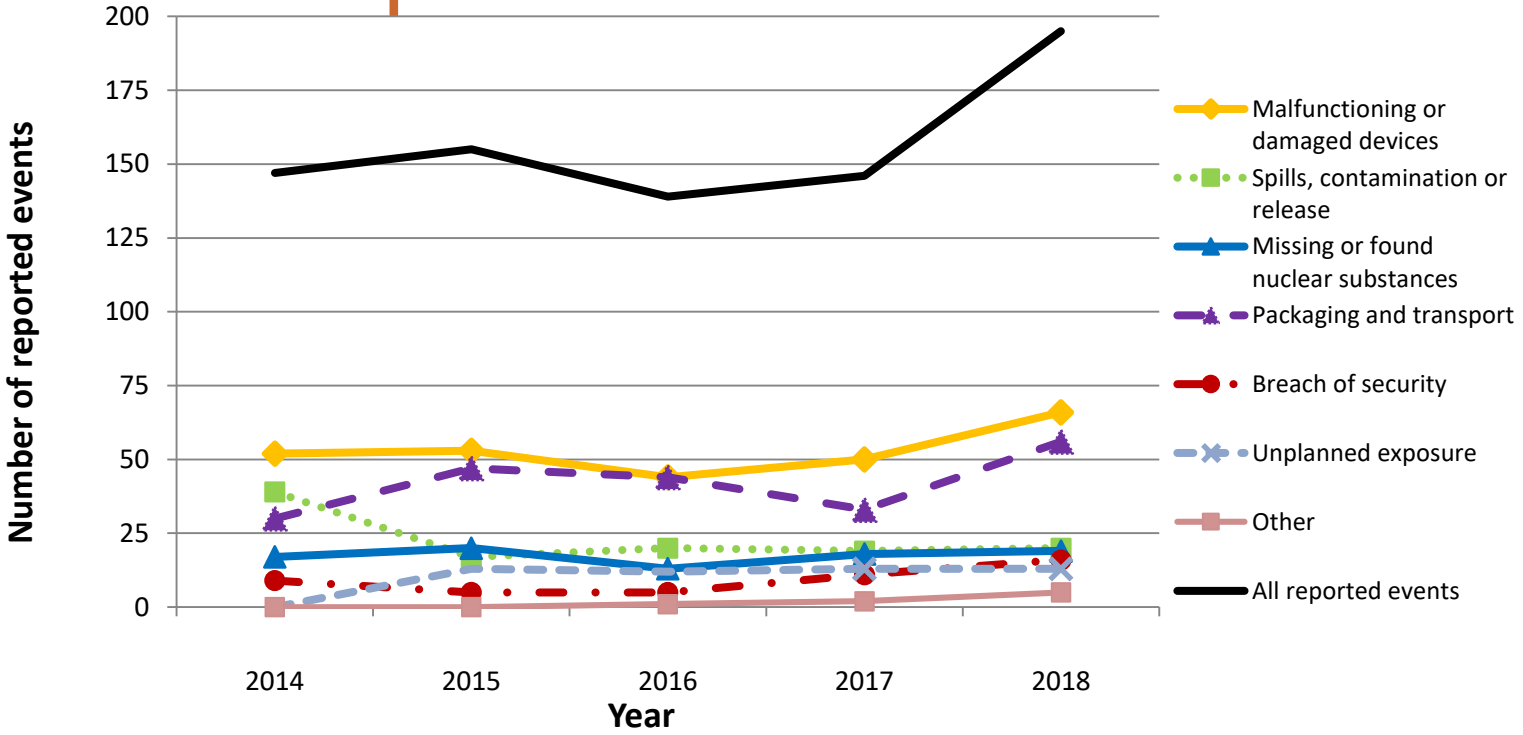
- Exposure in excess of ten times the annual limit for a NEW
- Loss/theft of a Category 1 sealed source with unknown safety provisions in place

Events Reported in 2018

All events were assessed by staff

Level 0	Level 1	Level 2	Level 3
190	3	2	0
No significance	Anomalies	Incidents	Serious incident

Events Reported in 2018



Increase in reported events at INES Level 0

INES Level 1 Event (1 of 3)

Lost Portable Gauge

Troxler 3340 portable gauge went missing from a job site in Quebec City

- Local police notified
- Gauge was not found

CNSC Actions

CNSC web report posted immediately following notification

Corrective Actions

Licensee now holds monthly safety and security meetings for all portable gauge users

No safety impact to public.

Low risk sealed source.

INES Level 1 Event (2 of 3)

Fixed gauge found outside regulatory control

- Peco Gamma 101P Fixed gauge discovered at scrap yard (non-licensee)
- Originated from bankrupt company

CNSC Actions:

- Licensed service provider retrieved gauge and arranged for disposal
- CNSC used Financial Guarantee Program to dispose of device
- CNSC investigation conducted to trace any other gauges of this type that could be potentially unlicensed
- Letter sent to manufacturer to remind them of Canadian requirements
- Information note sent to the Canadian Association of Recycling Industries (CARI) to inform of potential for this to happen again

No safety risk to public

INES Level 1 Event (3 of 3)

Non-Nuclear Energy Worker with dose over limits

Airline worker received potential dose of 1.06 mSv

CNSC Actions:

- Reported to the Commission as an Event Initial Report (EIR)
- CNSC reviewed dose information to recreate badge reading; unsuccessful and concluded it was likely a non-personal dose

Corrective Actions:

- Licensee could not justify non-personal dose with certainty; kept conservative personal dose to worker
- Licensee now issues electronic personal dosimeters (EPDs) to all workers

No health impacts for worker

INES Level 2 Event (1 of 2)

Nuclear Energy Worker with dose over limit

Tc-99m skin contamination to right wrist of worker (3.6 Sv)

CNSC Actions:

- Reported to the Commission as an Event Initial Report (EIR)
- Return to Work letter issued following closure of event

Corrective Actions:

- Worker immediately assigned to other duties to prevent further dose
- New personal protective equipment (PPE) purchased to prevent future occurrences
- Communication of event to all staff

No health impacts for worker

INES Level 2 Event (2 of 2)

Nuclear Energy Worker with dose over limit

I-131 skin contamination to left thumb of worker (1.7 Sv)

CNSC Actions:

- Reported to the Commission as Event Initial Report (EIR)
- Conducted an unplanned inspection of the licence
- Order was issued to stop work until appropriate procedures were put in place and new facility for therapy production is available

Corrective Actions:

- Workers immediately removed from work that may further increase dose
- Additional monitoring conducted
- Development and implementation of new standard operating procedures

No health impacts for worker

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CASE STUDIES IN REGULATORY INTERVENTIONS

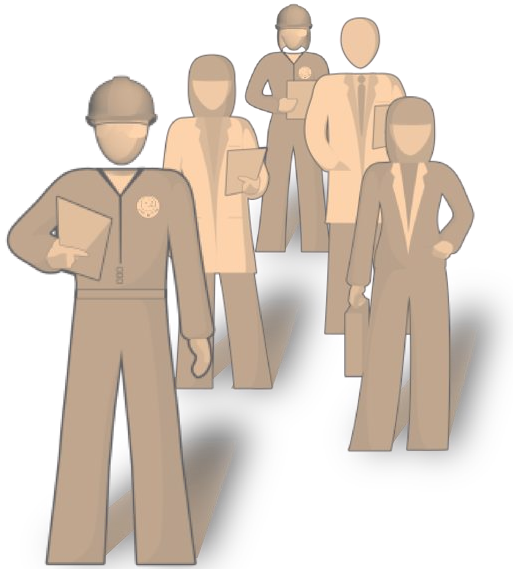
New for 2018 ROR

Case Studies in Regulatory Interventions

- CNSC monitor performance using a variety of metrics
  - Individual licensees and groups of licensees
- CNSC staff develop and implement regulatory strategies to intervene when performance doesn't meet expectations
- Case studies offer opportunity to:
  - Dive deeper into impact of regulatory strategies
  - Share longer-term story about performance and CNSC staff actions

Spotlight on Two Sub-Sectors Challenges

- Portable gauge
  - Historical and ongoing
- Nuclear medicine
  - New interventions
- Impacts of CNSC's approach



Different approaches for different activities

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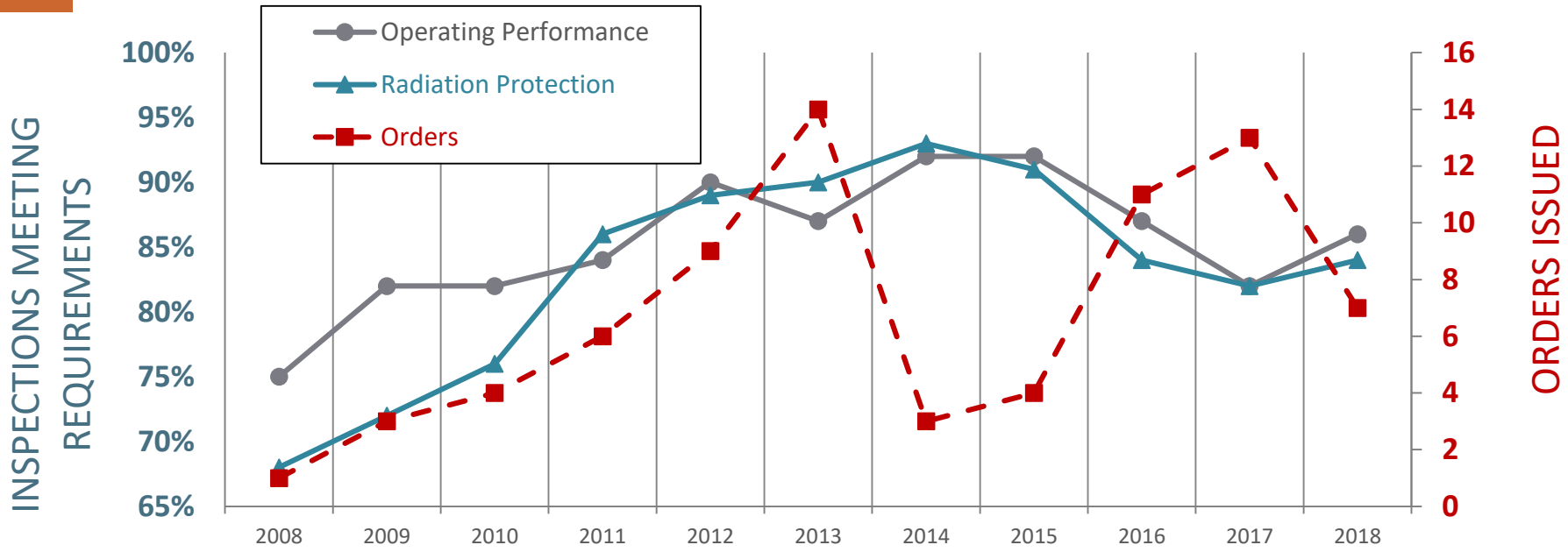
PORTABLE GAUGE SUBSECTOR

Use of Portable Gauges

- Medium risk
- Used to measure soil density and moisture
- Sealed sources
- Workers operate gauges in the field
  - Away from the Radiation Safety Officer (RSO)
  - Must transport gauges
  - Busy construction site
- Transient workforce with high turnaround
- Seasonal work in most places

Worker operating a portable gauge
(source: CNSC staff)

Historically Low Performance



Challenge to measure the impact of the different measures taken

CNSC Responses to Low Performance

2010

CNSC staff working group established to develop a unified strategy

2014

CNSC launched portable gauge workshops

2015

- Published quick reference guide and *"Working Safely with Portable Gauges"* booklet
- *Packaging and Transport of Nuclear Substances Regulations, 2015*
- Change to field inspections

2018

- 28 workshops held across Canada between 2015 and 2018
- CNSC produced safety video for portable gauge users and reorganized website
- Updated *"Working Safely with Portable Gauges"* booklet

Monitoring Performance

- Doses > 1mSv are decreasing
- 2018 inspections meeting expectations:
  - Management Systems: **98%**
  - Operating Performance: **86%**
  - Radiation Protection: **84%**

Performance is improving

Ongoing Initiatives to Improve Performance

- Seasonal mail-outs to portable gauge licensees to remind them of safe work practices and tools available
- Reorganization of the CNSC's portable gauge web page
- Developing a mobile application for portable gauge workers
- Continued monitoring and tracking performance through compliance activities

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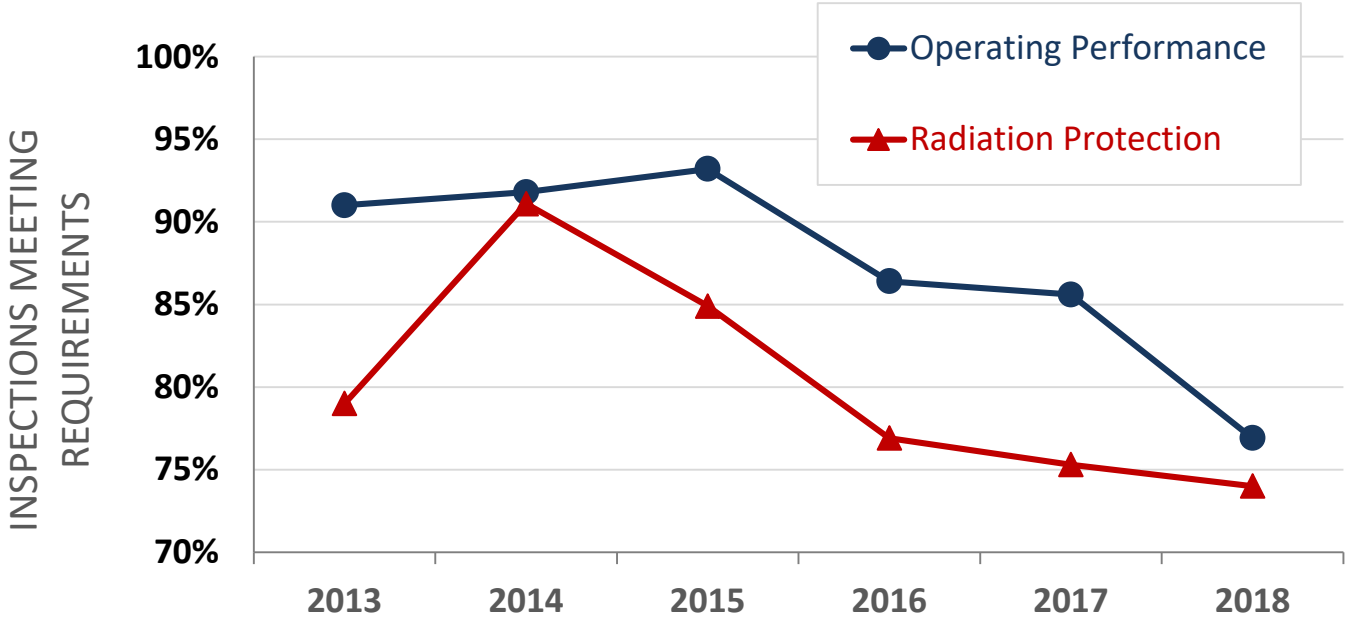
NUCLEAR MEDICINE SUBSECTOR

Nuclear Medicine

- Medium risk
- Administering nuclear substances to patients
- Work in controlled environment
- Registered nuclear medicine technologists, must write an exam prior to registration with College

Nuclear medicine licensee facility *(source: CNSC)*

Addressing the Decline in Performance



- **2016** Performance-based inspections
- **2017** Proposal for an evaluation of Radiation Safety Officers

Why an Evaluation?

- A systematic way to identify the challenges faced by the medical sector
- Performed to clearly understand the contributing issues and allowing the CNSC target those specific areas
- Results are a guide for CNSC staff to develop regulatory guidance for an effective radiation protection program

Evaluation report is published on CNSC website

Who and What Was Looked At

- Medical and academic and research sectors
- Focus on contributing factors that lead to success of Radiation Safety Officers (RSOs):
  - Infrastructure
  - Institutional
  - Interpersonal
  - Individual

Worker manipulating nuclear substances *(source: CNSC)*

Findings

- Radiation Safety Officers (RSOs) have capability, opportunity and motivation to provide training, disseminate information and conduct oversight activities
- Access to continuous improvement activities varies
  - Barriers include lack of time, money, management support
- RSOs in medical sector face more obstacles than counterparts in academic and research sector
  - Particularly pronounced for RSOs in large institutions

Action Plan

Short term (For years 2019 –2020):

- Increase regulatory scrutiny through prioritization of medical inspections in annual plan
- Review adequacy of existing outreach and communication activities
- Explore use of additional enforcement tools

Medium term

- Draft REGDOC-1.6.2, *Developing and Implementing an Effective Radiation Protection Program for the use of Nuclear Substances and Radiation Devices*
- Modernize communication tools
- Develop outreach and communication tools that target licensees with poor performance

Continued performance monitoring

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STAKEHOLDER ENGAGEMENT

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
  - Key lens on licensees that are struggling

CNSC staff participate in outreach activity *(source: CNSC)*

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CLOSING REMARKS

What Have CNSC Staff Been Doing In 2019?

- Reviewing our regulatory program for large, complex licensees
- Adjusting the inspection focus and planning process for nuclear substance and radiation device licences
- Implementing the regulatory strategy to improve radiation protection program design and implementation with a focus on the medical sector
- Ensuring we are agile and ready to regulate new technologies and new applications of existing technologies

Conclusion

- Licensees are operating safely
- CNSC staff maintain oversight through continued monitoring, data analysis, and innovation

Use of nuclear substances and prescribed equipment is safe

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

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ANNEX A

Annex A: Action Items

RIB Action 15138

Publication of the Technical Briefing on Nuclear Substances Presentation (18-M49)

Response

- Posted to the Nuclear Substances webpage in July 2019

  http://www.nuclearsafety.gc.ca/eng/nuclear-substances/index.cfm

  http://www.nuclearsafety.gc.ca/fra/nuclear-substances/index.cfm

Recommend closing the action item

Annex A: Action Items

RIB Action 15140

Compliance verification of DNSR licensees overdue for inspections

Response

The inspection planning process is discussed in section 3.7 of the *Regulatory Oversight Report on the Use of Nuclear Substances in Canada: 2018*

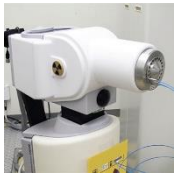
Recommend closing the action item

Annex B

Annex B: Categorization of Sealed Sources

Category 1	Very high risk	These sealed sources, if not safely managed or securely protected, would be likely to cause permanent injury (in some cases fatal) to a person handling or coming in contact with them for a period of a few minutes. Exposure would be fatal if a person were close to it in an unshielded manner for a few minutes to an hour.	- Self-shielded irradiators  - External beam radiotherapy  - Gamma knife 
Category 2	High risk	These sealed sources, if not safely managed or securely protected, could cause permanent injury to a person handling it, or coming in contact with them, for a short period of time (minutes to hours), or be fatal if close to it in an unshielded manner for a few days.	- Industrial radiography exposure devices 

Annex B: Categorization of Sealed Sources

Category 3	Moderate risk	These sealed sources, if not safely managed or securely protected, could cause permanent injury to a person either handling them, or, otherwise coming in contact with them, for some hours. Although unlikely, it could be fatal to be close to this amount of unshielded radioactive nuclear substances for a period of days to weeks.	- Fixed gauges  - High dose rate brachytherapy 
Category 4	Low risk	It is very unlikely that anyone would be permanently injured by these sealed sources. However, if this unshielded radioactive nuclear substance is not safely managed or securely protected, although unlikely, it could temporarily injure someone handling it, in contact with it, or who is close to it for several weeks.	- Moisture/density portable gauges 

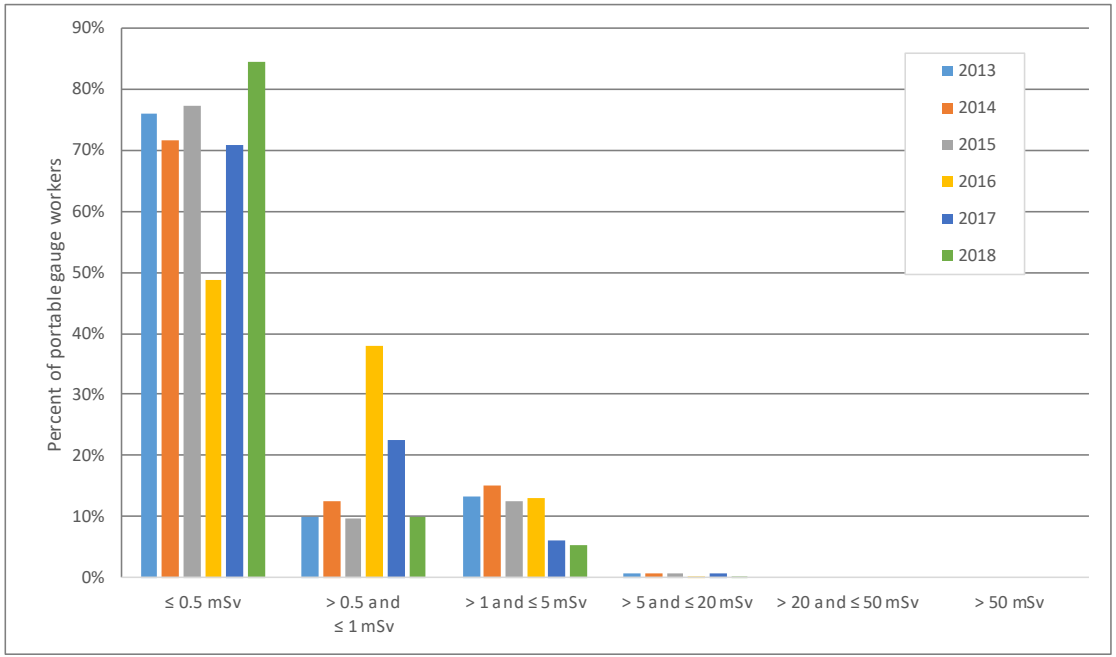
Annex B: Categorization of Sealed Sources

Category 5	Very low risk	No one could be permanently injured by this radioactive nuclear substance.	- Electron capture detectors  - Portable x-ray fluorescence analyzers 	- Radioactive seeds for cancer treatment 

Annex C

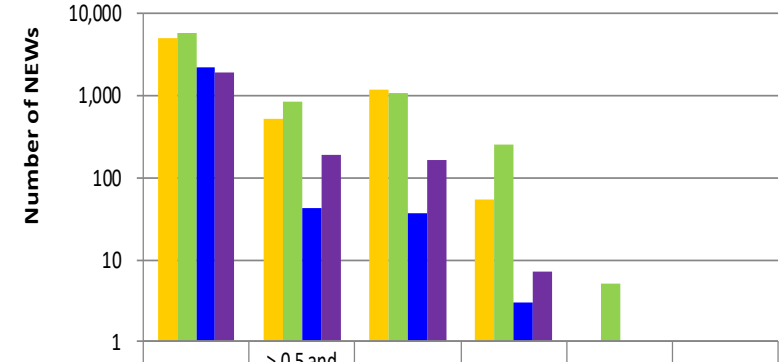
Annex C: Doses to workers

CMD 19-M29 Figure 7



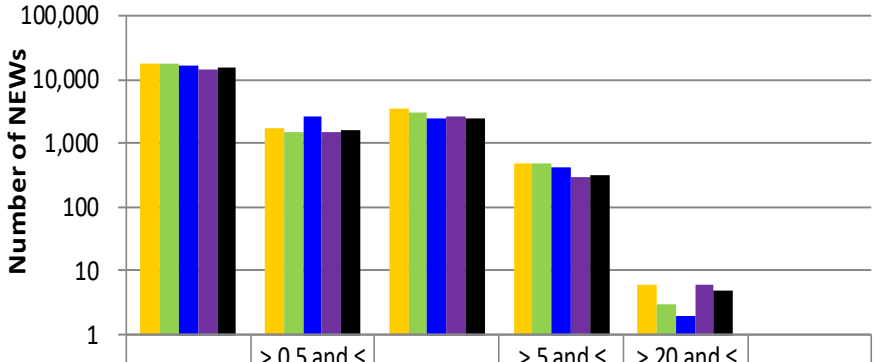
Annex C: Doses to workers

CMD 19-M29 Figure 10



	≤ 0.5 mSv	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
Medical	4,999	535	1,209	53	-	-
Industrial	5,718	846	1,093	258	5	
Academic and research	2,254	43	36	3	-	-
Commercial	1,884	194	166	7	-	-

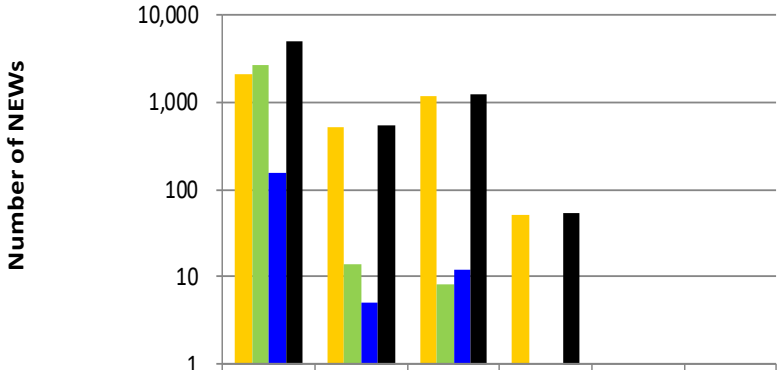
CMD 19-M29 Figure 11



	≤ 0.5	> 0.5 and ≤ 1	> 1 and ≤ 5	> 5 and ≤ 20	> 20 and ≤ 50	> 50
2014	18,254	1,720	3,420	499	6	-
2015	17,416	1,523	3,028	501	3	-
2016	16,350	2,636	2,384	424	2	-
2017	14,760	1,475	2,642	301	6	-
2018	14,855	1,618	2,504	321	5	-

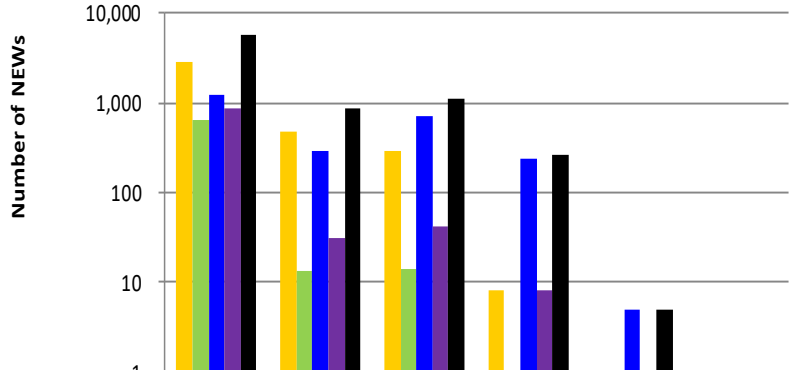
Annex C: Doses to workers

CMD 19-M29 Figure 25



	≤ 0.5 mSv	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
Nuclear medicine	2,130	515	1,182	52	-	-
Radiation therapy	2,635	14	8	-	-	-
Veterinary nuclear medicine	156	5	12	-	-	-
Medical sector	4,999	535	1,209	53	-	-

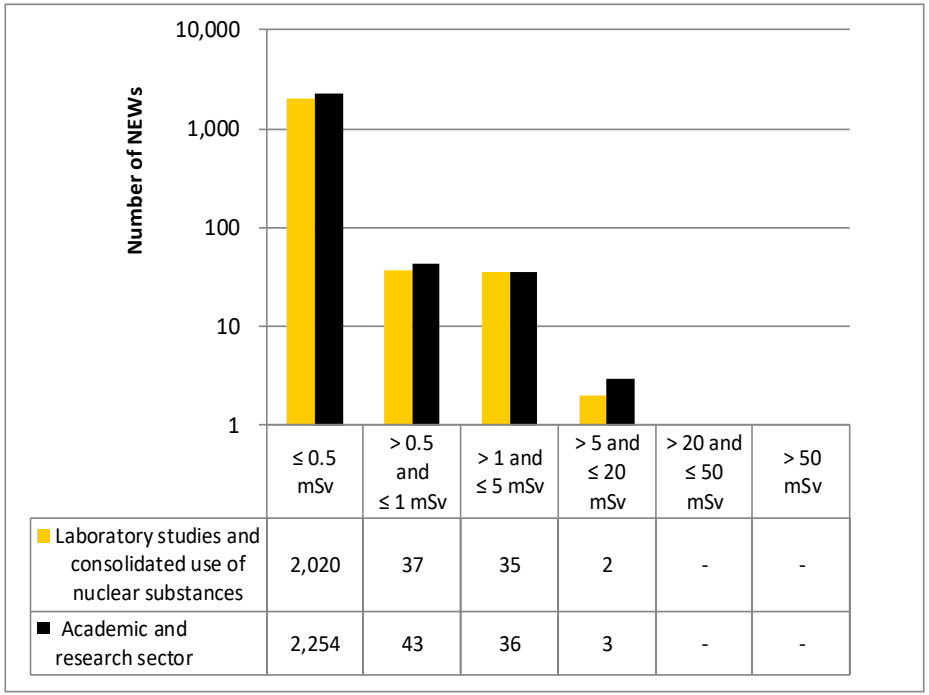
CMD 19-M29 Figure 26



	≤ 0.5 mSv	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
Portable gauge	2,796	487	293	8	-	-
Fixed gauge	644	13	14	-	-	-
Industrial radiography	1,205	297	723	239	5	-
Oil well logging	853	31	42	8	-	-
Industrial sector	5,718	846	1,093	258	5	-

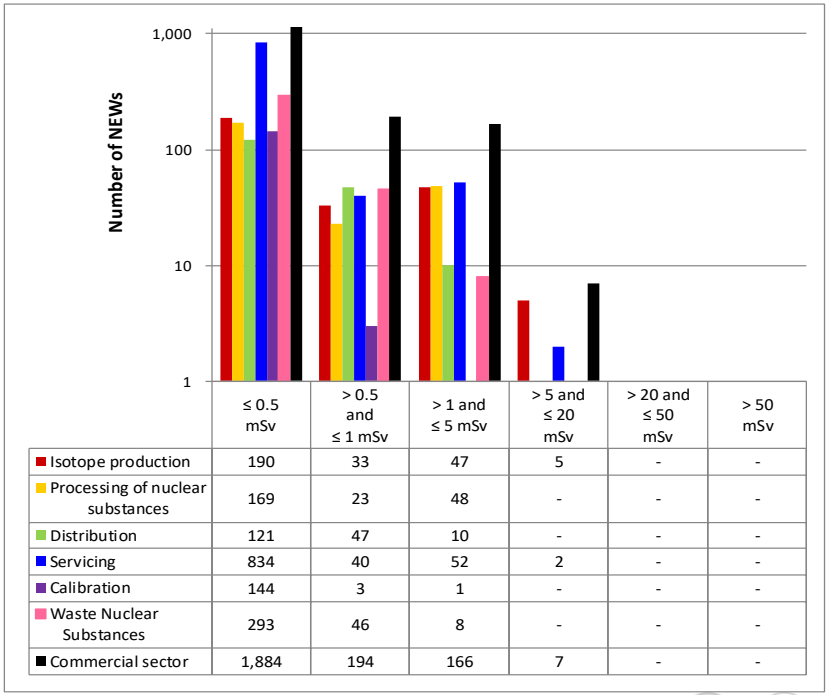
Annex C: Doses to workers

CMD 19-M29 Figure 27



	≤ 0.5 mSv	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
Laboratory studies and consolidated use of nuclear substances	2,020	37	35	2	-	-
Academic and research sector	2,254	43	36	3	-	-

CMD 19-M29 Figure 28



	≤ 0.5 mSv	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
Isotope production	190	33	47	5	-	-
Processing of nuclear substances	169	23	48	-	-	-
Distribution	121	47	10	-	-	-
Servicing	834	40	52	2	-	-
Calibration	144	3	1	-	-	-
Waste Nuclear Substances	293	46	8	-	-	-
Commercial sector	1,884	194	166	7	-	-