



# Regulatory Oversight Report on the Use of Nuclear Substances in Canada: 2017

Commission Meeting  
October 3, 2018  
CMD 18-M37.A

CNSC Staff Presentation





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## CNSC Regulatory Oversight

- Regulatory framework includes legislation, regulations, licences & certificates, and regulatory documents
- Licensees are responsible for safety
- CNSC oversight ensures licensed activities are safe through assessment, compliance verification and enforcement

## Risk-Informed Regulatory Approach





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# CNSC Regulatory Oversight Reports

- August 23, 2018: Research Reactors and Class IB Accelerators: 2016-17
- October 3, 2018: Use of Nuclear Substances in Canada: 2017
- November 8, 2018: Canadian Nuclear Generating Sites: 2017
- December 12/13, 2018: Uranium and Nuclear Substances Processing Facilities: 2017
- December 12/13, 2018: Uranium Mines, Mills, Historic and Decommissioned Sites: 2017

## Reporting on licensee performance based on CNSC oversight



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## Overview of Presentation

- ▶ Introduction
- ▶ Public Consultation
- ▶ Sector Overviews and Summaries
- ▶ Oversight Activities
- ▶ Overall Safety Performance
- ▶ Regulatory Developments
- ▶ Closing Remarks



**CNSC inspectors examining the collimator of Class II equipment used in medical applications  
(Source: CNSC)**



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# INTRODUCTION



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## Five Sectors



### Medical

Use of nuclear substances and prescribed equipment for diagnostic and therapeutic purposes.



### Industrial

Use of nuclear substances and prescribed equipment in industrial facilities or as part of fieldwork or construction.



### Academic and Research

Use of nuclear substances prescribed equipment in universities, colleges and research laboratories for research and teaching purposes.



### Commercial

Production, processing, storage and distribution of nuclear substances, and servicing and calibration of radiation devices and prescribed equipment.



### Waste

Management, handling, storage, and processing of low-level radioactive waste generated from nuclear facilities and activities

**In 2017, nuclear substances used safely in  
many activities across all sectors**



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## Licensees continued to operate safely and responsibly in 2017

- ▶ Licensees have appropriate safety programs to protect the health and safety of Canadians and the environment
- ▶ Licensees continued to maintain adequate measures to implement Canada's international obligations
- ▶ One worker exceeded the regulatory dose limit for extremities of 500 mSv in 2017

The use of nuclear substances in Canada is safe



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## What's new in 2017 report

- A sector dedicated to waste nuclear substances was added
  - Licences issued by a designated officer for activities related to management of low-level radioactive waste generated from licensed nuclear facilities and activities
- Relative risk ranking assigned to subsectors is included in the report





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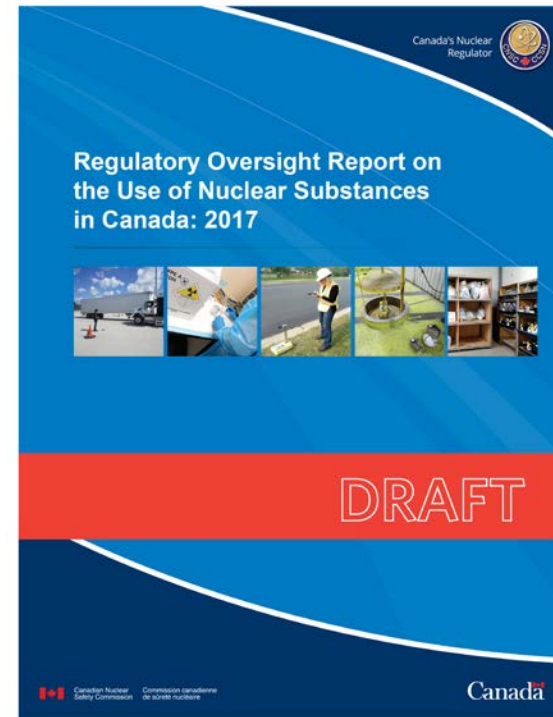
# PUBLIC CONSULTATION



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## Public Consultation

- Report was publically available for written comments for a period of 30 days
- One intervention received from:
  - Canadian Radiation Protection Association





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# SECTOR OVERVIEWS AND SUMMARIES



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## Medical Sector Overview

- 457 licences
- 9,750 workers
  - 6,706 Nuclear Energy Workers (NEWs)

Subsectors:

- Nuclear medicine (medium risk)
- Radiation therapy (medium risk)
- Veterinary nuclear medicine (medium risk)



**CNSC inspector inspecting usage of Class II  
prescribed equipment at a hospital  
(Source: CNSC)**



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## Industrial Sector Overview

- 1,287 licences
- 34,082 workers
  - 7,967 NEWs

### Subsectors:

- Portable gauge (medium risk)
- Fixed gauge (medium risk)
- Industrial radiography (high risk)
- Oil well logging (high risk)





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## Academic and Research Sector Overview

- 195 licences
- 6,715 workers
  - 2,640 NEWs

Subsectors:

- Laboratory studies (medium risk)
- Consolidated uses of nuclear substances (medium risk)





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## Commercial Sector Overview

- 246 licences
- 2,666 workers
- 1,734 NEWs

### Subsectors:

- Isotope production (medium risk)
- Processing of nuclear substances (medium risk)
- Distribution of nuclear substances (medium risk)
- Servicing radiation devices and prescribed equipment (medium risk)
- Calibration of radiation devices and prescribed equipment (medium risk)



Installation of a fixed gauge by a  
servicing company  
(Source: CNSC)



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## Waste Nuclear Substance Sector

- Licences issued by Designated Officer
- Licensed activities include temporarily storing, sorting, decontaminating, or repackaging waste before either being returned to facility or sent to licensed waste management facility
- Classified as low risk licensed activities
- Inspections planned based on the risk-informed program







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## Waste Nuclear Substance Sector Overview

- 6 licences
  - 5 licensees in Ontario
  - 1 licensee in Alberta
- 137 NEWs

### Types of waste:

- Low-level waste from research laboratories
  - Gloves, paper towels, liquid scintillation vials
- Low-level waste from nuclear power plants and fuel facilities
  - Laundry, metals, tooling and equipment



**Inspection of a waste nuclear substance licensee  
(Source: CNSC)**



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## Risk-informed Regulatory Program

- The risk-informed regulatory program provides:
  - A risk-ranking that recognized 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**

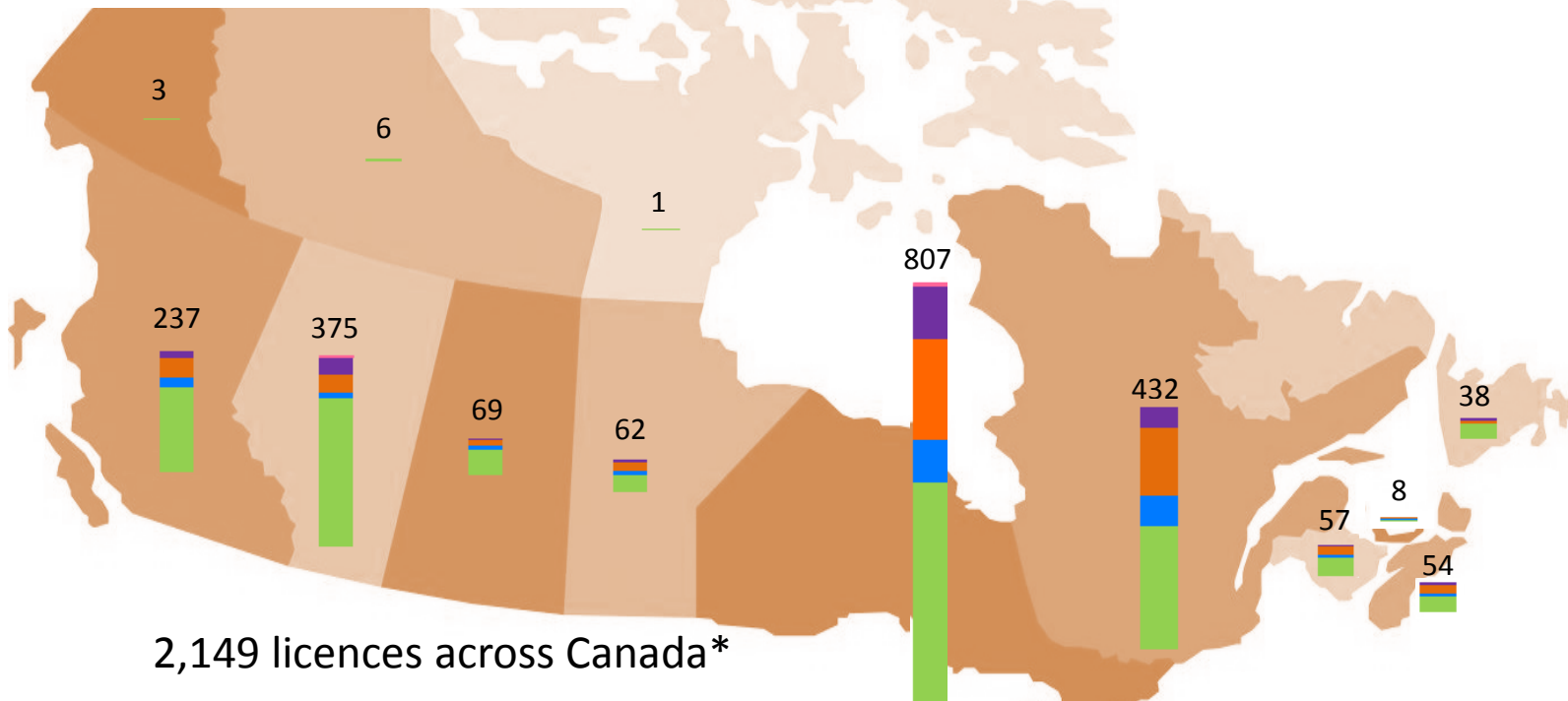


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# OVERSIGHT ACTIVITIES IN 2017



# Licensees Across Canada



2,149 licences across Canada\*

- Medical sector licences
- Industrial sector licences
- Research and academic sector licences
- Commercial sector licences
- Waste nuclear substance sector licences

\*Plus 42 licensees based outside Canada



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## Distribution Of Licences

2,191 licences held by 1,590  
licensees in 2017

**Decline in number of licences  
over time attributable to CNSC's  
policy to consolidate licences,  
and to economic conditions and  
business decisions of licensees  
(mergers and acquisitions,  
adoption of non-nuclear  
technologies)**

Sector	Number of licences				
	2013	2014	2015	2016	2017
Medical	552	536	494	470	457
Industrial	1,440	1,398	1,349	1,308	1,287
Academic and research	232	229	207	208	195
Commercial	256	248	245	247	246
Waste Nuclear Substance	8	8	6	7	6
<b>Total</b>	<b>2,488</b>	<b>2,419</b>	<b>2,301</b>	<b>2,240</b>	<b>2,191</b>

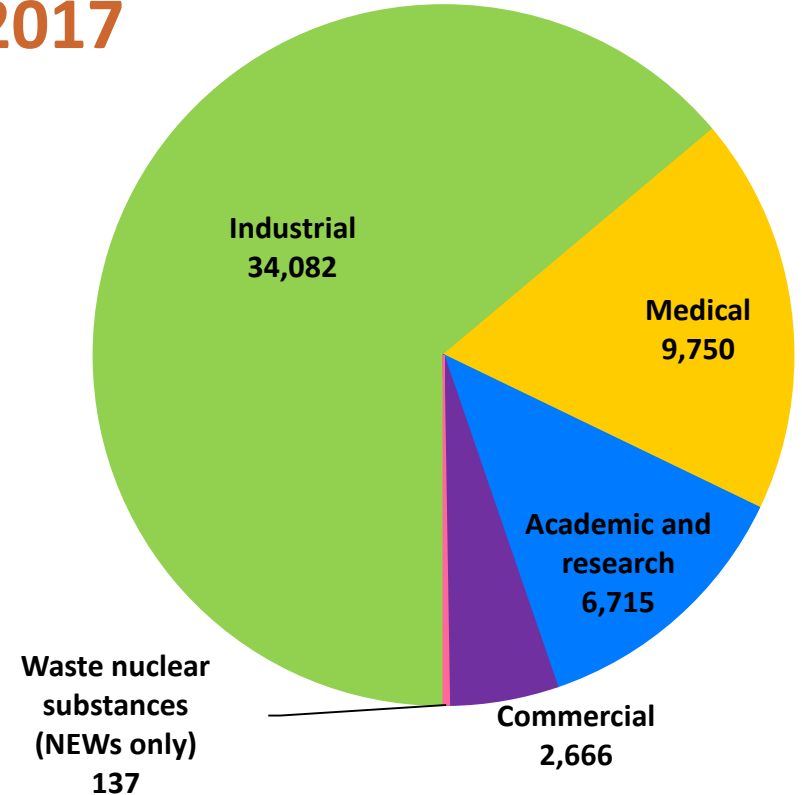


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## Distribution of Workers in 2017

53,350 workers within the five industry sectors.

- 19,184 Nuclear Energy Workers (NEWs)
- 34,166 non-NEWs





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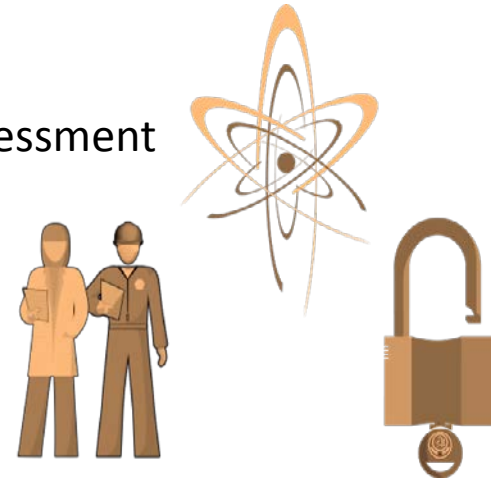
## Licensing and Certification

CNSC staff reviews applications and conducts technical assessment to determine if:

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

Licence Application Guides to assist applicants:

- REGDOC-1.4.1, *Licences Application Guide : Class II Nuclear Facilities and Prescribed Equipment* (draft)
- 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*





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## Certification of Exposure Device Operators (EDOs)

Licensees are required under the *Nuclear Substances and Radiation Devices Regulations* to only permit CNSC-certified personnel and supervised trainees to use exposure devices

- In 2017, the CNSC certified 87 new EDOs and renewed the certification of 302 EDOs
- Developments in 2017:
  - Updated EDO application form and CNSC Web page on EDO certification.
  - Published REGDOC-2.2.3, *Personnel Certification: Exposure Device Operators*



**Exposure device being used for non-destructive testing  
(Source: CNSC)**





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## Number of Licensing and Certification Decisions made by Designated Officers Related to Use of Nuclear Substances

Type of decision	Number of decisions in 2014	Number of decisions in 2015	Number of decisions in 2016	Number of decisions in 2017
Licensing	2,162	2,089	2,185	1,972
Certification of prescribed equipment	98	92	143	182
Certification of Exposure Device Operators	156	381	455	389
Certification of Class II Radiation Safety Officers	13	17	22	28
<b>Total</b>	<b>2,429</b>	<b>2,579</b>	<b>2,805</b>	<b>2,571</b>



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## Packaging and Transport

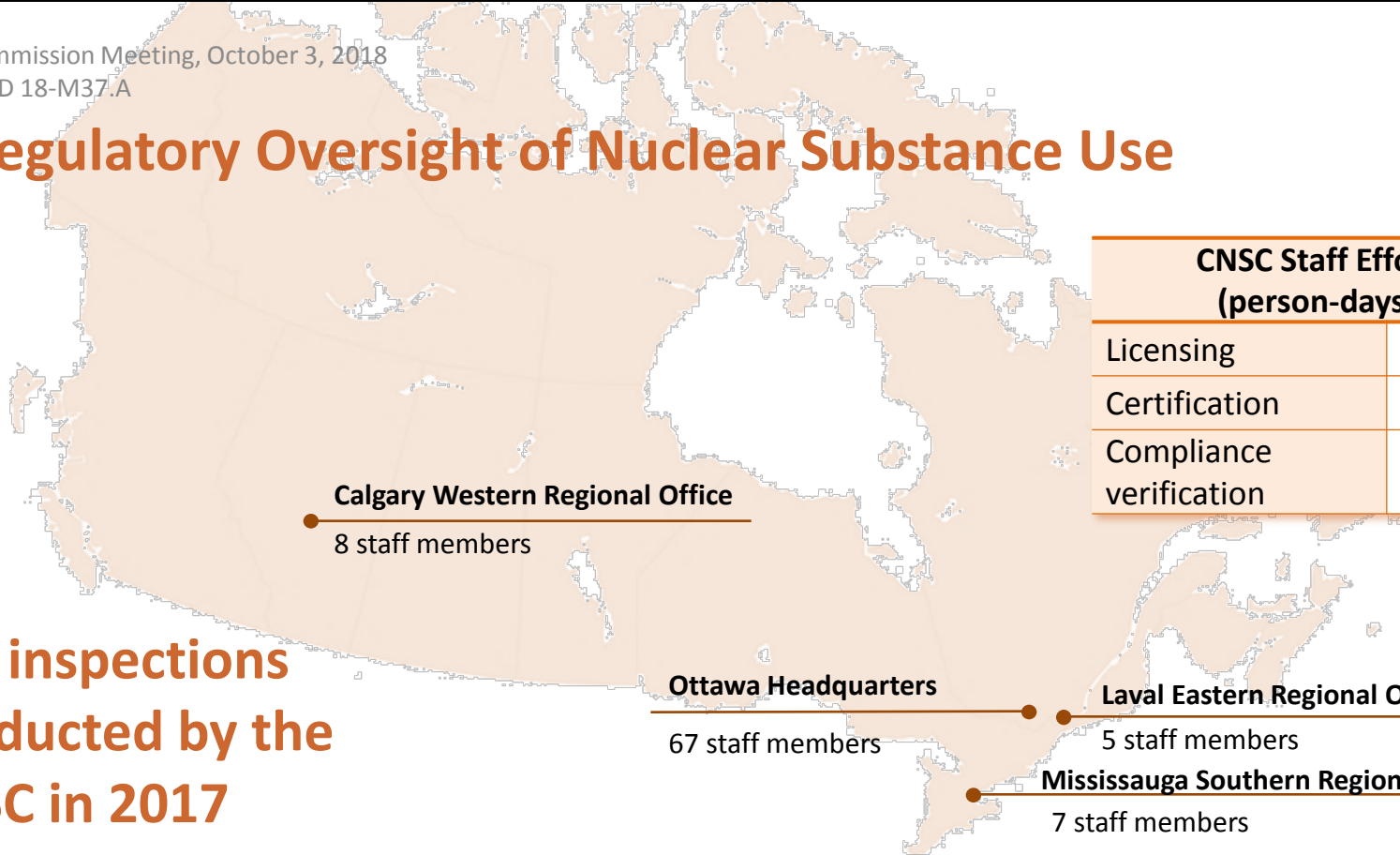
- Compliance with packaging and transport requirements is assessed
- Type of package required depends on nuclear substance being transported
- Package design requirements are specified in regulations
- Consignors, consignees and carriers must adhere to CNSC's *Packaging and Transport of Nuclear Substance Regulations, 2015*, and Transport Canada's *Transportation of Dangerous Goods Regulations*

**Approximately 1 million packages are safely transported in Canada each year**



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# Regulatory Oversight of Nuclear Substance Use



CNSC Staff Effort (person-days)	
Licensing	4,602
Certification	1,629
Compliance verification	7,280

## 944 inspections conducted by the CNSC in 2017



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## Inspection Planning

- Planning is based on risk-informed inspection frequencies and compliance history
- Inspections that are planned but not performed are tracked for execution in future planning cycles
- Inspections may be added to plan in response to licensee performance, events, or any other situations that may arise





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## Compliance Verification

- CNSC staff conduct compliance activities
  - Inspections
  - Desktop reviews
- Results of compliance activities are documented
- Non-compliances are tracked until addressed by the licensee to satisfaction of CNSC
- Repeated performance below expectations leads to increased regulatory oversight
  - 11 licensees that received below expectation or unacceptable SCA ratings in 2017 had a below expectation or unacceptable rating in same SCA in their previous inspection
  - Licensees addressed all items of non-compliance
  - Poor performance was considered by CNSC staff during inspection planning for 2018





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## Enforcement

- Enforcement actions are taken to compel licensees to comply with regulatory requirements
- Graduated approach to enforcement
- Range of tools available, including Orders, Administrative Monetary Penalties (AMPs) and licensing actions
  - The most appropriate enforcement action is selected and applied based on risk-informed decision making



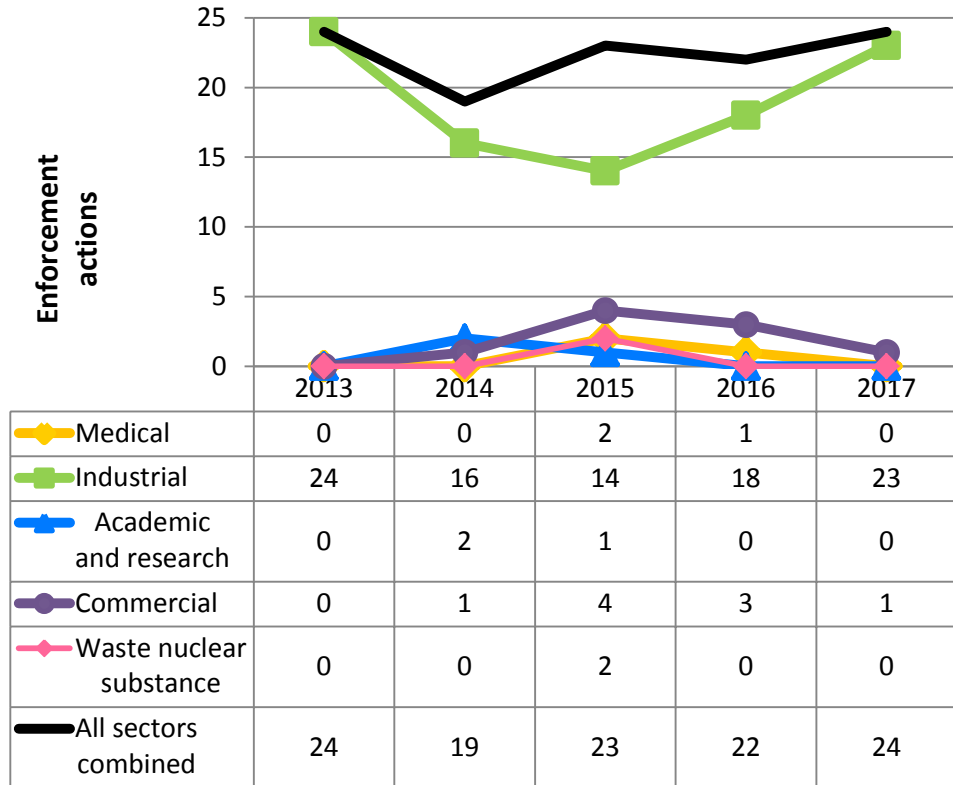
**CNSC inspector conducting an inspection  
of a portable gauge licensee  
(Source: CNSC)**



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# Enforcement Actions

- 24 escalated enforcement actions in the form of orders and AMPs taken in 2017 for safety and security reasons
  - 18 orders
  - 6 AMPs
- Licensees have met all terms and conditions of orders
- 1 AMP remains unpaid

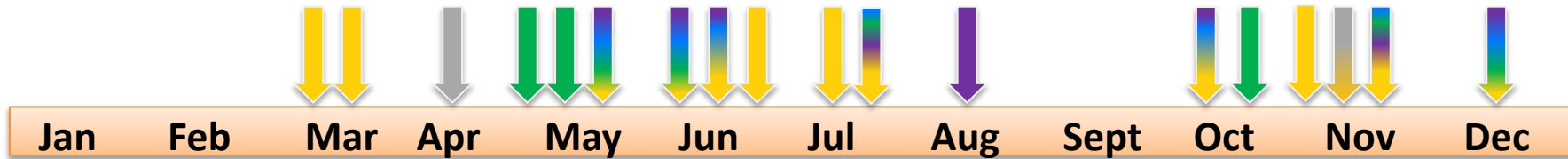


Number of enforcement actions (orders and AMPs)



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# Timely and Effective Stakeholder Engagement Throughout 2017



### Target Sector

- Medical
- Industrial
- Academic and research
- Commercial
- Waste nuclear substance
- Non-licensees

### Included:

- Newsletters
- Conferences
- Working Groups
- Workshops
- Webinars
- Industry Meetings
- Information Booths





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## Contributing to Safe Use of Nuclear Substances Worldwide

- Supporting new nuclear regulators
  - CNSC staff delivered IAEA regional training courses
  - CNSC supported emergency planning exercises for African nations
- Engaging in international initiatives
  - Peer Review Missions
  - Joint Convention on Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management
  - Code of Conduct on the Safety and Security of Radioactive Sources and Guidance on the Import and Export of Radioactive Sources



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# OVERALL SAFETY PERFORMANCE IN 2017



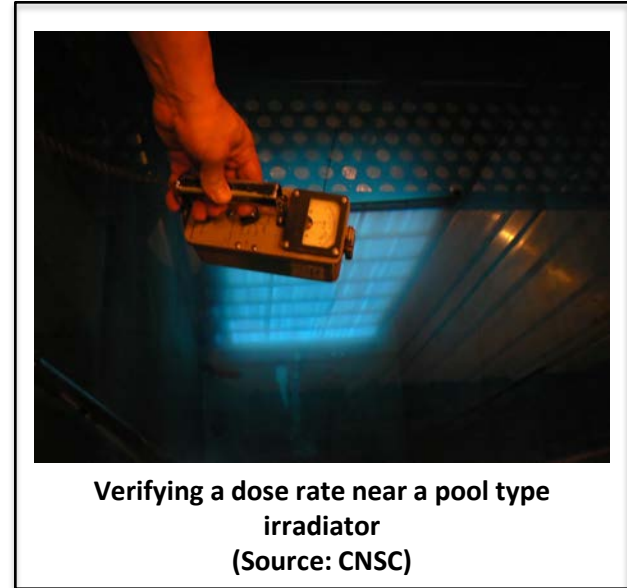
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## Measures of safety performance

- Doses to workers
- Performance results
- Reported events



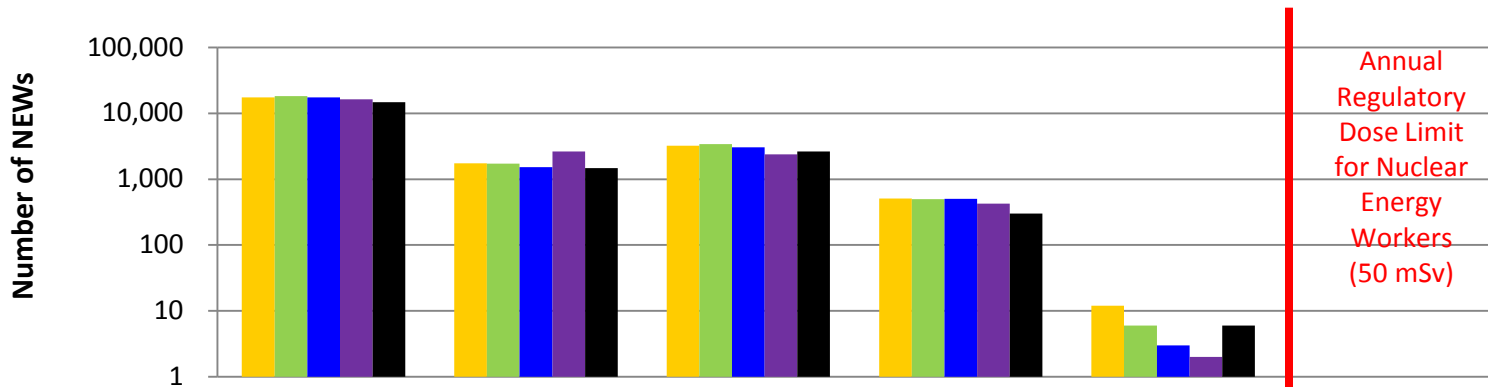
# Doses to workers





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# Annual effective dose to Nuclear Energy Workers remains low



Dose ranges (mSv)	<math><0.5\text{ mSv}</math>	0.5 – 1 mSv	1 – 5 mSv	5 – 20 mSv	20 – 50 mSv	>50 mSv
■ 2013 (22,405)	16,918	1,745	3,223	507	12	-
■ 2014 (23,688)	18,044	1,719	3,420	499	6	-
■ 2015 (22,322)	17,272	1,518	3,028	501	3	-
■ 2016 (22,606)	16,261	2,635	3,284	424	2	-
■ 2017 (19,148)	14,760	1,475	2,642	301	6	-

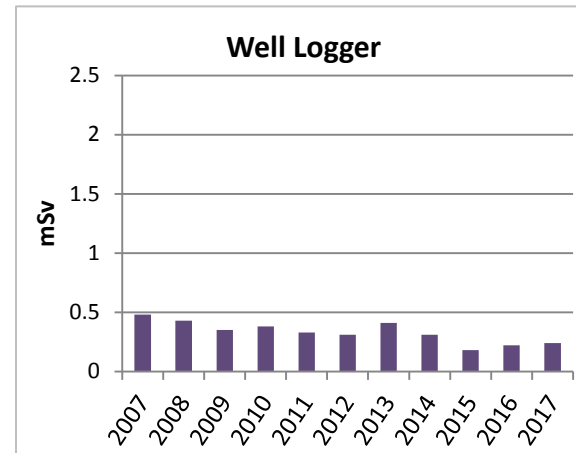
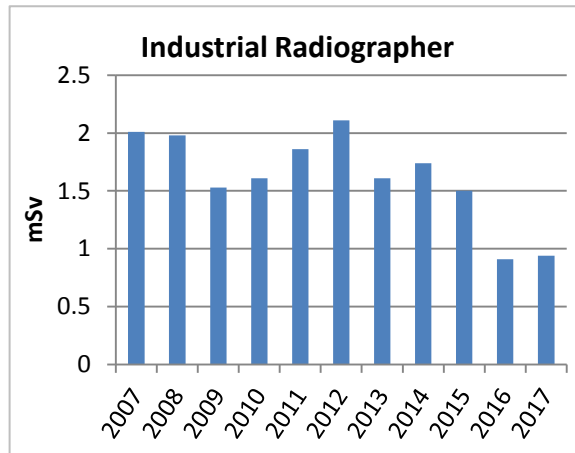
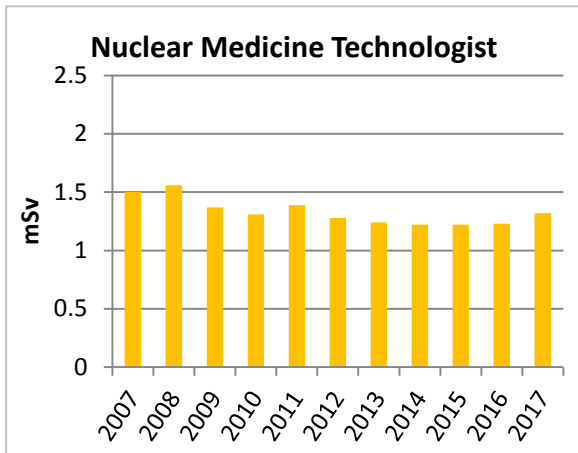
Year (# of workers)  
03-10-18

# of workers  
nuclearsafety.gc.ca



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# Commission Action – Additional Specificity of Worker Dose Statistics (Average Worker Dose)



Data are from “2017 Report on Occupational Radiation Exposures in Canada” published by Health Canada



# Performance results



**CNSC inspector measuring dose rates during an inspection**  
(Source: CNSC)



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## Safety Performance Highlights

- Licensees demonstrated satisfactory performance in the 5 SCAs covered in this report:
  - **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
  - **Environmental protection** – provisions in place to monitor and report releases to the environment. Only reported for waste nuclear substance sector.

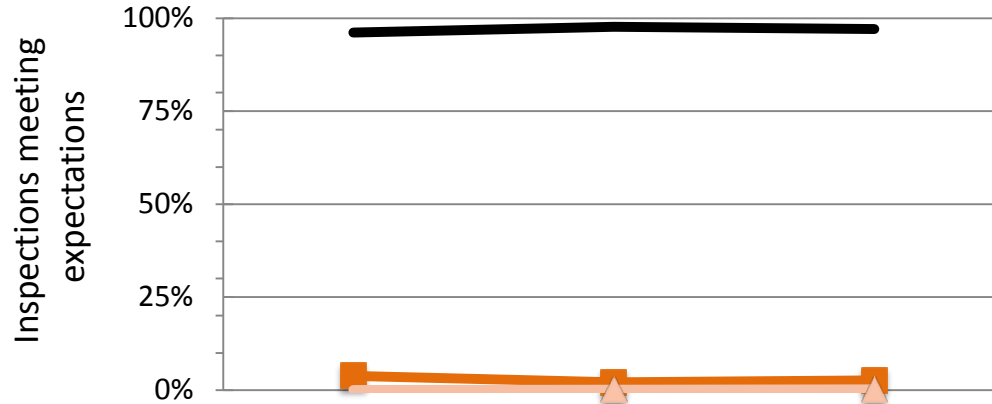




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# Evaluation of Management Systems (MS)

Order issued in one case of an unacceptable rating



	2015	2016	2017
— Fully satisfactory or satisfactory	1,241	1,265	840
■ Below expectations	49	27	23
▲ Unacceptable	0	2	2

Number of inspections



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# Evaluation of Management System for 2017

	Number of inspections					
	All sectors combined	Medical	Industrial	Academic and research	Commercial	Waste nuclear substance
Fully Satisfactory or Satisfactory	840	106	605	71	54	4
Below Expectations	23	4	14	2	3	0
Unacceptable	2	0	1	0	1	0
Total	865	110	620	73	58	4
<b>SCA % compliant</b>	<b>97 %</b>	<b>96 %</b>	<b>98 %</b>	<b>97 %</b>	<b>93 %</b>	<b>100 %</b>

**Strong performance across all sectors**

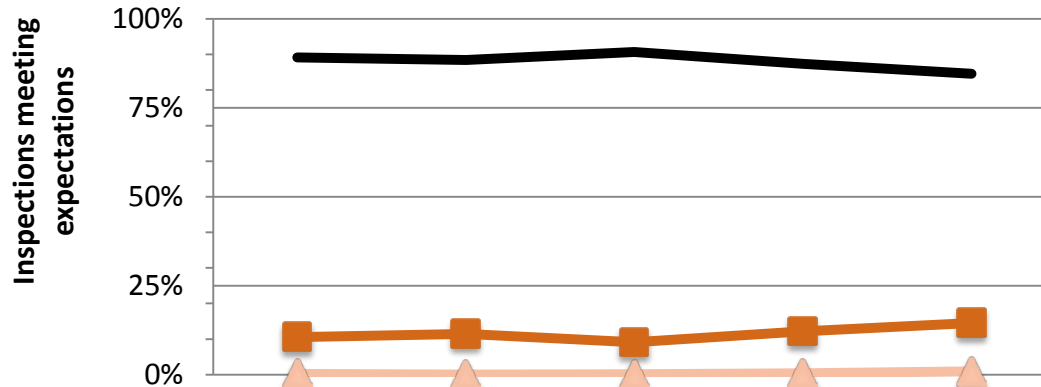


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# Evaluation of Operating Performance (OP)

All unacceptable OP ratings were given to portable gauge licensees

Orders issued in all 8 cases



	2013	2014	2015	2016	2017
— Fully satisfactory or satisfactory	1,406	1,269	1,189	1,151	747
■ Below expectations	166	164	120	161	128
▲ Unacceptable	4	1	2	5	8

Number of inspections



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# Evaluation of Operating Performance for 2017

	Number of inspections					
	All sectors combined	Medical	Industrial	Academic and research	Commercial	Waste nuclear substance
Fully Satisfactory or Satisfactory	747	100	511	73	59	4
Below Expectations	128	16	106	2	4	0
Unacceptable	8	0	8	0	0	0
Total	883	116	625	75	63	4
<b>SCA % compliant</b>	<b>85 %</b>	<b>86 %</b>	<b>82 %</b>	<b>97 %</b>	<b>94 %</b>	<b>100 %</b>

**Strong performance in waste, academic and research, and commercial sectors**



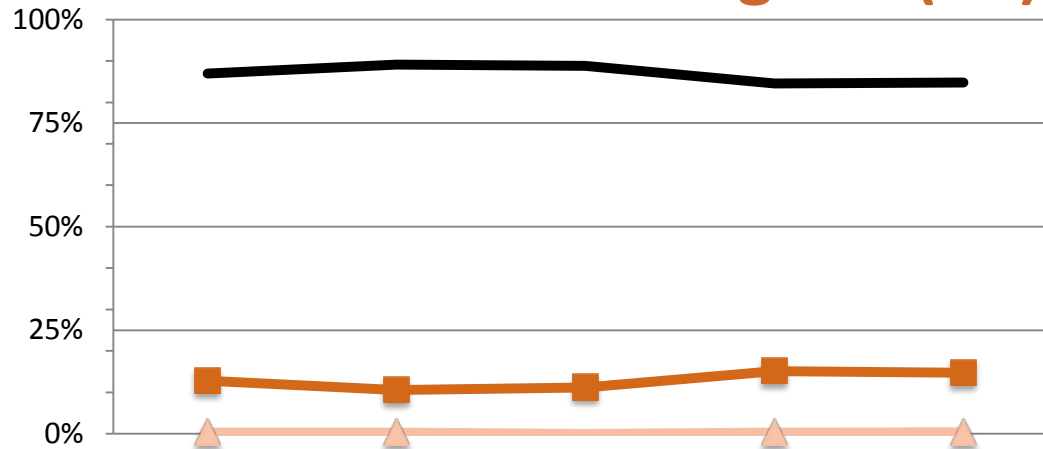
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# Evaluation of Radiation Protection Program (RP)

Orders issued in all cases of unacceptable RP ratings

Inspections meeting expectations



	2013	2014	2015	2016	2017
— Fully satisfactory or satisfactory	1,357	1,278	1,159	1,112	744
■ Below expectations	200	152	146	199	129
▲ Unacceptable	4	4	0	4	3

Number of inspections



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# Evaluation of Radiation Protection Program for 2017

	Number of inspections					
	All sectors combined	Medical	Industrial	Academic and research	Commercial	Waste nuclear substance
Fully Satisfactory or Satisfactory	744	94	518	69	59	4
Below Expectations	129	22	99	5	3	0
Unacceptable	3	0	3	0	0	0
Total	877	116	620	74	63	4
<b>SCA % compliant</b>	<b>85 %</b>	<b>81 %</b>	<b>84 %</b>	<b>93 %</b>	<b>94 %</b>	<b>100 %</b>

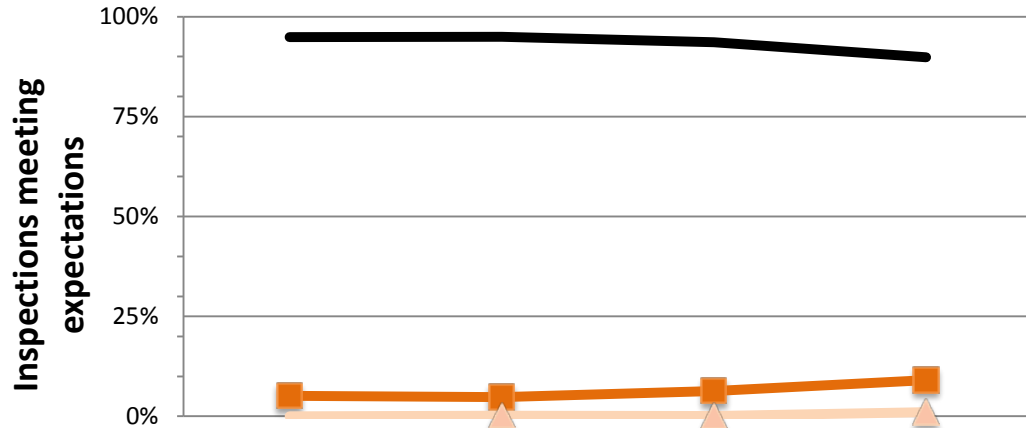
**Strong performance in waste, academic and research, and commercial sectors**



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# Evaluation of Security Measures

Orders issued in all cases of unacceptable ratings.



	2014	2015	2016	2017
— Fully satisfactory or satisfactory	1,274	1,157	1,159	764
■ Below expectations	69	59	78	77
▲ Unacceptable	0	2	1	9

Number of inspections



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## Evaluation of Security Measures for 2017

	Number of inspections					
	All sectors combined	Medical	Industrial	Academic and research	Commercial	Waste nuclear substance
Fully Satisfactory or Satisfactory	764	96	552	66	46	4
Below Expectations	77	22	49	3	3	0
Unacceptable	9	0	9	0	0	0
Total	850	118	610	69	49	4
<b>SCA % compliant</b>	<b>90 %</b>	<b>81 %</b>	<b>91 %</b>	<b>96 %</b>	<b>94 %</b>	<b>100 %</b>

**Licensees in all sectors have basic security measures in place**





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## Evaluation of Environmental Protection Measures

- Licensees' measures for protection of environment are dependent on activity
- Majority of DNSR licensees use sealed sources or radiation devices with no impact with environment
  - Designed to international standards, certified
  - Regular leak tests
- When unsealed sources are used, work practices, design of lab are assessed during licensing and verified during compliance activities
- CNSC oversight confirms no impact on the environment



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## Evaluation of Environmental Protection Measures for Waste Nuclear Substance Licensees

	Number of inspections				
	2013	2014	2015	2016	2017
Fully Satisfactory or Satisfactory	6	9	8	4	4
Below Expectations	0	0	0	0	0
Unacceptable	0	0	0	0	0
Total	0	0	0	0	0
<b>SCA % compliant</b>	<b>100 %</b>	<b>100 %</b>	<b>100 %</b>	<b>100 %</b>	<b>100 %</b>

**Licensees continue to manage and monitor releases**



# Event Reporting





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## Use of INES Scale for Radiological Events

- Provides a systematic, simple and internationally 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
- Events that could be rated as Level 1 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
- Events that could be rated as Level 2 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
- Events that could be rated as Level 3 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



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## Events Reported in 2017

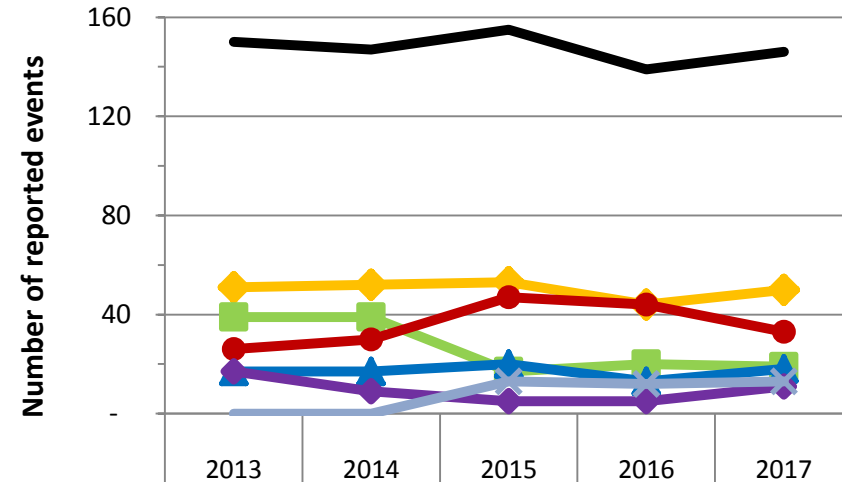
146 reported events

- All assessed by CNSC staff
- Total includes 1 fire and 1 flood at waste nuclear substance licensees

144 ranked INES level 0

1 ranked INES level 1

1 ranked INES level 2



	2013	2014	2015	2016	2017
Malfunctioning or damaged devices	51	52	53	44	50
Spills, contamination or release	39	39	17	20	19
Missing or found nuclear substances	17	17	20	13	18
Packaging and transport	26	30	47	44	33
Breach of security	17	9	5	5	11
Unplanned exposure	-	-	13	12	13
All reported events	150	147	155	139	146



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# Event Related to Lost or Stolen Radiological Sources in 2017

## 1 stolen portable gauge not recovered

- Device contains two low activity sealed sources (Category 4)
  - Am-241/Be
  - Cs-137
- Ranked Level 1 (Anomaly) on INES because it has not been found
- Police and CNSC notified at time of theft
- IAEA Incident Trafficking Database updated

**Risk to public low due to activity of sources involved**

INES Level	People and Environment	Radiological Barriers and Control	Defence-in-Depth
Level 7			
Level 6			
Level 5			
Level 4			
Level 3			
Level 2			
Anomaly Level 1			Low activity lost or stolen radioactive source, device or transport package
NO SAFETY SIGNIFICANCE (Below Scale/Level 0)			



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# Overexposure Event in 2017

## Nuclear energy worker at a hospital received dose in excess of 500 mSv extremity dose limit

- The equivalent dose to the hand was estimated by CNSC staff to be 2,366 mSv
- Incident (Level 2) on INES
- The event is closed
- CNSC staff performed a Type I inspection of the licensee involved
- Licensee is working to implement corrective actions from the inspection

### No adverse health effects have been reported

INES Level	People and Environment	Radiological Barriers and Control	Defence-in-Depth
Level 7			
Level 6			
Level 5			
Level 4			
Level 3			
<b>Incident Level 2</b>	Exposure of a worker in excess of the statutory annual limits.		
Level 1			
NO SAFETY SIGNIFICANCE (Below Scale/Level 0)			



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# REGULATORY DEVELOPMENTS





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# Trends in the Use of Nuclear Substances

## General trends in use

- Decrease in use of nuclear substances at universities, no decrease in licence numbers
- Decline in number of licences for sub-surface zone location and borehole tube tagging
- No longer any licensee for sub-surface tracer studies



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# Trends in the Use of Nuclear Substances

## Diversification of applications of nuclear technology

- Increased interest in diverse and novel sterilization applications
- Continued hybridization of medical equipment
- Introduction of intraoperative accelerators



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## Regulatory Focus in 2018

- Address decreasing compliance of portable gauge licensees with new resources for users and targeted communication with licensees
- Continuing the strategy for enhancing oversight of RSOs and radiation safety programs
- Verifying implementation of requirements in *REGDOC-2.12.3, Security of Nuclear Substances: Sealed Sources*
- Ongoing modernization of the regulatory framework
  - Drafting first revision of CSA PCP-09, *Certified Exposure Device Operator Personnel Certification Guide*
  - Publishing regulatory documents in development



Portable gauge being used at a  
construction site  
(Source: CNSC)



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# CLOSING REMARKS



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## Conclusion

Through licensing, inspections, reviews and assessments, staff conclude that licensees continued to maintain appropriate safety programs

- Licensee operations continued to be safe
- Licensees ensured that there is adequate and sufficient radiation protection in place for the health and safety of persons
- Licensees demonstrated that they have adequate provisions in place to ensure security of nuclear substances and prescribed equipment
- Whole body doses to workers continued to be low and below regulatory limits

## Continued Safe Use Of Nuclear Substances In Canada



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## ANNEXE – UPDATE ON THE EVALUATION PROJECT FOR ROLE OF THE RADIATION SAFETY OFFICER



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# Evaluation of the Role of Radiation Safety Officers

Work Breakdown	Status
<p>Phase 1 – Planning</p> <ul style="list-style-type: none"> <li>Developed Terms of Reference, data collection tools and formed the advisory committee</li> </ul>	Completed
<p>Phase 2 – Execution</p> <ul style="list-style-type: none"> <li>Conducted over 100 interviews with internal and external stakeholders ranging from CNSC staff, RSOs, applicant authorities, nuclear medicine technologists and auxiliary workers</li> <li>Administered 3 surveys and achieved a 74% response rate from RSOs</li> <li>Produced 11 case studies to better understand “what works for whom, in which context”</li> <li>Presented and validated emerging themes through a workshop at the Canadian Radiation Protection Association annual conference</li> </ul>	Completed
<p>Phase 3 – Reporting</p> <ul style="list-style-type: none"> <li>Completed preliminary findings report</li> <li>Draft final evaluation report (in approval process)</li> </ul>	In progress





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# ANNEXE – RATING METHODOLOGY



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## Rating Objectives

- Indicate to licensees where they need to focus effort and where they need to maintain current performance
- Provides overall picture to the Commission and the public
- Trending of ratings over time can inform regulatory program



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## Rating Definitions

- Each SCA is rated using a CNSC-wide standard rating system
  - FS – Fully Satisfactory
  - SA – Satisfactory
  - BE – Below Expectations
  - UA - Unacceptable



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# Overview of Rating Methodology



Identify Compliance Results

ROR presents aggregate ratings from inspections

Assess Compliance Results

- SCA grades for inspections
- Class II licences
    - Team consensus based on established criteria
  - Nuclear substances licences
    - Algorithm based on relative risk of regulatory requirements
  - Waste nuclear substance licences
    - FAC Team consensus

Rate Performance

Group licensees by sector

Calculate percentage of licensees in each sector that have grades of FS/S, BE, or UA for SCAs presented in the ROR