Canada's Nuclear Regulator

Regulatory Oversight Report on the Use of Nuclear Substances in Canada: 2015

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

Canada

Regulatory Oversight Report on the Use of Nuclear Substances in Canada: 2015

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1 Background

The Canadian Nuclear Safety Commission (CNSC) regulates the use of nuclear energy and materials to protect health, safety, security and the environment; to implement Canada's international commitments on the peaceful use of nuclear energy; and to disseminate objective scientific, technical and regulatory information to the public. Persons licensed by the CNSC are responsible for operating their facilities and managing their activities safely and are required to implement programs that make adequate provisions for protecting health, safety, security and the environment. The CNSC is responsible for setting the requirements and verifying compliance against those requirements.

Each year, CNSC staff assess the overall safety performance on the use of nuclear substances in Canada. Staff consider industry performance as a whole, as well as the performance of each sector (i.e., medical, industrial, academic and research, and commercial) separately. This assessment is summarized in this document.

For a comprehensive overview of the CNSC and its activities, consult the CNSC's annual report, *Regulating Nuclear Safety in Canada*.

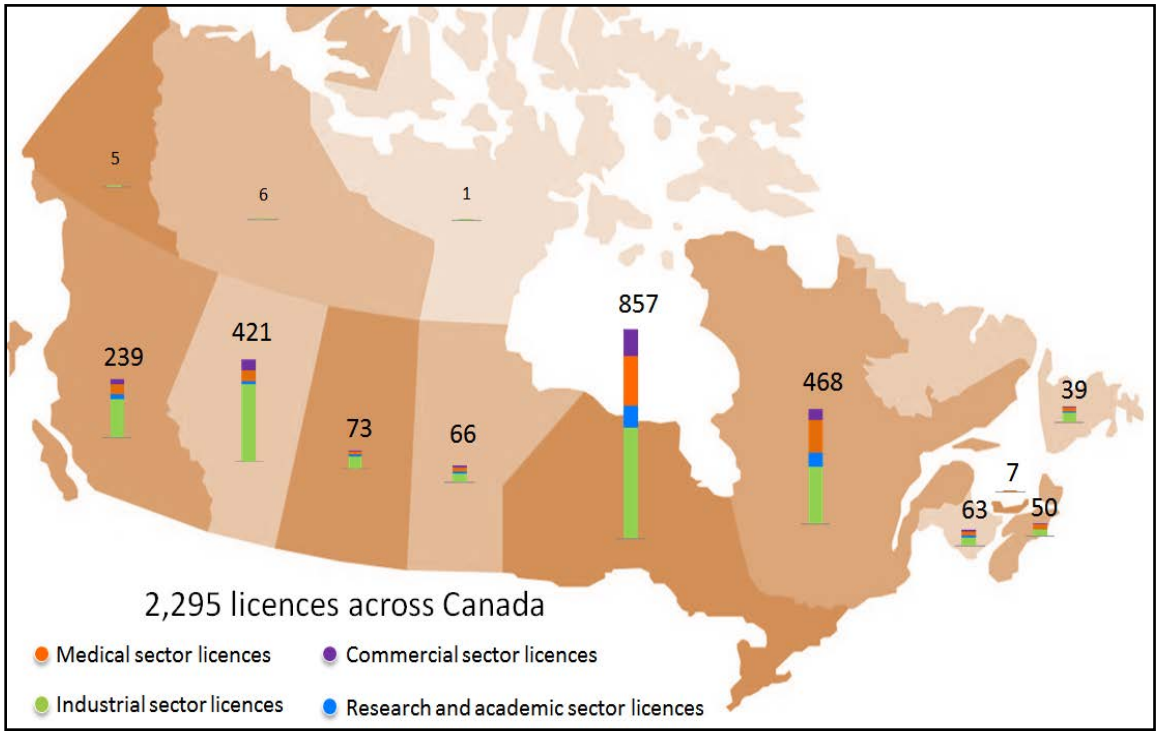
Regulatory oversight

The CNSC regulates the nuclear industry in Canada through a comprehensive program of licensing, certification, compliance verification and enforcement. For each nuclear industry sector described in this report, CNSC staff evaluate safety performance through inspections, assessments, reviews and evaluations of licensee programs and processes.

These regulatory programs cover various types of activities across all provinces and territories, as shown in Figure 1. Licensees include most hospitals in Canada, most Canadian universities and research institutions, and a wide variety of industrial manufacturing and production facilities including those that store, produce or service nuclear substances and devices.

The safe use of nuclear substances in Canada is demonstrated through licensees' compliance with the *Nuclear Safety and Control Act* (NSCA) as well as its associated regulations, and specific conditions set out in CNSC licences. The NSCA, its regulations and the licences require that licensees implement and maintain appropriate programs to ensure the safety and security of nuclear-related activities, minimize doses to workers and the public, protect the environment, and minimize consequences of events.

Figure 1: Map of Canada including examples of licensee locations



Safety and control area framework

To ensure comprehensive regulatory oversight and reporting of licensed activities, CNSC staff have developed a set of safety and control areas (SCAs). SCAs have been in use for a number of years, and represent a well-established set of technical areas that have proven effective in evaluating licensee safety performance of regulated facilities and activities under the CNSC's purview. The CNSC has defined 14 SCAs:

- management system
- human performance management
- operating performance
- safety analysis
- physical design
- fitness for service
- radiation protection
- conventional health and safety
- environmental protection
- emergency management and fire protection
- waste management
- security
- safeguards and non-proliferation
- packaging and transport

2 Report overview

This regulatory oversight report focuses on the results of compliance verification and enforcement activities in 2015 for licensees that use nuclear substances in four sectors:

- medical
- industrial
- academic and research
- commercial

Each sector performance is outlined in an individual section in this report.

The report does not cover uranium mines and mills, waste facilities, dosimetry services or Class I nuclear facilities such as nuclear power plants and nuclear research reactors. Also excluded as of 2015 are Class IB accelerator facilities, which will be covered in the *Regulatory Oversight Report for Nuclear Processing, Small Research Reactors and Class IB Accelerator Facilities*.

There are three parts to this report:

- regulatory process and developments
- overall industry safety performance assessment
- sector-specific safety performance assessments

2.1 Safety performance measures

CNSC staff review licensee documents and conduct field inspections to verify that licensees have implemented effective safety programs and practices. Results of these inspections provide information on key aspects of safety performance, within each SCA relevant to the licensed activity.

For the purpose of this report, the following four SCAs are the most relevant indicators of safety performance for licensees in the sectors covered in this report: management system, operating performance, radiation protection, and security. Compliance ratings – also referred to as inspection ratings – reflect overall licensee performance at a program level for each of these SCAs. The nature, type and safety significance of events reported by licensees, and the type of enforcement actions taken by the CNSC in 2015 are provided as supplementary indicators of safety performance. Data from 2011 to 2014 are included in figures for each of these safety indicators to identify five-year trends. Each performance measure is described below.

2.1.1 Doses to workers

All licensees are required to implement a radiation protection program that ensures that the radiation doses to workers are well below regulatory limits and kept as low as reasonably achievable (ALARA), with social and economic factors taken into account. Thus, ascertainment of the magnitude of doses received by workers is an integral part of a licensee's radiation protection program.

This report references two groups of workers that perform the types of work referenced in a CNSC licence: those designated as nuclear energy workers (NEWs) and those that are not designated as NEWs. The term NEW means a person who is required, in the course

of his or her business or occupation in connection with a nuclear substance or nuclear facility, to perform duties in circumstances that may result in receiving a dose of radiation greater than 1 millisievert (mSv) per year. A worker not designated as a NEW means a person who is unlikely to receive a dose greater than 1 mSv per year while performing duties in connection with a nuclear substance or nuclear facility. This report provides dose information for all workers, while primarily focusing on those designated as NEWs.

The CNSC's regulatory effective dose limits for NEWs are set at 50 mSv in any one-year dosimetry period and a total of 100 mSv over a five-year dosimetry period. The one-year dosimetry period covers January 1 to December 31 of every year. The five-year dosimetry period covered in this report started on January 1, 2011 and ended on December 31, 2015. During this period, none of the NEWs exceeded the five-year regulatory dose limit of 100 mSv. For all persons not designated as a nuclear energy worker, and for all members of the general public, the effective dose limit is 1 mSv per calendar year.

For activities where there is a need for direct handling of nuclear substances, doses to the hands are also monitored. These are known as extremity doses, and they are subject to a regulatory dose limit of 500 mSv in any one-year dosimetry period for NEWs and 50 mSv per calendar year for workers not designated as NEWs. The concept of a five-year dosimetry period is applied to neither extremity doses nor to the effective doses incurred by persons who are not NEWs.

Appendix A provides more information on occupational exposure, ascertaining worker doses and measures to be taken by licensees when a dose limit is exceeded.

2.1.2 Management system

For 2015, the regulatory oversight report now includes results of inspections ratings for the management system SCA. The sector-by-sector comparison is included in the overall section of the report and a summary of the inspection ratings is included for each sector.

The management system SCA covers the framework that establishes the processes and programs required to ensure that an organization achieves its safety objectives, continuously monitors its performance against those objectives, and fosters a healthy safety culture.

2.1.3 Operating performance

Operating performance refers to the licensee's ability to perform licensed activities in accordance with pertinent operational and safety requirements defined in the NSCA, its associated regulations and licence conditions. Licensees are expected to demonstrate that they comply with operational and safety requirements by providing workers with appropriate procedures for the safe use of nuclear substances and prescribed equipment, by ensuring that workers follow procedures, and by maintaining records that demonstrate compliance. Operating performance is also referred to as "operational procedures" in the inspection reports provided to licensees of nuclear substances and radiation devices. Appendix B shows the mapping between the CNSC regulatory naming convention in the inspection reports and those presented in this report for SCAs.

2.1.4 Radiation protection

Radiation protection programs are required for every licensee to ensure that contamination levels and radiation doses received by workers are monitored, controlled and maintained below regulatory dose limits, and kept ALARA, social and economic factors being taken into account. Licensees can meet these objectives by monitoring worker doses; posting radiation warning signs; planning appropriately for radiological emergencies; managing oversight of operational activities; instituting effective workplace practices that emphasize the use of time, distance and shielding to minimize exposure to radiation; and using appropriate protective equipment.

2.1.5 Security

The security SCA covers the physical security measures, practices and programs that licensees are required to have in place to prevent the loss, illegal use, illegal possession or illegal removal of nuclear substances during their entire lifecycle, including while they are in storage or during transport. The extent of the security measures required depends upon the types of nuclear substances used and activities performed by each licensee.

The safety and security of sealed sources is increased through effective control and tracking. Routine CNSC compliance inspections include requirements to verify sealed source tracking information.

To ensure proper regulatory oversight of the new requirements related to the phased implementation of REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources*, CNSC staff conduct enhanced security inspections for those in possession of category 1 and 2 sealed sources. Non-compliance details for these inspections are not included in this report due to their sensitive nature.

2.1.6 Enforcement actions

The CNSC may take a variety of compliance enforcement actions to ensure that licensees correct non-compliances in an effective and timely manner. The type of enforcement action taken is commensurate with the risk the non-compliance presents to the environment, the health and safety of workers and the public, and to national security. This report provides detailed information on the following types of enforcement actions taken by the CNSC: orders, administrative monetary penalties (AMPs), decertification of certified exposure device operators and decertification of radiation safety officers at Class II nuclear facilities. Appendix C provides a list of all orders and AMPs issued by the CNSC in 2015.

2.1.7 Reported events

Under the NSCA and its associated regulations, licensees are required to immediately report to the CNSC events related to their licensed activities that are of regulatory interest. Within 21 days of the initial report, licensees are required to submit a final report to the CNSC on the event. The final report must include an analysis of the cause and circumstances of the event, as well as any measures taken, or proposed to be taken, by the licensee to prevent recurrence. Together, the initial and final reports allow the CNSC to verify whether the licensee has taken appropriate measures to mitigate the event, and implemented adequate corrective actions to prevent recurrence.

The CNSC uses the International Nuclear and Radiological Event Scale tool to categorize events in the sectors covered by this report. Additional information on the INES classification can be found on the CNSC website.

2.2 Data collection

Compliance ratings, non-compliance data, and CNSC enforcement actions were obtained from the CNSC's compliance verification and enforcement program in 2015.

Annual compliance reports submitted by licensees in calendar year 2015 provided the data on doses incurred by all persons engaged in licensed activities in the four sectors covered in this report.

2.3 Changes in 2015

Under the Commission's direction, CNSC staff introduced the following changes:

- As of 2015, performance results for Class IB accelerator facilities will now be covered under the *Regulatory Oversight Report for Nuclear Processing, Small Research Reactors and Class IB Accelerator Facilities*.
- Compliance ratings for the management system SCA will be included in the report's overall section.
- A list of all reported events from the four sectors covered has been included as appendix D

3 Regulatory program for the use of nuclear substances

The possession, use, transfer, import, export, abandonment and storage of nuclear substances must be licensed by the CNSC when the amount of nuclear substance involved is greater than its exemption quantity (see Schedule 1 of the *Nuclear Substances and Radiation Devices Regulations*). Facilities where certain types of Class II prescribed equipment are installed must also be licensed by the CNSC prior to their construction, operation or decommissioning. A licence is also required to service radiation devices or Class II prescribed equipment.

All licensees that operate Class II nuclear facilities or that service a Class II prescribed equipment must have a certified radiation safety officer and a qualified temporary replacement. The radiation safety officer has the responsibility of the radiation protection program, ensuring that licensed activities are conducted safely and that all regulatory requirements are met.

All radiation devices and Class II prescribed equipment, as well as certain types of transport packages, must be certified by the CNSC before they can be used in Canada.

An integral part of the CNSC's regulatory oversight is the compliance and verification program, which measures licensee compliance with CNSC regulatory requirements. Regular inspections and desktop evaluations verify that licensees comply with the *Nuclear Safety and Control Act* (NSCA) and its associated regulations, as well as the conditions of their licences.

To determine appropriate levels of regulatory monitoring and control, CNSC staff establish compliance verification plans for each nuclear sector that are based on risk-informed regulatory oversight of each sector's activities. Modifications to the compliance plans are made on an ongoing basis in response to events and changes in licensees' performance.

For the activities covered in this report, the CNSC's risk-informed regulatory program is applied in the following way:

- Each licensed activity is assigned a weighting factor – a coefficient that represents the activity's relative significance with respect to risk.
    - Factors considered in weighting include the form of the nuclear substances (e.g., sealed source, unsealed source or radiation device), the location where the material is being used (e.g., a work site or a controlled facility), and the compliance history of licensees conducting licensed activities.
- Generally, licensees are inspected at a predetermined frequency of five years or less, based on their risk ranking.

The risk-informed regulatory program provides:

- a risk ranking that recognizes the potential safety impact of the licensed activity
- an effective and informed allocation of regulatory oversight effort according to the risk ranking by licensed activity and by licensee performance history
- an effective, transparent, consistent and comprehensive regulatory oversight

3.1 CNSC regulatory effort

The CNSC's risk-informed regulatory program applies resources and regulatory oversight commensurate with the risk associated with the regulated activity. Regulatory effort related to licensing, certification and compliance verification is derived from this program. A total of 1,568 inspections were completed in 2015. As shown in Table 1, the CNSC staff direct effort for regulating the use of nuclear substances in 2015 amounted to close to 13,400 person days or the annual equivalent of approximately 59 full-time staff.

Table 1: CNSC staff direct effort for regulating the use of nuclear substances in 2015, all sectors combined

Activity	Person days
Licensing	5,015
Certification	1,564
Compliance verification	7,372

3.2 Licensing

To obtain a licence, an applicant must submit an application to the CNSC. The CNSC will issue a licence only when the applicant:

- is deemed qualified to carry on the activity that the licence will authorize
- has demonstrated that it will protect the health and safety of persons and the environment
- has demonstrated that it will maintain national security
- has confirmed that it will adhere to international obligations to which Canada has agreed

CNSC staff perform a rigorous technical assessment of applications submitted to the CNSC. Each is assessed based on the risk ranking of proposed licensed activities.

The CNSC has produced a series of licence application guides that outline application expectations to ensure that the CNSC's expectations for licence applications are clear and to facilitate applicants' interactions with the regulator. These guides are reviewed regularly to ensure they continue to reflect modern regulatory expectations and provide useful guidance to the regulated community. This practice, in turn, facilitates CNSC licensing reviews and minimizes regulatory burden. Application forms and guides can be found on the CNSC website for nuclear substances and radiation devices as well as for Class II facilities and prescribed equipment.

When applying for licence renewals, existing licensees are subject to the same scrutiny as new applicants. The CNSC decision to renew a licence is based on the application information submitted as well as a satisfactory compliance performance history. This includes a review of compliance information such as inspection results, reported incidents and events, and annual compliance reports.

If the application satisfies the above requirements, the Commission, or a designated officer authorized by the Commission, may issue a licence authorizing the licensee to

conduct the activities requested in the application. The licence includes provisions that define and limit the scope of the authorized activities, as well as specific conditions that must be fulfilled by the licensee when conducting those activities.

3.2.1 Licence consolidation strategy

The CNSC has developed a licence consolidation strategy aimed at reducing administrative burden on organizations that hold multiple licences for various licenced activities such as hospitals and universities. This strategy included creating and issuing new consolidated licences for Class II nuclear facilities as well as reviewing the licence format and process for those that use nuclear substances and radiation devices.

Consolidation of Class II nuclear facility licences has allowed the CNSC to, for example, authorize a hospital with a medical linear accelerator to operate and service the accelerator under one licence instead of two. In other cases, it has allowed cancer centres to include several types of radiotherapy activities to be covered under a single licence instead of as many as five. In some cases, such as operating a cyclotron and radiation therapy facilities, licence consolidation is not desired since each licensee's radiation protection program and management structure is different.

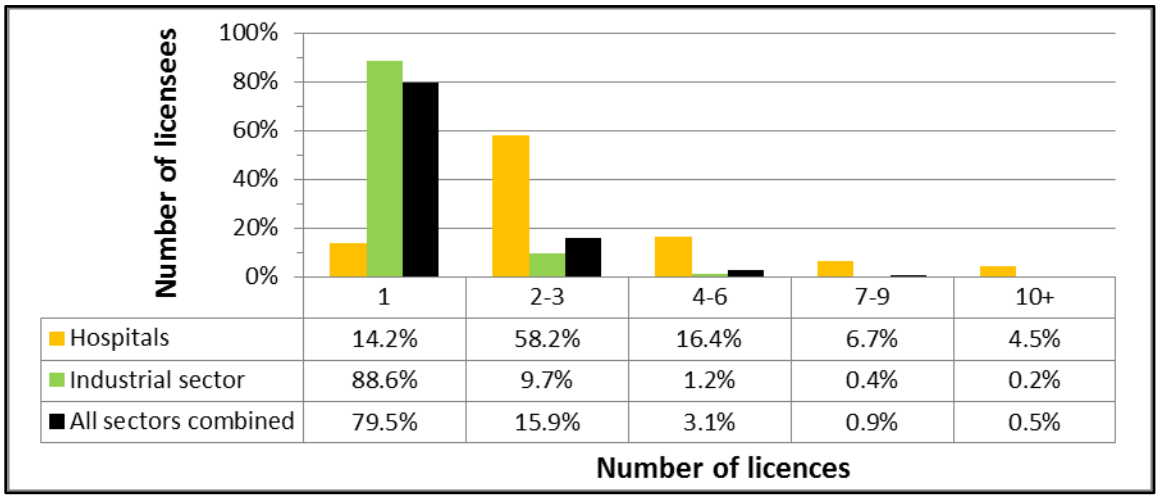
The majority of licences issued through the Directorate of Nuclear Substance Regulation are for the possession and use of nuclear substances and radiation devices. A comprehensive evaluation of the licensing process will be conducted in early 2016 as the first part of the implementation strategy to streamline the application process and reduce the number of licences required. Due to the number of licences and the volume of ongoing work, changes to the licensing approach must be carefully considered to minimize the impact on licensees. CNSC staff will continue to work with stakeholders, including the Canadian Radiation Protection Association/CNSC Working Group, to ensure that proposed changes will not adversely impact their operations while retaining strong regulatory oversight. As part of an ongoing improvement process, CNSC staff continue to review the licensing application guide and forms to clarify expectations for applicants. This led to the October 2015 revision of REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices*, which provided greater clarity and simplified requirements for applicants.

The number of licences issued by sector is shown in table 2 and the distribution of licences by select groups is provided in figure 2. Most licensees, as represented by the industry sector, perform one licensed activity and, therefore, require only one CNSC licence. Hospitals tend to conduct various licensed activities, such as diagnostic nuclear medicine, cancer therapy, production and processing of nuclear medicine isotopes and human research. These disparate activities are covered under specific CNSC licences which reflect the unique characteristics of such uses. As a result, hospitals typically hold more than one CNSC licence. In addition, a number of provinces are in the process of combining the administration of several hospitals under new provincial authorities. CNSC staff will continue to work with these licensees to ensure that there is the appropriate level of regulatory control while minimizing administrative burden wherever possible.

Table 2: Number of licences by sector, 2011–15

Sector	2011	2012	2013	2014	2015
Medical	568	561	552	536	494
Industrial	1,456	1,451	1,440	1,398	1,349
Academic and research	276	253	232	229	207
Commercial	250	248	256	248	245
Total	**2,550**	**2,513**	**2,480**	**2,411**	**2,295**

Figure 2: Distribution of licences, comparison of hospital licensees against licensees in the industrial sector and all sectors combined



3.3 Certification of prescribed equipment

An application for certification must be submitted to the CNSC before the prescribed equipment can be used in Canada. CNSC staff who conduct the technical evaluations of applications for certification are accredited as professional engineers as part of their job requirements. Upon receipt of an application, CNSC staff conduct a thorough technical review of the information contained in the submission to determine if:

- the radiation device, Class II prescribed equipment or transport package meets all CNSC regulatory requirements and is safe to use
- adequate measures are in place in respect of their use in order to protect the environment, national security, and the health, safety and security of persons

A CNSC quality assurance program, in the form of a peer review by another CNSC staff member, is in place for the review of new applications for certification of prescribed equipment and those where significant changes are made to the original design.

If satisfied that the design meets the above requirements, the Commission, or a designated officer authorized by the Commission, may issue a certificate for the radiation device, Class II prescribed equipment or transport package based on the recommendation of the CNSC staff member who conducted the technical evaluations.

If the design does not comply with the above requirements or if a certified model is found to be unsafe, the designated officer will contact the applicant and all affected parties, such as users in the case of a certified model, to inform them of the decision to either not certify the new model or to decertify a currently certified model. In these cases, the CNSC will provide the applicant and affected parties an opportunity to be heard in accordance with the process specified in the regulations.

Regulatory documents RD/GD-254, *Licence Application Guide: Certification of Radiation Devices or Class II Prescribed Equipment* and RD/GD-352, *Design, Testing and Performance of Exposure Devices* outline CNSC expectations for the certification of radiation devices and Class II prescribed equipment, while RD/GD 364, *Joint Canada - United States Guide for Approval of Type B(U) and Fissile Material Transportation Packages*, outlines CNSC expectations for the certification of transport packages. CNSC staff are reviewing RD/GD-254 and RD/GD-352 as part of the CNSC's commitment to maintaining a modern regulatory framework.

3.4 Certification of exposure device operators

In 2015, the CNSC certified 141 new exposure device operators (EDO) and renewed the certification of 240 certified EDOs.

Licensees are required under the *Nuclear Substances and Radiation Devices Regulations* to permit only CNSC-certified personnel and supervised trainees to use exposure devices containing nuclear substances. In industrial radiography, nuclear substances are used in exposure devices for the non-destructive examination of materials.

The CNSC EDO certification program is designed to ensure the continued competency of the operator, and maintain the safety and security of persons and devices when working with exposure devices. Certified individuals must demonstrate the ability to:

- handle, transport, store and operate exposure devices and any accessories to the devices safely and securely
- properly utilize radiation detection and monitoring equipment
- understand the obligation to comply with all relevant regulatory requirements

Since the CSA Group implemented its *Certified Exposure Device Operator Personnel Certification Guide* (CSA PCP-09) in 2015, certified EDOs must renew their certification every five years. This ensures that every certified EDO maintains the knowledge and skills required to operate an exposure device safely. To verify that EDOs have valid certifications, CNSC inspectors check EDO certification cards during inspections.

The CNSC may take regulatory action if the EDO is found to be operating contrary to safety protocols and conditions, or if the EDO is causing undue risk to the public or the environment.

3.5 Certification of Class II radiation safety officers

All licensees that operate Class II nuclear facilities or that service Class II prescribed equipment must have a certified radiation safety officer (RSO) and a qualified temporary replacement. The RSO ensures that licensed activities are conducted safely and all regulatory expectations are met.

There are two components to the RSO certification process:

- an assessment of the candidate's capabilities to perform the duties of the position, based on the submitted application
- an assessment of the candidate's knowledge of the licensed activities, based on an examination

RSO candidates must possess certain qualifications before they can be considered for certification. For most Class II licensed activities, candidates must have at least a bachelor's degree in engineering or science from a recognized university.[1] Alternative education qualifications may be reviewed on a case-by-case basis.

If the candidate is able to clearly demonstrate their knowledge, as it relates to the RSO position within their organization, the Commission or a designated officer authorized by the Commission may certify the candidate in the position of RSO.

The process for certification of Class II RSOs, along with guidance for applicants, is outlined in *REGDOC-2.2.3, Personnel Certification: Radiation Protection Officers*.

In 2015, the CNSC certified 17 of 19 applicants as Class II RSOs. In both cases where applicants failed to meet certification requirements, the licensee nominated another person to serve as RSO.

3.5.1 Class II RSO examination

The content of the examination focuses on five subjects:

- relevant provisions of the NSCA and its ensuing regulations
- principles of radiation safety
- radiation physics
- operational activities and facilities which are to be licensed by the CNSC
- radiation protection program of the facility

The content of the examination is tailored to:

- the operational risks of the licensed activity
- the organization's policies and procedures
- the candidate's academic background and work experience

Since the implementation of the certification of Class II RSO in 2005, the CNSC has certified approximately 200 RSOs. The CNSC plans to administer all Class II licence application examinations online in late 2016. (Examinations are currently conducted orally, either in person or over the telephone.) The change is expected to assist the CNSC enhance objectivity when examining candidates, and shorten the certification process for each candidate.

[1] Exceptions may be made for certain lower risk activities, such as the operation of mobile industrial accelerators and oil well logging accelerators.

3.6 RSO appointment for nuclear substances and radiation device licences

There are approximately 2,300 RSOs appointed for nuclear substances and radiation device licences. The designation of RSO for nuclear substances and radiation devices licences is the responsibility of the person responsible for the management and control of the licensed activity. The RSO is the person the CNSC will contact about radiation safety and compliance matters. The appointment of these RSOs does not involve a certification process.

The CNSC requires the RSO's qualifications be included in a licence application and will determine if the RSO has sufficient knowledge and expertise with regards to the applicant's proposed activities. The RSO may be a consultant hired by the applicant to carry out this role, provided that the consultant is clearly designated by the applicant authority to do so. Such information must be communicated to the CNSC as part of the licence application process. Alternate RSOs may be utilized where a licensee has multiple locations of licensed activity.

Unless otherwise noted by the applicant authority, the RSO will be considered to have the authority to act for the applicant and will have signing authority for all matters encompassed by the CNSC licence.

For high-risk activities, CNSC staff perform additional verifications. They meet with applicant RSOs during a pre-licensing visit to verify the RSO's knowledge of the company's radiation protection program and confirm the applicant's understanding of their obligations as a licensee. Staff plan visits and prepare the interview following review of the application and the applicant's radiation protection program. During the visit, CNSC staff review the location of the proposed licensed activities while ensuring that candidates have strong radiation safety knowledge as well as advanced training in operational and emergency procedures. If it is deemed that the appointed RSO does not have adequate knowledge, the licensing decision will be pending on the appointment of a suitable RSO.

3.7 Licensing and certification decisions

In 2015, CNSC designated officers made a total of 2,579 licensing and certification decisions. The majority of these were licensing decisions in relation to activities covered in this report, as shown in Table 3. In addition, the Commission amended 2,332 licences in 2015 to include licence conditions related to new requirements for financial guarantee and security of sealed sources.

Even after factoring for this increase in the number of licence amendments, there was an increase in the number of licensing decisions made in 2015. This increase was partly due to the cyclical nature of licence renewals as well as an increase in the number of licence transfers. For every new licence transfer, such as when there is a change to the corporate number, the old licences are revoked and a new licence is issued under the new corporate number. The CNSC has developed a simplified licence transfer form to facilitate these transactions.

Table 3: Licensing and certification decisions in 2015, all sectors combined

Type of decision	Number of decisions
Licensing (issuance of new licences, licence renewals, licence amendments, licence revocations and licence transfers)	2,089
Certification of prescribed equipment (radiation devices, Class II prescribed equipment and transport packages)	92
Certification of EDOs (issuance of new certification and renewal of certification	381
Certification of Class II RSOs	17
Total	**2,579**

3.8 Compliance verification and enforcement

The CNSC verifies compliance by conducting site inspections and reviewing licensee documentation and operational activities. Licensees are required to report routine performance data through annual compliance reports and the occurrence of specific types of events. In addition, the CNSC conducts investigations of unplanned events, public complaints or accidents involving nuclear substances.

The CNSC uses a graded approach to enforcement to encourage compliance and deter future non-compliances. When a non-compliance (or a continued non-compliance) has been identified, CNSC staff assess its risk and safety significance in order to determine appropriate enforcement action. The chosen enforcement action is commensurate with the risk that the non-compliance presents to the environment, the health and safety of workers and members of the public, and to national security. Enforcement actions vary with non-compliance severity, and can include orders and administrative monetary penalties. Each is a discrete and independent response to a non-compliance.

In 2015, CNSC staff conducted 1,568 inspections to verify compliance with CNSC regulatory requirements, including 217 enhanced security inspections to verify compliance against the requirements of REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources*. Escalated compliance enforcement actions were taken against licensees in the medical, industrial, academic and research, and commercial sectors in 21 instances. The majority of them were in response to inspection findings.

As part of CNSC staff efforts to consolidate compliance activities, the CNSC transferred compliance verification activities related to the import and export of high-risk sealed sources in the sectors covered in this report to the Directorate of Nuclear Substance Regulation. Field inspections were initiated in 2016. Additional information on the results of these inspections will be included in the 2016 edition of this regulatory oversight report.

3.8.1 Mobile Inspection Kit project

Also part of the CNSC's continuous improvement process, the Mobile Inspection Kit (MIK) project makes use of new technologies to better equip CNSC inspectors in performing their compliance verification activities. The CNSC's MIK is an electronic application developed for use on a tablet. As shown in Figure 3, the MIK enables CNSC inspectors to easily capture inspection findings and results, generate inspection reports, and transfer inspection data to CNSC databases electronically.

The MIK project was launched as a two-phase pilot in 2014. The first phase involved a group of CNSC inspectors performing a few inspections and gathering feedback on how the tool and process could be improved. In late summer 2015, additional CNSC inspectors were equipped with tablets in a much wider pilot. The second phase of the pilot project involved the development of an online portal through which licensees will be able to download preliminary inspection reports about their facilities and activities. This version was released in the spring of 2016, and further piloting of this final phase will occur over the year. The pilot phase of the project is expected to be completed in late 2016.

Figure 3: CNSC inspector using a MIK tablet during an inspection

While the feedback gathered so far shows that some items still need to be addressed, tablets clearly have a useful and significant role to play in a mobile regulatory environment. In September 2015, the Canadian Association of Members of Public Utility Tribunals (CAMPUT) presented the 2015 CAMPUT Award for Innovation and Leadership to the CNSC for the MIK project.

Building on collaboration with the Community of Federal Regulators in 2014, CNSC staff delivered a tailored presentation on the MIK project to Transport Canada and the National Energy Board. Both organizations plan to launch similar initiatives.

3.9 Reporting

Licensees are expected to meet all regulatory reporting requirements, as prescribed in the NSCA, its associated regulations and their licence conditions. In addition to the submission of their annual compliance reports on licensed activities, licensees are required to immediately report on specific types of events related to licensed activities that require immediate mitigating measures by the licensee.

3.10 Stakeholder engagement

Clarity of requirements is one of the CNSC's corporate priorities. Stakeholder engagement and outreach are two tools the CNSC uses to meet this priority. Outreach and engagement lead to an increased awareness and better understanding of the regulatory process and requirements. These, in turn, lead to increased workplace safety. CNSC staff take all opportunities to perform outreach, including while on inspection.

Outreach sessions held throughout Canada in 2015 provided licensees and other persons the opportunity to interact with the regulator outside the scope of an inspection or licensing activities.

3.10.1 Outreach sessions

Since 2009, the CNSC has offered an outreach program for licensees that use nuclear substances and prescribed equipment. The presentations made by CNSC staff and discussions associated with outreach are meant to inform licensees and other persons regulated by the CNSC on recent and upcoming regulatory changes, and provide education regarding the CNSC's expectations for licensing and compliance requirements.

In 2015, the CNSC outreach program addressed recent and upcoming regulatory developments and other areas of regulatory focus, such as:

- the importance of maintaining proper inventory control of nuclear substance and prescribed equipment
- the importance of reviewing previously approved procedures
- changes to the CNSC licensing program such as financial guarantees and a revised licence application guide
- changes to the compliance verification program, such as the use of MIK tablets among inspectors and electronic inspection reports
- reporting requirements related to skin contamination events
- reporting requirements related to annual compliance reports
- the new *Packaging and Transport of Nuclear Substances Regulations, 2015*

- new security expectations in REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources*
- upcoming changes to the *Radiation Protection Regulations*

3.10.2 Newsletters

In 2009, the CNSC introduced the *DNSR Newsletter* as an outreach vehicle for disseminating regulatory and safety information to licensees that use nuclear substances and prescribed equipment in Canada. The newsletter articles address various regulatory compliance issues and support the regulator's commitment to keep both licensees and the public informed. Regular editions of the newsletter provide valuable information to licensees in all sectors; special editions focus on either a specific subsector or an area of regulatory interest.

All newsletters are posted on the CNSC website and are sent to recipients on the CNSC subscription list. In addition, in 2015, CNSC added direct delivery of the newsletter to licensee RSOs by email in order to better reach its target audience and improve distribution among licensees and their workers.

Two DNSR Newsletter editions were published in 2015: one regular and one special edition. The regular edition provided information on the financial guarantee program, reported events presented to the Commission during the past year, and the discussion paper DIS-14-02, *Modernizing the CNSC's Regulations*. The special edition focused on the importance of maintaining control of sealed sources and how to prevent loss of control.

3.10.3 Industrial radiography working group

In 2009, a CNSC industrial radiography working group was established to foster improved communications between the CNSC and the industry. The working group meets twice a year to discuss best practices and safety performance, and provides a forum in which stakeholders can stay informed of new developments from both technical and regulatory perspectives. The CNSC holds two separate annual meetings with the radiography industry-at-large, one in Leduc, AB, and the other in Ottawa, ON. Staff use these meetings to address recent and upcoming regulatory developments and discuss other areas of regulatory focus. The meetings act as a venue for industry members to communicate with CNSC staff, ask questions and share information on best practices and lessons learned. Staff routinely provide and discuss trending data on compliance with regulatory requirements.

In 2015, several presentations were delivered on the EDO certification process (PCP-09) implementation from both CNSC and Natural Resources Canada perspectives. Guest presentations were delivered on the importance of maintenance and inspection of exposure devices and on safety culture. The meeting in Leduc, AB, was attended by approximately 70 participants. The meeting in Ottawa, ON, was the best-attended annual eastern meeting to date, with 22 participants.

The industrial radiography working group meetings took place in Calgary and Edmonton, AB. The group reviewed previous meeting minutes, discussed items of interest and planned for the outreach strategy for the industry-at-large meetings.

3.10.4 Canadian Radiation Protection Association working group

In 2014, a working group was established between the CNSC and the Canadian Radiation Protection Association (CRPA). In 2015, this working group continued its efforts to promote strong radiation safety cultures within licensed facilities. The working group approved its terms of reference in 2015. The CRPA shared these terms with its members.

For almost three decades, CNSC staff have delivered regulatory-focused presentations and participated in regulatory workshops at the CRPA's annual conferences. At the 2015 conference in Winnipeg, MB, CNSC staff delivered several presentations relating to events that occurred earlier in 2015 and to reporting requirements for specific types of events. CNSC managers also participated in a panel discussion on various regulatory topics. A virtual meeting was also held in September 2015, keeping with plans for the group to meet at least twice annually.

3.10.5 Canadian Organization of Medical Physicists

The Canadian Organization of Medical Physicists (COMP) represents medical physicists working in radiotherapy facilities in the medical sector. Many certified radiation safety officers at Class II nuclear facilities are members of COMP.

In 2015, CNSC staff delivered presentations and posters on regulatory issues (shown in Figure 4) at the COMP annual conference, attended the COMP winter school and submitted quarterly articles on regulatory topics of interest to radiotherapy licensees to *InterACTIONS*, COMP's professional newsletter. In order of publication date, the article topics included:

- presenting the 2013 edition of this regulatory oversight report at the November 2014 Commission meeting
- safety culture
- correcting inaccurate submissions
- a retrospective of the regulatory process for Class II facilities

The winter school was attended by 80 people, the majority of which were physicians, physicists and radiation therapists from Canada, the United States and India. Highlights of the 2015 winter school included a talk about the characteristics of high reliability organizations and strategies for managing change.

Figure 4: CNSC staff presenting at the COMP winter school

3.10.6 Portable gauge workshops

Established in 2014, the CNSC regulatory workshop for portable gauge licensees was created to promote compliance and safety culture within this industrial subsector. The workshops consist of presentations delivered by CNSC staff, a question-and-answer session and general discussions. The presentations focus on radiation protection, compliance programs, worker training, transport of nuclear gauges and reporting requirements. CNSC staff developed this workshop in response to negative trending data related to the use of enforcement actions against licensees in this subsector.

CNSC staff offered 14 portable gauge workshops across Canada in 2015. Positive results have already been observed. There has been a marked improvement in compliance among, and fewer CNSC enforcement actions taken against, the licensees in the portable gauge subsector. CNSC staff will continue offering these workshops in 2016.

4 Regulatory developments

This section provides details of the regulatory developments that took place in 2015 and 2016 relating to regulatory programs for licensees covered in this report.

4.1 *Packaging and Transport of Nuclear Substances Regulations, 2015*

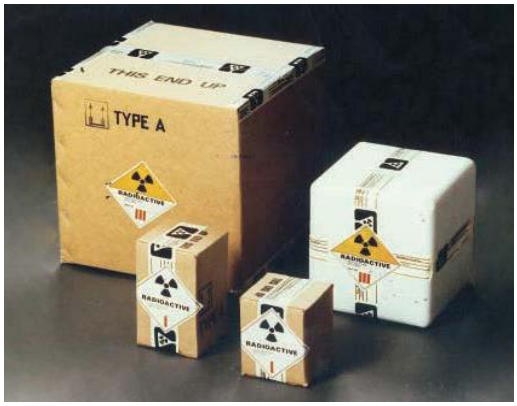
The packaging and transport of nuclear substances is jointly regulated by the CNSC and Transport Canada. Packages that are used for the transport of nuclear substances, some of which are shown in Figure 5, must comply with the CNSC's *Packaging and Transport of Nuclear Substances Regulations, 2015* (PTNSR 2015), with Transport Canada's *Transportation of Dangerous Goods Regulations* and the International Atomic Energy Agency's (IAEA) *Regulations for the Safe Transport of Radioactive Material 2012 Edition*.

In June 2015, the Government of Canada published the PTNSR 2015 in the *Canada Gazette, Part II*. These revised regulations align to the IAEA transport regulations and ensure continued alignment by including an ambulatory reference, which adopts future editions of the international regulations as they become available.

These revised regulations clarified existing requirements and ensured continued safe and efficient transport of nuclear substances. In particular, they provide additional clarity in the areas of radiation protection program requirements, reporting requirements, the transport of large objects and the discovery of material containing unidentified nuclear substances. For example, the PTNSR 2015 includes new provisions related to the transport of material containing unidentified nuclear substances discovered while in transport. Some examples include:

- shipments containing scrap metal coming from oil drilling operations
- domestic waste containing medical isotopes from patients that have undergone medical procedures
- shipments containing contaminated materials such as metal shelving and kitchenware

Figure 5: Transport packages



A new exemption has been introduced for those shipments that have low radiation dose rates. This exemption allows for limited movement of these shipments provided the CNSC is notified, allowing for their safe transport and proper characterization.

In addition to the PTNSR 2015, REGDOC-2.14.1, *Information Incorporated by Reference in Canada's Packaging and Transport of Nuclear Substances Regulations, 2015* was published in February 2016. This document serves as a technical reference document, linking provisions of the PTNSR 2015 to relevant content in the IAEA regulations, as well as the *Nuclear Safety and Control Act* (NSCA), CNSC regulations, and other related information.

4.2 REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices*

In October 2015, REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices*, became the standard regulatory document that sets out guidance for applicants when preparing and submitting applications for licences to carry out activities related to nuclear substances and radiation devices. The new document provides additional information on CNSC's regulatory expectations and includes forms that applicants can use or modify to suit their application needs.

4.3 REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources*

Mandatory compliance with REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources* came into effect on May 31, 2015 for licensees with category 1 and 2 high-risk sealed sources. Licensees with category 3, 4 or 5 sealed sources must comply with regulatory requirements by May 31, 2018.[2] The regulatory document sets out the minimum security measures to prevent the loss, sabotage, illegal use, illegal possession or illegal removal of sealed sources while in transport or in storage. The measures take into consideration aggregate quantities of radioactive sources. REGDOC 2.12.3 is aligned with the IAEA Code of Conduct as well as IAEA *Nuclear Security Series (NSS) 14 Nuclear Security Recommendations on Radioactive Material and Associated Facilities*.

To ensure proper regulatory oversight of these new requirements, CNSC inspectors have been conducting enhanced security inspections for those in possession of high-risk sealed sources. In 2015, CNSC staff conducted 217 enhanced security inspections. Details on these inspections are not provided in this report due to their sensitive nature.

4.4 Financial guarantee licence condition

In 2015, the CNSC introduced a new licence condition requiring licensees to provide financial guarantees that there will be sufficient resources to terminate their licensed activities safely. When licensees terminate their activities, they must properly account for the safe disposal of all licensed material and equipment, and demonstrate that all locations associated with the licence are free of radioactive contamination. A financial guarantee does not relieve licensees from complying with regulatory requirements for termination of licensed activities. However, it ensures that there are funds available to the CNSC when licensees are unable to carry out safe termination. Whereas financial guarantees are well established for Class I nuclear facility licences, this is the first time such a program has been implemented for licensees in the nuclear substance sectors. This new requirement came into effect on April 1, 2015. All licensees are in compliance.

[2] The CNSC maintains a detailed list of categories of sealed sources on its website.

4.5 CSA Standard PCP-09, Certified Exposure Device Operator Personnel Certification Guide

In November 2015, CSA standard PCP-09, Certified Exposure Device Operator Personnel Certification Guide, replaced the CNSC's G-229, *Certification of Exposure Device Operators*. The new guidance document details the requirements for exposure device operator certification and offers guidance on the best way to achieve and maintain certification. CNSC staff are overseeing a phased implementation to ensure a successful transition to the standard.

4.6 Guidance on the handling of the deceased implanted with nuclear substances

Following a request by stakeholders for clarification, CNSC staff are developing guidance for the handling of the deceased that have been implanted or injected with nuclear substances as well as those that have inhaled or ingested nuclear substances. The guidance is intended for coroners, and funeral home and crematorium workers. It can be used when providing services to families of deceased patients who have undergone diagnosis or therapy using nuclear medicine. It will inform readers of the risks that are present (minimal in all cases) and recommend best practices to help keep doses to the workers, families and the public at ALARA levels. This document is expected to be drafted in 2016 and published for consultation in early 2017. The information will be included in REGDOC-2.7.1, *Radiation Protection*, in a section for the handling of the deceased.

4.7 Regulatory focus in 2016

The CNSC focus in 2016 will continue to be on effective regulatory oversight and continuous improvement, including:

- undertaking a lean assessment of regulatory program in order to optimize internal processes for delivery of efficient regulatory program
- reviewing the licensing process and continuing the consolidation of licences
- separation of the licensing and compliance activities for import and export of Category 1 and 2 sealed sources
- leveraging experience from inspecting Class II facilities in a move to concentrate on more complex inspections across all sectors
- clarifying expectations for reportable events with the development of regulatory document REGDOC-3.1.2, Part II, *Reporting Requirements for Nuclear Substances and Radiation Devices* to clarify regulatory reporting requirements for situations listed in the regulations
- enhancing oversight of RSOs across all sectors
- implementation of regulatory document REGDOC-2.1.2, *Safety Culture*, which provides information on safety culture applicable to all licensees and sets out requirements and guidance related to fostering a healthy safety culture.
- Increasing focus on performance based inspections

5 Safety performance – all sectors combined

This section provides an overview of the overall performance of the industry sectors covered in this report.

5.1 Overall safety assessment

CNSC staff conducted 1,568 inspections across all sectors in 2015 to verify compliance with CNSC regulatory requirements, including 217 enhanced security inspections to verify new security requirements. All sectors continued to demonstrate adequate performance within all safety and control areas (SCAs). The majority of inspected licensees in 2015 were found to be compliant in the four SCAs covered in this report:

- In management system, 96.2 percent of licensees ensured that adequate processes and programs were in place to achieve their safety objectives.
- In operating performance, 90.6 percent of licensees made adequate provisions for the health, safety and security of persons, and protection of the environment.
- In radiation protection, 88.7 percent of licensees continued to ensure that exposure of workers and the public to ionizing radiation remained as low as reasonably achievable.
- In security, 95 percent of licensees demonstrated that they have adequate provisions in place to prevent the loss, sabotage, illegal use, illegal possession or illegal removal of sealed sources and prescribed equipment in their care and control.

For those in possession of high-risk sealed sources, enhanced security inspections were conducted in 2015. Of those inspected, 77.4 percent (168 of 217 inspections) were found to be compliant with the regulatory requirements. Licensees have put in measures to correct all non-compliances identified during these inspections. The majority of non-compliances for enhanced security requirements were administrative items related to security plans.

Effective dose to workers continued to be below regulatory limits in 2015, consistent with previous reporting years. Doses for 53,700 workers were reported to the CNSC in the four sectors covered in this report. Of those workers, 22,322 were designated as nuclear energy workers (NEWs) while 31,378 were not designated as NEWs.

One NEW received an equivalent dose above the regulatory limit for extremities of 500 millisieverets (mSv) as a result of an event that was reported to the Commission in June 2015. Further details on this event are provided in section 5.8.

Apart from this event, neither workers (designated as NEWs or not) nor members of the public exceeded applicable effective regulatory dose limits in 2015.

For 2015, CNSC staff assessed all 155 events reported by the licensees and which are covered in this report. Reported events have been ranked using the International Nuclear and Radiological Event Scale. Of these, 149 were ranked as level 0 (no safety significance), six were ranked as level 1 (anomaly) and one was ranked as level 2 (incident). The level 2 event involved the worker who received a dose that exceeded the applicable regulatory limit mentioned above.

For all of the events reported, licensees implemented appropriate response measures to mitigate the impacts of the events and to limit radiation exposure to workers and the public. CNSC staff reviewed the measures put in place by licensees and found them to be satisfactory.

5.2 Management system

The management system SCA covers the framework that establishes the processes and programs required to ensure that an organization achieves its safety objectives, continuously monitors its performance against those objectives, and fosters a healthy safety culture.

All sectors demonstrated satisfactory performance within the management system SCA, with 96.2 percent of inspected licensees (1,233 of 1,282 inspections) found to be in compliance with regulatory requirements. A breakdown of the inspection ratings for 2015 is shown in Table 4.

The majority of non-compliances in this SCA included conducting activities contrary to a licence, failure to comply with regulatory requirements related to having records at work locations, and failure to notify the CNSC of changes in contacts for licensed activities. For licensees such as hospitals that hold multiple licences for various activities, non-compliances observed during inspections mostly related to inadequate management oversight of their radiation protection program.

Table 4: Inspection ratings for management system in 2015, sector-by-sector comparison

Rating	All sectors combined	Medical	Industrial	Academic and research	Commercial
Fully satisfactory or satisfactory	1,233	227	837	67	102
Below expectations	49	15	23	4	7
Unacceptable	0	0	0	0	0
Total	**1,282**	**242**	**860**	**71**	**109**
Percent compliant (%)	**96.2**	**93.8**	**97.3**	**94.4**	**93.6**

5.3 Operating performance

Operating performance refers to the licensee's ability to perform licensed activities in accordance with pertinent operational and safety requirements defined in the *Nuclear Safety and Control Act* (NSCA), its associated regulations and licence conditions. Licensees are expected to demonstrate that they comply with operational and safety requirements by providing workers with appropriate procedures for the safe use of nuclear substances and prescribed equipment, by ensuring that workers follow procedures, and by maintaining records that demonstrate compliance.

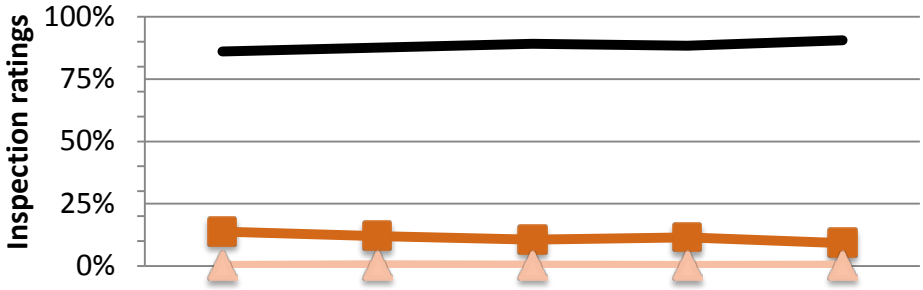
All sectors continued to demonstrate adequate performance within the operating performance SCA in 2015, with 90.6 percent of inspected licensees (1,181 of 1,303 inspections) found to be in compliance with regulatory requirements.

Two inspections received unacceptable ratings in the operating performance SCA in 2015. In both cases, the inspectors issued orders to portable gauge licensees to ensure corrective actions were taken immediately. Compliance with regulatory requirements is unacceptable when compliance within the overall SCA is significantly below expectations, or there is evidence of systemic failure in safely conducting activities. Without immediate corrective action, there is a high probability that the deficiencies will lead to an unreasonable risk.

Inspection ratings for all sectors combined are shown in Figure 6 and a sector-to-sector comparison appears in Figure 7. Despite the stability of the overall industry, the academic and research sector rating in this SCA has been trending negatively since 2013. As a response to this trend, CNSC staff have modified a component of their outreach strategy to increase focus on this sector in 2016.

The majority of non-compliances in this SCA included failure to comply with regulatory requirements related to retention of records, worker obligations, and sealed source leak testing.

Figure 6: Inspection ratings for operating performance, 2011–15

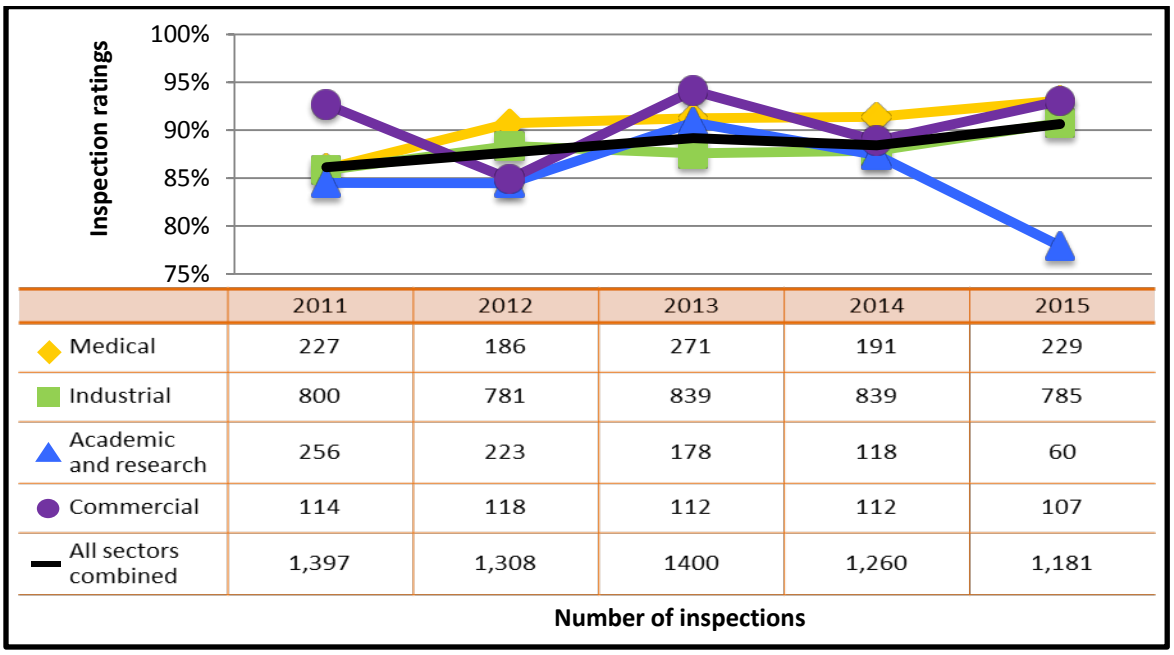


	2011	2012	2013	2014	2015
Fully satisfactory or satisfactory	1,397	1,308	1,400	1,260	1,181
Below expectations	224	179	166	164	120
Unacceptable	1*	5*	4*	1*	2*

*Order Issued to licensee

Number of inspections

Figure 7: Sector-to-sector comparison of inspection ratings meeting or exceeding expectations for operating performance, 2011–15



	2011	2012	2013	2014	2015
Medical	227	186	271	191	229
Industrial	800	781	839	839	785
Academic and research	256	223	178	118	60
Commercial	114	118	112	112	107
All sectors combined	1,397	1,308	1400	1,260	1,181

Number of inspections

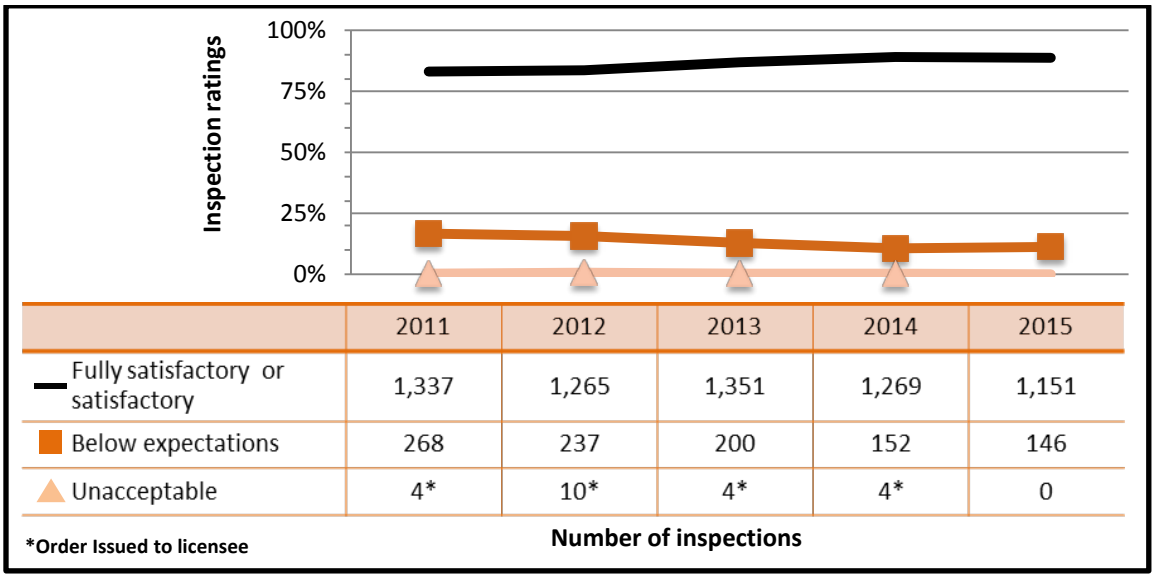
5.4 Radiation protection

Radiation protection programs are required for every licensee to ensure that contamination levels and radiation doses received by workers are monitored, controlled and maintained below regulatory dose limits, and kept at levels that are as low as reasonably achievable (ALARA), social and economic factors being taken into account. Licensees are expected to monitor worker doses, post radiation warning signs, plan appropriately for radiological emergencies, manage oversight of operational activities, institute effective workplace practices that emphasize the use of time, distance and shielding to minimize exposure to radiation, and use appropriate protective equipment.

All sectors demonstrated adequate performance within this SCA, with 88.7 percent of inspected licensees (1,151 of 1,297 inspections) found to be compliant with regulatory requirements. The remaining inspected licences received ratings of below expectations.

Inspection ratings for all sectors combined are shown in Figure 8. A sector-to-sector comparison is presented in Figure 9. The majority of non-compliances included survey meters not being calibrated, inadequate implementation of measures to ensure that doses are kept ALARA, and improper posting of signs at boundaries and points of access.

Figure 8: Inspection ratings for radiation protection, 2011–15

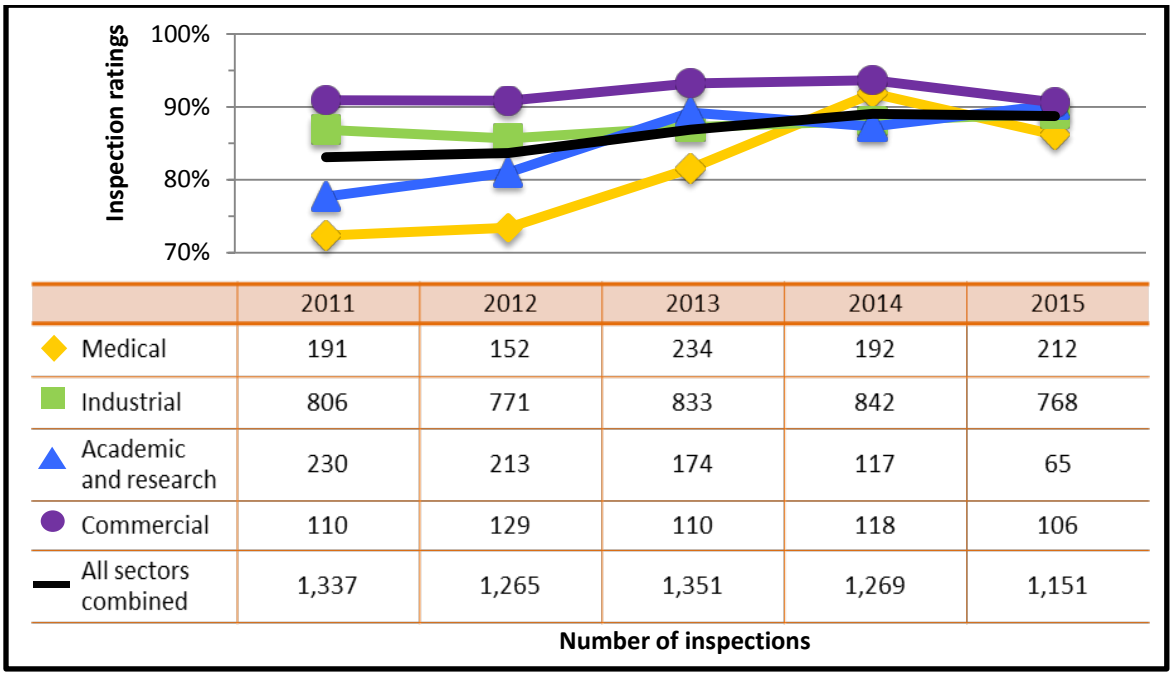


	2011	2012	2013	2014	2015
Fully satisfactory or satisfactory	1,337	1,265	1,351	1,269	1,151
Below expectations	268	237	200	152	146
Unacceptable	4*	10*	4*	4*	0

*Order Issued to licensee

Number of inspections

Figure 9: Sector-to-sector comparison of inspection ratings meeting or exceeding expectations for radiation protection, 2011–15



	2011	2012	2013	2014	2015
Medical	191	152	234	192	212
Industrial	806	771	833	842	768
Academic and research	230	213	174	117	65
Commercial	110	129	110	118	106
All sectors combined	1,337	1,265	1,351	1,269	1,151

Number of inspections

5.5 Security

Licensees are required to have in place physical security measures, practices and programs to prevent the loss, illegal use, illegal possession or illegal removal of nuclear substances during their entire lifecycle, including while they are in storage or during

transport. The extent of the security measures required depends upon the types of nuclear substances used and activities performed by each licensee.

Overall, all sectors showed satisfactory ratings for the security SCA in 2015, with 95 percent of inspected licensees (1,149 of 1,210 inspections) found to be compliant with regulatory requirements. Two inspections were given an "unacceptable" rating and resulted in the inspector issuing an order to each licensee to ensure corrective actions were taken immediately.

CNSC staff verified licensee compliance against requirements described in REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources*. For those in possession of high-risk sources, enhanced security inspections were conducted in 2015. Of those inspected, 77.4 percent (168 of 217 inspections) were found to be compliant with regulatory requirements.

Licensees addressed and corrected all non-compliances identified during inspections to the satisfaction of the CNSC. Table 5 summarizes the performance of all sectors combined for this SCA for 2014 and 2015, while Table 6 provides a sector-to-sector comparison for both years.

Table 5: Inspection ratings for security, 2014 and 2015

Rating	2014	2015
Fully satisfactory or satisfactory	1,265	1,149
Below expectations	69	59
Unacceptable	0	2
Total	**1,334**	**1,210**
Percent compliant (%)	**94.8**	**95**

Table 6: Sector-to-sector comparison of inspection ratings that met or exceeded expectations for security 2014 and 2015

Sector	2014		2015	
	Number of inspections	Percent compliant (%)	Number of inspections	Percent compliant (%)
Medical	188	96.3	223	98.2
Industrial	931	94	828	94.2
Academic and research	123	97.6	70	91.4
Commercial	92	96.7	89	96.6
All sectors	**1,334**	**94.8**	**1,210**	**95**

Compliance with the mandatory tracking of high-risk sealed sources was satisfactory in 2015. Of the 134 inspected licensees, 119 (or 91 percent) were found to be compliant with this requirement. CNSC staff ensured that the 12 instances of non-compliances were

adequately addressed by the licensees. The majority of non-compliances for high-risk sealed source tracking requirements were administrative items such as incorrect or misidentification of licensee addresses, device information or source location.

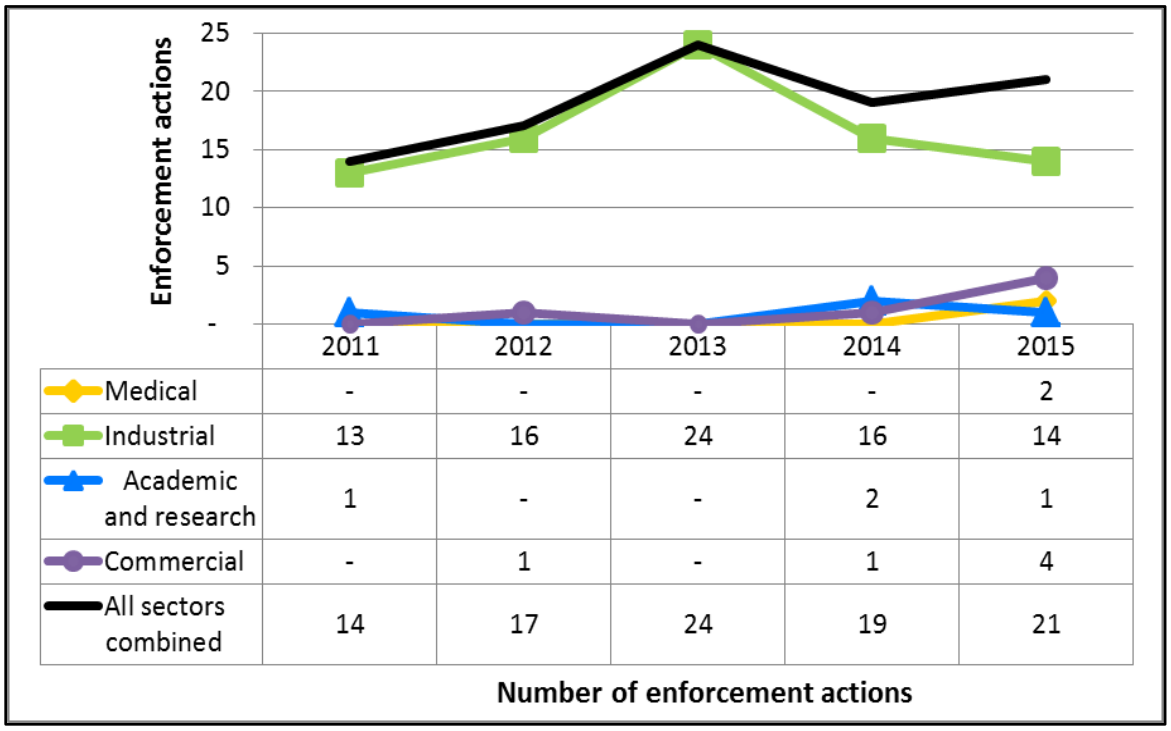
Further information on this topic is available in the *National Sealed Source Registry and Sealed Source Tracking System Annual Report*.

5.6 Enforcement actions

In 2015, the CNSC escalated 21 compliance enforcement actions against licensees in the medical, industrial, academic and research, and commercial sectors. CNSC staff issued orders and directed licensees to take immediate corrective measures in 15 instances, as shown in Figure 10. In each case, the licensee immediately complied with the order. Once the CNSC was satisfied that the licensee had addressed the order's terms and conditions, the order was closed. All orders issued in 2015 are closed. CNSC designated officers issued administrative monetary penalties (AMPs) in six instances in 2015, all of which have been paid. A breakdown of the 21 enforcement actions is provided for each of the sector while a summary of orders and AMPs taken by the CNSC in 2015 is provided in appendix C. Further information on regulatory actions, including escalated enforcement actions, taken by the CNSC is also available on the CNSC website.

The CNSC decertified one exposure device operator in 2015. This stemmed from an inspection in 2014 that identified non-compliances relating to the use of survey meters and supervision of exposure device operator trainees. Due to a significant health and safety risk, an order was issued to the company requiring them to immediately remove the certified exposure device operator from all activities related to the use of an exposure device until it was demonstrated to the CNSC that the operator was no longer likely to pose a risk to the health and safety of persons.

Figure 10: CNSC enforcement actions[3] from 2011 to 2015, sector-to-sector comparison



	2011	2012	2013	2014	2015
Medical	-	-	-	-	2
Industrial	13	16	24	16	14
Academic and research	1	-	-	2	1
Commercial	-	1	-	1	4
All sectors combined	14	17	24	19	21

Number of enforcement actions

5.7 Reported events

Licensees are required to have programs in place for the management of unplanned events and accidents. The situations that warrant mandatory reporting and the content of the reports are set out in the NSCA, its regulations and the conditions of their licence. CNSC staff review, assess and track all events reported by licensees.

Reported events have been ranked using the International Nuclear and Radiological Event Scale (INES), a tool for communicating the safety significance of nuclear and radiological events to the public. This tool allows the establishment of a proper perspective of an event's safety significance. The scale has been used to classify events at nuclear power plants since 1990 and has been extended over the years to apply to all nuclear industry installations. By 2006, it had been adapted to all events associated with the transport, storage and use of radioactive sources and nuclear substances. Note that the scale is not a tool to compare safety performances among facilities or organizations, but to effectively communicate the safety significance of events.

In 2015, there were 155 events related to nuclear substances reported to the CNSC by licensees in the sectors covered in this report. Of these events, 149 were ranked as INES level 0 (no safety significance) and six were ranked as level 1 (anomaly) based on the

[3] All 15 orders were issued by inspectors. One was reviewed by the Commission following a request by the company named in the order. Two of the six AMPs were issued following, or in conjunction with, orders. One order was issued to an individual.

quantity of nuclear substances involved and the type of event reported (stolen portable gauges).

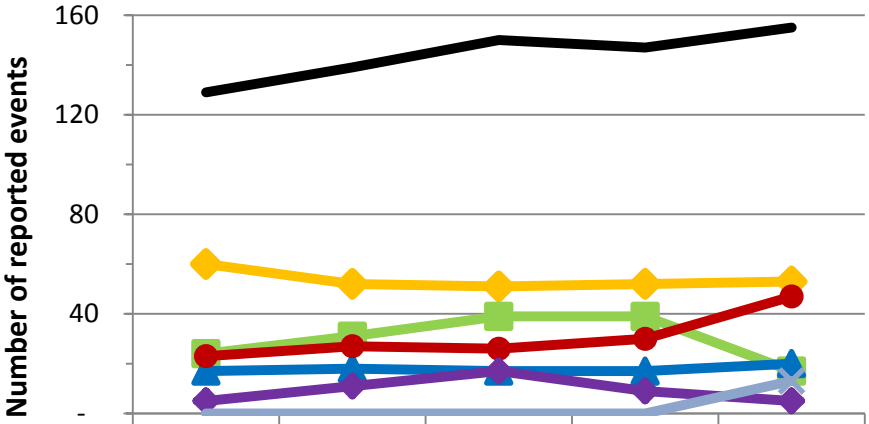
The remaining event – ranked as level 2 (incident) – occurred when a NEW received an extremity dose of 1.7 Sv, which is above the regulatory limit of 500 mSv. Further details on this event and effective doses to the workers are provided in section 5.8.

A breakdown of reported events by type is shown in Figure 11 and a complete list of all reported events in 2015 is provided in appendix D.

For all of the events reported, the licensees implemented adequate response measures to mitigate the impacts of the events and to limit radiation exposure to workers or any radiological impact on the environment. CNSC staff reviewed these measures, along with licensee corrective actions to prevent recurrence of the events, and found them to be satisfactory.

As part of their final, detailed reports on events, licensees are required to identify probable causes of events and propose corrective actions to prevent recurrence. In many cases, probable causes were related to workers not following procedures. As a result, the majority of measures taken by licensees to prevent recurrence related to retraining staff on procedures and emphasizing the importance of procedural adherence.

Figure 11: Reported events from 2011 to 2015, all sectors combined



	2011	2012	2013	2014	2015
Malfunctioning or damaged devices	60	52	51	52	53
Spills, contamination or release	24	31	39	39	17
Missing or found nuclear substances	17	18	17	17	20
Packaging and transport	23	27	26	30	47
Breach of security	5	11	17	9	5
Unplanned exposure	-	-	-	-	13
All reported events	129	139	150	147	155

Note: Unplanned exposure is listed as a discrete event for the first time in this year's report. It represents those events that have led to non-routine exposures to workers or members of the public. Events of this type in previous years were covered under breach of security.

5.7.1 Malfunctioning or damaged devices

There were 53 events related to damaged or malfunctioning devices of systems. Of these, 39 were reported as damaged devices:

- Fourteen involved damage to portable gauges, which were hit or run over by vehicles at construction sites, as shown in Figure 12
- Eleven involved damage to fixed gauges, with most events related to damage to the shutter handle
- Eleven involved damage to exposure devices following a drop or an impact

- two involved receipt of a damaged irradiated target
- one involved damage to a X-ray fluorescence analyzer from a drop

None of the above resulted in damage to the source or resulted in source leakage. There was no release to the environment or exposure to members of the public as a result of these events.

The remaining 14 events corresponded to malfunctioning devices:

- five involved malfunctioning fixed gauges where the shutter failed to close properly
- four involved malfunctioning exposure devices where the sealed source failed to retract into the shielded position or the device failed the pre-operation verifications
- two involved malfunctioning portable gauges
- one involved a malfunctioning device discovered while conducting a radiation survey
- one involved error codes associated with use of a brachytherapy unit
- one involved an intrusion alarm found to be not working properly

Figure 12: Damaged portable gauge

All malfunctioning devices were taken out of service as required by the *Nuclear Substances and Radiation Devices Regulations*. Any radiation exposure to a person as a result of the events was well below the annual public regulatory dose limit of 1 mSv. All of the events in this section are closed.

5.7.2 Spill, contamination or release

All licensees are required to document, record and investigate every skin contamination event to ensure work practices are optimized and to minimize the probability of repeat occurrences. None of the spill, contamination or release events reported in 2015 posed a risk to the environment or resulted in members of the public receiving a dose.

There were 17 events related to spills, unplanned releases or contamination of personnel reported:

- Twelve involved contamination resulting from mishandling of unsealed nuclear substances
- two involved spills during the production of gallium-68
- one involved a spill of copper-61 inside a cyclotron vault

- one involved a release of gaseous carbon-11 to the environment through an exhaust system
- one involved a release of solid waste to the environment above allowable release limits by 0.003 megabecquerel per kilogram

These events only include situations where spills or contamination occurred outside of fume hoods, hot cells or other normal means of containment. The nuclear substances involved had half-lives ranging from a few hours to a few days. In all cases, workers received doses well below the annual public regulatory dose limit of 1 mSv. These events had a negligible impact on the environment or the public. All of these events are closed.

5.7.3 Missing or found nuclear substances

Licensees are required to have in place physical security measures, practices and programs to prevent the loss, illegal use, illegal possession or illegal removal of nuclear substances during their entire lifecycle, including while they are in storage or during transport.

In 2015, there were 20 reported events involving lost or stolen nuclear substances and one report of a found nuclear substance. The sealed sources or radiation devices were recovered in seven of the 20 instances. At the time of writing, eight events remained under investigation. The sealed sources or radiation devices had not yet been recovered. A further five events were closed, as there was very low risk associated with the nuclear substances involved and/or the type of event reported.

Events involving lost, stolen or recovered radiation devices and sealed sources are reported in the *Lost or Stolen Sealed Sources and Radiation Devices Report*, which is updated regularly. Table *7* provides a summary of the events that occurred in 2015.

Table 7: Summary of 21 events involving missing or found nuclear substances

#	Date	Event summary	Sealed source category	INES rating level	Status
2393	Jan. 21	Four excepted packages containing very low-risk sources (i.e., static eliminators) were delivered to a licensee, but could not be located following receipt.	5	0	Sources not recovered. Event closed as the radioactive sources involved are of very low risk.
2400	Feb. 2	Two vials of technetium-99m (4.9 GBq) were reported missing from a storage location.	N/A	0	Nuclear substance not recovered. Event closed as the nuclear substances involved had a short half-life.
2503	Feb. 10	A sample of mixed isotopes used for testing was reported missing.	N/A	0	Nuclear substance recovered. Event closed.
2370	Feb. 12	Six fixed gauges containing low-risk sources were reported missing from a licensed facility by a CNSC inspector during an inventory check.	4	0	Fixed gauges found
2407	Mar. 13	Discovery of a very low-risk X-ray fluorescence analyzer that was reported stolen in 2007.	5	0	Event closed.
2451	Apr. 20	A very low-risk sealed source was reported missing following a quarterly inventory check.	5	0	Source not recovered. Still under investigation.
2463	May 19	Loss of a very low-risk sealed source, used as a radiolabel during surgery, reported after pathology.	5	0	Source not recovered. Event closed.
2502	Jun. 17	A very low-risk sealed source was reported missing.	5	0	Source recovered. Event closed.
2491	Jun. 20	A vehicle storing a portable gauge that contained a low-risk source was broken into and the gauge was stolen.	4	1	Portable gauge not recovered. Still under investigation.

#	Date	Event summary	Sealed source category	INES rating level	Status
2556	Jun. 25	Three very low-risk sealed sources were stolen from a storage facility.	5	0	Sources not recovered. Still under investigation.
2500	Jun. 29	A portable gauge containing a low-risk source was stolen from a locked vehicle.	4	1	Portable gauge recovered. Event closed.
2507	Jul. 1	Report of a stolen vehicle storing a portable gauge containing a low-risk source.	4	1	Portable gauge recovered. Event closed.
2576	Sep. 15	Two Type A packages, containing technetium-99m (65 GBq) fell from the open back door of a vehicle while in transport.	N/A	0	Nuclear substances recovered. Event closed.
2590	Sep. 21	A very low-risk calibration source was removed from a liquid scintillation counter, and subsequently reported missing.	5	0	Source not recovered. Still under investigation.
2591	Sep. 30	A very low-risk check source used for the calibration of survey meters was reported missing following an internal inventory audit.	5	0	Source not recovered. Still under investigation.
2612	Oct. 5	A very low-risk iodine-125 sealed source was reported missing following a patient treatment.	5	0	Source not recovered. Event closed as the nuclear substances involved had a short half-life.
2598	Oct. 7	A portable gauge containing low-risk sources was stolen from a construction site.	4	1	Portable gauge not recovered. Still under investigation.
2627	Nov. 7	A vehicle storing a portable gauge that contained a low-risk source was reported stolen.	4	1	Portable gauge recovered. Event closed.

#	Date	Event summary	Sealed source category	INES rating level	Status
2671	Dec. 1	During routine pick-up of iodine-125 seeds from pathology, nuclear medicine staff discovered that a seed was missing. No seed was located after surveys of samples generated from the specimen, pathology work areas, and waste and storage locations.	5	0	Source not recovered. Event closed
2701	Dec. 2	Five low-risk sealed sources reported missing while CNSC staff was performing inventory verification at a facility. Three have been recovered.	4	0	Three sources recovered. Still under investigation.

CNSC staff presented the following event at a public Commission meeting:

- In February 2015, the Centre hospitalier universitaire de Québec reported the theft of two vials containing a total of approximately 4.9 GBq of technetium-99m, a radioisotope used for medical imaging diagnostics. An investigation concluded that Mario Mignault had illegally removed and used, on seven separate occasions in 2014 and 2015, technetium-99m without a licence to possess, use and store this nuclear substance. The individual was issued an administrative monetary penalty in relation to these activities. CNSC staff presented this event at the June 2015 Commission public meeting, at which time the matter was closed.

5.7.4 Breach of security

The extent of the security measures required depends upon the types of nuclear substances used and activities performed by each licensee. In 2015, there were five events reported to the CNSC relating to breaches of security.

- One involved unauthorized access to a secure nuclear medicine area that was appropriately marked with radiation warning signs. The licensee's investigation concluded that workers were using this room as a passage to get to another area in the hospital, using a work-around for the door lock. Appropriate corrective measures were taken. The licensee enhanced security measures, made the door more secure, and educated staff on why such rooms are off-limits to non-nuclear medicine staff. These measures were reviewed by CNSC staff and found to be satisfactory.
- One involved discovery of stolen master keys providing access to a storage location containing nuclear substances. The licensee took measures to ensure security of the sources by rekeying the door locks.

- One involved an exposure device left unattended for approximately one hour. The licensee reminded its staff to always maintain visual contact with devices that are being used, as per procedures.
- One involved an intruder that entered a secured licensed facility, and escorted offsite. The licensee has since repaired the gate the intruder used to enter the facility.
- One involved an unsuccessful attempt to break into a storage facility. The licensee welded metal boxes around the locking mechanisms to prevent bolt cutters and pry bars from reaching the lock. The approach prevented the thief from gaining access to the nuclear substances.

There was no access to, or theft of, the nuclear substances or radiation devices as a result of any of these events. These events are closed.

5.7.5 Packaging and transport

Approximately 1 million packages containing nuclear substances are safely transported each year in Canada. In 2015, there were 47 events reported to the CNSC relating to packaging and transport.

- Nineteen were road accidents involving vehicles transporting the nuclear substances. No damage was reported to the packages following the accidents.
- Eight involved external damage to packages. The licensee investigations concluded that there was no external contamination and that the packages maintained their integrity.
- Five involved delays in the delivery of the packages.
- Four involved improper transport of portable gauges. In each case, the gauge was not transported in a proper package.
- Three involved packages that were discovered to have internal contamination once they were opened. The contamination was contained within the package and no external contamination was found.
- Two involved packages not labelled in accordance with the *Packaging and Transport of Nuclear Substances Regulations, 2015*. Both related to the improper labelling of the type or quantity of radioactive material being shipped. In each case, licensees took appropriate corrective measures to prevent recurrence.
- Two involved broken tamperproof package seals while in transport. The licensee's investigations concluded that the seals broke while the package was in transport, and not as a result of an attempt to gain access to the package's content.
- One involved an exposure device that was returned from a servicing company with a missing locking mechanism required for use.
- One involved receipt of a package with surface contamination above regulatory limits. The amount of surface contamination was limited. Workers received doses well below the public regulatory dose limit of 1 mSv.
- One involved a package containing technetium-99m that was dropped. The isomer spilled due to the container not being sealed property.

- One involved a vehicle carrying packages containing technetium-99m that caught fire.

These events had a negligible impact on the environment or members of the public. All events are closed.

5.7.6 Unplanned exposures to people

This event classification is new for 2015. In previous editions of this report, events that led to unplanned exposures to people were classified among the other types of events covered in this report. The change allows for a section in this report for all events of this type to be consolidated.

During the use of nuclear substances, there may be situations that lead to unplanned exposures to people. Often these events involve people entering restricted work areas, such as for industrial radiography exposure devices.

In 2015, there were 13 events reported to the CNSC that led to unplanned exposures to people. This total is similar to those recorded in previous years. Only one of these events led to a dose above a regulatory dose limit. All events are closed.

- Eight involved breaches of safety barriers where workers entered restricted areas that were established prior to the use of exposure devices. In all cases, the workers received doses well below the public regulatory dose limit of 1 mSv as the sealed source was in the locked position and not exposed.
- One involved a worker who inadvertently placed a hand into the radiation beam of a fixed gauge while the shutter was open. The dose received was calculated to be less than 0.01 mSv.
- One involved skin contamination of a worker during a nuclear medicine procedure. The dose received was well below the public regulatory dose limit of 1 mSv.
- One involved a worker who stole two vials of iodine-123 from a hospital's nuclear medicine department to self-administer the nuclear substances and perform thyroid uptake scans. Although the event was reported in 2015, the self-administered scans occurred on two separate occasions in 2011 and 2013.
- One involved a worker who received a dose due to a failure to follow procedure while servicing an exposure device. The dose received was calculated to be approximately 0.02 mSv.
- The remaining event resulted in a NEW receiving an extremity dose above the regulatory limit of 500 mSv. More details on this event and corrective actions taken by licensees are provided in section 5.8.

5.8 Effective doses to workers

A total of 53,700 workers in the four nuclear sectors covered in this report were monitored for occupational doses in 2015, of which 22,322 were designated as NEWs.

One NEW from the commercial sector exceeded the annual regulatory extremity dose limit of 500 mSv for the hands. The worker in question, who was processing fluorine-18

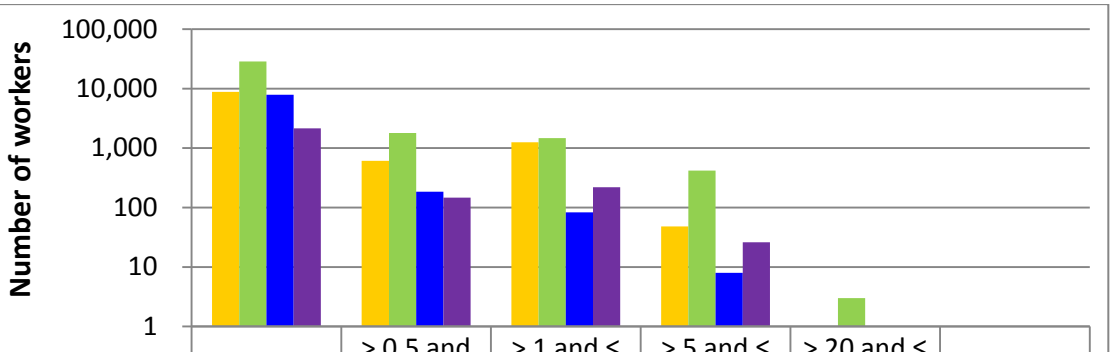
in a hot cell, handled a large quantity of this radioisotope without shielding. As a result, the worker was exposed to a relatively high extremity dose. The dose to the worker's left hand was conservatively estimated by CNSC staff to be 1.7 Sv, which is above the annual regulatory limit for extremities, but below the thresholds for deterministic effects. The effective dose to the worker was estimated to be 15 mSv as a result of this event. As a result of licensed activities, no other worker or members of the public were exposed to levels of radiation above the regulatory dose limits, as doses were kept ALARA.

In response to this situation, the licensee removed the worker from duties associated with nuclear substances in accordance with the *Radiation Protection Regulations*. CNSC staff conducted an inspection as part of the review and assessment of the event. As a result of the inspection, the CNSC issued an order to the Montreal Neurological Institute and Hospital to cease isotope production until the company had remedied the staffing levels and implemented improved contamination control measures. This event was presented at the June 2015 Commission meeting and is considered closed.

The following figures (figures 13, 14, 15, 17, 18, 24, 25, 32, 39 and 40) have been presented using logarithmic scales.

Figure 13 shows the dose distribution for all workers in 2015. All workers that received a dose above 1 mSv in 2015 were NEWs.

Figure 13: Annual effective doses to all workers in 2015, sector-by-sector comparison



	≤ 0.5	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
Medical	8,793	610	1,253	48	-	-
Industrial	28,632	1,797	1,472	419	3	-
Academic and research	7,862	184	83	8	-	-
Commercial	2,143	147	220	26	-	-

The differences in doses to workers among sectors reflect the nature of the various activities within those sectors. Figure 14 shows the doses received by the 22,322 NEWs monitored in 2015 while Figure 15 shows the doses of NEWs from 2011 to 2015.

Figure 14: Annual effective doses to NEWs in 2015, sector-by-sector comparison

	≤ 0.5	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
Medical	5,560	516	1,253	48	-	-
Industrial	7,506	793	1,472	419	3	-
Academic and research	2,721	70	83	8	-	-
Commercial	1,485	139	220	26	-	-

Figure 15: Annual effective doses to NEWs from 2011 to 2015, all sectors combined

	≤ 0.5	> 0.5 and ≤ 1	> 1 and ≤ 5	> 5 and ≤ 20	> 20 and ≤ 50	> 50
2011	5,305	733	822	130	2	-
2012	7,882	820	1,446	157	-	-
2013	16,918	1,745	3,223	507	12	-
2014	18,044	1,719	3,420	499	6	-
2015	17,272	1,518	3,028	501	3	-

Note: For 2011 and 2012, the doses provided were based on only a representative sample of annual compliance reports within each sector.

6 Medical sector

Licensees in the medical sector use nuclear substances and operate accelerators and other equipment for diagnostic and therapeutic purposes in hospitals and medical clinics. In 2015, the medical sector accounted for 494 CNSC licences and 10,704 total workers, of which 7,377 were designated as nuclear energy workers (NEWs).

The results of CNSC staff evaluation of the regulatory performance of all medical sector licensees inspected in 2015 are included in the overall results. The following three subsectors are highlighted in further detail:

- nuclear medicine
- radiation therapy
- veterinary nuclear medicine

6.1 Summary of safety assessment

Based on their evaluation and verification of licensee performance, CNSC staff concluded that the safety performance of the medical sector was satisfactory in 2015.

Doses received by NEWs in this sector remained low, with the majority of workers receiving doses below 1 millisievert (mSv). No NEW received a dose in excess of annual regulatory limits.

Of the inspected licensees in 2015, the majority were found to be compliant in the four SCAs covered in this report:

- 93.8 percent were compliant in management system
- 93.1 percent were compliant in operating performance
- 86.2 percent were compliant in radiation protection
- 98.2 percent were compliant in security

In cases where non-compliances were noted, licensees took appropriate corrective actions, satisfactory to CNSC staff, to address the non-compliances.

The CNSC issued two administrative monetary penalties (AMPs) in the medical sector in 2015, one to a licensee and one to an individual. The first was issued to Alberta Health Services for failure to give information to an inspector about the loss of control of two sealed sources. Further information on this event can been found in the May 2014 and August 2014 Commission meeting minutes. The second AMP was issued to Mario Mignault for illegal removal and use of a nuclear substance without a CNSC licence. This event was presented at the June 2015 Commission meeting.

6.2 Sector overview

Medical applications using radiopharmaceuticals target specific tissues and organs, and allow for the delivery of nuclear substances to specific areas of the body for diagnostic testing or treatment.

Diagnostic nuclear medicine studies assist in the diagnosis of medical conditions based on the physiological functions of organs, tissues or bones. Radiopharmaceuticals containing nuclear substances such as technetium-99m, gallium-67 and fluorine-18 are administered to patients for imaging purposes. Examples of common diagnostic nuclear

medicine procedures include myocardial perfusion scans (to visualize heart function and blood flow), bone scans (to evaluate bone metabolism, infection or tumours) and renal scans (to evaluate kidney function).

Radioisotopes are also used in many therapeutic nuclear medicine procedures. For example, iodine-131 is used to treat diseases of the thyroid gland, while other isotopes such as yttrium-90 may be used in conjunction with antibodies for site-specific treatment of certain cancers.

Medical linear accelerators (as shown in Figure 16) and brachytherapy equipment are also used for therapeutic procedures. These devices are used to treat cancer by delivering carefully controlled doses of radiation to cancerous tissue.

Veterinary nuclear medicine uses techniques similar to those employed in human nuclear medicine. Veterinary clinics across the country offer a wide range of diagnostic and therapeutic nuclear medicine procedures and, in some cases, radiation therapy treatment using medical accelerators.

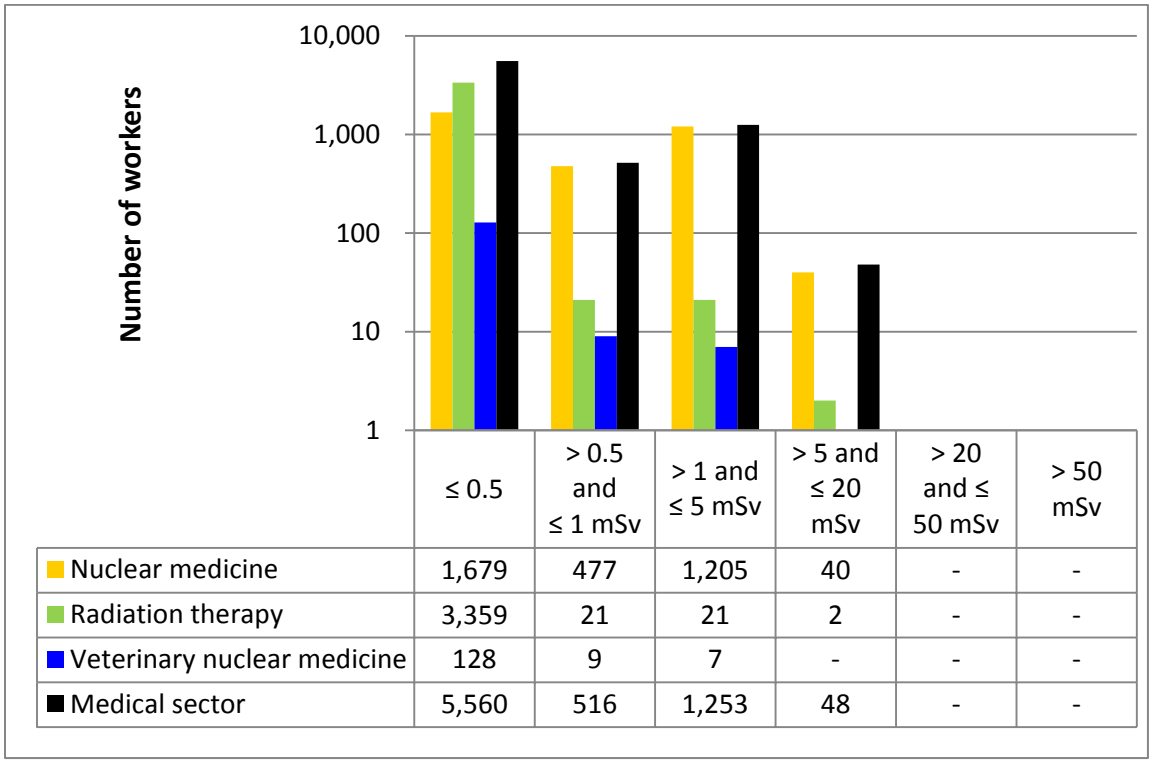
Figure 16: A medical linear accelerator used for cancer treatment

6.3 Safety performance measures

6.3.1 Doses to workers

NEWs in the nuclear medicine subsector continued to receive higher doses than workers in other medical subsectors as a result of directly administering nuclear substances to patients and constantly working in environments where patients are in close proximity to health professionals. The vast majority of these NEWs received doses below 5 mSv, as shown in Figure 17. The doses to NEWs in the nuclear medicine subsector over the period of 2011 to 2015 are shown in Figure 18.

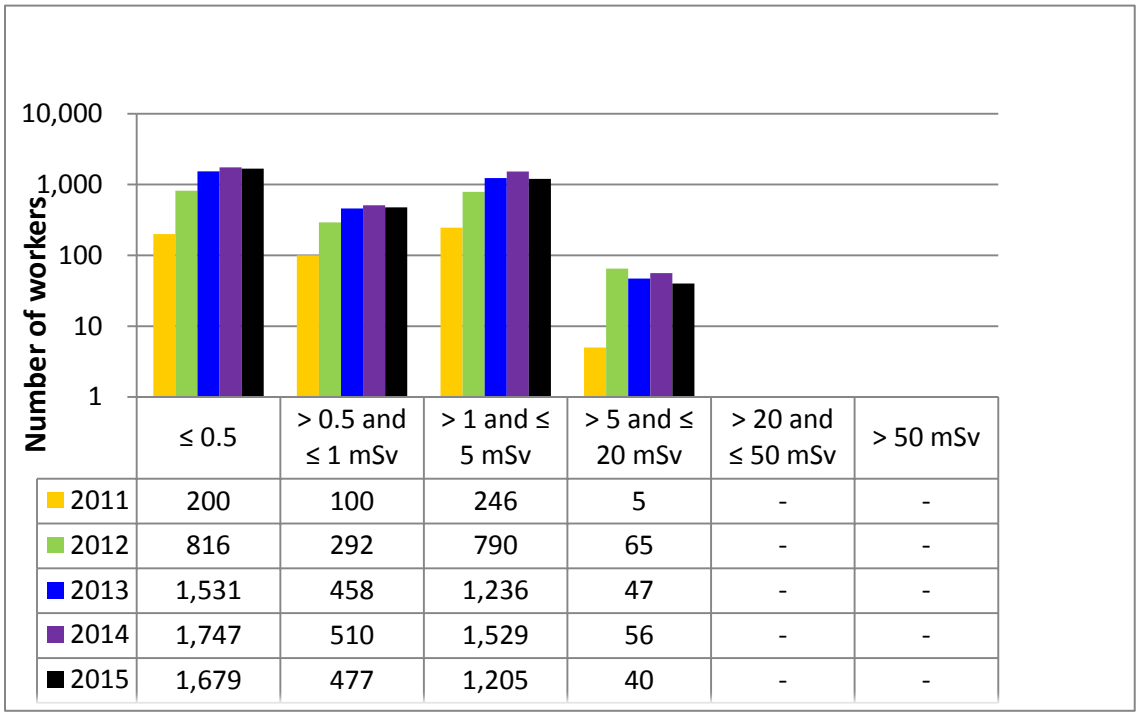
Figure 17: Medical sector performance – annual effective doses to NEWs in 2015



	≤ 0.5	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
Nuclear medicine	1,679	477	1,205	40	-	-
Radiation therapy	3,359	21	21	2	-	-
Veterinary nuclear medicine	128	9	7	-	-	-
Medical sector	5,560	516	1,253	48	-	-

Note: The total number of NEWs shown in the medical sector row is the aggregate for the entire sector, including subsectors not highlighted in this report.

Figure 18: Nuclear medicine subsector performance, annual effective doses to NEWs, 2011–15



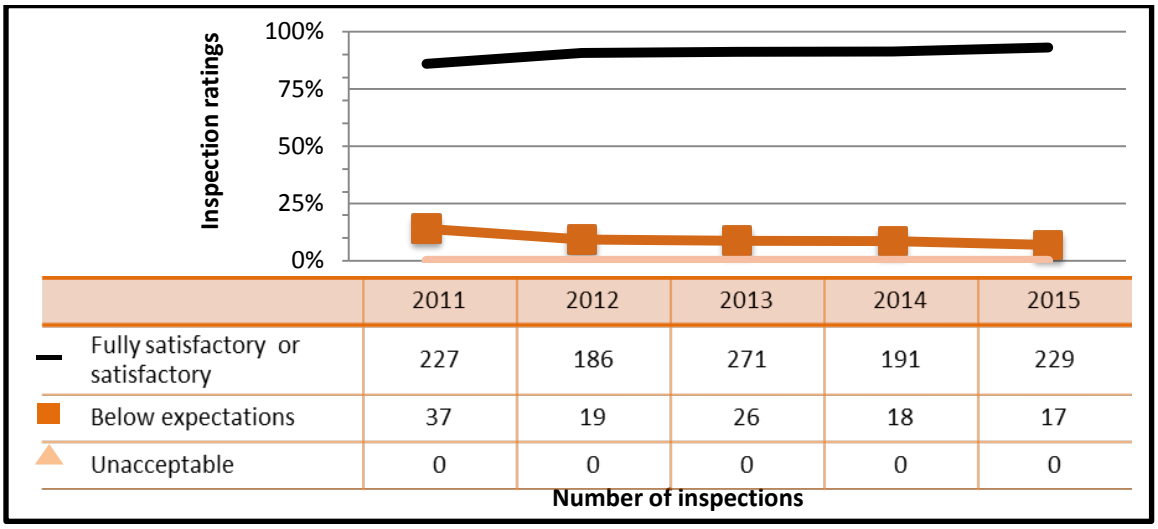
	≤ 0.5	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
2011	200	100	246	5	-	-
2012	816	292	790	65	-	-
2013	1,531	458	1,236	47	-	-
2014	1,747	510	1,529	56	-	-
2015	1,679	477	1,205	40	-	-

Note: For 2011 and 2012, the doses provided were based on only a representative sample of annual compliance reports within each sector.

6.3.2 Operating performance

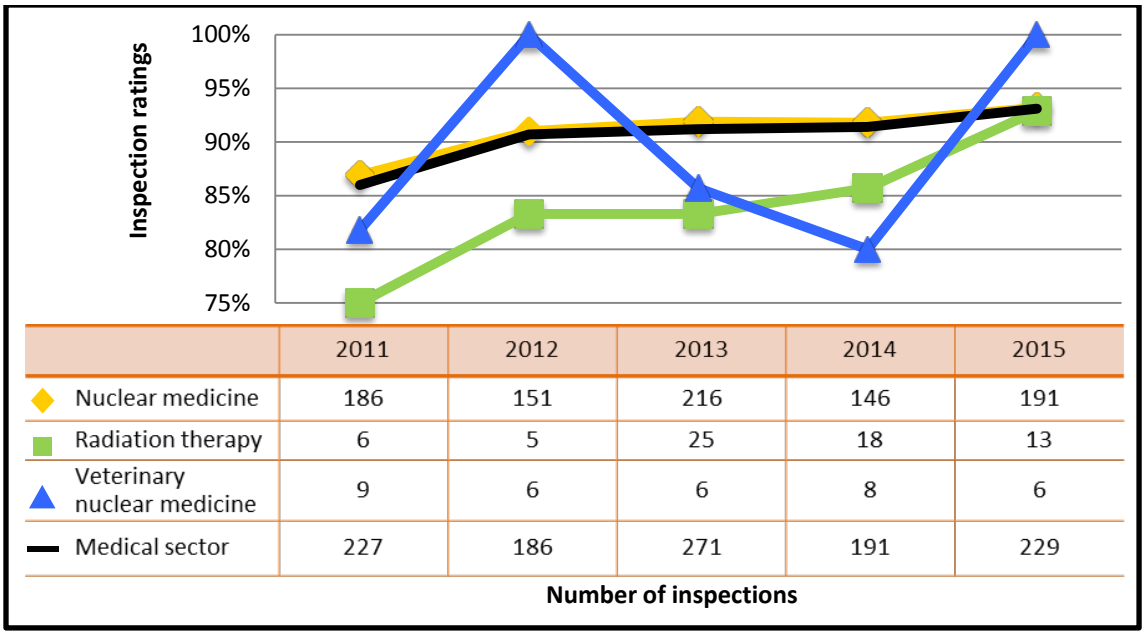
The overall compliance rating for operating performance in the medical sector was 93.1 percent (229 of 246 inspections) in 2015. As shown in Figure 19, the majority of licensees inspected by the CNSC were found to be compliant. A sector-to-subsector comparison of inspection ratings is provided in Figure 20.

Figure 19: Medical sector performance – details of operating performance inspection ratings, 2011–15



	2011	2012	2013	2014	2015
Fully satisfactory or satisfactory	227	186	271	191	229
Below expectations	37	19	26	18	17
Unacceptable	0	0	0	0	0

Figure 20: Medical sector performance comparison with highlighted subsectors – inspection ratings that met or exceeded expectations of operating performance, 2011– 2015



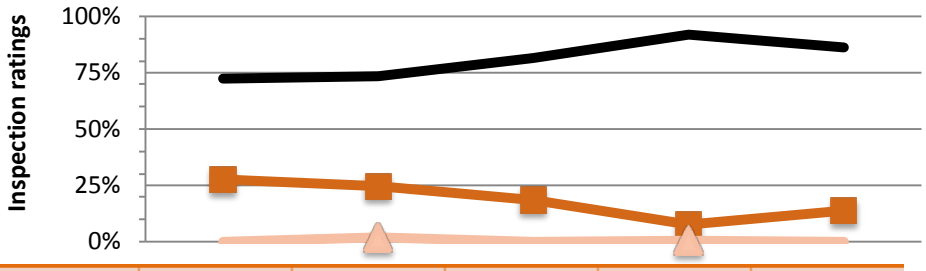
	2011	2012	2013	2014	2015
Nuclear medicine	186	151	216	146	191
Radiation therapy	6	5	25	18	13
Veterinary nuclear medicine	9	6	6	8	6
Medical sector	227	186	271	191	229

Note: The number of inspections shown in the medical sector row is the aggregate for the entire sector, including subsectors not highlighted in this report.

6.3.3 Radiation protection

The overall compliance rating for radiation protection in the medical sector was 86.2 percent (203 of 240 inspections) in 2015, as shown in Figure 21. A sector-to-subsector comparison of inspection ratings is provided in Figure 22.

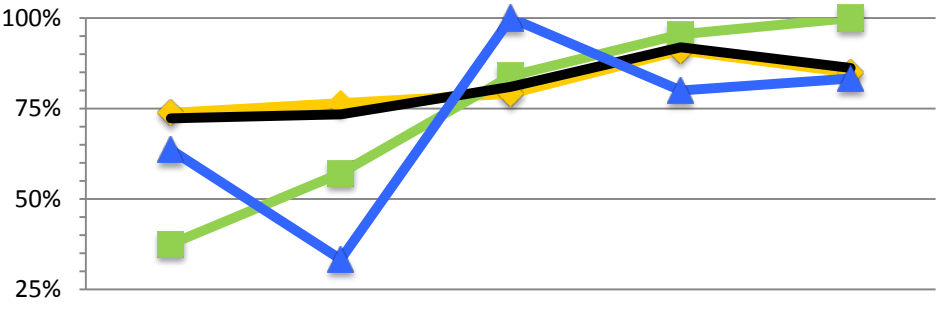
Figure 21: Medical sector performance – inspection ratings of radiation protection, 2011–15



	2011	2012	2013	2014	2015
Fully satisfactory or satisfactory	191	152	234	192	212
Below expectations	73	51	53	16	34
Unacceptable	0	4	0	1	0

Number of inspections

Figure 22: Medical sector performance comparison with highlighted subsectors – inspection ratings meeting or exceeding expectations of radiation protection, 2011–15



	2011	2012	2013	2014	2015
Nuclear medicine	158	127	185	144	174
Radiation therapy	3	4	21	21	15
Veterinary nuclear medicine	7	2	7	8	5
Medical sector	191	152	238	192	212

Number of inspections

Note: The number of inspections shown in the medical sector row is the aggregate for the entire sector, including subsectors not highlighted in this report.

6.3.4 Security

The compliance rating for security SCA for licensees in the medical sector was 98.2 percent (219 of 223 inspections) in 2015, as shown in Table 8.

Table 8: Medical sector performance – inspection ratings for security in 2014 and 2015

Ratings	2014	2015
Fully satisfactory or satisfactory	181	219
Below expectations	7	4
Unacceptable	0	0
Total	**188**	**223**
Percent compliant (%)	**96.3**	**98.2**

7 Industrial sector

Licensees in the industrial sector use nuclear substances either in industrial facilities or as part of fieldwork or construction. In 2015, this sector accounted for 1,349 CNSC licences and 32,323 total workers. Of these workers, 10,193 were designated as nuclear energy workers (NEWs).

The results of CNSC staff evaluation of the regulatory performance of all industrial sector licensees inspected in 2015 are included in the overall results. The following four subsectors are highlighted in further detail:

- portable gauge
- fixed gauge
- industrial radiography
- oil well logging

7.1 Summary of safety assessment

Based on their evaluation and verification of licensee performance, CNSC staff concluded that the safety performance of the industrial sector was satisfactory in 2015.

Doses received by NEWs in this sector remained low, with the majority of workers receiving doses below 1 millisievert (mSv). No NEW received a dose in excess of the annual regulatory limits.

Of all the inspected licensees in 2015, the majority of them were found to be compliant in the four SCAs covered in this report:

- 97.3 percent were compliant in management system
- 90.8 percent were compliant in operating performance
- 89.1 percent were compliant in radiation protection
- 94.2 percent were compliant in security

In cases where non-compliances were noted, licensees took appropriate corrective actions, satisfactory to CNSC staff, to address the non-compliances.

The CNSC took 14 escalated enforcement actions against licensees in the industrial sector in 2015. Of these, 13 were orders and one was an administrative monetary penalty. The CNSC also decertified one exposure device operator. Further details of these enforcement actions are provided in section 7.3.5.

7.2 Sector overview

Typical applications of nuclear substances in the industrial sector include the measurement of physical parameters such as density, moisture content and geological composition in civil engineering. They are also used for level and flow rate in industrial facilities (such as those that support oil and gas exploration, mining and manufacturing). These nuclear substances are found in radiation devices such as fixed nuclear gauges which monitor production processes in many industries, and portable nuclear gauges which are often used to measure moisture and density in soil, and the compaction of asphalt in road construction.

In industrial radiography, nuclear substances are used in exposure devices for the non-destructive examination of materials. Persons operating these devices, or supervising trainees in the operation of such devices, must be certified by the CNSC. Exposure devices that are used for industrial radiography, as shown in Figure 23, are engineered and operated using multiple safety barriers to reduce the potential for accidental occupational exposure. One example is dense material, such as depleted uranium, which shields users against the intense radioactivity of the source contained inside the device.

Industrial applications of nuclear substances are as varied as the processes to which they are applied. Specific radioisotopes are chosen based on the type of radiation they emit, the intensity of their radiation and the intended application. For example, the nuclear substance chosen for industrial radiography depends on the size and density of the material to be imaged. Cobalt-60, with its high-energy gamma radiation, is used for large structures and dense materials such as structural concrete. When the material does not require the penetrating power of cobalt-60, other nuclear substances, such as iridium-192 or selenium-75, are used instead. Cesium-137, another gamma emitter, is most commonly used in portable and fixed gauges to measure density. In other industrial uses, such as measuring moisture content, portable gauges most commonly use neutron-emitting nuclear substances such as americium-241/beryllium.

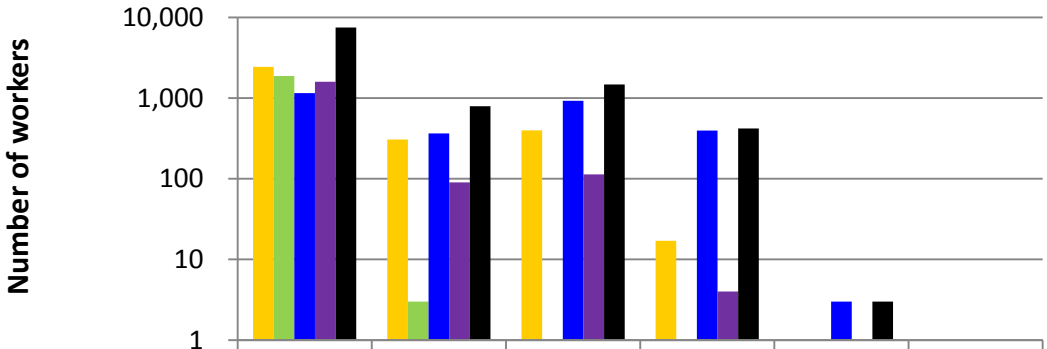
Figure 23: An exposure device being used for material testing

7.3 Safety performance measures

7.3.1 Doses to workers

NEWs in the industrial radiography subsector continued to receive higher doses than workers in other industrial subsectors as show in Figure 24. This is a result of working in close proximity to exposure devices containing high activity sealed sources. Figure 25 shows the doses to NEWs in the industrial radiography subsector over the period of 2011 to 2015.

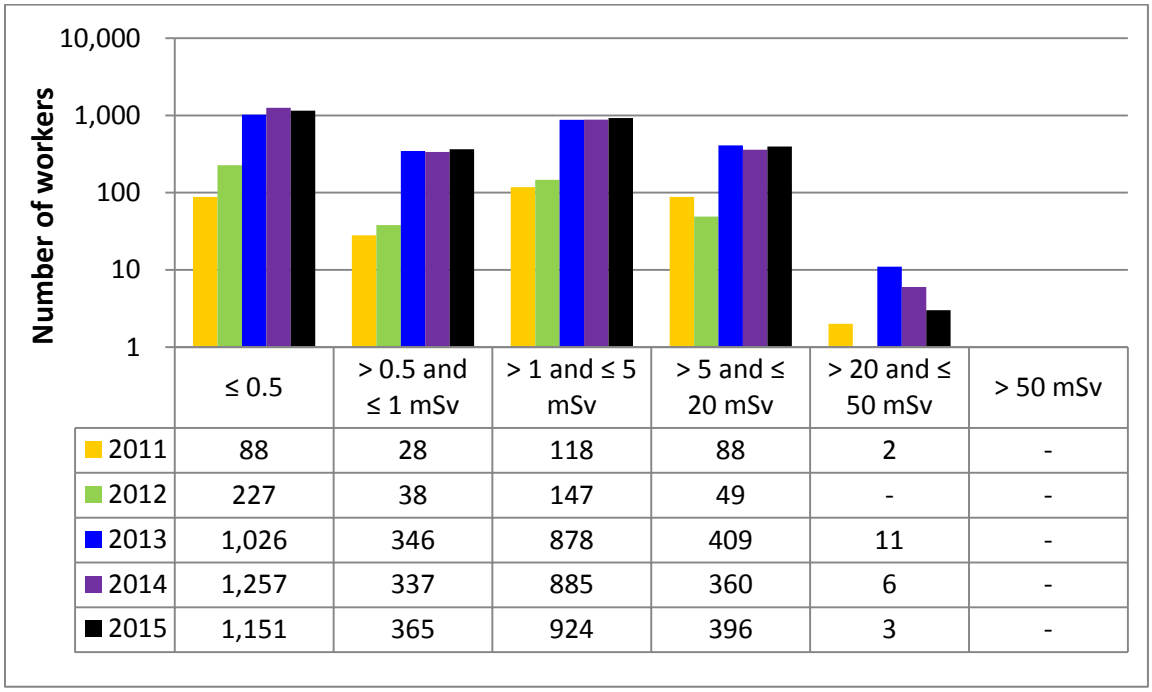
Figure 24: Industrial sector performance – annual effective doses of NEWs in 2015



	≤ 0.5	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
Portable gauge	2,437	306	398	17	-	-
Fixed gauge	1,881	3	-	-	-	-
Industrial radiography	1,151	365	924	396	3	-
Oil well logging	1,595	90	113	4	-	-
Industrial sector	7,506	793	1,472	419	3	-

Note: The total number of NEWs shown in the industrial sector row is the aggregate for the entire sector, including subsectors not highlighted in this report.

Figure 25: Industrial radiography subsector performance – annual effective doses to NEWs, 2011–15

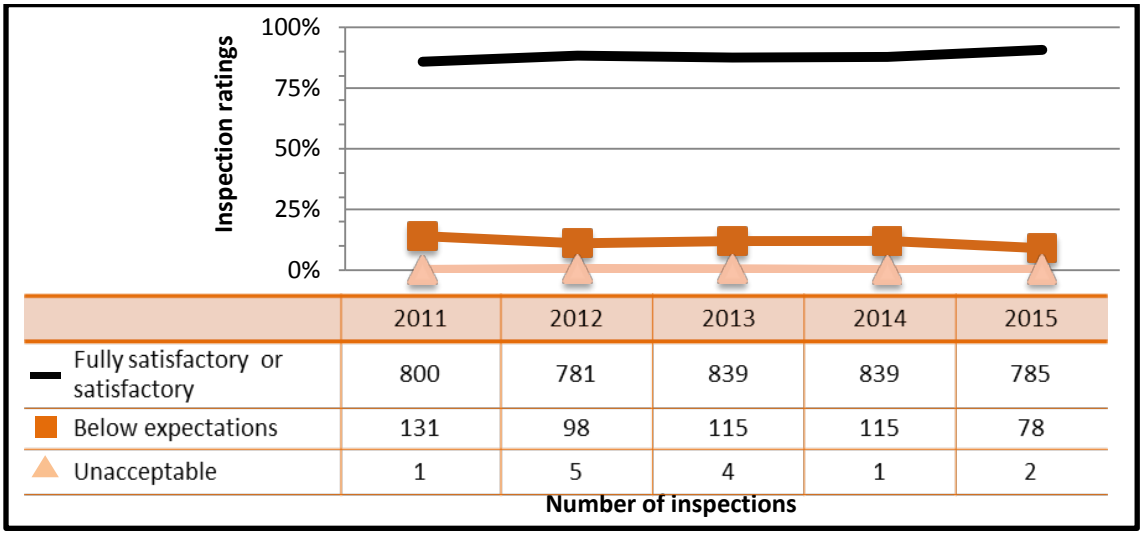


	≤ 0.5	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
2011	88	28	118	88	2	-
2012	227	38	147	49	-	-
2013	1,026	346	878	409	11	-
2014	1,257	337	885	360	6	-
2015	1,151	365	924	396	3	-

7.3.2 Operating performance

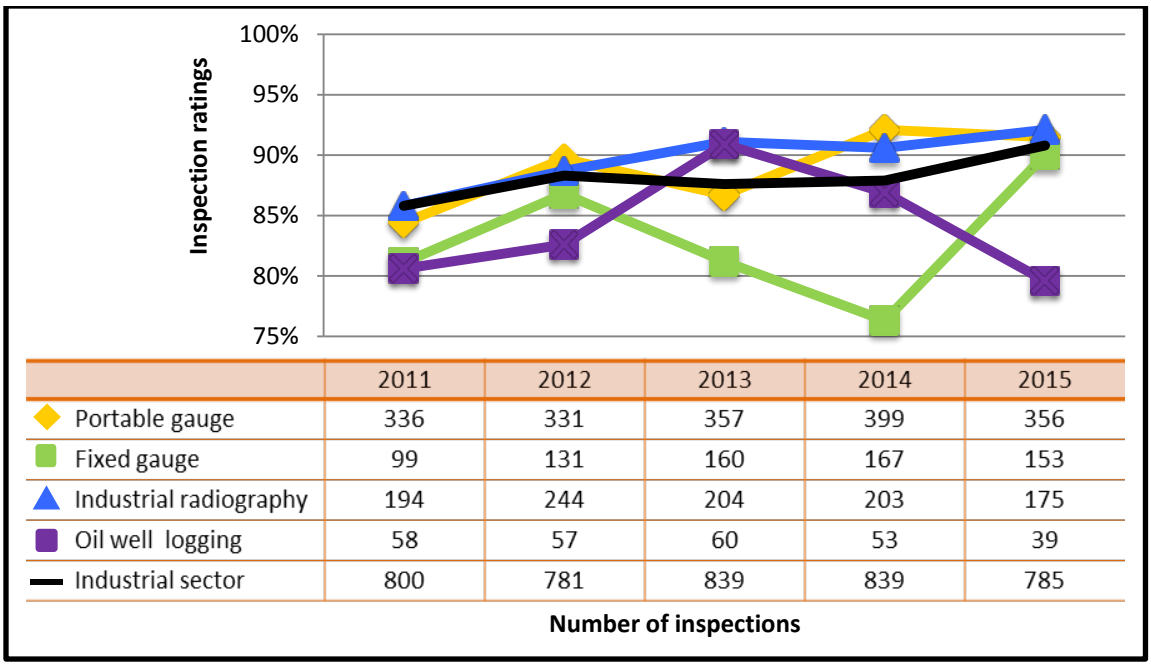
The compliance rating for operating performance in the industrial sector was 90.8 percent (782 of 860 inspections) in 2015, as shown in Figure 26. The licensees received unacceptable ratings in operating performance. The circumstances of each are discussed in section 7.3.4. A sector-to-subsector comparison of inspection ratings is provided in Figure *27*. The oil well logging subsector rating in this SCA has been trending negatively since 2013. The most common type of non-compliance was administrative in nature and involved not keeping worker records according to regulatory requirements. As a response to this trend, CNSC staff have modified a component of their outreach strategy to increase its focus on record keeping in 2016.

Figure 26: Industrial sector performance – inspection ratings of operating performance, 2011–15



	2011	2012	2013	2014	2015
Fully satisfactory or satisfactory	800	781	839	839	785
Below expectations	131	98	115	115	78
Unacceptable	1	5	4	1	2

Figure 27: Industrial sector performance comparison with highlighted subsectors – inspection ratings meeting or exceeding expectations of operating performance, 2011–15



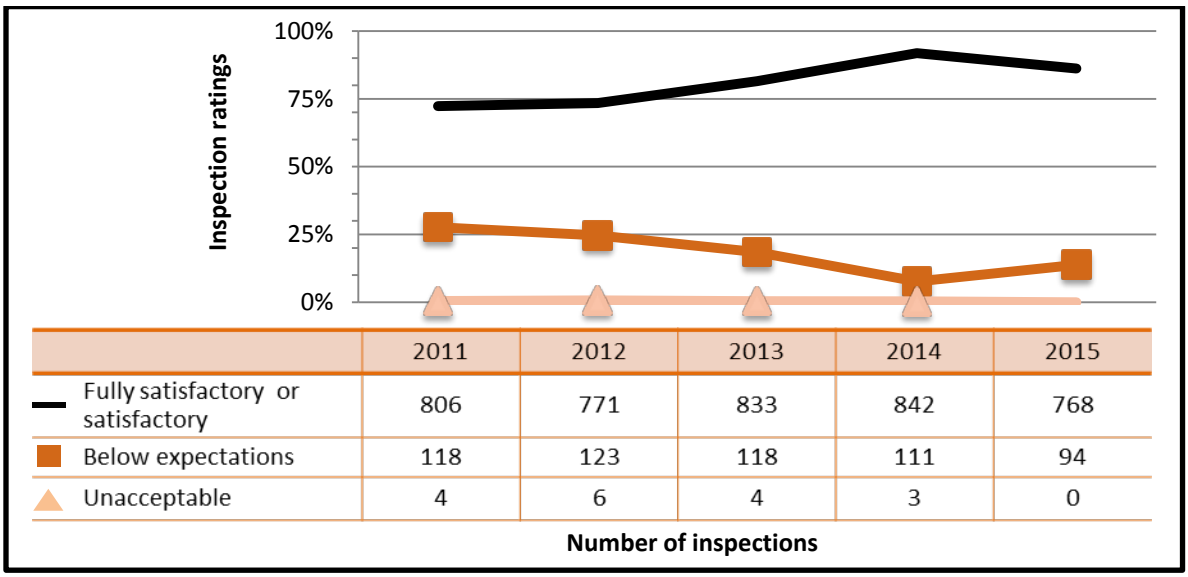
	2011	2012	2013	2014	2015
Portable gauge	336	331	357	399	356
Fixed gauge	99	131	160	167	153
Industrial radiography	194	244	204	203	175
Oil well logging	58	57	60	53	39
Industrial sector	800	781	839	839	785

Note: The number of inspections shown in the industrial sector row is the aggregate for the entire industrial sector, including subsectors not highlighted in this report.

7.3.3 Radiation protection

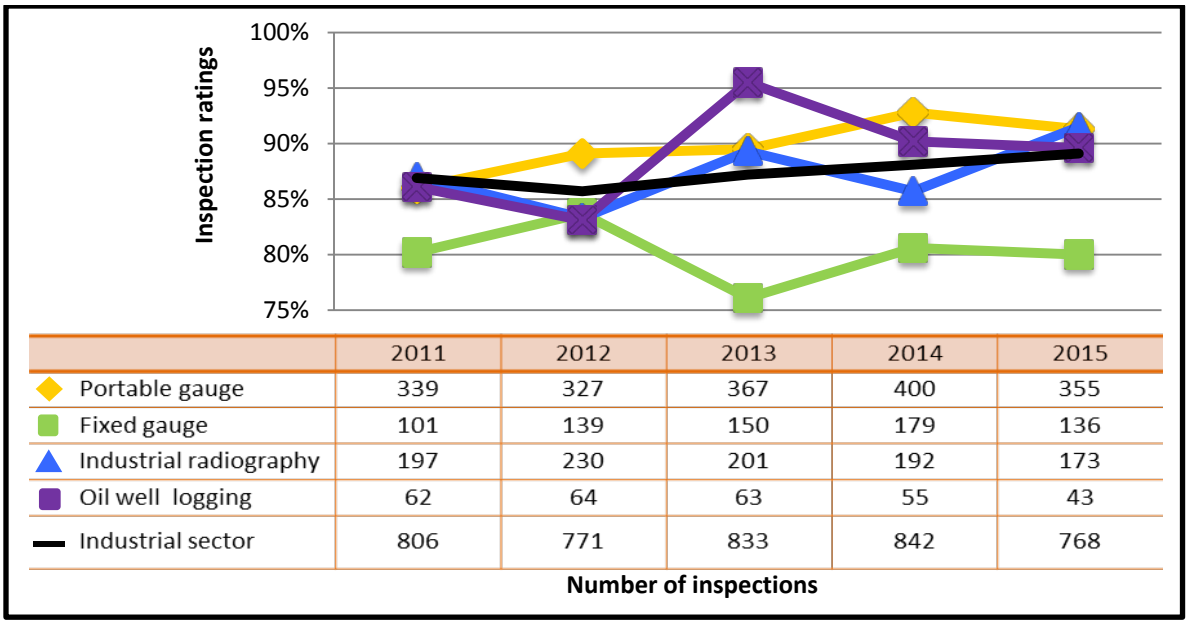
The compliance rating for radiation protection SCA for licensees in the industrial sector was 89.1 percent (765 of 859 inspections) in 2015, as shown in Figure 28. A sector-to-subsector comparison of inspection ratings is provided in Figure 29.

Figure 28: Industrial sector performance – inspection ratings of radiation protection, 2011–15



	2011	2012	2013	2014	2015
Fully satisfactory or satisfactory	806	771	833	842	768
Below expectations	118	123	118	111	94
Unacceptable	4	6	4	3	0

Figure 29: Industrial sector performance comparison with highlighted subsectors – inspection ratings meeting or exceeding expectations of radiation protection, 2011–15



	2011	2012	2013	2014	2015
Portable gauge	339	327	367	400	355
Fixed gauge	101	139	150	179	136
Industrial radiography	197	230	201	192	173
Oil well logging	62	64	63	55	43
Industrial sector	806	771	833	842	768

Note: The number of inspections shown in the industrial sector row is the aggregate for the entire industrial sector, including subsectors not highlighted in this report.

7.3.4 Security

The compliance rating for security SCA for licensees in the industrial sector was 94.2 percent (780 of 828 inspections) in 2015, as shown in Table 9. Two licensees received unacceptable ratings in this SCA. Both cases related to the security of portable gauges used at work sites. CNSC inspectors issued orders to both licensees.

Table 9: Industrial sector performance – inspection ratings for security for 2014 and 2015

Ratings	2014	2015
Fully satisfactory or satisfactory	875	780
Below expectations	56	46
Unacceptable	0	2
Total	**931**	**828**
Percent compliant (%)	**94.0**	**94.2**

7.3.5 Enforcement actions

The CNSC took 14 escalated enforcement actions against licensees in the industrial sector in 2015. These consisted of 13 orders and one administrative monetary penalty (AMP). The number of enforcement actions taken against licensees in this sector is consistent with previous year and is mainly due to the large number of licensees compared to other sectors. CNSC staff monitor the number of enforcement actions closely and take necessary measures to correct negative trends. A good example of this is the creation of the portable gauge workshops established in 2014.

The CNSC issued four orders against licensees in the portable gauge subsector[4], three in the industrial radiography subsector and three in the fixed gauge subsector. Two other orders were taken against licensees in the X-ray fluorescence subsector and one in the oil well logging subsector. A distribution of orders by industrial subsectors from 2011 to 2015 is shown in Figure 30. The CNSC issued the AMP in conjunction with an order to an industrial radiography licensee as a result of failure to assist or give information requested by an inspector.

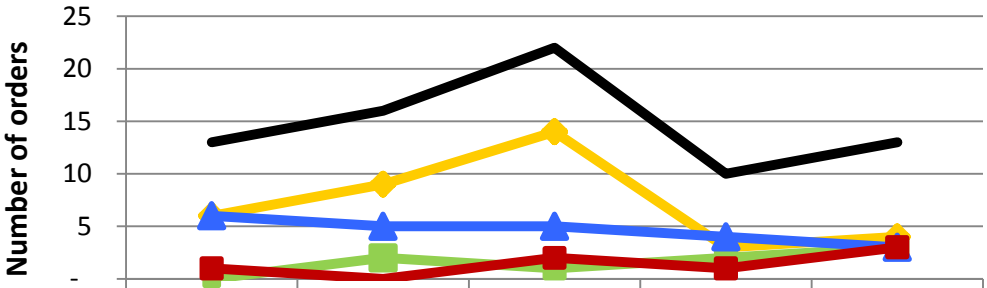
All licensees to whom orders were issued complied with the terms and conditions of the orders and implemented corrective measures to the satisfaction of CNSC staff. The licensee who was issued an AMP has paid the penalty amount.

The CNSC decertified one exposure device operator in 2015 stemming from an inspection in 2014 that identified non-compliances relating to the use of survey meters and supervision of exposure device operator trainees. Due to the significant health and safety risk, an order was issued to the company requiring them to immediately remove

[4] The two portable gauge licensees mentioned in sections 7.3.2 and 7.3.4 are included in this total.

the certified exposure device operator from all activities related to the use of an exposure device until it is demonstrated to the CNSC that the operator was no longer likely to pose a risk to the health and safety of persons.

Figure 30: Summary of orders in the industrial sector, 2011–15



	2011	2012	2013	2014	2015
Portable gauge	6	9	14	3	4
Fixed gauge	-	2	1	2	3
Industrial radiography	6	5	5	4	3
Other	1	-	2	1	3
Industrial sector	13	16	22	10	13

Details of all enforcement actions issued in 2015 are provided in appendix C.. Further information on regulatory actions, including escalated enforcement actions, taken by the CNSC is available on the CNSC website.

8 Academic and research

Licensed activities in the academic and research sector are conducted in universities, colleges and research laboratories. In 2015, this sector accounted for 207 licences and 8,137 total workers, of which 2,882 were designated as nuclear energy workers (NEWs).

Safety performance results are provided for all licensees included in the academic and research sector, with the laboratory studies and consolidated uses of nuclear substances subsectors highlighted in further detail.

8.1 Summary of safety assessment

The academic and research sector continued to show satisfactory safety performance in 2015.

Doses received by NEWs in this sector remained very low, with the majority of workers receiving doses below 1 millisievert (mSv).

Of all the inspected licensees in 2015, the majority of them were found to be compliant in the four safety and control areas (SCAs) covered in this report:

- 94.4 percent were compliant in management system
- 77.9 percent were compliant in operating performance
- 90.3 percent were compliant in radiation protection
- 91.4 percent were compliant in security

In cases where non-compliances were noted during the inspection, licensees took appropriate corrective actions, satisfactory to CNSC staff, to address the non-compliances.

The CNSC issued one administrative monetary penalty (AMP) to a licensee in 2015 for illegally transferring a radiation device to a person who does not hold a CNSC licence to possess such a device. The device has since been transferred to an authorized person.

CNSC laboratory

CNSC staff conducted a compliance inspection and an enhanced security inspection at the CNSC laboratory in October 2015. They concluded that the use of nuclear substances at the CNSC laboratory is safe. Doses received by NEWs working at the CNSC laboratory remained very low, with all workers receiving doses below 1 mSv.

8.2 Sector overview

This sector focuses mainly on biological and biomedical research that primarily uses open (unsealed) nuclear substances, as shown in Figure 31. The sector also uses sealed sources, radiation devices and accelerators for teaching as well as for pure and applied research.

Figure 31: A radioimmunoassay kit used to measure and quantify insulin in a lab study

CNSC laboratory

As part of its regulatory functions, the CNSC conducts certain activities regulated under the *Nuclear Safety and Control Act* (NSCA). To ensure oversight transparency, CNSC management has separated the organization's work as a licensee (which resides within the Technical Support Branch) from its work as a regulator (under the responsibility of the Regulatory Operations Branch).

The CNSC laboratory provides calibration services and analytical services for CNSC staff, including CNSC inspectors. To provide these services, the CNSC holds two licences: one for its gamma calibration irradiator located at its laboratory in Ottawa, and a second for consolidated uses of nuclear substances that covers all other activities conducted by the CNSC at its laboratory or elsewhere in Canada. Both licences were issued in accordance with the NSCA and are regulated using the same licensing and compliance verification processes that would apply to other, similar licensees.

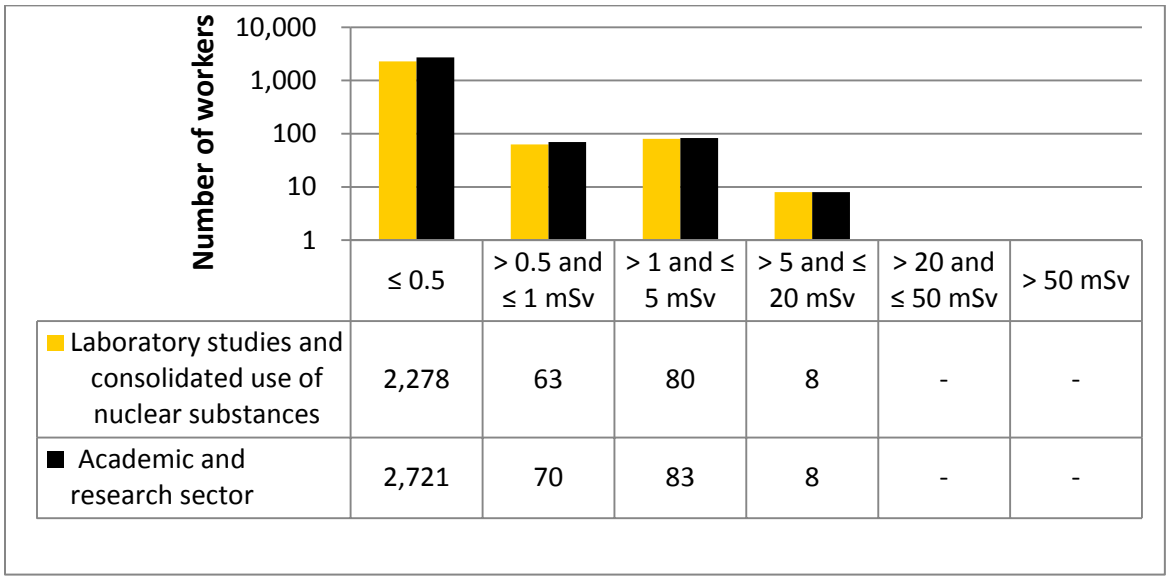
In this report, the CNSC laboratory is included in the laboratory studies and consolidated use of nuclear substances subsector. Its specific performance results are provided to demonstrate that the CNSC, as both regulator and licensee, is reporting on its licensed activities in a transparent manner.

8.3 Sector performance measures

8.3.1 Doses to workers

Doses received by NEWs in this sector remained very low, with the majority of workers receiving doses below 1 mSv. Among the workers shown in Figure 32 are 11 CNSC employees designated as NEWs who worked under CNSC laboratory licences. All 11 received doses below 0.5 mSv.

Figure 32: Academic and research sector performance comparison with the laboratory studies and consolidated use of nuclear substances subsector – annual effective doses of NEWs in 2015



	≤ 0.5	> 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	2,278	63	80	8	-	-
Academic and research sector	2,721	70	83	8	-	-

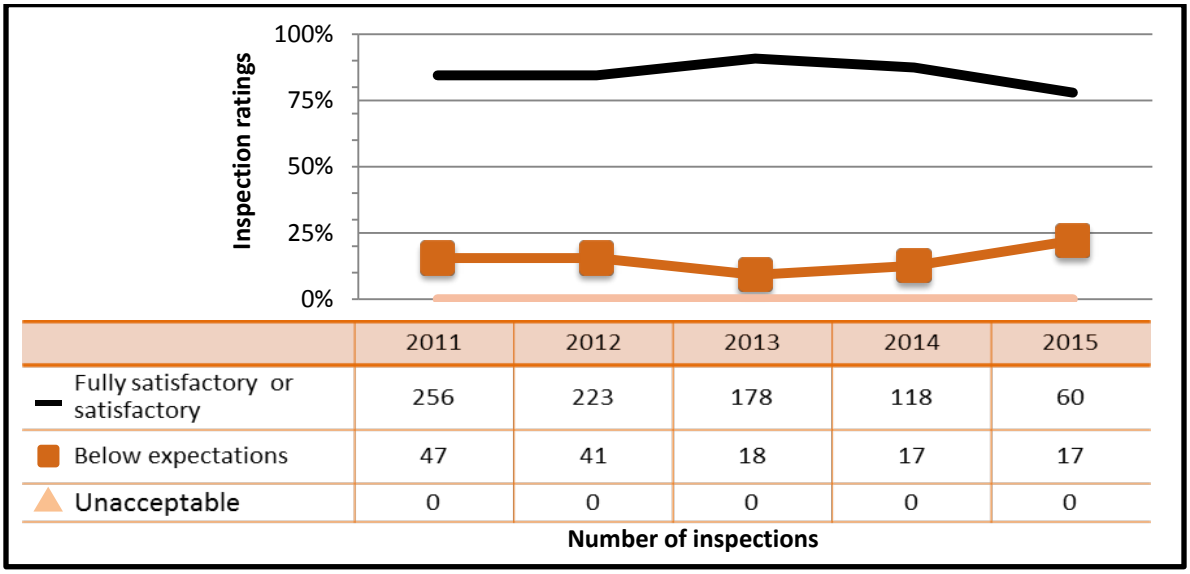
Note: The total number of NEWs shown in the academic and research sector row is the aggregate for the entire sector, including subsectors not highlighted in this report.

8.3.2 Operating performance

The overall compliance rating for operating performance in the academic and research sector was 77.9 percent (60 of 77 inspections) in 2015, as shown in Figure 33. Performance in this SCA has been trending negatively since 2013, when 90.8 percent of inspected licensees were found to be compliant. A sector-to-subsector comparison for operating performance ratings is provided in Figure 34. The laboratory studies and consolidated uses of nuclear substances subsector is the main driver of the rating in this SCA. The main non-compliances found involved workers not following procedures. As a response to this trend, CNSC staff have modified a component of their outreach strategy to increase its focus on this sector in 2016.

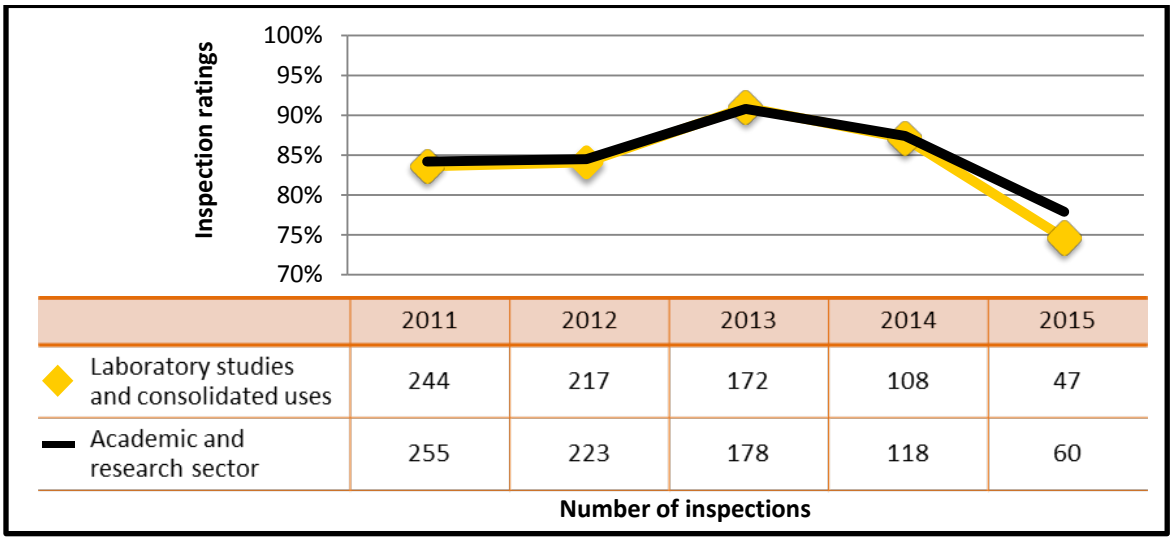
In 2014, the CNSC inspection program for the laboratory studies and consolidated uses of nuclear substances subsector was revised based on the positive safety performance ratings and the low-risk level associated with these licensed activities. The frequency of CNSC inspections was changed from annually to every two years, which is reflected in the decrease in the number of inspections conducted in 2014 and 2015 for this subsector.

Figure 33: Academic and research sector performance – inspection ratings of operating performance, 2011–15



	2011	2012	2013	2014	2015
Fully satisfactory or satisfactory	256	223	178	118	60
Below expectations	47	41	18	17	17
Unacceptable	0	0	0	0	0

Figure 34: Academic and research sector performance comparison with the laboratory studies and consolidated use of nuclear substances subsector – inspection ratings meeting or exceeding expectations of operating performance, 2011–15



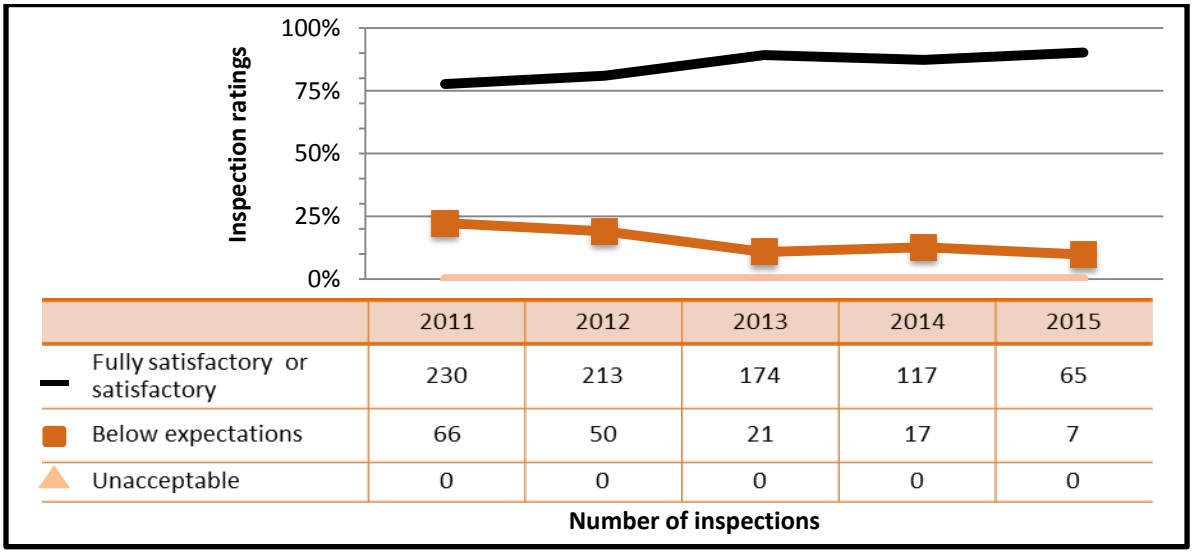
	2011	2012	2013	2014	2015
Laboratory studies and consolidated uses	244	217	172	108	47
Academic and research sector	255	223	178	118	60

Note: The number of inspections shown in the academic and research row is the aggregate for the entire sector, including subsectors not highlighted in this report.

8.3.3 Radiation protection

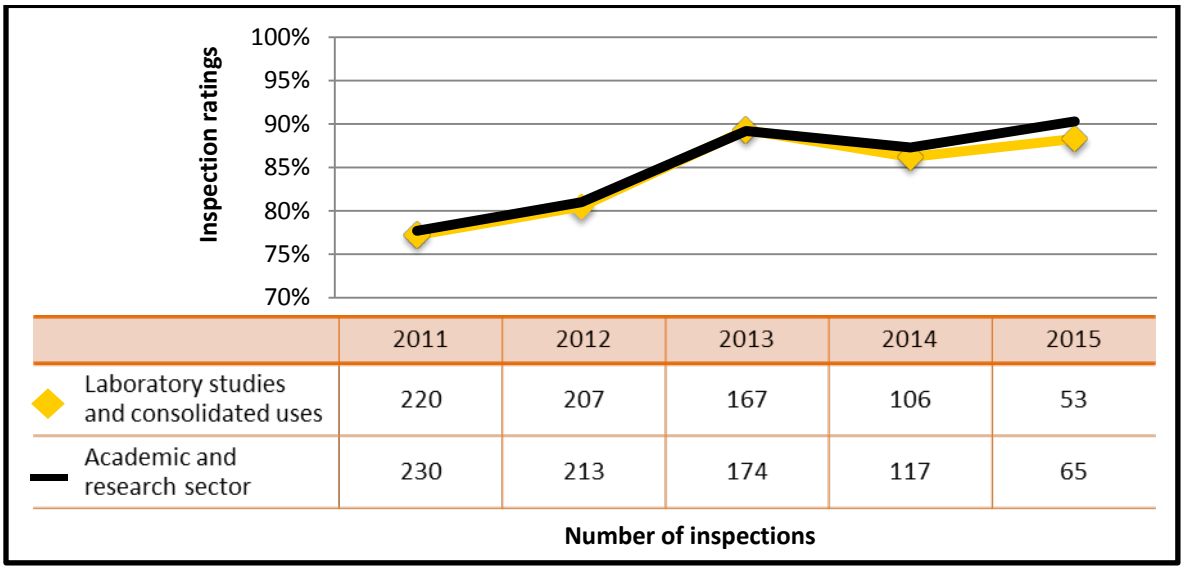
The overall compliance rating for radiation protection in the academic and research sector was 90.3 percent (65 of 73 inspections) in 2015, as shown in Figure 35. A sector-to-subsector comparison for radiation protection ratings is provided in Figure 36.

Figure 35: Academic and research sector performance – inspection ratings of radiation protection, 2011–15



	2011	2012	2013	2014	2015
Fully satisfactory or satisfactory	230	213	174	117	65
Below expectations	66	50	21	17	7
Unacceptable	0	0	0	0	0

Figure 36: Academic and research sector performance comparison with the laboratory studies and consolidated use of nuclear substances subsector – inspection ratings meeting or exceeding expectations of radiation protection, 2011–15



Note: The number of inspections shown in the academic and research row is the aggregate for the entire sector, including subsectors not highlighted in this report.

8.3.4 Security

The compliance rating for security SCA for licensees in the academic and research sector was 91.4 percent (64 of 70 inspections) in 2015, as shown in Table 10.

Table 10: Academic and research sector performance – inspection ratings for security for 2014 and 2015

Ratings	2014	2015
Fully satisfactory or satisfactory	120	64
Below expectations	3	6
Unacceptable	0	0
Total	**123**	**70**
Percent compliant (%)	**97.6**	**91.4**

9 Commercial sector

The commercial sector encompasses a number of licensed activities related to the production, processing, storage and distribution of nuclear substances, the calibration of radiation detection instruments, as well as the servicing of radiation devices and Class II prescribed equipment as a commercial enterprise. In 2015, this sector accounted for 246 CNSC licences and 2,536 total workers, including 1,870 designated as nuclear energy workers (NEWs).

Safety performance results are provided for all licensees included in the commercial sector, with the following five subsectors highlighted in further detail:

- isotope production accelerators
- processing of nuclear substances
- distribution of nuclear substances
- servicing of radiation devices and prescribed equipment
- calibration of radiation devices and prescribed equipment.

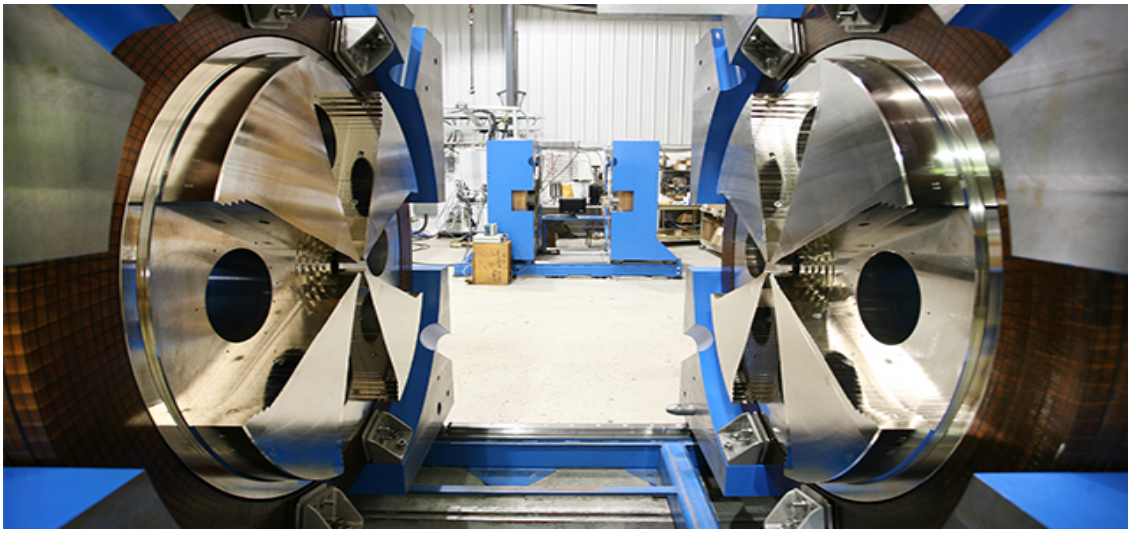
Figure 37 shows the internal components of a partially assembled cyclotron used for the production of radioisotopes while Figure 38 shows NEWs processing nuclear substances into radioisotopes.

9.1 Summary of safety assessment

The commercial sector continued to show adequate safety performance in 2015.

Doses received by NEWs in this sector remained low, with the majority of workers receiving doses below 1 millisievert (mSv). There was one worker, designated as a NEW, who received an extremity dose of 1.7 Sv as a result of an event described in section 5.8. The effective dose for this worker was calculated to be 15 mSv.

Figure 37: Isotope production accelerator



Of all the inspected licensees in 2015, the majority of them were found to be compliant in the four SCAs covered in this report:

- 96.1 percent were compliant in management system
- 94.3 percent were compliant in operating performance
- 91.6 percent were compliant in radiation protection
- 96.6 percent were compliant in security

In cases where non-compliances were noted during the inspection, licensees took appropriate corrective actions, satisfactory to CNSC staff, to address the non-compliances.

The CNSC took four escalated enforcement action licensees in the commercial sector. Inspectors issued two orders and two administrative monetary penalties (AMPs).

The CNSC issued an order to a cyclotron facility licensed to produce radioisotopes requiring the facility to stop production until the licensee ensured there were a sufficient number of trained and qualified workers in place and a radiation monitor was installed in the production area. The order was issued during an inspection by CNSC staff as part of the assessment of an event that was reported by the licensee involving a NEW receiving a dose above regulatory limits.

Figure 38: NEWs processing nuclear substances into radioisotopes

The other order and one of the two AMPs were issued to a servicing licensee following a notification by the manufacturer of the Class II prescribed equipment that the licensee had performed unauthorized installation and upgrades to a medical linear accelerator, without requesting prior approval of the modifications to the CNSC.

The remaining AMP was issued in 2015 to a processing of nuclear substances subsector licensee (Isologic Innovative Radiopharmaceuticals Ltd.) for an event that occurred in 2014 relating to the delivery of a number of packages that were contaminated above regulatory limits. CNSC staff presented this event at the November 2014 and December 2014 Commission meetings.

9.2 Sector overview

Isotope production cyclotrons can produce a range of different radioisotopes that are widely used in the diagnosis, management and treatment of disease. Most licensees in the processing of nuclear substances subsector process isotopes to provide products and services used for the prevention, diagnosis and treatment of disease. Others use tritium gas to manufacture self-luminous light sources. Nuclear substances are found in devices that are commonly used by Canadians, such as smoke detectors. These devices may not require a licence for their possession by the end user; however, their manufacture and initial distribution in Canada are licensed by the CNSC.

9.3 Safety performance measures

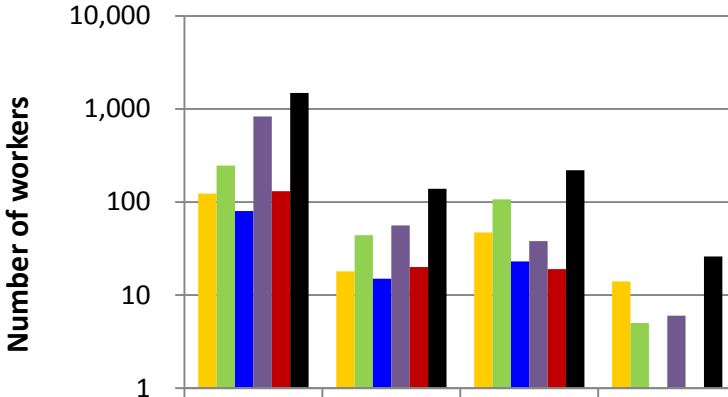
9.3.1 Doses to workers

NEWs in the isotope production accelerators and processing of nuclear substances subsectors continued to receive higher doses than workers in other commercial subsectors, as shown in Figure 39. This is due to their manual handling of nuclear substances and activated cyclotron components. The vast majority of NEWs in these subsectors received doses below 5 mSv in 2015.

There was one NEW who received an equivalent dose above the regulatory limit for extremities of 500 mSv as a result of an event that was reported to the Commission in June 2015. The effective dose to the worker was calculated to be 15 mSv. Further details on this event are provided in section 5.8.

Annual effective doses and annual extremity doses for NEWs in the isotope production accelerators subsector from 2011 to 2015 are shown in Figure 40 and Figure 41, respectively. Annual effective doses for NEWs in the processing of nuclear substances subsector from 2011 to 2015 are shown in Figure 42.

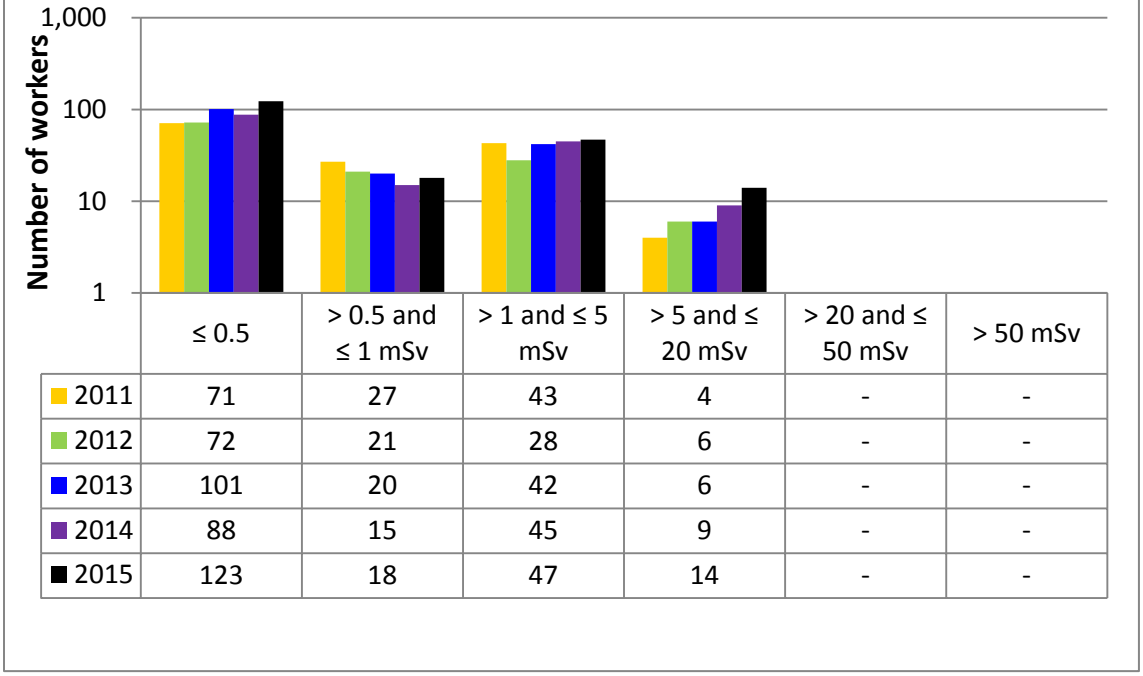
Figure 39: Commercial sector performance comparison with select subsectors – effective doses to NEWs in 2015



	≤ 0.5	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
Isotope production	123	18	47	14	-	-
Processing of nuclear substances	246	44	107	5	-	-
Distribution	80	15	23	-	-	-
Servicing	831	56	38	6	-	-
Calibration	131	20	19	-	-	-
Commercial sector	1,485	139	220	26	-	-

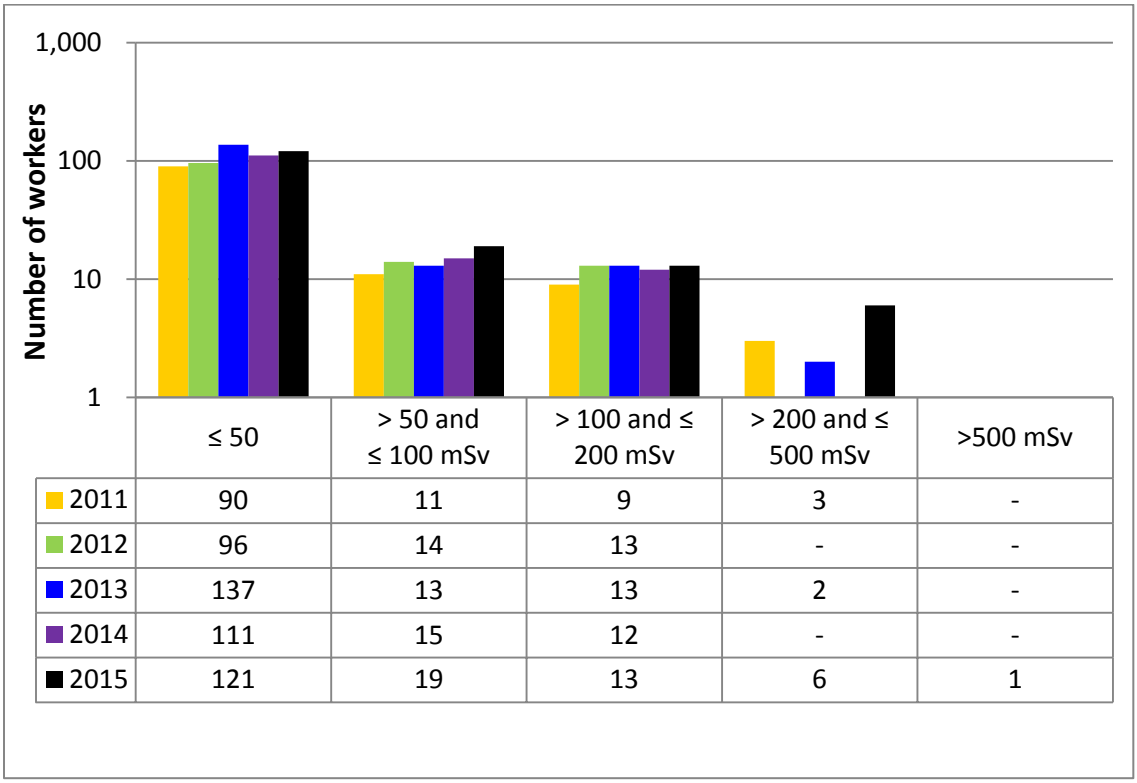
Note: The total number of NEWs shown in the commercial sector is the aggregate for the entire sector, including subsectors not highlighted in this report.

Figure 40: Isotope production accelerators subsector performance – annual effective doses to NEWs, 2011–15



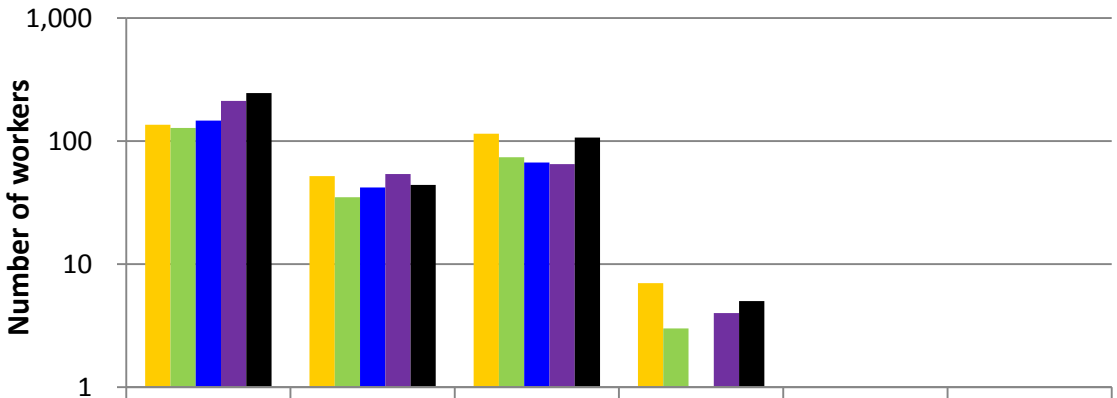
	≤ 0.5	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
2011	71	27	43	4	-	-
2012	72	21	28	6	-	-
2013	101	20	42	6	-	-
2014	88	15	45	9	-	-
2015	123	18	47	14	-	-

Figure 41: Isotope production accelerators subsector performance – annual extremity doses to NEWs, 2011–15



	≤ 50	> 50 and ≤ 100 mSv	> 100 and ≤ 200 mSv	> 200 and ≤ 500 mSv	>500 mSv
2011	90	11	9	3	-
2012	96	14	13	-	-
2013	137	13	13	2	-
2014	111	15	12	-	-
2015	121	19	13	6	1

Figure 42: Processing of nuclear substance subsector performance – annual effective doses to NEWs, 2011–15



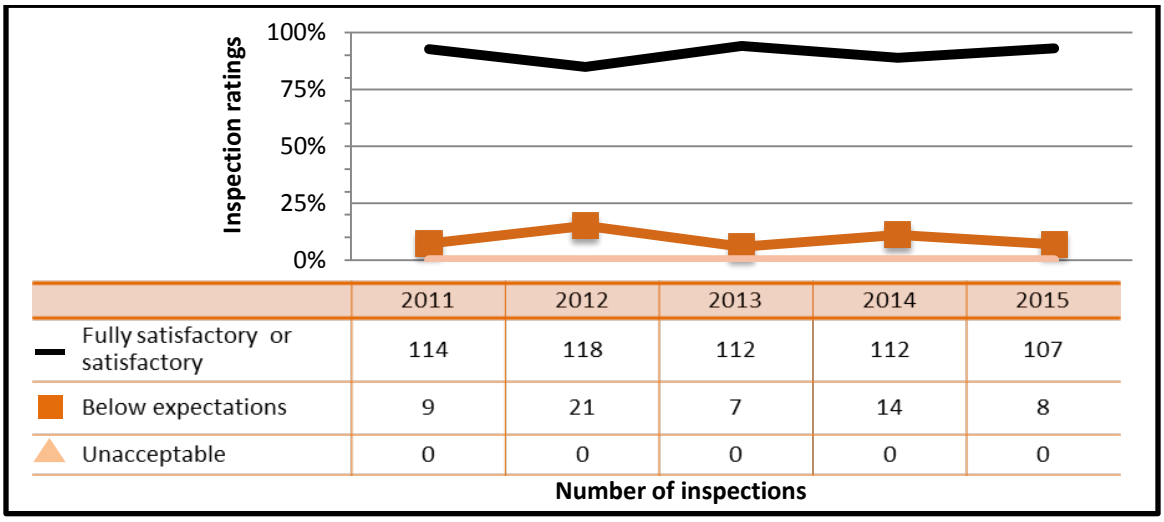
	≤ 0.5	> 0.5 and ≤ 1 mSv	> 1 and ≤ 5 mSv	> 5 and ≤ 20 mSv	> 20 and ≤ 50 mSv	> 50 mSv
2011	136	52	115	7	-	-
2012	128	35	74	3	-	-
2013	147	42	67	-	-	-
2014	212	54	65	4	-	-
2015	246	44	107	5	-	-

9.3.2 Operating performance

The overall compliance rating in 2015 for operating performance in the commercial sector was 94.3 percent (107 of 115 inspections), as shown in Figure 43. A sector-to-subsector comparison for operating performance ratings is provided in Figure 44.

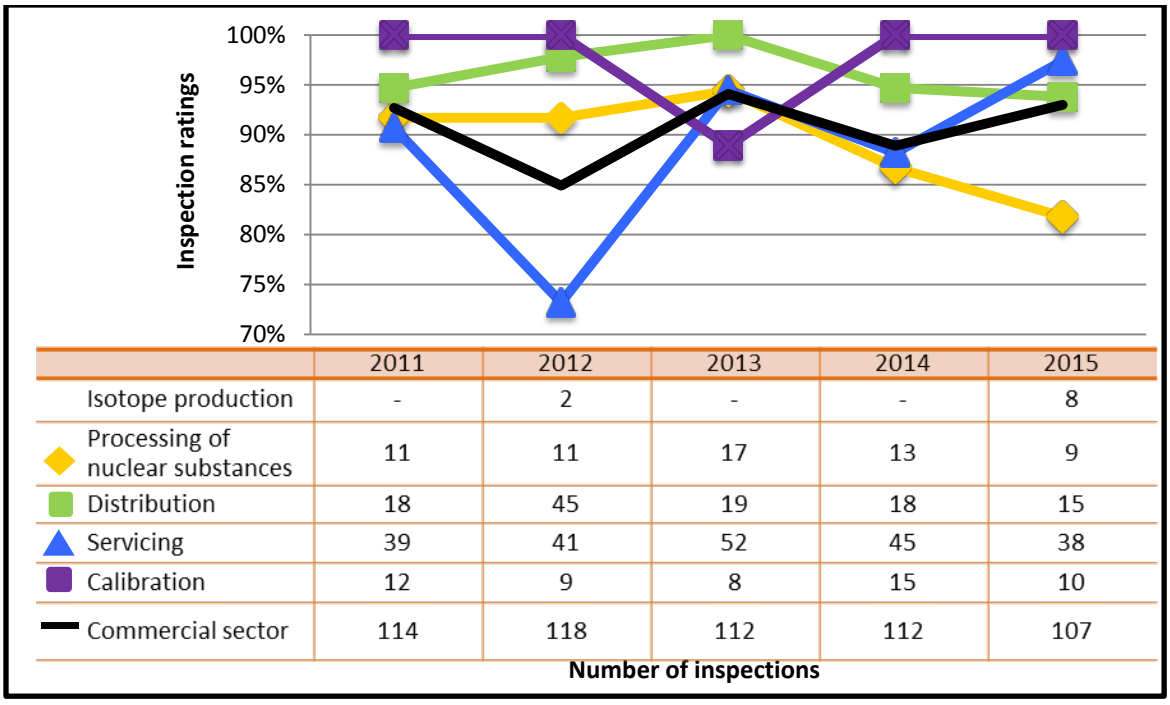
The processing of nuclear substance subsector has showed a downward trend in compliance ratings since 2013. This trend is mostly related to the comparatively small number of inspections conducted and the number of licensees that received below expectations ratings (two of 11 inspections), rather than a trend in overall safety performance.

Figure 43: Commercial sector performance – inspection ratings of operating performance, 2011–15



	2011	2012	2013	2014	2015
Fully satisfactory or satisfactory	114	118	112	112	107
Below expectations	9	21	7	14	8
Unacceptable	0	0	0	0	0

Figure 44: Commercial sector performance comparison with highlighted subsectors – inspection ratings meeting or exceeding expectations of operating performance, 2011–15



	2011	2012	2013	2014	2015
Isotope production	-	2	-	-	8
Processing of nuclear substances	11	11	17	13	9
Distribution	18	45	19	18	15
Servicing	39	41	52	45	38
Calibration	12	9	8	15	10
Commercial sector	114	118	112	112	107

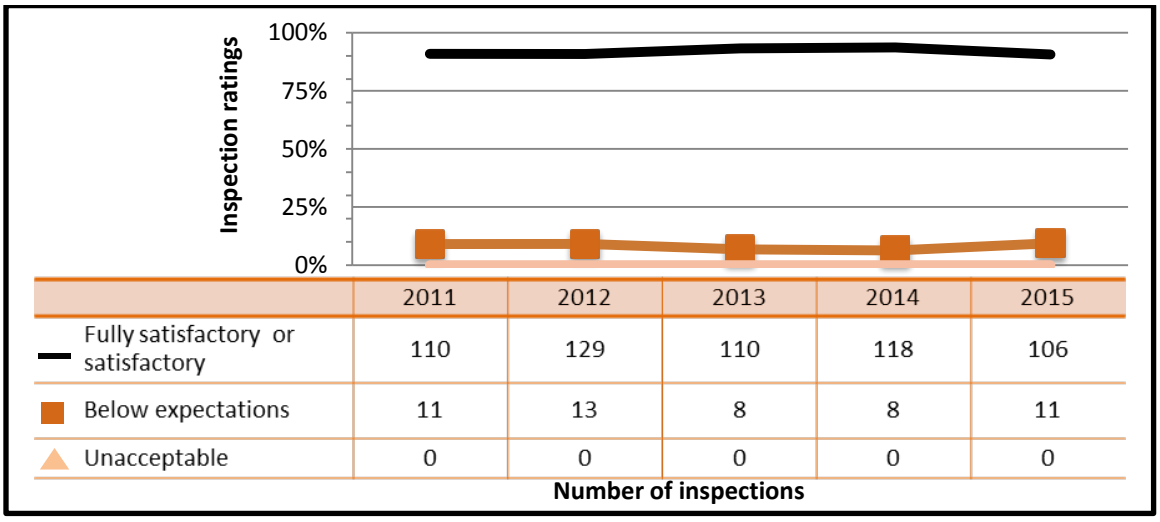
Note: The number of inspections shown in the commercial sector row is the aggregate for the entire commercial sector, including subsectors not highlighted in this report. The trend line was not provided for the isotope production accelerators subsector due to low number of inspections conducted.

9.3.3 Radiation protection

The overall compliance rating for radiation protection in the commercial sector was 91.6 percent (106 of 117 inspections) in 2015, as shown in Figure 45. A sector-to-subsector comparison for radiation protection ratings is provided in Figure 46.

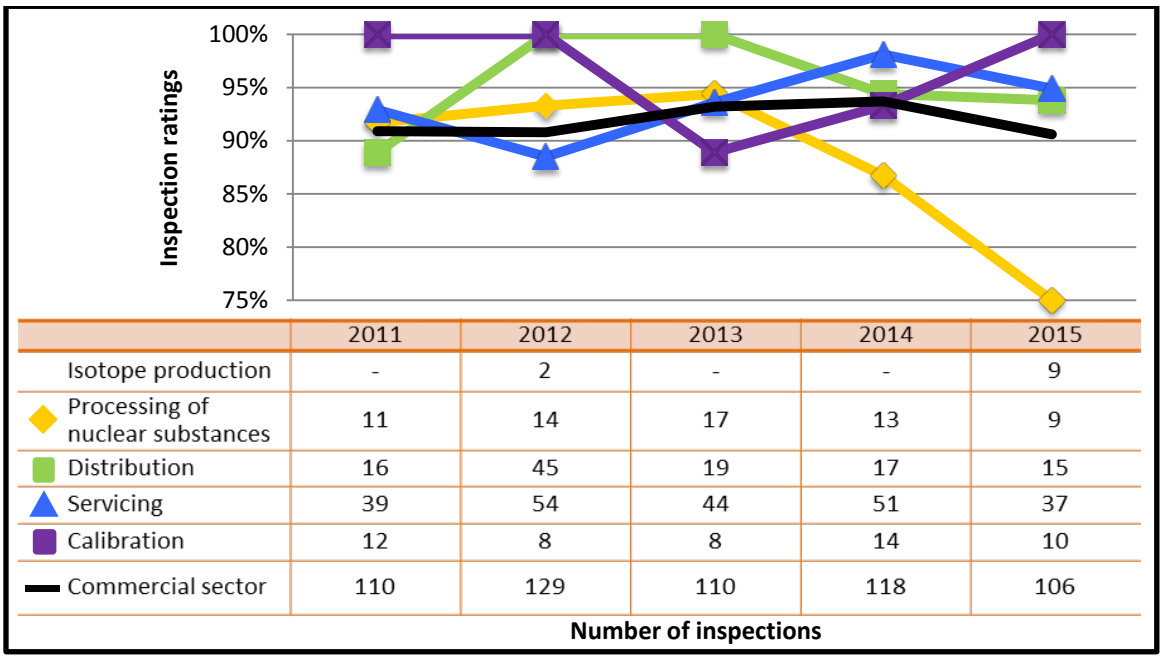
The downward trend in compliance ratings for the processing of nuclear substance subsector is again mostly related the comparatively small number of inspections performed compared to other sectors, rather than a negative trend in safety performance.

Figure 45: Commercial sector performance – inspection ratings of radiation protection, 2011–15



	2011	2012	2013	2014	2015
Fully satisfactory or satisfactory	110	129	110	118	106
Below expectations	11	13	8	8	11
Unacceptable	0	0	0	0	0

Figure 46: Commercial sector performance comparison with highlighted subsectors – inspection ratings meeting or exceeding expectations of radiation protection, 2011–15



	2011	2012	2013	2014	2015
Isotope production	-	2	-	-	9
Processing of nuclear substances	11	14	17	13	9
Distribution	16	45	19	17	15
Servicing	39	54	44	51	37
Calibration	12	8	8	14	10
Commercial sector	110	129	110	118	106

Note: The number of inspections shown in the commercial sector row is the aggregate for the entire commercial sector, including subsectors not highlighted in this report. The trend line was not provided for the isotope production accelerators subsector due to low number of inspections conducted.

9.3.4 Security

The compliance rating for security SCA for licensees in the commercial sector was 96.6 percent (86 of 89 inspections) in 2015, as shown in Table 11.

Table 11: Commercial sector performance – inspection ratings for security for 2014 and 2015

Ratings	2014	2015
Fully satisfactory or satisfactory	89	86
Below expectations	3	3
Unacceptable	0	0
Total	**92**	**89**
Percent compliant (%)	**96.3**	**96.6**

10 Conclusion

CNSC staff continued their ongoing regulatory oversight of licensees in the medical, industrial, academic and research, and commercial sectors. Staff conducted compliance verification activities consisting of field inspections, desktop reviews and technical assessments of licensee activities, and concluded that the use of nuclear substances in Canada is safe. The evaluations of findings for the safety and control areas (SCAs) covered in this report show that, overall, licensees made adequate provisions for the protection of the health, safety and security of persons and the environment from the use of nuclear substances, and took the measures required to implement Canada's international obligations.

Compliance verification

In 2015, CNSC staff conducted 1,568 inspections to verify compliance with CNSC regulatory requirements across all sectors, including 217 enhanced security inspections related to the implementation of REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources*. Of inspected licensees, the majority were found to be compliant in the four SCAs covered in this report:

- 96.2 percent were compliant in management system
- 90.6 percent were compliant in operating performance
- 88.7 percent were compliant in radiation protection
- 95 percent were compliant in security

Those licensees failing to meet requirements took appropriate corrective measures to address non-compliances found during inspections. CNSC staff systematically tracked all non-compliances until licensees took the appropriate corrective measures to address them. All corrective measures put in place by licensees were reviewed by CNSC staff and found to be satisfactory.

Effective doses to workers

Doses to workers remained very low in 2015, consistent with previous years. One of the 22,319 NEWs received an equivalent dose above the CNSC regulatory dose limit of 500 millisieverts (mSv) for extremities. Appropriate corrective actions were taken by the licensee in response to this event, which CNSC staff reported to the Commission in June 2015. Other than this event, none of the workers designated as NEWs exceeded the one- or five-year dose limits of 50 mSv and 100 mSv, respectively. Neither members of the public nor workers not designated as NEWs exceeded the one-year dose limit of 1 mSv.

Enforcement actions

In 2015, the CNSC took escalated compliance enforcement actions in 21 instances. It issued 15 orders and six administrative monetary penalties to ensure that the health and safety of workers, the Canadian public and the environment were being adequately protected. Most of the enforcement actions were taken against licensees in the industrial sector, consistent with trends from previous years. All licensees to whom orders were issued have implemented corrective measures, which were reviewed by CNSC staff and found to be satisfactory. All six administrative monetary penalties issued have been paid.

In 2015, one exposure device operator was decertified based on non-compliances observed during an inspection.

Reported events

Licensees reported 155 events to the CNSC that are covered in this report – all of which were assessed by CNSC staff. Of the total number of events reported, 148 were categorized as level 0 (no safety significance) on the International Nuclear and Radiation Events Scale. A further six events were ranked as level 1 (anomaly) due to the quantity of nuclear substances involved and the type of event reported (i.e., the loss of nuclear substances). The remaining event – ranked at level 2 (incident) – resulted in a NEW receiving an extremity dose above the regulatory dose limit for extremities as mentioned above.

There were no releases of nuclear substances to the environment that had an adverse radiological impact or that resulted in a person receiving a dose in excess of the regulatory limit for members of the public.

For all reported events, licensees implemented appropriate response measures to mitigate the impacts of the events and to limit radiation exposure to workers and the public. These measures were reviewed by CNSC staff and found to be satisfactory.

Regulatory focus in 2016

In 2016, the CNSC will continue to focus on effective regulatory oversight and continuous improvement, with greater emphasis on:

- optimizing flow in processes for delivery of efficient service while creating value for stakeholders
- reviewing the licensing process and continuing the consolidation of licences
- import and export of category 1 and 2 sealed sources
- leveraging experience from inspecting Class II facilities in a move to concentrate on more complex inspections across all sectors
- clarifying expectations for reportable events
- enhancing oversight of radiation safety officers across all sectors

Conclusion

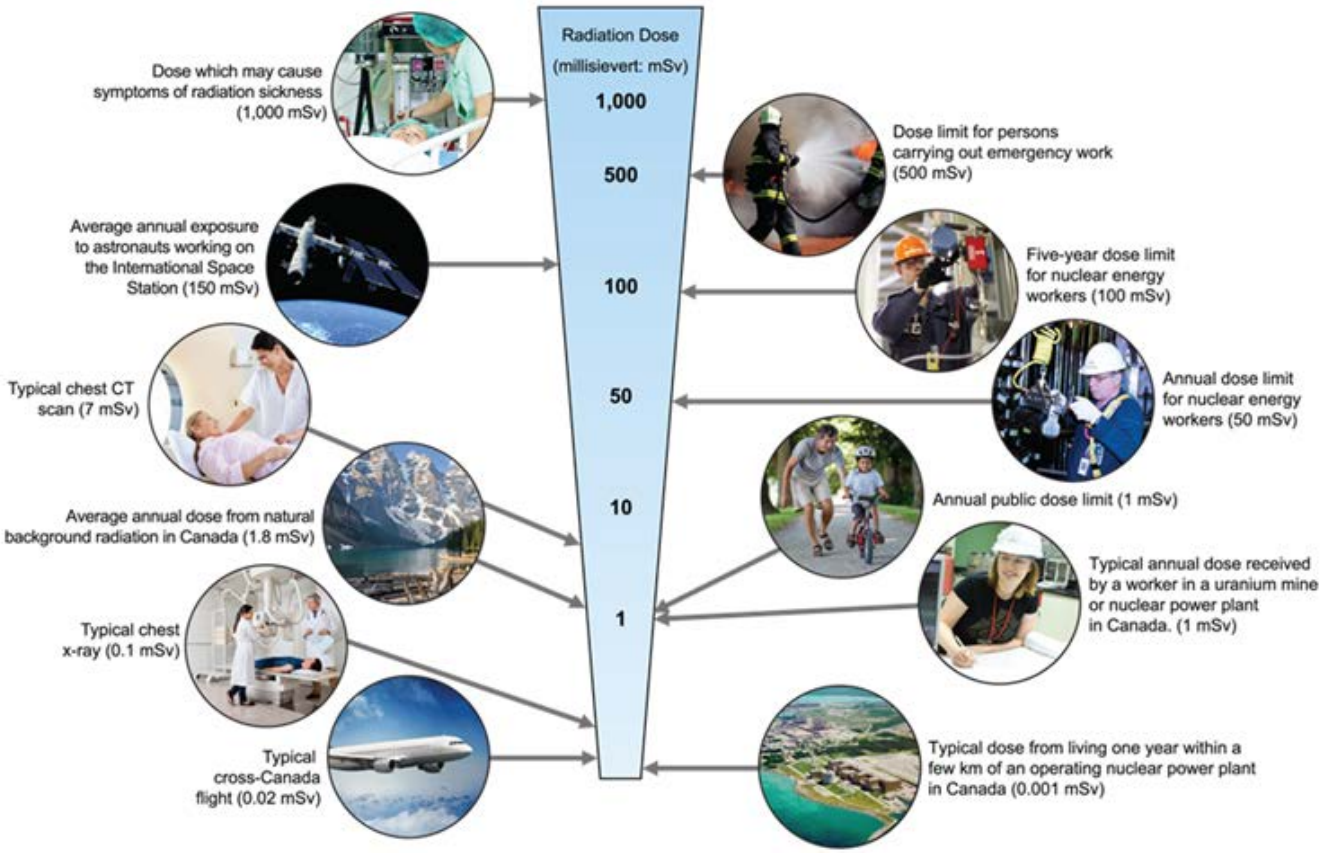
The use of nuclear substances in Canada is safe. Adequate provisions for the protection of the health, safety and security of persons and the environment from the use of nuclear substances are in place.

Appendix A: Radiation exposure

Non-occupational exposure to radiation can occur in many situations. For example, a person may be exposed to radiation during an airplane flight or by undergoing a medical procedure such as a chest X-ray. Natural background radiation contributes to radiation exposure received by all persons living on earth. The average annual dose from natural background radiation is approximately 1.8 millisieverts (mSv) in Canada and 2.4 mSv worldwide. Among major Canadian cities, Winnipeg has the highest annual average dose from background radiation at 4.1 mSv.

Figure 47 provides some perspective on these situations as they relate to occupational radiation exposures received by workers and the public as a result of nuclear activities licensed by the CNSC.

Figure 47: Doses in perspective



Ascertaining effective dose

In this report, effective dose refers to the dose received by the whole body. Each licensee is required to ascertain the effective dose received by each worker engaged in activities authorized under their CNSC licence. Doses may be ascertained by direct measurement (through monitoring) or by estimation, in accordance with the *Radiation Protection Regulations.* The *Radiation Protection Regulations* also stipulate that the licensee must use a licensed dosimetry service for monitoring every nuclear energy worker who has a reasonable probability of receiving an effective dose of greater than 5 mSv per year. However, regardless of the potential

for occupational exposure, licensees conducting licensed activities in certain industries, such as industrial radiography, are always required to use a licensed dosimetry service provider to ascertain doses for the nuclear energy workers they employ (under subsection 30(3) of the *Nuclear Substances and Radiation Devices Regulations*).

When a dose limit is exceeded

In a situation where a worker may have exceeded a regulatory dose limit, licensees are required to remove the worker from any activities that may add to his or her dose, investigate the cause of the exposure, take action to prevent a recurrence, and report to the CNSC. CNSC staff review the information provided by the licensee following each investigation. Depending on the circumstances, the Commission, or in most cases a designated officer authorized by the Commission, may authorize the worker to return to work according to the process defined in the *Radiation Protection Regulations.* The return-to-work authorization may specify conditions and prorated dose limits for the remainder of the dosimetry period.

Appendix B: Safety and control area naming conventions

Safety and control areas (SCAs) used in this report reflect the standardized set and naming convention approved for CNSC licensed activities, as shown the left-hand column of Table 12. For historical reasons, a modified naming convention of SCAs is used for the inspections of nuclear substances activities covered in this report (i.e., licensees that use nuclear substances). See the right-hand column of Table 12. In the near future, the CNSC intends to adopt the standardized naming convention of SCAs for all types of licensees that use nuclear substances. It should be noted that not all SCAs are considered for the inspection of nuclear substances activities and facilities.

Table 12: Differences in naming conventions for safety and control areas

Safety and control area	Safety and control area: Inspection reports
Management system	Organization and management Quality management
Human performance management	Training and qualification
Operating performance	Operational procedures
Safety analysis	Facility shielding design Facility safety systems
Physical design	Facility shielding design Facility safety systems
Fitness for service	Entrance and exit monitors Alarms and status machines Fault indicators
Radiation protection	Radiation protection
Conventional health and safety	Non-radiological health and safety
Environmental protection	Environmental protection
Emergency management and fire protection	Emergencies and unplanned events Fire protection
Waste management	Environmental protection
Security	Security
Safeguards	International obligations and safeguards
Packaging and transport	Packaging and transport

Appendix C: Enforcement actions issued in 2015

CNSC designated officers issued a total of 21 enforcement actions in the form of 15 orders and six administrative monetary penalties (AMPs) in 2015. Details of the orders issued are shown in Table 13. Details of AMPs are provided in Table 14.

Table 13: Orders issued to licensees in 2015

Issue date and location	Licensee (subsector)	Measures taken by the licensee	Closure date
Jan. 28 Cambridge, ON	Babcock & Wilcox Canada Ltd. (Industrial radiography)	Ceased to use two of its exposure devices until the company performed the required maintenance on the devices, including their various accessories.	Jan. 29
Feb. 2 Montreal, QC	Montreal Neurological Institute and Hospital (Isotope production)	Ceased the production of radio-labelled tracers until a sufficient number of trained and qualified workers were in place and a radiation monitor was installed in the production area. Ceased processing any radioisotopes until it had implemented adequate controls to prevent radioactive contamination.	Mar. 2
Mar. 3 Calgary, AB	Big Guns Energy Services Inc. (Oil well logging)	Placed all of its nuclear substances in secure storage until the company trained all of its workers in accordance with the company's procedures, corrected all non-compliances with applicable regulatory requirements observed during the inspection, and effectively implemented its radiation protection program.	Mar. 19
May 21 Calgary, AB	Baker Hughes Canada Company (Fixed gauge)	Ceased using vehicles on which fixed nuclear gauges were attached until it labelled these gauges with the correct safety marks and labels, and its vehicles displayed appropriate transport placarding. Updated its transport documentation with corrected information about the gauges.	Jun. 23

Issue date and location	Licensee (subsector)	Measures taken by the licensee	Closure date
May 29 Brooks, AB	All Test International Inc. (Industrial radiography)	Placed all nuclear substances in storage until the company corrected deficiencies identified in its radiation protection and dose monitoring programs. Implemented corrective measures to address all non-compliance items identified by the CNSC inspection report.	Jul. 3
July 29 Broadview, SK	J.K. Metals Ltd. (X-ray fluorescence)	Placed the device in secure storage until the company obtained a valid CNSC licence allowing possession of the device.	Aug. 28
Aug. 7 Ottawa, ON	Groupe ABS Inc. (Portable gauge)	Prevented one of its workers from using and transporting portable nuclear gauges until the company demonstrated to the CNSC that the worker was adequately trained to use and transport the device.	Aug. 31
Aug. 12 Sherbrooke, QC	Labo S.M. Inc. (Portable gauge)	Prevented one of its workers from using portable nuclear gauges until the company demonstrated to the CNSC that the worker was adequately trained to use the device.	Sep. 21
Aug. 19 Burnaby, BC	Stasuk Testing & Inspection Ltd. (Industrial radiography)	Prohibited a worker (a certified exposure device operator) from operating an exposure device, or supervising a trainee operating an exposure device, until the company implemented corrective measures and addressed all non-compliances identified during the inspection.	Sep. 30

Issue date and location	Licensee (subsector)	Measures taken by the licensee	Closure date
Nov. 9 Atlanta, GA (USA)	Elekta Inc. (Servicing)	• Ceased installation of uncertified configurations of medical linear accelerators. • Ceased performing upgrades. • Applied for certification of their equipment to reflect new upgraded configurations • Established procedures for performing the upgrades in Canada. • Notified the CNSC of locations where the installations had taken place in Canada. • Notified the affected Canadian operators.	Dec. 16
Nov. 30 Vancouver, BC	Rock Tech Lithium Inc. (X-ray fluorescence)	Recovered a radiation device and properly transferred it to another person authorized by the CNSC to possess such a device.	Open
Dec. 4 Dunmore, AB	GEM Testing Ltd. (Portable gauges)	Ceased using radiation devices prescribed in its licence until it addressed non-compliances to the CNSC's satisfaction.	Jan. 12, 2016
Dec. 8 Laval, QC	Englobe Corp. (Portable gauges)	Prevented one of its workers from using portable nuclear gauges until the company demonstrated to the CNSC that the worker was adequately trained to use the device.	Jan. 15, 2016
Dec. 9 Sudbury, ON	Ontario Ministry of Northern Development and Mines (Fixed gauge)	Put in place specific measures for the safety and security of the nuclear gauges and made arrangements for their transfer to a CNSC-licensed recipient.	Jan. 27, 2016
Dec. 17 Medicine Hat, AB	Porocel of Canada Ltd. (Fixed gauge)	Ceased any activities requiring entry into a vessel or hopper fitted with a radiation device until the company had conducted a full investigation of all vessel entries, including radiation dose estimates. Retrained its workers and implemented a radiation protection program to CNSC's satisfaction.	Jan. 25, 2016

Table 14: Administrative monetary penalties issued in 2015

Issue date and location	Licensee or individual	Reason for issuing AMP	Closure date
Jan. 19 London, ON	University of Western Ontario (Laboratory studies and consolidated uses of nuclear substances)	Illegal transfer of a radiation device to a person who does not hold a CNSC licence to possess such a device.	Jan. 26
Jan. 26 Lachine, QC	Isologic Innovative Radiopharmaceuticals Ltd. (Processing of nuclear substances)	Failure of consignor or carrier to act in accordance with paragraphs 501 to 547 of the International Atomic Energy Agency's *Regulations for the Safe Transport of Radioactive Material.*	Feb. 27
Jan. 28 Cambridge, ON	Babcock & Wilcox Canada Ltd. (Industrial radiography)	Failure to assist or give information requested by an inspector.	Jan. 29
Jan. 28 Edmonton, AB	Alberta Health Services (Radiation therapy)	Knowingly making a false or misleading statement to the Commission.	Mar. 3
Jun. 2 Montreal, QC	Mario Mignault, owner of Pro Rayons-X Inc. (Diagnostic and therapeutic nuclear medicine)	Illegal removal and use of a prescribed quantity of a nuclear substance without a CNSC licence to possess, use, transport and store this nuclear substance.	Jun. 26
Nov. 9 Atlanta, GA (USA)	Elekta Inc. (Servicing)	Failure to properly install and upgrade Class II prescribed equipment rendering it uncertified contrary to Section 10(a) of the *Class II Nuclear Facilities and Prescribed Equipment Regulations.*	Dec. 9

Appendix D: List of reported events in 2015

Table 15 includes all reported events by licensees in 2015, categorized using the International Nuclear and Radiological Event Scale (INES) tool.

Table 15: List of reported events in 2015

#	Date	INES rating	Type	Sector	Event summary
2357	Jan. 28	2	Unplanned exposure to a person	Commercial	Unplanned exposure to a worker who exceeded the regulatory dose limit of 500 millisieverts (mSv) for hands. This event was presented at the June 2015 Commission meeting.
2491	Jun. 20	1	Missing or found	Industrial	A vehicle storing a portable gauge that contained a low-risk (category 4) source was broken into and the gauge was stolen.
2500	Jun. 29	1	Missing or found	Industrial	A portable gauge containing a low-risk (category 4) source was stolen from a locked vehicle.
2507	Jul. 1	1	Missing or found	Industrial	A vehicle storing a portable gauge that contained a low-risk (category 4) source was reported stolen.
2598	Oct. 7	1	Missing or found	Industrial	A portable gauge containing low-risk (category 4) sources was stolen from a construction site.
2627	Nov. 7	1	Missing or found	Industrial	A vehicle storing a portable gauge that contained a low-risk (category 4) source was reported stolen.
2424	2011 and 2013[5]	1	Unplanned expsoures	Medical	Two vials containing iodine-123 were stolen by a hospital's nuclear medicine worker who later self-administered the nuclear substances to perform thyroid uptake scans on two separate occasions.

[5] This event was reported in 2015, but occurred in 2011 and 2013.

#	Date	INES rating	Type	Sector	Event summary
2442	Sep. 11, 2014[6]	0	Breach of security	Industrial	An intruder unsuccessfully attempted to break into a storage facility.
2360	Jan. 6	0	Damaged device	Industrial	An exposure device was damaged from a fall, preventing the sealed source to be fully returned to its shielded position.
2505	Jan. 7	0	Packaging and transport	Industrial	A Type A package (portable gauge) was delivered to an improper location.
2352	Jan. 8	0	Damaged device	Industrial	An exposure device was damaged from a fall, preventing the sealed source to be fully returned to its shielded position.
2350	Jan. 10	0	Packaging and transport	Industrial	A vehicle containing nuclear substances (exposure device) was involved in an accident.
2375	Jan. 12	0	Packaging and transport	Industrial	An exposure device was sent for servicing and returned to the licensee with a missing locking system as required for use.
2359	Jan. 21	0	Malfunctioning device	Industrial	An exposure device, which did not appear to be damaged, did not have its sealed source fully retract into the shielded position.
2393	Jan. 21	0	Missing or found	Industrial	Four excepted packages that contained very low-risk (category 5) sources (static eliminators) were delivered to a licensee, but could not be located following receipt.
2364	Jan. 27	0	Spill, contamination or release	Medical	Spill of a nuclear substance during a medical procedure.
2366	Jan. 30	0	Packaging and transport	Commercial	A vial contained within a Type A package was discovered to be broken inside the package upon opening.

[6] This event was reported to the CNSC on January 1, 2015.

#	Date	INES rating	Type	Sector	Event summary
2372	Jan. 31	0	Damaged device	Industrial	A fixed gauge was damaged when it fell from its mounted position while in use.
2400	Feb. 2	0	Missing or found	Medical	Two vials of technetium-99m (4.9 GBq) were reported stolen from a storage location.
2371	Feb. 3	0	Breach of security	Industrial	An intruder that entered a secured licensed facility was escorted offsite.
2369	Feb. 10	0	Packaging and transport	Industrial	Two Type A packages containing portable gauges did not arrive at their destination within the expected time. The packages were returned to the licensee facility.
2374	Feb. 10	0	Packaging and transport	Commercial	Two Type A packages were discovered damaged by a carrier at their facility.
2402	Feb. 10	0	Malfunctioning device	Industrial	A closed shutter on a fixed gauge could not be locked.
2503	Feb. 10	0	Missing or found	Academic	A sample of mixed isotopes used for testing reported missing.
2370	Feb. 12	0	Missing or found	Industrial	Six fixed gauges that contained low-risk (category 4) sources were reported missing from a licensed facility by a CNSC inspector during inventory check.
2380	Feb. 17	0	Packaging and transport	Medical	A vehicle containing nuclear substances was involved in an accident.
2385	Feb. 17	0	Spill, contamination or release	Academic	Spill of a nuclear substance during an elution process.
2394	Feb. 17	0	Spill, contamination or release	Medical	Spill of a nuclear substance during a medical procedure.
2384	Feb. 19	0	Packaging and transport	Industrial	A vehicle containing nuclear substances was involved in an accident.

#	Date	INES rating	Type	Sector	Event summary
2411	Feb. 23	0	Damaged device	Industrial	A fixed gauge was damaged when it fell from its mounted position while in use.
2387	Feb. 25	0	Spill, contamination or release	Medical	Spill of a nuclear substance by a technician working behind a shielded workstation.
2389	Feb. 25	0	Packaging and transport	Commercial	A vehicle containing technetium-99m caught fire.
2392	Feb. 27	0	Damaged device	Industrial	An exposure device was damaged when it fell during work.
2396	Mar. 3	0	Unplanned exposure to a person	Industrial	Unplanned exposure of a member of the public found within an area where radiography work was taking place.
2395	Mar. 5	0	Spill, contamination or release	Medical	Spill of a nuclear substance in a target shielded vault of a cyclotron due to an operator error.
2403	Mar. 5	0	Spill, contamination or release	Medical	Spill of a nuclear substance onto a workstation by a technician.
2406	Mar. 5	0	Packaging and transport	Commercial	A Type A package was damaged while in transport.
2405	Mar. 10	0	Malfunctioning device	Industrial	A fixed gauge shutter was discovered to have inaccurate readings during operations.
2412	Mar. 12	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.
2407	Mar. 13	0	Missing or found	Commercial	Discovery of a very low-risk (category 5) X-ray fluorescence analyzer that was reported stolen in 2007.
2417	Mar. 13	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.
2427	Mar. 21	0	Breach of security	Medical	It was discovered that master keys providing access to a storage location containing nuclear substances were stolen.
2399	Mar. 23	0	Packaging and transport	Medical	A Type A package was released to the wrong recipient by a carrier.

#	Date	INES rating	Type	Sector	Event summary
2420	Mar. 28	0	Packaging and transport	Medical	An aircraft containing Type A packages crash landed at an airport due to poor weather conditions.
2450	Mar. 31	0	Damaged device	Industrial	A fixed gauge shutter handle was reported damaged.
2425	Apr. 3	0	Malfunctioning device	Industrial	A fixed gauge, which did not appear to be damaged, did not have its sealed source fully retract into the shielded position.
2453	Apr. 10	0	Unplanned exposure to a person	Industrial	Unplanned exposure of a member of the public found within an area where radiography work was taking place.
2513	Apr. 10	0	Damaged device	Industrial	A fixed gauge was damaged when it fell to the ground while dismounting a section of a vessel.
2443	Apr. 15	0	Packaging and transport	Commercial	A Type A package was delivered to the improper location.
2451	Apr. 20	0	Missing or found	Medical	Missing very low-risk (category 5) sealed source during a quarterly inventory check.
2430	Apr. 21	0	Packaging and transport	Medical	A Type A package was found to be wet and damaged upon receipt.
2432	Apr. 21	0	Packaging and transport	Industrial	A vehicle containing nuclear substances (portable gauge) was involved in an accident.
2435	Apr. 21	0	Packaging and transport	Medical	A package containing technetium-99m was spilled due to the container not being sealed properly.
2431	Apr. 22	0	Spill, contamination or release	Medical	Contamination of a technician during preparation of a medical procedure.
2478	Apr. 29	0	Unplanned exposure to a person	Industrial	Unplanned exposure of a worker within an area in which radiography work was taking place.
2438	May 1	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.

#	Date	INES rating	Type	Sector	Event summary
2469	May 1	0	Spill, contamination or release	Medical	Spill of a nuclear substance caused by use of a non-approved adapter.
2452	May 5	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.
2455	May 5	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.
2449	May 7	0	Packaging and transport	Commercial	A Type A package was delivered to the improper location.
2468	May 11	0	Damaged device	Industrial	A fixed gauge was discovered damaged following a visual inspection.
2473	May 12	0	Packaging and transport	Industrial	A vehicle containing nuclear substances (portable gauge) was involved in an accident.
2460	May 15	0	Spill, contamination or release	Commercial	Copper-61 spilled inside a cyclotron vault.
2463	May 19	0	Missing or found	Medical	Loss of a very low-risk (category 5) sealed source, used as a radiolabel during surgery, after pathology.
2466	May 21	0	Packaging and transport	Medical	A package was received without a safety seal. The package did not show evidence of tampering.
2483	May 21	0	Malfunctioning device	Industrial	An exposure device, which did not appear to be damaged, did not have its sealed source fully retract into the shielded position.
2462	May 23	0	Packaging and transport	Industrial	A vehicle containing nuclear substances (portable gauge) was involved in an accident.
2472	May 24	0	Unplanned exposure to a person	Industrial	Unplanned exposure of a worker who inadvertently placed a hand into the radiation beam of a fixed gauge while the shutter was in the open position.
2482	May 25	0	Malfunctioning device	Industrial	A fixed gauge shutter handle did not function properly following use.

#	Date	INES rating	Type	Sector	Event summary
2490	May 25	0	Damaged device	Industrial	A fixed gauge was damaged device while in use.
2475	Jun. 2	0	Breach of security	Medical	A room containing nuclear substances was accessed by hospital workers using a workaround for a door lock.
2486	Jun. 5	0	Packaging and transport	Industrial	A vehicle containing nuclear substances (portable gauge) was involved in an accident.
2496	Jun. 7	0	Damaged device	Industrial	An exposure device guide tube was damaged preventing the sealed source to be fully returned to its shielded position.
2488	Jun. 11	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.
2493	Jun. 12	0	Unplanned exposure to a person	Industrial	Unplanned exposure of a member of the public found within an area where radiography work was taking place.
2502	Jun. 17	0	Missing or found	Medical	A very low-risk (category 5) sealed source was reported missing. The source was found in storage and accounted for within a short period of time.
2556	Jun. 25	0	Missing or found	Commercial	Three very low-risk (category 5) sealed sources were stolen from a facility storage.
2506	Jun. 27	0	Malfunctioning device	Medical	A gamma cell irradiator was discovered to be malfunctioning while conducting a radiation survey.
2509	Jul. 1	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.
2692	Jul. 1	0	Spill, contamination or release	Academic	Release of iodine-125 (in the form of solid waste) into the environment.
2508	Jul. 2	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.

#	Date	INES rating	Type	Sector	Event summary
2517	Jul. 7	0	Spill, contamination or release	Medical	Spill of a vial of technetium-99m which was dropped on the floor.
2520	Jul. 7	0	Unplanned exposure to a person	Commercial	A worker received a dose due to a failure to follow the procedure while servicing an exposure device.
2512	Jul. 8	0	Damaged device	Industrial	A X-ray fluorescence analyzer was damaged when it fell from a ladder.
2516	Jul. 13	0	Packaging and transport	Industrial	A vehicle containing nuclear substances (portable gauge) was involved in an accident.
2518	Jul. 13	0	Damaged device	Industrial	A fixed gauge was damaged when the screws holding the gauge mounting plate broke.
2525	Jul. 15	0	Packaging and transport	Industrial	A portable gauge was transported unsecured and outside of its Type A package in the back of a truck.
2530	Jul. 19	0	Packaging and transport	Industrial	A vehicle containing nuclear substances (portable gauge) was involved in an accident.
2538	Jul. 20	0	Packaging and transport	Industrial	A vehicle containing nuclear substances (portable gauge) was involved in an accident.
2527	Jul. 21	0	Unplanned exposure to a person	Industrial	Unplanned exposure of a member of the public found within an area where radiography work was taking place.
2531	Jul. 24	0	Packaging and transport	Industrial	A portable gauge fell on the ground while in transport due to improper securing in the vehicle. This resulted in a temporary loss of control of the gauge.
2533	Aug. 4	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.
2536	Aug. 6	0	Malfunctioning device	Industrial	A fixed gauge shutter did not function properly following use.

#	Date	INES rating	Type	Sector	Event summary
2540	Aug. 11	0	Packaging and transport	Industrial	A vehicle containing nuclear substances (portable gauge) was involved in an accident.
2574	Aug. 11	0	Packaging and transport	Commercial	A package was discovered to have internal contamination when it was opened. The contamination was contained within the package. No external contamination was found.
2539	Aug. 12	0	Damaged device	Industrial	An exposure device was damaged preventing the sealed source to be fully returned to its shielded position.
2541	Aug. 12	0	Damaged device	Industrial	A fixed gauge shutter handle was discovered damaged in a storage area.
2554	Aug. 13	0	Packaging and transport	Industrial	A Type A package containing nuclear substances (fixed gauge) was damaged while dropped during transport.
2545	Aug. 17	0	Packaging and transport	Industrial	A Type A package was damaged during transport
2535	Aug. 18	0	Packaging and transport	Commercial	A package was discovered to have internal contamination once it was opened. The contamination was contained within the package. No external contamination was found.
2562	Aug. 18	0	Packaging and transport	Industrial	A vehicle containing nuclear substances (portable gauge) was involved in an accident.
2544	Aug. 19	0	Packaging and transport	Commercial	Two Type A packages were damaged during transport.
2550	Aug. 20	0	Packaging and transport	Medical	A package was discovered to have internal contamination once it was opened. The contamination was contained within the package. No external contamination was found.
2560	Aug. 25	0	Malfunctioning device	Medical	An intrusion alarm was found to be not working properly.

#	Date	INES rating	Type	Sector	Event summary
2564	Aug. 25	0	Damaged device	Industrial	The remote control for an exposure device was damaged following contact with a hot pipe during exposure. This prevented the sealed source from being fully returned to its shielded position.
2705	Aug. 25	0	Unplanned exposure to a person	Industrial	Unplanned exposure of a member of the public found within an area where radiography work was taking place.
2561	Aug. 27	0	Unplanned exposure to a person	Medical	Unplanned exposure (i.e., skin contamination) of a worker who had sustained skin contamination during a medical procedure.
2580	Sep. 1	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.
2579	Sep. 8	0	Malfunctioning device	Industrial	Two portable gauges were found with malfunctioning shutters due to asphalt mixture in the mechanisms.
2578	Sep. 9	0	Damaged device	Industrial	An operator damaged an exposure device connector during connection.
2576	Sep. 15	0	Missing or found	Commercial	Two Type A packages, containing technetium-99m (65 GBq) fell off the back of a vehicle during transport.
2587	Sep. 15	0	Packaging and transport	Industrial	A package was discovered to have surface contamination above the regulatory limit.
2588	Sep. 15	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.
2590	Sep. 21	0	Missing or found	Commercial	A very low-risk (category 5) calibration source had been removed from a liquid scintillation counter and was reported missing.
2585	Sep. 28	0	Damaged device	Industrial	A fixed gauge with the shutter open was damaged due to falling off of a production drum.

#	Date	INES rating	Type	Sector	Event summary
2596	Sep. 28	0	Packaging and transport	Industrial	A vehicle containing nuclear substances (portable gauge) was involved in an accident.
2602	Sep. 28	0	Packaging and transport	Medical	An excepted package containing nuclear substances was damaged during transport.
2591	Sep. 30	0	Missing or found	Industrial	A very low-risk (category 5) check source used for the calibration of survey meter was found missing during an internal inventory audit.
2594	Sep. 30	0	Packaging and transport	Industrial	A parked vehicle containing nuclear substances (portable gauge) was struck by construction equipment.
2607	Sep. 30	0	Damaged device	Industrial	An exposure device was damaged due to falling onto the floor.
2601	Oct. 3	0	Unplanned exposure to a person	Industrial	Unplanned exposure of a worker within an area where radiography work was taking place.
2612	Oct. 5	0	Missing or found	Medical	A very low-risk (category 5) iodine-125 sealed source was found missing following a patient treatment.
2604	Oct. 7	0	Malfunctioning device	Industrial	The source connector and control cable of an exposure device did not function properly during pre-operational verifications.
2615	Oct. 8	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.
2608	Oct. 13	0	Packaging and transport	Industrial	A vehicle containing nuclear substances (exposure device) was involved in an accident.
2610	Oct. 15	0	Packaging and transport	Industrial	A portable gauge fell from the back of vehicle while being transported due to improper securing in the vehicle.
2621	Oct. 15	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.

#	Date	INES rating	Type	Sector	Event summary
2611	Oct. 19	0	Damaged device	Industrial	An exposure device guide tube was damaged by a pipe that fell onto it.
2618	Oct. 19	0	Packaging and transport	Industrial	A vehicle containing nuclear substances (portable gauge) was involved in an accident.
2616	Oct. 21	0	Spill, contamination or release	Commercial	Spill of iodine-131 inside a shielded and vented manufacturing cell.
2617	Oct. 22	0	Packaging and transport	Commercial	Two Type B packages containing sealed sources were shipped without being identified as containing nuclear substances.
2620	Oct. 22	0	Damaged device	Industrial	A portable gauge was damaged at a construction site.
2622	Oct. 27	0	Damaged device	Industrial	An exposure device was damaged due to falling onto a metal tank floor.
2624	Oct. 28	0	Malfunctioning device	Industrial	The shutter of a portable gauge did not close properly following use.
2628	Oct. 29	0	Spill, contamination or release	Medical	Spill of a vial containing sodium iodine solution (NAI-131) in a lab.
2625	Nov. 3	0	Damaged device	Industrial	A shutter handle from a fixed gauge was damaged during routine maintenance.
2636	Nov. 7	0	Unplanned exposure to a person	Industrial	Unplanned exposure of a worker within an area where radiography work was taking place.
2630	Nov. 9	0	Spill, contamination or release	Medical	Spill of technetium-99m due to human error during a medical procedure.
2648	Nov. 11	0	Packaging and transport	Medical	A package was discovered to have been potentially tampered with while in transport.
2659	Nov. 11	0	Damaged device	Commercial	A package was received with a damaged irradiated target.
2640	Nov. 20	0	Damaged device	Industrial	An exposure device was damaged due to falling during dismounting.

#	Date	INES rating	Type	Sector	Event summary
2643	Nov. 23	0	Malfunctioning device	Industrial	A sealed source became disconnected from its drive cable while in use in an exposure device.
2647	Nov. 23	0	Damaged device	Industrial	A fixed gauge was damaged when it fell onto temporary scaffolding while being dismounting from its installed position.
2650	Nov. 27	0	Packaging and transport	Industrial	A vehicle transporting nuclear substances was involved in an accident.
2651	Nov. 27	0	Malfunctioning device	Medical	An error code associated with use of a high-dose rate brachytherapy unit identified a potential issue with the sealed source.
2671	Dec. 1	0	Missing or found	Medical	A very low-risk (category 5) iodine-125 sealed source was discovered missing during a routine follow-up from pathology.
2701	Dec. 2	0	Missing or found	Medical	Five low-risk (category 4) sealed sources were found missing while CNSC staff performed inventory verification at a facility. Three of the five missing sources have since been recovered.
2661	Dec. 3	0	Spill, contamination or release	Medical	Spill of fluorine-18 during a medical procedure.
2658	Dec. 4	0	Spill, contamination or release	Medical	Spill of a vial containing 13 GBq of technetium-99m was dropped in a nuclear medicine department.
2668	Dec. 9	0	Spill, contamination or release	Medical	Release of 25 GBq of gaseous carbon-11 (in the form of CO_2 gas) to the environment through an exhaust system.
2665	Dec. 10	0	Packaging and transport	Industrial	A vehicle transporting nuclear substances was involved in an accident.
2667	Dec. 10	0	Breach of security	Industrial	An exposure device was left unattended for approximately one hour.

#	Date	INES rating	Type	Sector	Event summary
2670	Dec. 11	0	Packaging and transport	Industrial	A portable gauge was transported in backscatter mode with the trigger locked, contrary to transport procedures.
2693	Dec. 17	0	Packaging and transport	Academic	A radiation device was mistakenly shipped back to the manufacturer for repair in a package not identified as containing nuclear substances.
2673	Dec. 28	0	Damaged device	Commercial	A package was received with a damaged irradiated target.

Appendix E: Compliance rating levels

The following rating levels, as shown in Table 16 reflect a recent transition in the rating terminology used by the CNSC. While inspection reports still use the previous rating levels, licensees that use nuclear substances and radiation devices can expect this transition to take place in time.

Table 16: Compliance rating terminology

Previous rating level	Description	New rating level	Description
A	Exceeds expectations	**FS**	Fully satisfactory
B	Meets expectations	**SA**	Satisfactory
C	Improvement is required	**BE**	Below expectations
D	This area is seriously compromised		
E	Breakdown	**UA**	Unacceptable

Fully satisfactory (FS)

Compliance with regulatory requirements is fully satisfactory. Compliance within the area exceeds requirements and CNSC expectations. Compliance is stable or improving, and any problems or issues that arise are promptly addressed.

Satisfactory (SA)

Compliance with regulatory requirements is satisfactory. Compliance within the area meets requirements and CNSC expectations. Any deviation is only minor, and any issues are considered to pose a low risk to the achievement of regulatory objectives and CNSC expectations. Appropriate improvements are planned.

Below expectations (BE)

Compliance with regulatory requirements falls below expectations. Compliance within the area deviates from requirements or CNSC expectations to the extent that there is a moderate risk of ultimate failure to comply. Improvements are required to address identified weaknesses. The licensee or applicant is taking appropriate corrective action.

Unacceptable (UA)

Compliance with regulatory requirements is unacceptable, and is seriously compromised. Compliance within the overall area is significantly below requirements or CNSC expectations, or there is evidence of overall non-compliance. Without corrective action, there is a high probability that the deficiencies will lead to unreasonable risk. Issues are not being addressed effectively, no appropriate corrective measures have been taken, and no alternative plan of action has been provided. Immediate action is required.

Appendix F: Grading inspections

For all inspections, CNSC inspectors evaluate a licensee's performance against regulatory requirements found in the *Nuclear Safety and Control Act*, its regulations, and conditions included in the licensee's licence. During an inspection, the inspector verifies compliance with specific regulatory requirements and assigns a grade (i.e., a compliance rating) based on his or her observations. (Please refer to appendix E for information on the compliance ratings for inspection.) Each requirement is ranked according to the relative risk of the particular regulatory requirement: high, medium or low. The requirements are linked to a particular safety and control area (SCA), and each SCA has different numbers of requirements. (Note that not all regulatory requirements are inspected during every inspection.) Please refer to appendix B for the list of all SCAs.

For the vast majority of licensees, inspection results are entered into a licensing and compliance system which uses a complex algorithm to calculate an overall grade for each SCA based on the inspector's grades.

The SCA grade is based on the worst grade of the high-risk requirements. The SCA grade will be the lowest grade assigned to a high-risk requirement by an inspector, unless an unacceptable rating was assigned to a medium-risk requirement. In cases where a medium-risk requirement has been assessed as unacceptable, then the SCA grade will be one grade lower than the lowest grade assigned to high-risk requirement.

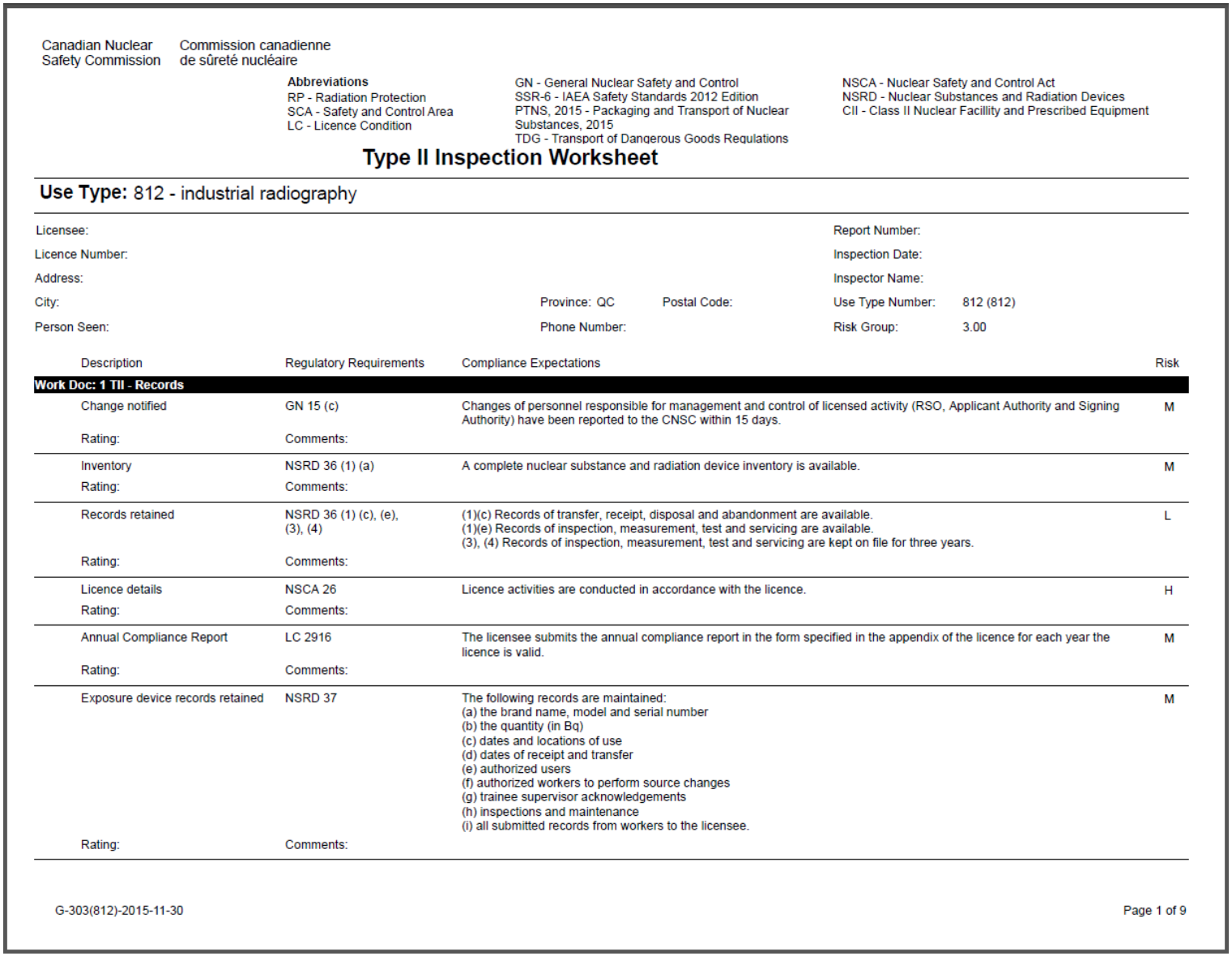
If no high-risk requirements were inspected, then the SCA grade equals the worst grade from the medium-risk requirements.

If no high-risk or medium-risk requirements were inspected, then no grade is assigned for that SCA. In other words, no SCA grade is assigned if the data comes from low-risk requirements only.

For inspections not recorded in the licensing and compliance system, inspectors review each compliance expectation and use their judgment to determine the overall rating of the SCA.

Figure 48 shows a blank inspection worksheet used by inspectors to conduct a compliance inspection. The inspection worksheet shown is specific to industrial radiography . Figure 49 shows the criteria used in inspections of accelerators and Class II facilities.

Figure 48: Blank inspection worksheet



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Abbreviations
RP - Radiation Protection
SCA - Safety and Control Area
LC - Licence Condition
GN - General Nuclear Safety and Control
SSR-6 - IAEA Safety Standards 2012 Edition
PTNS, 2015 - Packaging and Transport of Nuclear Substances, 2015
TDG - Transport of Dangerous Goods Regulations
NSCA - Nuclear Safety and Control Act
NSRD - Nuclear Substances and Radiation Devices
CII - Class II Nuclear Facility and Prescribed Equipment

Type II Inspection Worksheet

Use Type: 812 - industrial radiography

Licensee:			Report Number:	
Licence Number:			Inspection Date:	
Address:			Inspector Name:	
City:	Province: QC	Postal Code:	Use Type Number:	812 (812)
Person Seen:	Phone Number:		Risk Group:	3.00

Description	Regulatory Requirements	Compliance Expectations	Risk
Work Doc: 1 TII - Records			
Change notified	GN 15 (c)	Changes of personnel responsible for management and control of licensed activity (RSO, Applicant Authority and Signing Authority) have been reported to the CNSC within 15 days.	M
Rating:	Comments:		
Inventory	NSRD 36 (1) (a)	A complete nuclear substance and radiation device inventory is available.	M
Rating:	Comments:		
Records retained	NSRD 36 (1) (c), (e), (3), (4)	(1)(c) Records of transfer, receipt, disposal and abandonment are available. (1)(e) Records of inspection, measurement, test and servicing are available. (3), (4) Records of inspection, measurement, test and servicing are kept on file for three years.	L
Rating:	Comments:		
Licence details	NSCA 26	Licence activities are conducted in accordance with the licence.	H
Rating:	Comments:		
Annual Compliance Report	LC 2916	The licensee submits the annual compliance report in the form specified in the appendix of the licence for each year the licence is valid.	M
Rating:	Comments:		
Exposure device records retained	NSRD 37	The following records are maintained: (a) the brand name, model and serial number (b) the quantity (in Bq) (c) dates and locations of use (d) dates of receipt and transfer (e) authorized users (f) authorized workers to perform source changes (g) trainee supervisor acknowledgements (h) inspections and maintenance (i) all submitted records from workers to the licensee.	M
Rating:	Comments:		

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Work Doc: 1 TII - Records			
Source change records	NSRD 34 (1)	Person who performs source change: (1) shall have written authorization from the licensee (refer to NSRD 30 (5)); (2) shall record (a) the device surface dose rates resulting from the source change and (b) the DRD reading; and (3) shall report the dose rate in (2) to the licensee.	M
Rating:	Comments:		
Records retained	GN 28	(2) The CNSC was notified 90 days prior to the disposal of any prescribed records.	L
Rating:	Comments:		
Device certification and transfer	NSRD 11	(1) The radiation device in use is a certified model (unless authorized in the licence). (2) The radiation device transferred to other licensees is a certified model.	H
Rating:	Comments:		
Storage notification	LC 2298-1	Upon requested by the CNSC, the licensee notified the CNSC of the storage site of each nuclear.	M
Rating:	Comments:		
Transfer documents	NSRD 19	(1) A copy of the most recent leak test result is provided for all transfers of radiation devices as well as instructions to follow in the event of an accident. (2) A copy of the most recent leak test result is provided for all transfers of sealed source or nuclear substance used as shielding.	L
Rating:	Comments:		
Authorized transfer	GN 13	All transfers of nuclear substances or radiation devices have been done to authorized licensees.	H
Rating:	Comments:		
Leak test	NSRD 18 (1) (a), (b), (d)	Leak testing is performed at the required frequency following acceptable procedures.	L
Rating:	Comments:		
Leak test/event	NSRD 18 (1) (c)	Leak testing was performed immediately after any event that may have damaged the sealed source(s).	L
Rating:	Comments:		
Failed leak test	NSRD 18 (3)	Appropriate actions were taken upon detection of a leaking source.	M
Rating:	Comments:		
Head hose nozzle cap dye-penetrant tests	LC 2720 - 1	The dye-penetrant inspection of the nozzle cap has been performed annually. The nozzle cap was removed from service if cracks were apparent.	M
Rating:	Comments:		
Maintenance requirements	LC 2719-1	The S-tube inspection is performed at the frequency specified by the manufacturer and the exposure device is removed from service if wear-through was apparent.	M
Rating:	Comments:		
Device accidents	NSRD 21	Any radiation device involved in an accident or incident has been tested/inspected and confirmed to be functioning properly prior to return to use.	H
Rating:	Comments:		
Reportable events	GN 29	Incidents and unplanned events have been immediately reported to the CNSC and a detailed written report was submitted within 21 days (refer to NSRD 38).	H
Rating:	Comments:		

Work Doc: 1 TII - Records			
Reporting requirements	PTNS 37-38-40	The consignor, the carrier and the consignee must provide an immediate report to CNSC (PTNS 37 (1)) and a 21 day report (PTNS 38) when becoming aware of any of the following situations: - failure to comply with the requirements of section 26; - a conveyance carrying radioactive material is involved in an accident; - package damage or tampering or leaking; - radioactive material lost, stolen or loss of control; - radioactive material has escaped from a containment system, a package or a conveyance during transport; - failure to comply with the Act and Regulations can lead to a situation in which the environment, the health and safety of persons or national security is adversely affected; - the level of non-fixed contamination as defined in the IAEA Regulations, during transport exceeds limits; - licensee has provided reports of damage or tampering discovered while opening packages as per PTNS 40(4), (5), (6).	H
Rating:	Comments:		
Training and sufficient workers	GN 12 (1) (a), (b)	There are (a) a sufficient number of trained and (b) qualified workers to carry on licensed activity.	M
Rating:	Comments:		
Worker records retained	NSRD 36 (1) (b), (d), (2)	(1)(b) The name of each worker who handles nuclear substances and/or radiation devices is recorded. (1)(d) Training records for all workers who handle nuclear substances and/or radiation devices are available. (2) Worker training records are kept on file for three years after termination.	M
Rating:	Comments:		
Appointment of supervisor of trainee	NSRD 32	The licensee has obtained a written consent from any qualified CEDO requested to supervise a named trainee.	M
Rating:	Comments:		
TDG training certificate on file	TDG 6.6, 6.7	A copy of the TDG training certificate is kept on file for two years and is available to the inspector.	M
Rating:	Comments:		
List of NEWs	RP 24	A record including names and job category of each NEW is available.	L
Rating:	Comments:		
Nuclear Energy Workers informed	RP 07	(1) Each NEW has been informed in writing of their NEW designation, of the risks associated with their work, of the regulatory dose limits and of their individual dose. (2) Female NEW has been informed in writing of their rights (RP 07) and obligations (RP 11). (3) A signed acknowledgment form is available for each NEW.	M
Rating:	Comments:		
Ascertainment and recording of doses	RP 05	(1) Personnel doses are ascertained and recorded. (2) Doses are determined by (a) direct measurement or (b) estimation.	H
Rating:	Comments:		
Dose limits/body	RP 13 (1)	Dose limits not exceeded.	H
Rating:	Comments:		
Action Levels	LC 2700	Upon becoming aware of an action level, specified in the Appendix: Licence documents, has been reached the licensee: (a) investigated the situation, (b) took the necessary corrective action, and (c) notified the CNSC within 48 hr.	M
Rating:	Comments:		
Licensed dosimetry	RP 08	A licensed dosimetry service is used where the effective dose of a NEW will likely exceed 5 mSv in a one-year period.	H
Rating:	Comments:		

Work Doc: 1 TII - Records			
Meter calibrated	NSRD 20	Survey meter that is used has been calibrated within the previous twelve months of its use.	H
Rating:	Comments:		
Shipping doc kept 2 years	TDG 3.11	Shipping documents used are kept on file for two years.	M
Rating:	Comments:		
Competent authority certificates	PTNS 25 (2)(c)	Consignor has competent authority certificates for applicable sources and packages (refer to SSR-6 561).	M
Rating:	Comments:		
Type A package certification	PTNS 42	Type A package design, test results and packaging instructions kept on file for two years after last shipment.	H
Rating:	Comments:		
Act/Regs available	GN 12 (1) (k)	A copy of the Act and Regulations (paper or electronic copy) are readily available to all workers.	L
Rating:	Comments:		
Sealed Source Tracking	LC 2404-6	The CNSC is notified of any transfer, receipt, export or import of a sealed source in accordance with the licence condition.	H
Rating:	Comments:		
Import Export Restrictions	LC 2480	The licensee is not authorized to import or export all items described in the schedule, Parts A and B, of the Nuclear Non-proliferation Import and Export Control Regulations, and specifically listed in the licence condition.	H
Rating:	Comments:		
Export restrictions/sealed sources	LC 2408-8	Export of sealed sources is within the limits specified in the licence condition. An export licence has been issued for any exports of sealed sources exceeding the limits specified in the licence condition.	H
Rating:	Comments:		
Work Doc: 2 TII - Operation/Storage			
Worker's obligations	GN 17	Every worker: (a) uses equipment, devices, facilities and clothing in a responsible and reasonable manner in accordance with the Act, Regulations and Licence Conditions; (b) complies with procedures and measures established by the licensee; (c) informs the licensee or supervisor of any situation where there may be: (i) an increase in the risk to the environment or the health and safety of persons; (ii) a threat to security; (iii) a failure to comply with regulatory requirements; (iv) sabotage, theft, loss or illegal use or possession of prescribed equipment, or (v) a release into the environment not authorized by the licence; (d) observes and obeys all notices and warning signs; and (e) takes all reasonable precautions to ensure the safety and security of individuals, the environment and the nuclear substances or facilities.	H
Rating:	Comments:		
Posting of Signs	RP 21	A radiation warning symbol is posted: (a) at the boundary of and at every point of access where there is more than 100 times the Exemption Quantity (EQ) of nuclear substances; or (b) where the radiation dose rate could exceed 0.025 m µSv/h.	H
Rating:	Comments:		
Contact details posted	NSRD 23	The name or job title and a 24 hr. telephone number are posted in a readily visible location where the nuclear substance is stored or used (refer to RP 21).	H
Rating:	Comments:		

Work Doc: 2 TII - Operation/Storage			
Radiation Warning Sign	RP 22	When a radiation warning symbol is used, it is posted in accordance with regulations.	L
Rating:	Comments:		
Frivolous posting of signs	RP 23	Radiation warning symbols are not posted where there is no radiation, nuclear substance or prescribed equipment.	L
Rating:	Comments:		
Security indicators	GN 12 (1) (c), (g), (h), (i), (j)	Provisions are in place to ensure the security of nuclear substances and radiation devices and the health and safety of persons. This may be achieved through restricted access (for example use of locks, alarms, and security systems) and reporting of incidents including loss, theft and sabotage.	H
Rating:	Comments:		
Sealed Source Security Requirements	LC 2490-1	Licensees have in place security measures including: -Inventory accounting -Access control measures -Up-to-date security plan -Information security measures -Intrusion detection with monitoring and testing -Response protocol -Secure storage of substances and devices -Security awareness program -Vehicle security measures	H
Rating:	Comments:		
Post licence	GN 14	(1) A copy of the licence or an appropriate notice is posted in a conspicuous place at the site of the licensed activity. (2) The complete licence is available at field locations.	L
Rating:	Comments:		
Container/Device labelled	RP 20	Each container or device containing greater than one Exemption Quantity of nuclear substance(s) is labelled with the radiation warning symbol and the required wording.	H
Rating:	Comments:		
Field devices I.D.	NSRD 22	Device is labelled with contact information including a 24 hour telephone number.	M
Rating:	Comments:		
Use of equipment & procedures	GN 12 (1) (e)	Licensee ensures equipment, clothing and procedures are used appropriately at the site of the licensed activity.	H
Rating:	Comments:		

Work Doc: 2 TII - Operation/Storage

Operator obligations	NSRD 31	The operator demonstrates the following requirements are being met: (1) (a & h) a survey meter, meeting required specifications, is used during the operation of the exposure device including to confirm that the sealed source assembly is returned to the shielded position within the exposure device; (b) tongs, shielding, and cutter are available; (c, d, & f) personal monitoring equipment (TLD, DRD, alarming dosimeter) is worn on the trunk of the body; (e) DRD reading is recorded daily; (g) pre-operational function tests are performed; (i) exposure to non-NEW is limited to 0.1 mSv per week and 0.5 mSv per year; (j & k) a signed barrier is established to prevent entry into an area with a dose rate above 0.1 mSv/h (RWS needed at 0.025 mSv/h, refer to RP 21); (l) exposure device is locked when not in use; (m) reporting of incidents; (4) does not use an exposure device that is not functioning properly or has a surface dose rate above 2 mSv/h. (5) radiation dose received during a daily shift does not exceed 2 mSv and if the dose exceeds 2 mSv work is immediately stopped and licensee is notified; and (6) only specially trained personnel (or personnel that are under the guidance of specially trained personnel) are authorized to respond to incidents involving exposure devices (refer to sub-section a) to d) of the present section for details).	H
Rating:	Comments:		
Radiation safety	NSRD 17	Referenced emergency procedures are available to workers at the site of licensed activity.	M
Rating:	Comments:		
CEDO to operate	NSRD 24	The operation of the exposure device is performed by a CEDO or a trainee who is acting under direct supervision and continuous observation of a CEDO.	H
Rating:	Comments:		
Trainee knowledge and supervision	NSRD 33	CEDO maintains continuous and direct supervision of a trainee. The trainee has sufficient knowledge to safely operate the exposure device.	H
Rating:	Comments:		
Storage	LC 2575-2	(a) Access to storage areas containing nuclear substances or radiation devices is restricted to authorized personnel. (b) Dose rates at occupied areas outside storage areas do not exceed 2.5 µSv/hr. (c) Dose limits are not exceeded as a result of nuclear substances or radiation devices in storage.	H
Rating:	Comments:		
Records Requirements-Exposure Devices	LC 2217-1	Prescribed records and operating procedures are maintained at site locations where nuclear substances are used or stored for more than 30 consecutive days.	M
Rating:	Comments:		
Device provided & maintained	GN 12 (1) (d)	Required devices have been provided and have been maintained according to manufacturer's instruction.	M
Rating:	Comments:		
Operation notification	LC 2524-0	The CNSC is notified of each job site when requested.	M
Rating:	Comments:		
Location notification	LC 2300-2	CNSC was informed in writing, within seven days, of sites where licensed activities were conducted for more than 90 days. Discontinuance of such sites was also reported within 7 days.	M
Rating:	Comments:		
Inaccuracies Notification	LC 2920-6	Changes to documents listed in the licence appendix have been reported to the CNSC.	L
Rating:	Comments:		
Operation Limitations - General	LC 2917	Activities and procedures, as listed in the licence appendix, are followed.	L
Rating:	Comments:		

Work Doc: 2 TII - Operation/Storage			
Licensee obligations	NSRD 30 (1), (3), (4), (6)	The following obligations are met: (1) the device is tagged and locked; (3) a survey meter that meets the requirements, emergency equipment, personal monitoring equipment (TLD, DRD, alarming), radiation warning sign for the 0.1 mSv/h barrier and DRD forms are available; (4) only a functioning exposure device with a surface dose rate less than 2 mSv/h is used; and (6) non-NEW dose is within 0.1 mSv per week and 0.5 mSv per year.	H
Rating:	Comments:		
ALARA/RP program	RP 04 (a)	The licensee has implemented a radiation protection program that keeps doses ALARA and includes: (i) management control over work practices; (ii) personnel qualification and training; (iii) control of occupational and public exposure to radiation; and (iv) planning for unusual situations.	H
Rating:	Comments:		
Work Doc: 4 TII - Packaging and Transport			
Transport document requirement	PTNS 29(1)	The consignor of radioactive material provides a shipping document that includes the following (refer to TDG 3.5 and SSR-6 546): - consignor and consignee names and addresses; - 24 hour contact number; - number of packages; - UN number*; - shipping name*; - Class # 7*; - radionuclide identification*; - form*; - maximum activity*; - category of package*; - transport index*; - competent authority certificate number(s)*. For consignments of more than one package, the required information (*) must be given for each package. - Consignor's certification with printed name of the consignor - PTNS 25(1), TDG 3.6.1	M
Rating:	Comments:		
Transport document location	TDG 3.7	Shipping document is located within driver's reach or in a door pocket on the driver's side.	M
Rating:	Comments:		
Vehicle placarded	TDG 4.15	Vehicle must be placarded on four sides when: - package is III-Yellow 4.16.1(2)(i); - package weight exceeds 500 kg; or - exception of PTNS 28(2)(a) is used.	H
Rating:	Comments:		
Exposure device exception	PTNS 28(2)(a)	Exposure devices transported under section 28(2)(a) do not require labelling in accordance with SSR-6 538 to 540, if the following criteria are met: - the device is certified – PTNS 28(2)(a) and NSRD 30(1)(a); - is transported with goods from one consignor only and in a conveyance that is not carrying passengers; - the package and the overpack, if one is used, are clearly marked with the word "RADIOACTIVE" or "RADIOACTIF" PTNS 28(2)(a)(iii); and - the vehicle displays 4 Class 7 placards - PTNS 28(2)(a)(ii).	M
Rating:	Comments:		
Package secured in vehicle	PTNS 25 (4)	Consignments are segregated and securely stowed (refer to SSR-6 562, 564, 574 - PTNS 25(1) and TDG 5.4). Category II-Yellow and III-Yellow packages are not carried in compartments occupied by passengers - SSR-6 563.	H
Rating:	Comments:		

Work Doc: 4 TII - Packaging and Transport			
Type B package requirements	PTNS 28 (1)	A Type B package must be prepared and labelled in accordance with PTNS 28(1) and associated requirements from SSR-6. Package requirements are as follows: - name of consignor or consignee on package - SSR-6 531; - shipping name - SSR-6 532 and TDG 4.11; - UN number - SSR-6 532 and TDG 4.12; - "Type B" marking - SSR-6 535 (c); - fire proof trefoil SSR-6 536; - competent authority mark - SSR-6 535(a); - gross mass marked if exceeding 50 kg - SSR-6 533. If PTNS 28(2)(a) exception is not used the following is required : - two (I-white, II-Yellow or III-Yellow) labels - SSR-6 538, 539 and TDG 4.6, 4.7, 4.10 which include radionuclide (most restrictive), maximum activity; - transport index on labels, SSR-6 540; - package integrity must not be compromised - PTNS 24 and SSR-6 306.	H
Rating:	Comments:		
Showing proof of TDG training	PTNS 25 (1)	A person handling dangerous goods must provide their training certificate or copy of it to an inspector immediately upon request. TDG 6.8	M
Rating:	Comments:		
TDG training certificate	TDG 6.1, 6.3, 6.5	The employer is responsible for: 6.1(2)(a) ensuring that only an adequately trained worker who holds a valid TDG certificate handle Class 7 dangerous goods ; or 6.1 (2)(b) performs those activities in the presence and under the direct supervision of a person who is adequately trained and who holds a training certificate in accordance with this Part. 6.3 issuing training certificate that includes: - the employer's business address; - the employee's name; - aspects of handling and transporting; - employee and employer signatures; and - the expiry date of the certificate (TDG 6.5).	M
Rating:	Comments:		

Disclaimer - CNSC licensees may use this worksheet voluntarily to ascertain the CNSC`s general expectations regarding regulatory requirements. Such requirements would generally be assessed during a Type I and Type II Inspection of licences issued pursuant to the Nuclear Substances and Radiation Devices Regulations. The expectations listed for each regulatory requirement are only provided as a guide. Similar worksheets will be used by CNSC staff for on-site inspections. Inspections, will, however, be carried out on a case-by-case basis in the context of the licensed activities and the circumstances of individual situations. This worksheet is not intended to limit the scope of CNSC inspections or the powers of CNSC inspectors. Licensees should contact the CNSC to obtain information regarding their specific licence requirements.

APPENDIX A
RATING SYSTEM (GRADES)

A - Exceeds requirements

Assessment topics or programs meet and consistently exceed applicable CNSC requirements and performance expectations. Performance is stable or improving. Any problems or issues that arise are promptly addressed, such that they do not pose an unreasonable risk to the maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agreed.

B - Meets requirements

Assessment topics or programs meet the intent or objectives of CNSC requirements and performance expectations. There is only minor deviation from requirements or the expectations for the design and/or execution of the programs, but these deviations do not represent an unreasonable risk to the maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agreed. That is, there is some slippage with respect to the requirements and expectations for program design and execution. However those issues are considered to pose a low risk to the achievement of regulatory performance requirements and expectations of the CNSC.

C - Below requirements

Performance deteriorates and falls below expectations, or assessment topics or programs deviate from the intent or objectives of CNSC requirements, to the extent that there is a moderate risk that the programs will ultimately fail to achieve expectations for the maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agreed. Although the risk of failing to meet regulatory requirements in the short term remains low, improvements in performance or programs are required to address identified weaknesses. The licensee or applicant has taken, or is taking appropriate action.

D - Significantly below requirements

Assessment topics or programs are significantly below requirements, or there is evidence of continued poor performance, to the extent that whole programs are undermined. This area is compromised. Without corrective action, there is a high probability that the deficiencies will lead to an unreasonable risk to the maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agreed. Issues are not being addressed effectively by the licensee or applicant. The licensee or applicant has neither taken appropriate compensating measures nor provided an alternative plan of action.

E - Unacceptable

Evidence of an absence, total inadequacy, breakdown, or loss of control of an assessment topic or a program. There is a very high probability of an unreasonable risk to the maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agreed. An appropriate regulatory response, such as an order or restrictive licensing action has been or is being implemented to rectify the situation.

N/A – Not applicable

N/C – Not checked

Figure 49: Grading criteria for accelerator and Class II facilities

SCA	Fully satisfactory (FS)	Satisfactory (SA)	Below expectations (BE)	Unacceptable (UA)	Mitigating factor	Aggravating factor	Grade	Explanation/ justification
Radiation protection	Radiation doses are equal to or less than the norm for the sector. Contamination, if applicable, did not affect a worker.	Increased dose below reportable limits. Contamination that could affect a worker.	Exposure to a worker in excess of regulatory limits. An incident that would result in a licensee exceeding action level limits (see section 6 of the *Radiation Protection Regulations*). Limited contamination that could affect a few persons or limited area.	Exposures to multiple workers in excess of regulatory limits. Widespread contamination to several persons or within a place.				
Physical design	No significant weaknesses in any element of the facility design.	Reduced redundancy that is not likely to prevent a safety-related system from meeting its design intent.	Compromise to barriers where defence in depth would be considered reduced, however redundancy remains. Compromise to safety due to a situation that was not previously evaluated and is believed to be probable.	Compromise to barriers where defence in depth would be considered inadequate. Compromise to safety due to a situation that was not previously evaluated and is believed to be probable.				

SCA	Fully satisfactory (FS)	Satisfactory (SA)	Below expectations (BE)	Unacceptable (UA)	Mitigating factor	Aggravating factor	Grade	Explanation/ justification
Operating performance	No significant lapses in conduct of licensed activities in accordance with licensee procedures or processes.	Partial failure to conduct licensed activities in accordance with one licensee procedure or processes.	Failure to conduct licensed activities in accordance with one or more licensee procedures and processes.	Widespread systemic failure to ensure licensed activities conducted according to licensee procedures and processes.				
Fitness for service	No significant risk that systems or components will not remain effective or that equipment will not be able perform its intended function when called upon to do so.	Partial failure to ensure single system or components remain effective or equipment is able to perform its intended function when called upon to do so.	Failure to ensure single system or components remain effective or equipment is able to perform its intended function when called upon to do so.	Widespread systemic failure to ensure systems and components remain effective and equipment is able to perform its intended function when called upon to do so.				
Security	No significant weaknesses in security.	Weaknesses in access control or barrier.	Failure in one or more barriers designed to delay access to security category I or II sources.	Widespread systemic failure to adhere to security plan.				
Packaging and transport	No significant weaknesses in packaging and transport procedures and processes.	Failure in one of the licensee's packaging and transport procedures and processes.	Failure in one or more elements of the licensee's packaging and transport procedures and processes.	Widespread systemic failure to adhere to licensee's packaging and transport procedures and processes.				

Appendix G: Abbreviations and glossary

Abbreviations

ALARA	as low as reasonably achievable
CNSC	Canadian Nuclear Safety Commission
GBq	gigabecquerel
INES	International Nuclear and Radiological Event Scale
MBq	megabecquerel
mSv	millisievert
NEW	nuclear energy worker
NSCA	*Nuclear Safety and Control Act*
Sv	sievert

Glossary

cyclotron

A particle accelerator that speeds up particles in a circular motion until they hit a target at the perimeter of the cyclotron. Some cyclotrons are used to produce medical isotopes.

effective dose

The sum of the products, expressed in sieverts, obtained by multiplying the equivalent dose of radiation received by, and committed to, each organ or tissue set out in column 1 of an item of Schedule 1 by the weighting factor set out in column 2 of that item. (Source: *Radiation Protection Regulations*)

enforcement actions

The set of activities associated to compel a licensee back into compliance and to deter further non-compliances with the *Nuclear Safety and Control Act*, its regulations, and licences, decisions and certificates issued by the CNSC.

exposure device

A radiation device that is designed for carrying out gamma radiography, and includes any accessory to the device such as a sealed source assembly, a drive mechanism, a sealed source assembly guide tube and an exposure head. (Sources: *Nuclear Substances and Radiation Devices Regulations*; *Packaging and Transport of Nuclear Substances Regulations, 2015*)

five-year dosimetry period

The period of five calendar years beginning on January 1 of the year following the year in which the *Radiation Protection Regulations* came into force, and every subsequent period of five calendar years.

fixed nuclear gauge

A radiation device that is attached to a structure and enables the nuclear substance it holds to be used for its radiation properties to measure process-related parameters (such as liquid flow or liquid level).

medical linear accelerator

An accelerator that produces a collimated beam of high-energy photons (i.e., X-rays) that are used to deliver controlled doses of radiation for therapeutic purposes.

natural background radiation

Radiation that is emitted from naturally occurring radioactive materials and cosmic rays.

nuclear energy worker

A person who is required, in the course of his or her business or occupation in connection with a nuclear substance or nuclear facility, to perform duties in such circumstances that there is a reasonable probability that he or she may receive a dose of radiation that is greater than the prescribed limit for the general public. (Source: *Nuclear Safety and Control Act*)

nuclear medicine technologist

A medical radiation technologist certified by the Canadian Association of Medical Radiation Technologists. The nuclear medicine technologist works in the field of nuclear medicine and performs various duties such as preparing and administering radiopharmaceuticals, taking images of different organs and bodily structures, using computers to process data and enhance images, analyzing biological specimens and working closely with all members of the healthcare team.

one-year dosimetry period

The period of one calendar year beginning on January 1 of the year following the year in which the *Radiation Protection Regulation* came into force, and every subsequent period of one calendar. (Source: *Radiation Protection Regulations*)

portable nuclear gauge

A portable radiation device used to measure density, level, thickness or moisture content.

prescribed equipment

The equipment prescribed by section 20 of the *General Nuclear Safety and Control Regulations*.

Section 20 states that each of the following items is prescribed equipment for the purposes of the *Nuclear Safety and Control Act*:

- a package, special form radioactive material, low dispersible radioactive material, fissile-excepted radioactive material, radioactive material that has a basic radionuclide value that is not listed in the IAEA Regulations and an instrument or article that has an alternative activity limit for an exempt consignment, as those terms are defined in subsection 1(1) of the *Packaging and Transport of Nuclear Substances Regulations, 2015*
- a radiation device and a sealed source, as defined in section 1 of the *Nuclear Substances and Radiation Devices Regulations*
- Class II prescribed equipment, as defined in section 1 of the *Class II Nuclear Facilities and Prescribed Equipment Regulations*

- equipment that is capable of being used in the design, production, operation or maintenance of a nuclear weapon or nuclear explosive device

All controlled nuclear equipment is prescribed equipment for the purposes of the *Nuclear Safety and Control Act*, with respect to the import and export of that equipment.

radiation device

A device that contains more than the exemption quantity of a nuclear substance and that enables the nuclear substance to be used for its radiation properties for various purposes such as industrial radiography, oil exploration, road construction and industrial processes.

radiopharmaceutical

A drug containing a radioactive substance that is used in medical imaging and cancer treatment.

sealed source

A radioactive nuclear substance in a sealed capsule or in a cover to which the substance is bonded, where the capsule or cover is strong enough to prevent contact with or the dispersion of the substance under the conditions for which the capsule or cover is designed. (Sources: *Class I Nuclear Facilities Regulations*; *Class II Nuclear Facilities and Prescribed Equipment Regulations*; *Nuclear Substances and Radiation Devices Regulations*)

unsealed source

A source other than a sealed source. (Source: *Nuclear Substances and Radiation Devices Regulations*) These nuclear substances are in a physical form where dispersion of the radioactive material is possible during use or handling. Usually a liquid, they may also be in solid, powder or gaseous form. Unsealed sources are commonly used in medical diagnostic and therapeutic treatments, as well as in laboratory research applications. Also called open source.