Canada's Nuclear Regulator

Nuclear Substances in Canada: A Safety Performance Report for 2011

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Nuclear Substances in Canada: A Safety Performance Report for 2011

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NUCLEAR SUBSTANCES IN CANADA: A SAFETY PERFORMANCE REPORT FOR 2011

1.0 EXECUTIVE SUMMARY

This safety report for the 2011 calendar year elaborates on the safety performance of the nuclear sectors regulated by the Canadian Nuclear Safety Commission (CNSC) with respect to the use of nuclear substances in medical, industrial and commercial applications, as well as in the academic and research environment.

The safe use of nuclear substances requires compliance with the *Nuclear Safety and Control Act* as well as CNSC regulations and licence conditions. It also requires the minimization of the consequences of incidents and occupational radiation doses. Safety performance is measured in terms of licensees' regulatory compliance, reported incidents and occupational doses to workers. This report provides information on 2,550 CNSC licences in four CNSC-regulated sectors:

Medical sector
The medical sector uses nuclear substances and nuclear energy for diagnostic and therapeutic purposes in health care. This sector contained 568 CNSC licences as of December 31, 2011. The licensed activities can be grouped into nuclear medicine and radiation therapy.

Industrial sector
The industrial sector uses nuclear substances in civil engineering and in the delivery of services such as industrial radiography and oil well logging. This is the largest of the reported sectors, containing 1,456 licences as of December 31, 2011.

Academic and research sector
The licensed activities in the academic and research sector focus primarily on biological and biomedical research that uses open-source radioisotopes, research particle accelerators and research irradiators. This sector contained 276 licences as of December 31, 2011.

Commercial sector
The commercial sector focuses primarily on the production and sale of nuclear substances and the third-party servicing of radiation devices and prescribed equipment. This sector contained 250 licences as of December 31, 2011.

The safety performance of CNSC licensees is measured in terms of the following performance metrics:

- doses to workers
- inspection ratings of operating performance
- inspection ratings of radiation protection
- inspection ratings of sealed source tracking
- reported incidents and events
- enforcement activities – orders

Figures 1 to 6 compare the performance of the four sectors for each of these metrics, respectively.

1.1 DOSES TO WORKERS

Figure 1: Sector-to-sector comparison – Percentage of nuclear energy workers and other workers who received whole body doses of less than 1 mSv per year

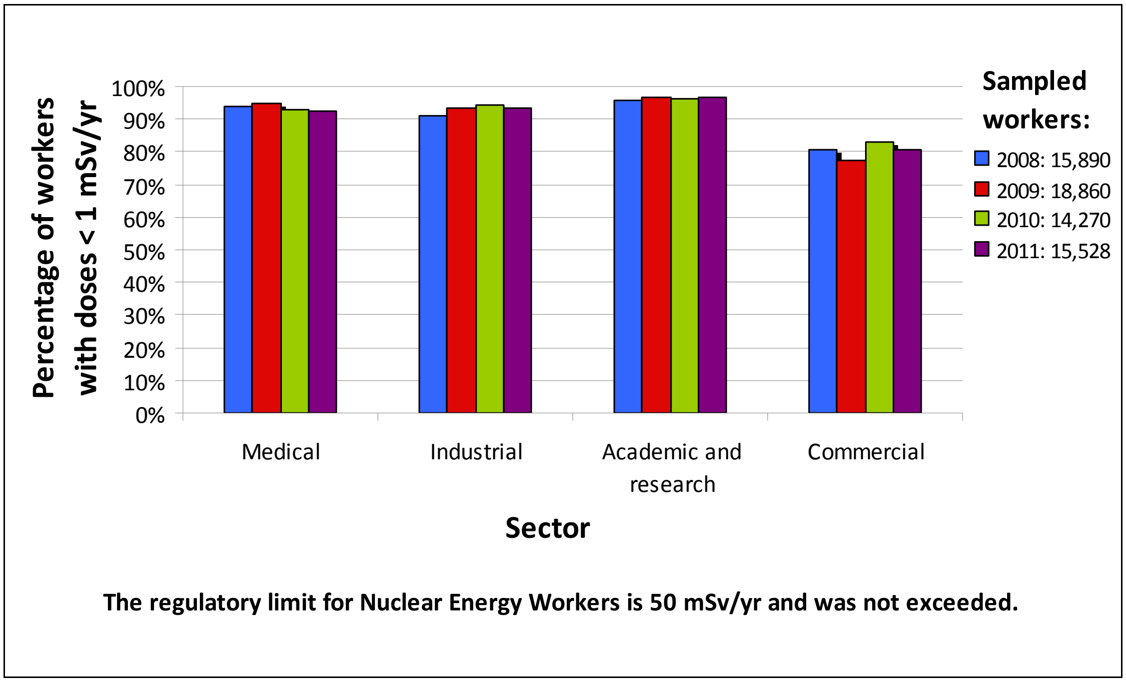
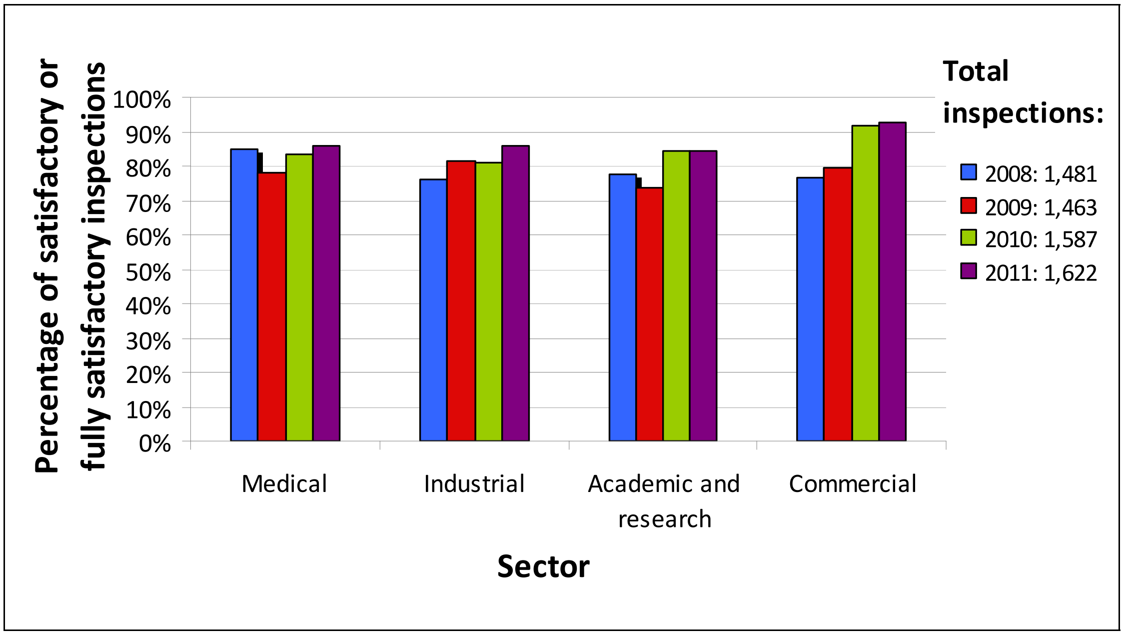


Figure 1 shows the percentage of sampled workers – nuclear energy workers (NEWs) and other workers – who received doses of less than 1 mSv/year, which is the prescribed limit for the public, from 2008 to 2011. Doses received by these workers in 2011 remained essentially constant when compared to doses received in 2010.

Although not shown in figure 1, NEWs in all nuclear sectors received doses significantly lower than the regulatory limit of 50 mSv/year. NEWs are also subject to a regulatory limit of 100 mSv over a five-year period. However, because this reporting period started on January 1, 2011, it will not be possible to report on a five-year overexposure until December 31, 2015.

1.2 INSPECTION RATINGS OF OPERATING PERFORMANCE

Figure 2: Sector-to-sector comparison – Inspection ratings of operating performance



As shown in figure 2, licensees in all sectors showed improvement in their compliance levels for operating performance during 2011, when compared to the previous three years. The commercial sector has shown the greatest improvement over the four-year reporting period, increasing from 76% of inspections rated "fully satisfactory" or "satisfactory" in 2008 to 93% in 2011 – making it the strongest of the four sectors in terms of operating performance inspection ratings for the past two years. There were 1,622 inspections encompassing a review of licensees' operating performance performed in 2011. In general, the trends were positive with respect to compliance within the safety area of operating performance.

1.3 INSPECTION RATINGS OF RADIATION PROTECTION

Figure 3: Sector-to-sector comparison – Inspection ratings of radiation protection

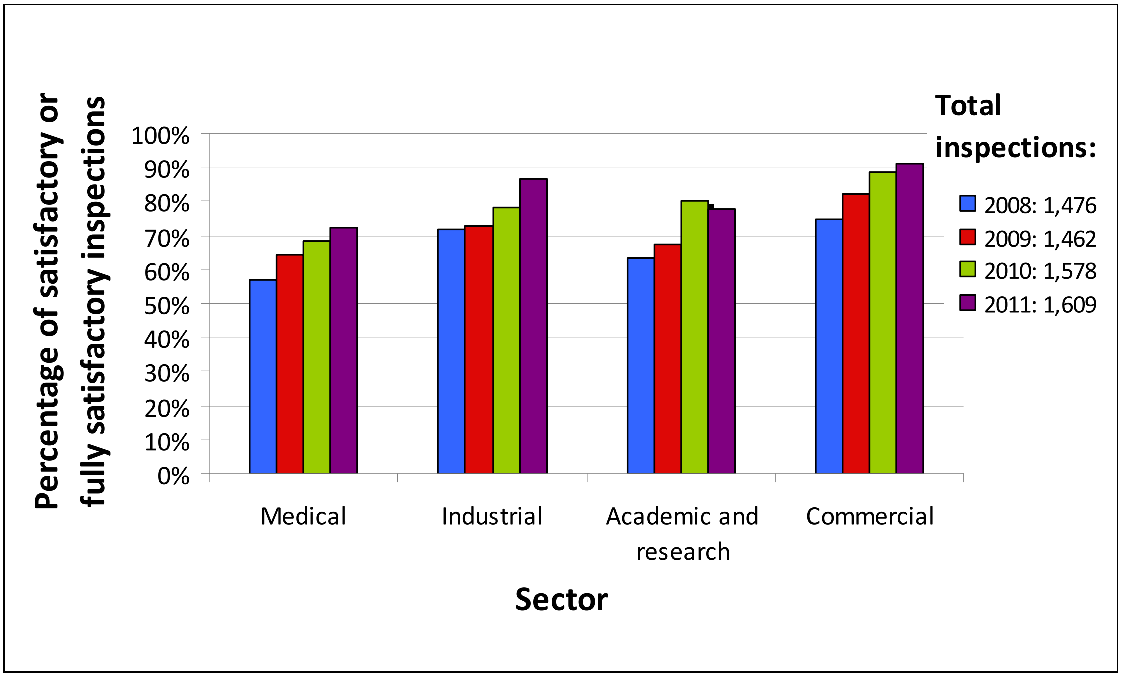
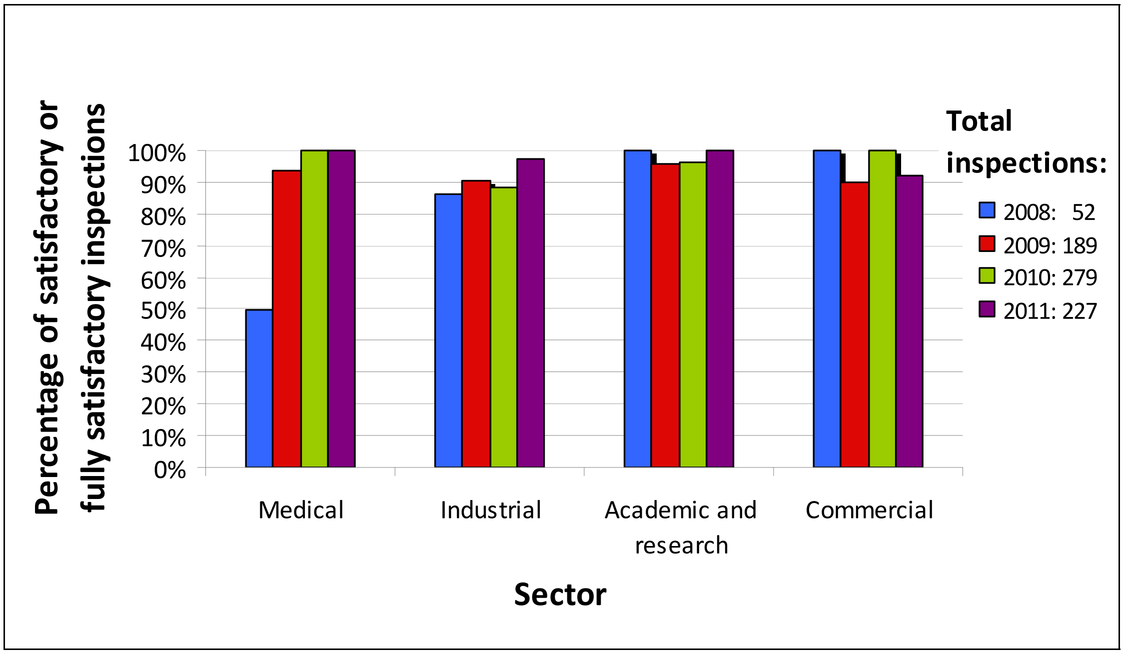


Figure 3 shows that, over the four-year period covered by this report, most sectors improved their compliance levels for the radiation protection safety area. The exception was the academic and research sector, which essentially remained consistent with the previous year. The industrial sector saw the most notable increase: 87% of its inspected licensees were found to be compliant in 2011 compared to 78% in 2010. Although the medical sector has been showing continuous improvement over this reporting period with an overall compliance level of 72% in 2011, its radiation protection inspection ratings are still systematically behind the other sectors. In 2011, the CNSC performed 1,609 inspections of the radiation protection safety area, with generally positive trends between 2008 and 2011.

1.4 INSPECTION RATINGS OF SEALED SOURCE TRACKING

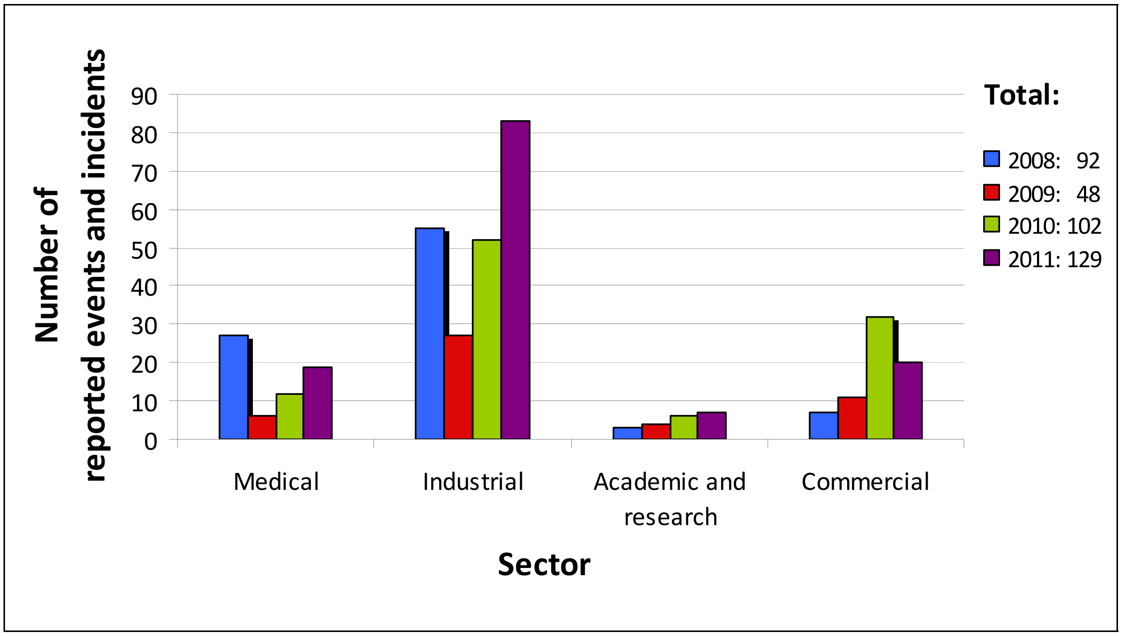
Figure 4: Sector-to-sector comparison – Inspection ratings of sealed source tracking



All sectors in figure 4 showed strong compliance levels with the regulatory requirements for the tracking of high-risk sealed sources. Fewer inspections of this safety area are conducted because only licensees in possession and control of high-risk sealed sources are subject to the mandatory sealed source tracking requirements. As required under their licences, these licensees must report source movements to the CNSC within a prescribed timeframe. Compliance levels were generally consistent with previous reporting years.

1.5 REPORTED INCIDENTS AND EVENTS

Figure 5: Sector-to-sector comparison – Reported events and incidents



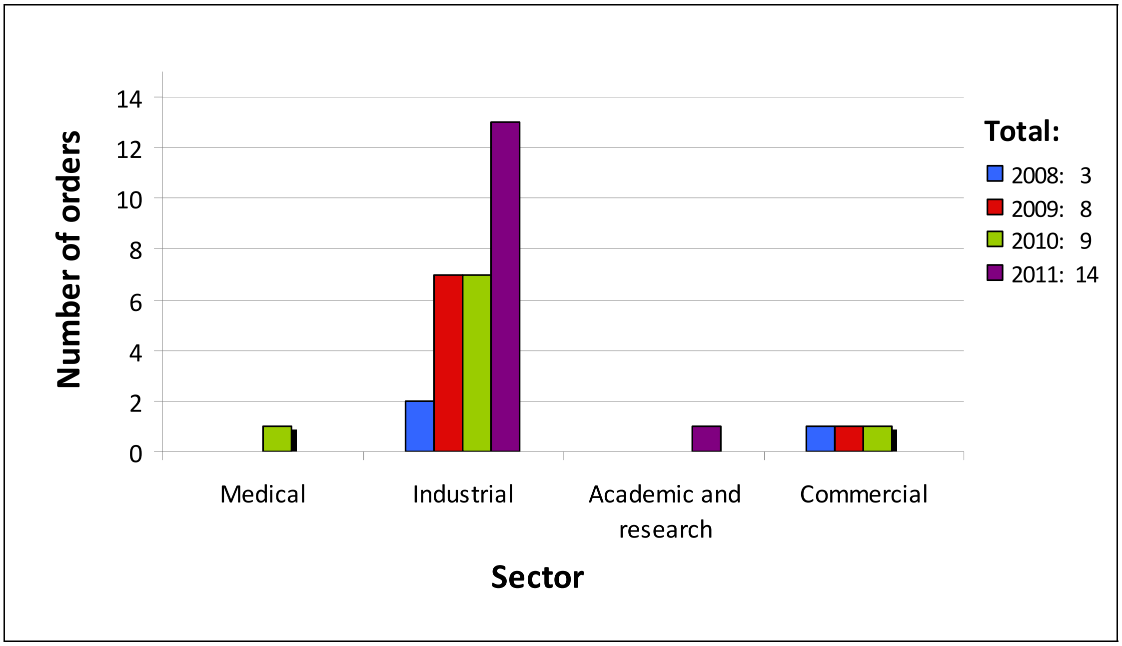
The number of reported events and incidents increased in 2011 compared to previous years. Figure 5 shows that this was more noticeable in the industrial sector, mainly due to a rise in the number of incidents involving portable nuclear gauges (hereafter referred to as “portable gauges”). The commercial sector is an exception, as it saw a decrease in its number of reported events and incidents in 2011 compared to 2010. In fact, the number of spills and contamination incidents in this sector decreased by 68%, most likely as a consequence of preventive measures implemented by licensees. Future data will demonstrate whether this is a long-term trend.

In 2011, across all four sectors, there were 17 events related to missing nuclear substances. Six events involved nuclear substances that were found in various locations, including metal recycling facilities through the use of portal alarm monitors. Four events involved nuclear substances that were recovered shortly after they were reported lost or stolen. Seven other events are being investigated by licensees and involve very low to low-risk sources. Although the majority of the events were satisfactorily resolved, the CNSC continues to enforce full compliance with safety and security requirements for nuclear substances regardless of the level of risk.

None of the events or incidents reported to the CNSC in 2011 resulted in any person receiving a dose in excess of regulatory limits. In all cases, licensees implemented appropriate measures to mitigate event consequences and to limit radiation exposure to workers and the public.

1.6 ENFORCEMENT ACTIVITIES – ORDERS

Figure 6: Sector-to-sector comparison – CNSC orders to licensees



As shown in figure 6, the number of CNSC orders issued to licensees increased in 2011 when compared to 2010, partly due to an increase in the number of field inspections being conducted. Of the 13 orders issued to the industrial sector, six were to portable gauge licensees, six to industrial radiography licensees, and one to an oil well logging licensee. One order was issued to a university in the academic and research sector, and no orders were issued to licensees in either the commercial or medical sectors in 2011.

2.0 PURPOSE

This document reports on the safety performance of the following CNSC-regulated sectors for the 2011 calendar year:

- medical
- industrial
- academic and research
- commercial

3.0 SCOPE

This report focuses on the use of nuclear substances and prescribed equipment in medical, industrial and commercial applications, as well as for academic and research purposes. This safety performance report covers the 2011 calendar year. It does not cover Class I nuclear facilities such as nuclear power plants, nuclear research reactors, uranium mines and mills, waste facilities, dosimetry services, or import and export activities. However, it does include high-energy particle accelerators, classified as Class IB nuclear facilities.

4.0 INTRODUCTION

The CNSC's mission is to regulate the use of nuclear energy, nuclear substances and prescribed equipment to protect the health, safety and security of Canadians and the environment; and to implement Canada's international commitments on the peaceful use of nuclear energy. Under the *Nuclear Safety and Control Act*[1] (NSCA), the CNSC's mandate involves four major areas:

- regulating the development, production and use of nuclear energy in Canada to protect health, safety and the environment
- regulating the production, possession, use and transport of nuclear substances, and the production, possession and use of prescribed equipment and prescribed information
- implementing measures respecting international control of the development, production, transport and use of nuclear energy and substances, including measures respecting the non-proliferation of nuclear weapons and nuclear explosive devices
- disseminating objective scientific, technical and regulatory information concerning the activities of the CNSC and the effects of the development, production, possession, transport and use of nuclear substances on the environment and on the health and safety of Canadians

This report provides objective information and data that licensees may use for their own performance improvement initiatives. To identify trends, safety performance results in 2008, 2009 and 2010 are also included.

For a comprehensive overview of the CNSC, readers are invited to consult the CNSC's *2011–12 Annual Report*.[2]

[1] Available online at laws-lois.justice.gc.ca/eng/acts/N-28.3/index.html
[2] Available online at http://www.nuclearsafety.gc.ca/eng/readingroom/reports/annual/

Nuclear substances are used in a wide range of applications in Canada. Many day-to-day commodities are produced with the aid of nuclear substances licensed by the CNSC, some of which are contained in radiation devices. Common uses of these devices include static eliminators used in the production of plastics to remove static electricity, fixed nuclear gauges (hereafter referred to as "fixed gauges") that control the fluid levels of factory-filled beverage bottles, and portable gauges that measure moisture and density in soil and the thickness of asphalt in new road construction.

Nuclear substances are also found in devices that protect the health and safety of Canadians, including smoke detectors and security screening equipment. They do not require a licence for possession by the end user; however, their manufacture and initial distribution in Canada are licensed by the CNSC.

Medical applications using radiopharmaceuticals are designed to target and treat specific tissues and organs, allowing for the delivery of a nuclear substance to specific areas of the body. Radiopharmaceuticals are widely used in the diagnosis and treatment of diseases such as cancer and heart disease.

Examples of nuclear substances found in academic areas include those in irradiators to irradiate cells or samples in research laboratories. Particle accelerators are used in research in the fields of subatomic physics, materials and biomedicine. They can also be used to generate some of the nuclear substances used in medical and research facilities. Nuclear substances are also found in teaching and research laboratories for diverse activities such as the use of a gas chromatograph to analyze environmental samples.

Commercial uses of nuclear substances fall mainly into the production and processing of medical isotopes, as well as the servicing of nuclear gauges and exposure devices. Servicing licences often include the installation, repair and non-routine maintenance of radiation devices or prescribed equipment.

5.0 SAFETY PERFORMANCE MEASURES

5.1 SELECTION OF PERFORMANCE MEASURES

This report centres on ratings obtained from the CNSC's onsite compliance inspections of three key metrics: operating performance, radiation protection and the tracking of high-risk sealed sources. The CNSC deems these to be the most relevant indicators of safety performance and the most representative of the regulated sectors covered in this report. The following provides information on the assessment of inspection ratings related to the three performance metrics common to all sub-sectors:

- **Operating performance:** This metric is one of the safety and control areas and part of the management function; it is also referred to as "operational procedures". It includes an overall review of the operations of the facility or activity, as well as the activities that enable effective performance and the fostering of a safety culture.
- **Radiation protection:** This metric is another one of the safety and control areas, and is considered one of the core control processes; it covers the implementation of a radiation protection program in accordance with the CNSC's *Radiation Protection Regulations*. This program must ensure that contamination and radiation doses received are monitored and controlled.
- **Sealed source tracking:** This metric relates to the tracking of high-risk sealed sources in Canada, in accordance with Canada's commitment to the International Atomic Energy Agency's *Code of Conduct on the Safety and Security of Radioactive Sources*. The National Sealed Source Registry (NSSR) is a CNSC-managed database that maintains inventory information on these sealed sources in Canada. The movement of high-risk sources is tracked through the Sealed Source Tracking System (SSTS), the use of which is mandatory only for licensees using these high-risk sources. For more information on the SSTS, readers are invited to consult the NSSR and SSTS annual reports.[3] The CNSC requires licensee compliance with the tracking of these sealed sources to guarantee adequate traceability and accountability of these sources.

Two additional performance measures are used in this report since they can indicate the overall licensee performance with respect to the entire set of safety and control areas. These include:

- occupational doses (also referred to as "dose to workers"), which provide an objective measure of a sector's safety performance
- the change in incident frequency from year to year (which is of greater interest than the higher number of incidents that some sectors have shown, due to the nature of their licensed activities)

For greater clarity, sectors are broken down into smaller sub-sectors based on similarities in licensed activities. In an effort to provide an overview of each sector, the number of sub-sectors is kept to a minimum in this report. For the high-energy particle accelerators sub-sector, additional performance measures are covered in this report to provide a more

[3] Available online at nuclearsafety.gc.ca/eng/readingroom/reports/ssts/index.cfm

comprehensive review of these complex facilities. These performance measures are defined in Appendix B.

In summary, the safety performance of each sector is evaluated using inspection ratings of operating performance, radiation protection and high-risk sealed source tracking, as well as doses to workers, and reported incidents and events.

Although the CNSC assesses all licence applications before issuing or renewing licences, not all licensees require the same level of regulatory oversight and compliance verification. The CNSC has adopted a risk-informed regulatory program and, as such, may not inspect all licensees every year. A high-risk licensed activity may be subject to more detailed oversight and inspections, and necessitate the submission of an annual compliance report (ACR) by the licensee. A low-risk licensed activity may require only the submission of an ACR.

This risk-informed approach guides the CNSC in applying increasingly restrictive measures of enforcement, including orders, to promote licensee compliance. In addition to orders, licensees may choose to voluntarily restrict their operations until they implement measures to restore their compliance with the *Nuclear Safety and Control Act* (NSCA), regulations and licence conditions. The CNSC may also utilize other measures to promote and enforce compliance such as increasing the frequency of its compliance verification activities. Appendix A provides more information on the CNSC's risk-informed approach for regulating the nuclear sectors in this report.

There are 2,550 licences that fall into the medical, industrial, academic and research, and commercial sectors covered in this report. CNSC inspectors planned and performed more than 1,600 compliance inspections in 2011. Appendix C provides a detailed comparison of safety performance measures among sectors. It includes a summary of the number of licences by sector, as well as an overall comparison of dose to workers, inspection rating results, and the number of reported events and incidents for each of the four sectors.

5.2 COMPLIANCE RATINGS

Compliance ratings are based on a licensee's compliance with the NSCA, regulations and licence conditions. When needed, the CNSC enforces compliance using a graduated approach, whereby the actions taken are commensurate with the risk presented by the infraction. This can be in the form of a simple written notification to the licensee for low-risk infractions, or more extensive regulatory oversight following medium-risk infractions. The CNSC may issue an order for an infraction that presents immediate risks to the environment or to the health or safety of persons, or for repeated violations that may indicate significant degradation in licensee safety performance.

The CNSC follows up on all enforcement actions to ensure that licensees have taken all necessary corrective actions to restore compliance with CNSC requirements. This section contains definitions of the performance measures used to produce this report, and section 5.3 defines the rating system.

5.2.1 DOSES TO WORKERS

This information represents the dose records of persons in CNSC-licensed activities who may be subjected to occupational exposures to radiation. The data is extracted from dose reports provided by licensees in their ACRs for 2011. For the purpose of this performance measure, CNSC staff analyzed a representative sample of worker dose records from randomly selected ACRs from licensees in each sector.

Performance objective:

> Doses to workers are below the regulatory limits and As Low As Reasonably Achievable (ALARA).[4]

The prescribed whole body dose limit for members of the public is 1 mSv/year, whereas the limits for a nuclear energy worker (NEW) are a maximum of 50 mSv in a one-year dosimetry period and 100 mSv in a five-year dosimetry period.

5.2.2 OPERATING PERFORMANCE

Operating performance relates to the licensee's ability to perform licensed activities in accordance with the NSCA, regulations and their licence conditions. The licensee is expected to demonstrate that operational and safety requirements are met, that appropriate procedures concerning the use and maintenance of equipment are provided to and followed by workers, and that appropriate documentation that demonstrates compliance is maintained. To verify these program elements, CNSC staff review documents and perform field inspections of operational procedures and practices.

Performance objective:

> Licensee operations are safe, with adequate regard for health, safety, security, environmental protection, and conform to Canada's international obligations.

5.2.3 RADIATION PROTECTION

Radiation protection relates to the program that a licensee puts in place to protect persons from unnecessary exposure to ionizing radiation. The licensee is expected to demonstrate that adequate provisions are in place to maintain doses below regulatory limits and ALARA. This objective can be met through the monitoring of worker doses, posting of radiation warning signs, appropriate planning for radiological emergencies, management oversight of operational activities, and effective workplace practices emphasizing time, distance and shielding and the use of appropriate protective equipment.

Performance objective:

> Licensees ensure that there is adequate protection in place for the health and safety of persons with respect to ionizing radiation.

[4] Refer to G-129, Rev.1, *Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)"*. Available online at nuclearsafety.gc.ca.

5.2.4 SEALED SOURCE TRACKING

The CNSC's Sealed Source Tracking System (SSTS) provides a greater degree of regulatory oversight for radioactive sealed sources in Canada. Licensees are required to report to the CNSC on the movement of high-risk radioactive sealed sources, using the SSTS as appropriate. Records are maintained to demonstrate compliance.

Performance objective:

> Licensees have adequate measures in place to track and report the movement of high-risk radioactive sealed sources to the CNSC in a timely and accurate manner, via the SSTS, and to implement appropriate safeguard measures where applicable.

5.2.5 REPORTED INCIDENTS AND EVENTS

Licensees are required under the NSCA and its regulations or through specific licence conditions to immediately report to the CNSC any incidents or events related to their licensed activities. Within 21 days following the initial report, licensees are required to submit a more detailed final report to the CNSC on the incident or event. This final report is to include a root-cause analysis and measures taken or proposed by the licensee to prevent recurrence. Together, the initial and final reports allow the CNSC to ensure that adequate corrective actions are taken by the licensee.

Performance objective:

> Licensees have adequate measures in place to report incidents and events and to demonstrate an effective root-cause analysis of reportable events. This analysis ensures that licensee programs continually improve and remain relevant and effective.

5.3 COMPLIANCE RATING SYSTEM

To indicate the level of licensee compliance with regulatory requirements, the CNSC has adopted a graduated grading scheme for the regulated sectors covered by this report. Although a five-letter system is often used for operational purposes during compliance inspection, the CNSC adopted a four-level compliance rating system in 2008 for reporting purposes. Refer to Appendix A for further information on the two rating systems. The grades used by the CNSC for reporting purposes are described here.

Fully satisfactory

Safety and control measures implemented by the licensee are highly effective. In addition, compliance with regulatory requirements is fully satisfactory, exceeding CNSC expectations. Overall, compliance is stable or improving, and any problems or issues that arise are promptly addressed. It is important to note that the grade assigned to an inspection is a compounded result of multiple criteria and requirements; therefore, a "fully satisfactory" grade is rare.

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6.0 SAFETY PERFORMANCE OF LICENSEES

6.1 MEDICAL SECTOR

6.1.1 DESCRIPTION

Licensees in the medical sector use nuclear substances or accelerators for diagnostic imaging and therapeutic purposes in hospitals and medical clinics. This sector accounted for 568 CNSC licences as of December 31, 2011.

Figure 7: A radioisotope being administered to a patient using a shielded syringe.
Source: CNSC.

Nuclear medicine studies determine the cause of medical problems based on the function of the organ, tissue or bone. Radiopharmaceuticals containing nuclear substances such as Technetium 99m, Carbon 11 and Fluorine 18 are administered to patients for imaging purposes, as shown in figure 7. These images are captured by licensed equipment such as a positron emission tomography (PET) scanner or a gamma camera.

Examples of common nuclear medicine diagnostic procedures include myocardial perfusion scans to visualize heart blood flow and function; bone scans to evaluate bones for integrity, infection or tumour; and renal perfusion scintiscans to create an image of the kidney.

Figure 8: Medical linear accelerator.
Source: CNSC.

Medical linear accelerators, as shown in figure 8, are the most commonly used tool to deliver radiation therapy. The technology used in these devices has advanced rapidly over the last 15 years. Modern linear accelerators can deliver treatments faster and more accurately than before and have evolved into hybrid treatment and imaging devices, some of which can generate computed tomography (CT) images in addition to delivering the radiation treatment.

Radioisotopes are also used in many therapeutic procedures. For example, Iodine 131 is used to treat diseases of the thyroid, Phosphorus 32 to treat certain blood disorders, and other isotopes are used in conjunction with antibodies for site-specific treatment of certain cancers.

Veterinary nuclear medicine uses the same principles as human nuclear medicine to diagnose and treat animals. Injured horses have bone scans using Technetium 99m and cats have thyroid disorders treated with doses of Iodine 131.

A unique challenge for licensees offering veterinary nuclear medicine services is the control of animals that have received doses of radiopharmaceuticals. The CNSC requires licensees to house the animals in controlled environments and effectively manage animal waste while at the veterinary clinic. In addition, there are strict limits imposed on the release of treated animals to ensure the dose to the owner is kept As Low As Reasonably Achievable (ALARA). The CNSC accomplishes these goals by a thorough review of clinic procedures, licence conditions and collaborative efforts between licensing and inspection staffs to ensure the requirements are being met.

For the purpose of this report, the following sub-sectors were identified within the medical sector: diagnostic and therapeutic nuclear medicine, radiation therapy, and veterinary nuclear medicine. Together, these sub-sectors account for 73% or 412 licences of the 568 licences in the medical sector.

6.1.2 DOSES TO WORKERS

The data in this section represents the dose records of persons who may be subjected to occupational exposures to radiation associated with CNSC-licensed activities. The dose data is extracted from dose reports provided by licensees in their annual compliance reports (ACRs) for 2008 to 2011. For the purpose of this performance measure, CNSC staff analyzed a representative sample of worker dose records from randomly selected ACRs from licensees in each sector.

The term "sampled workers" in this section's figures represents the number of workers whose dose data was analyzed. There were 3,589 workers sampled in 2011. The majority of medical-sector employees received low occupational doses, consistent with previous years. As shown in figure 9, nearly 90% of all medical-sector employees received less than 0.5 mSv in 2011. For comparison, the average Canadian receives a dose of 2 mSv/year from natural background radiation.

There were 555 nuclear energy workers (NEWs) sampled in the area of diagnostic and therapeutic nuclear medicine. As shown in figure 10, 99% of the NEWs received less than 5 mSv in 2011. Furthermore, more than 54% received doses lower than the 1 mSv/yr public dose limit and all NEWs in this area received doses under 20 mSv/yr, below the regulatory limit of 50 mSv/yr.

As shown in figure 11, one worker of the 296 sampled other workers (not designated as NEWs) exceeded the 1 mSv/yr dose limit for members of the public. This was identified in the licensee's ACR in 2011. CNSC staff investigated the report and worked with the licensee to ensure appropriate corrective measures were implemented.

As shown in figure 12 and figure 13, occupational dose data provided by licensees indicates that radiation therapy workers continued, as in past years, to receive very low doses. More than 99% of sampled NEWs and 100% of other workers in radiation therapy received less than 1 mSv/year during 2011.

Occupational dose data in figure 14 and figure 15 illustrate that veterinary nuclear medicine workers received very low doses, although slightly higher overall than nuclear medicine technologists who work with human patients.

Results from 2011 show that 19% of NEWs received a dose in excess of 1 mSv but less than 5 mSv, well below the regulatory limit of 50 mSv/yr. No sampled workers in this category received a dose in excess of 5 mSv. Of the 80 other workers sampled in this sub-sector, no worker exceeded the 1 mSv regulatory limit in 2011 and more than 98% of workers received a dose of less than 0.5 mSv.

Figure 9: Medical sector – Annual whole body doses to nuclear energy workers and other workers

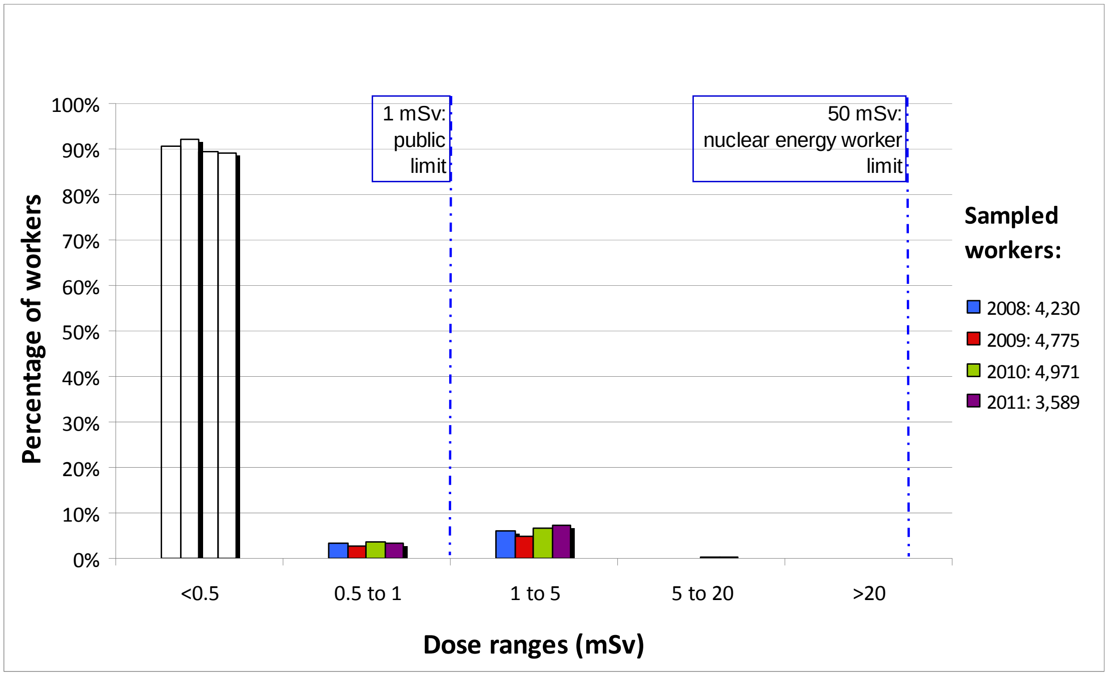


Figure 10: Diagnostic and therapeutic nuclear medicine – Annual whole body doses to nuclear energy workers

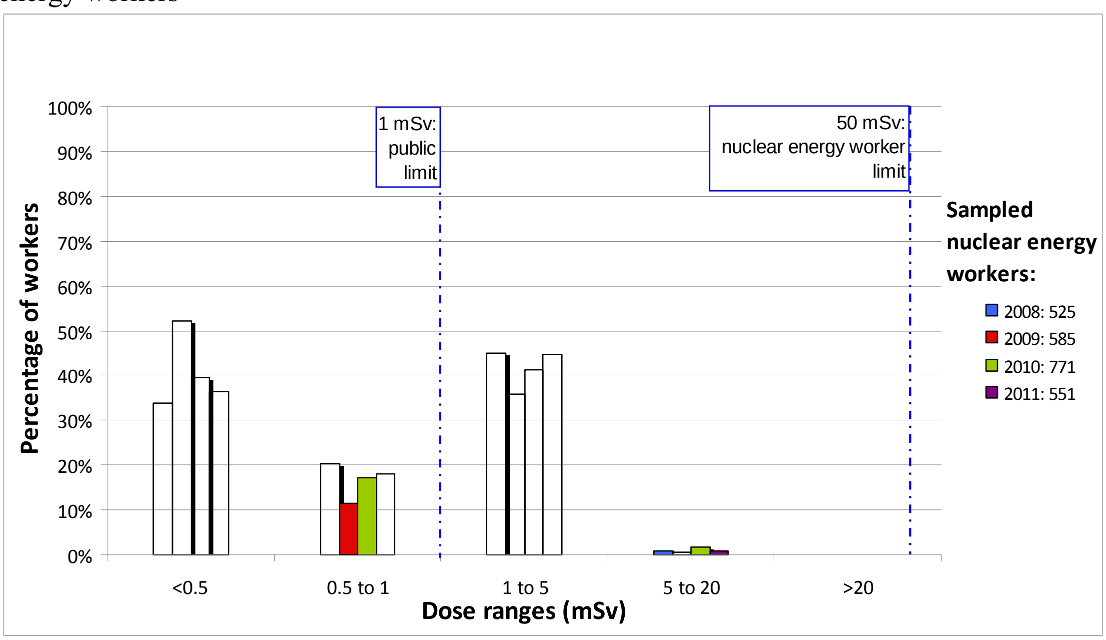


Figure 11: Diagnostic and therapeutic nuclear medicine – Annual whole body doses to other workers

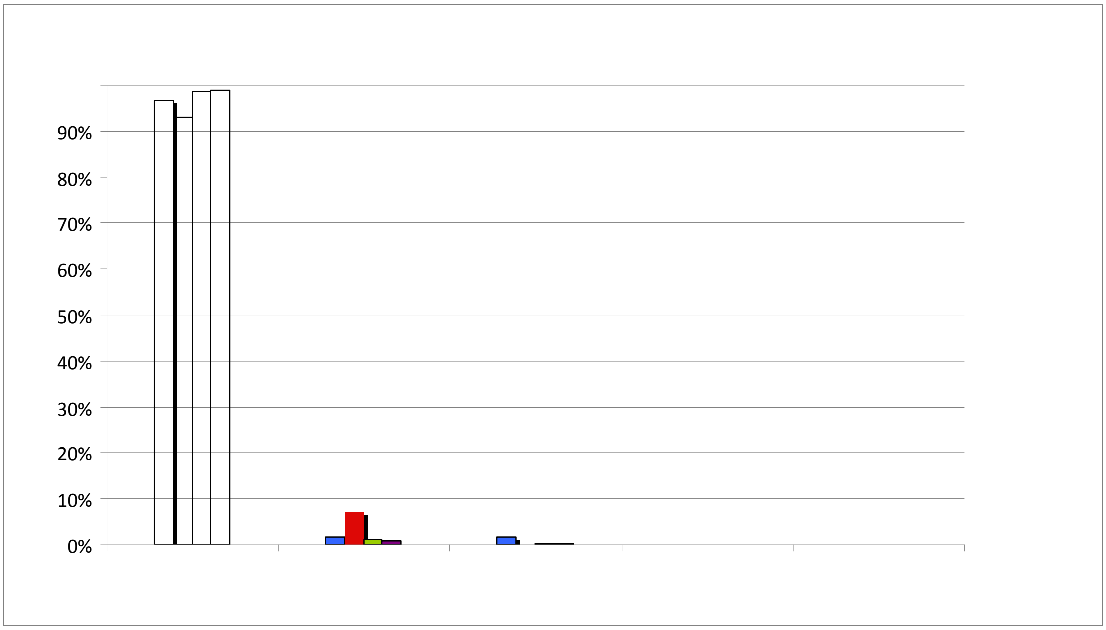


Figure 12: Radiation therapy – Annual whole body doses to nuclear energy workers

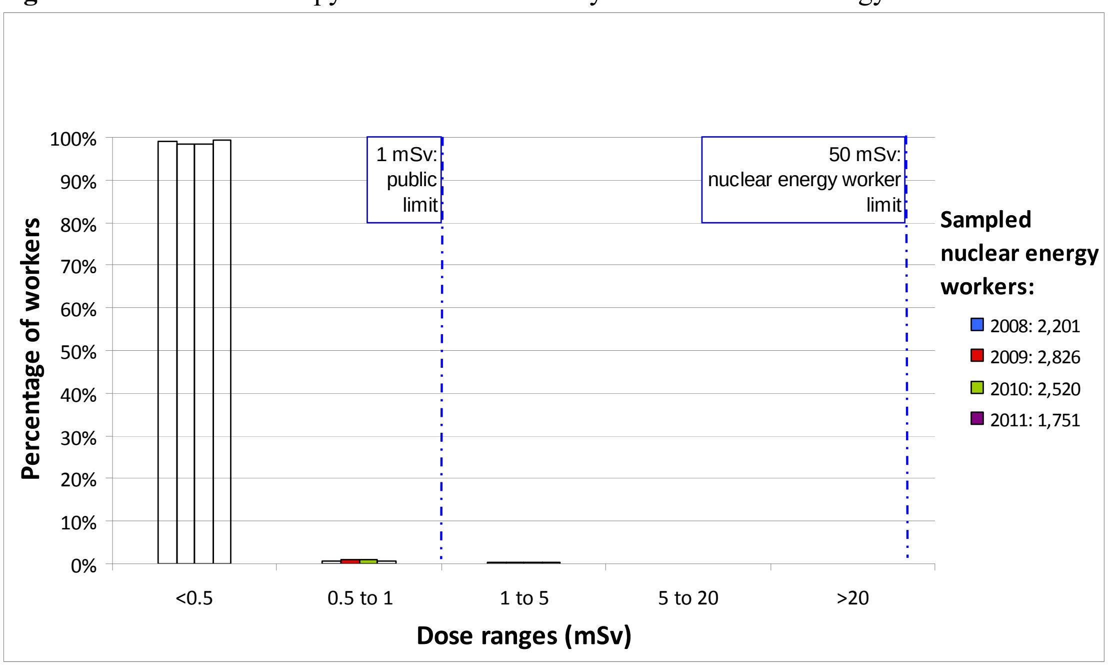


Figure 13: Radiation therapy – Annual whole body doses to other workers

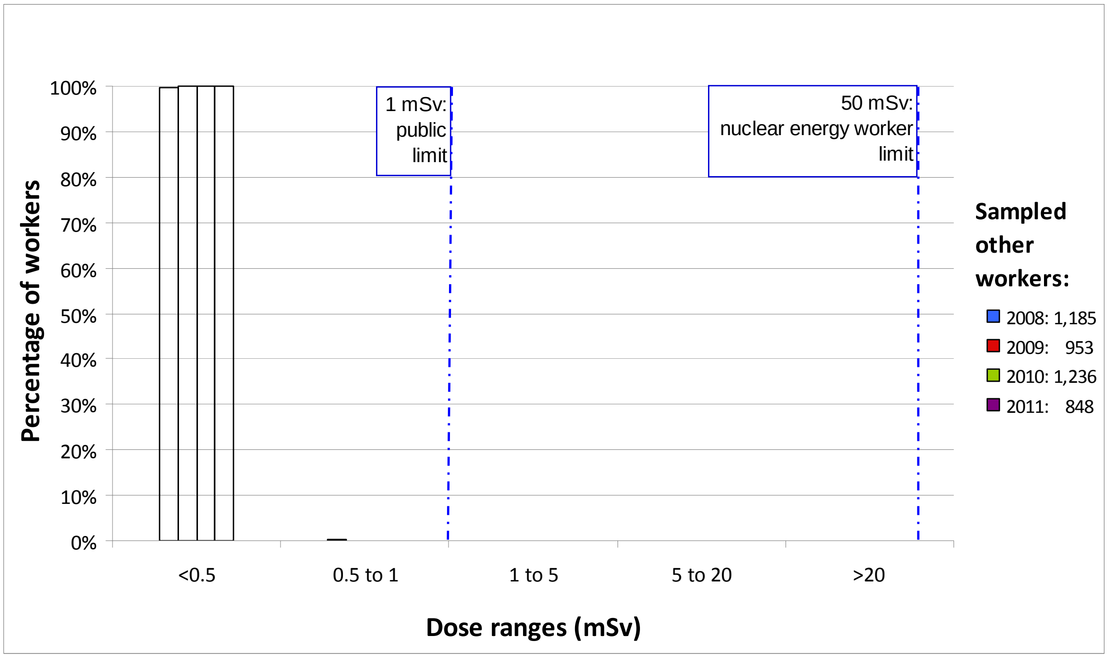


Figure 14: Veterinary nuclear medicine – Annual whole body doses to nuclear energy workers

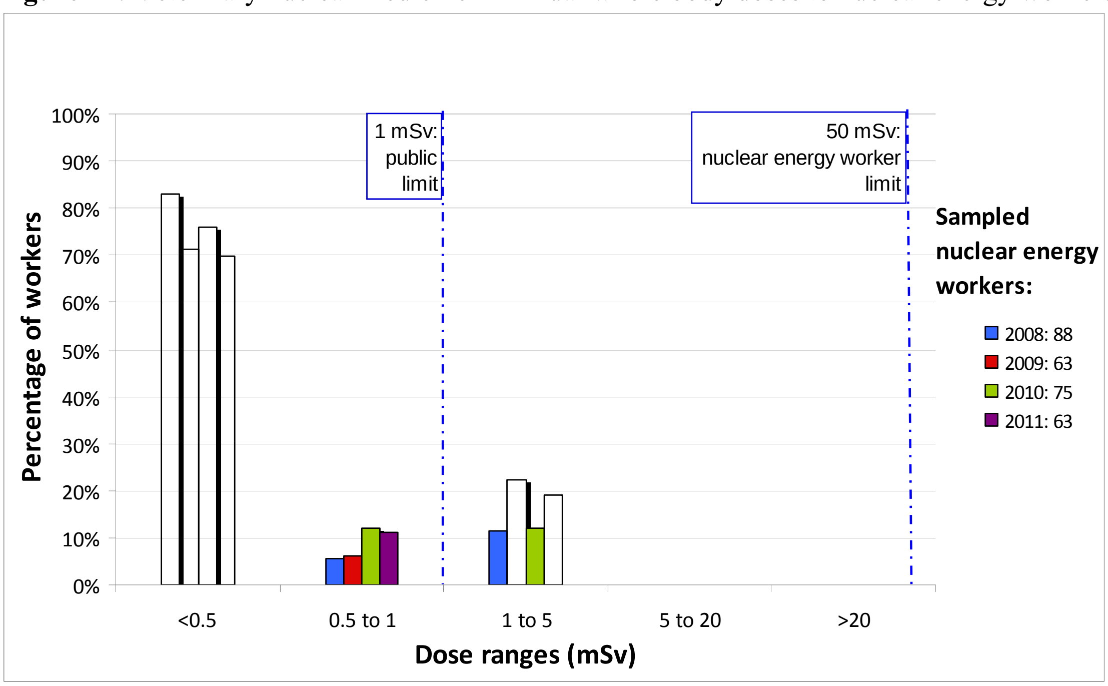
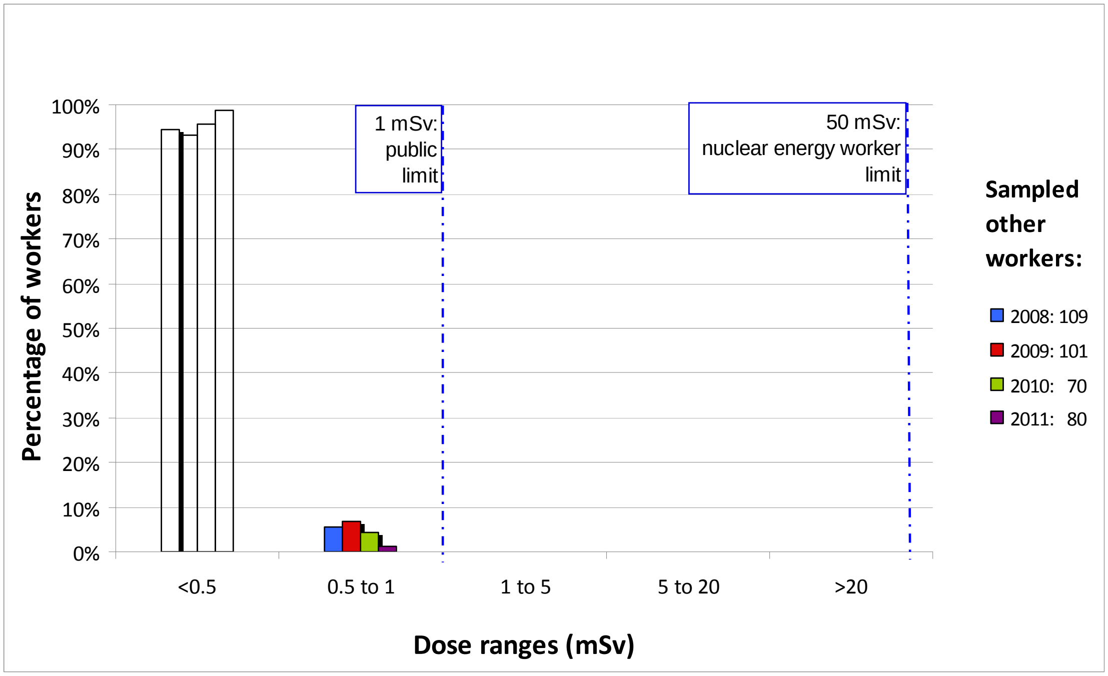


Figure 15: Veterinary nuclear medicine – Annual whole body doses to other workers

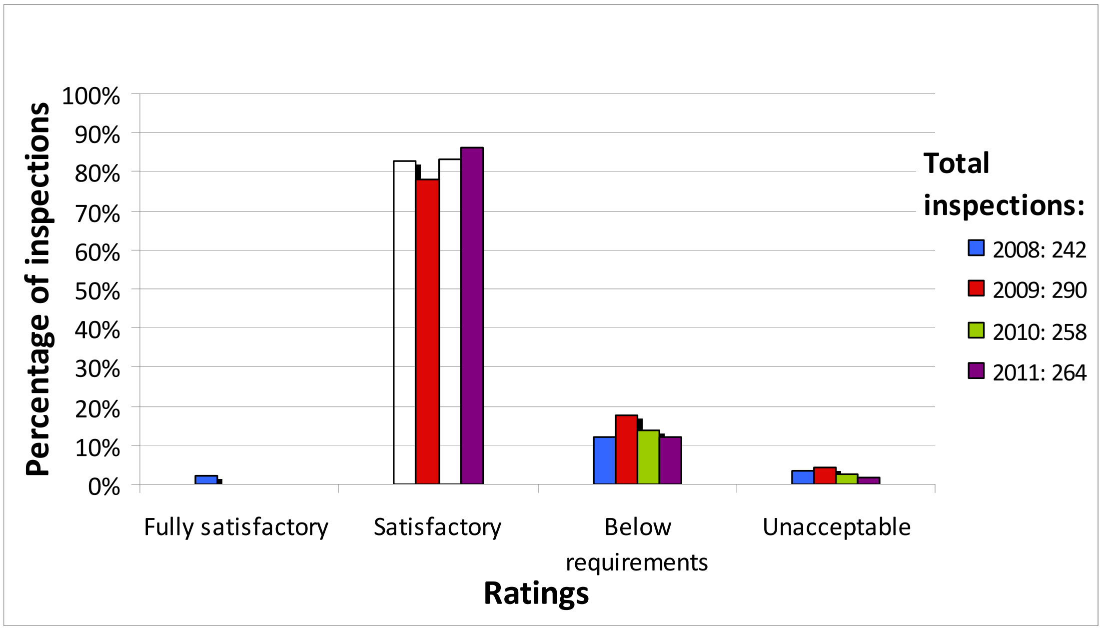


6.1.3 INSPECTION RATINGS OF OPERATING PERFORMANCE

As shown in figure 16, based on ratings of operating performance, the medical sector demonstrated good compliance with 86% of the inspected licensees found to be compliant in 2011, up from 83% in 2010. Of the inspected licensees found to be non-compliant, 12% had a “below requirements” rating for non-compliances that did not significantly affect safety and 2% had non-compliances rated as “unacceptable.” An “unacceptable” rating is significantly below requirements, with deficiencies that could lead to an unreasonable risk to the health and safety of workers, the public or the environment if left uncorrected.

Typical non-compliances in this sector include failure to adhere to the licensee’s own policies and procedures, and inadequate or improper quality assurance methods. To ensure that licensees address and correct all non-compliances, the CNSC used various enforcement actions such as written action notices and communication with senior management. For detailed results of inspection ratings, refer to Appendix C.3.

Figure 16: Medical sector – Inspection ratings of operating performance

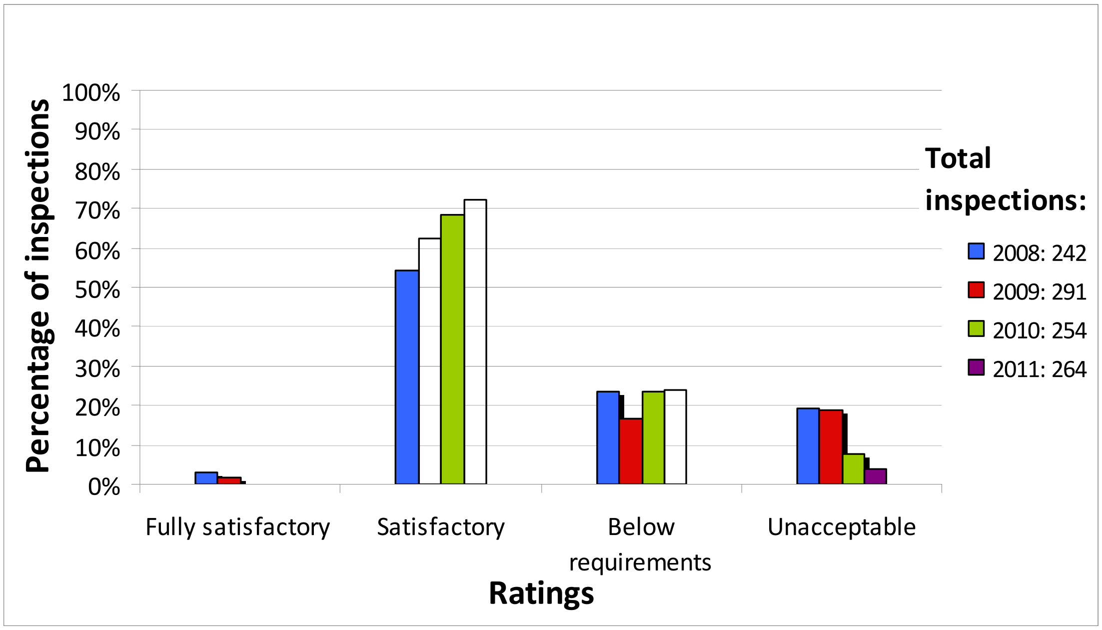


6.1.4 INSPECTION RATINGS OF RADIATION PROTECTION

The radiation protection program represents the management of radiation safety at a given medical centre and includes related management practices and training, as well as the minimization and measurement of occupational doses.

Figure 17 shows continued improvement in radiation protection inspection ratings in 2011. “Fully satisfactory” and “satisfactory” ratings accounted for 86% of inspection results in this category. Typical non-compliances in this sector include failure to maintain an up-to-date list of nuclear energy workers (NEWs) and failure to perform thyroid screening within the timeframe specified by the licence condition. The CNSC’s enforcement actions to address these types of non-compliance include requiring licensees to provide regular progress reports in resolving the non-compliances, or increasing the frequency of inspections. For detailed results of inspection ratings, refer to Appendix C.4.

Figure 17: Medical sector – Inspection ratings of radiation protection

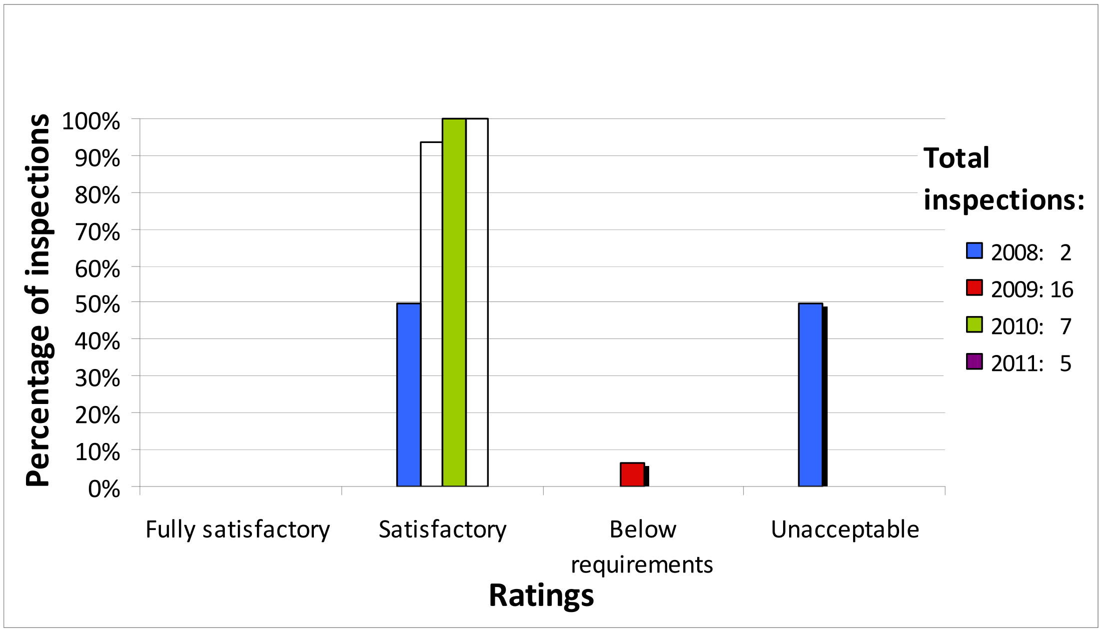


6.1.5 INSPECTION RATINGS OF SEALED SOURCE TRACKING

As shown in figure 18, inspection ratings for sealed source tracking indicate that licensees in the medical sector met requirements in all five CNSC inspections performed in 2011. For detailed results of inspection ratings, refer to Appendix C.5. For more information on this subject, readers are invited to consult the *National Sealed Source Registry and Sealed Source Tracking System Annual Report*, available on the CNSC Web site.[5]

[5] Available online at nuclearsafety.gc.ca/eng/readingroom/reports/ssts/index.cfm

Figure 18: Medical sector – Inspection ratings for sealed source tracking



6.1.6 REPORTED EVENTS AND INCIDENTS

As shown in figure 19, licensees in the medical sector reported 19 events in 2011.

Two of these events involved electrical malfunctions of radiation devices, with no radiological consequences or exposures.

Thirteen incidents involved spills or contamination in nuclear medicine facilities; these incidents can be attributed to the fact that the nuclear substances being handled are typically in liquid form. These spills resulted mainly from nuclear medicine technologists who dropped vials or spilled liquid while drawing it from vials. Other incidents of spills or contamination occurred during the administration of a nuclear substance to a patient, usually when an intravenous line was inadvertently disconnected or when a patient vomited. Typical isotopes used in the medical sector have half-lives that are measured in hours or a few days, so spills can be addressed by the licensee with minimal impact on clinical operations.

The medical sector also reported three incidents of missing nuclear substances. In one case, a worker dropped an eye plaque containing 20 low-risk Gold 198 seeds, each with an activity of 54.4 MBq and a half-life of 2.64 days. Nineteen seeds were immediately recovered, with the twentieth seed recovered three weeks later. There were no doses to person as a result of this incident.

In the second incident, a worker accidentally dropped a 614 kBq Cobalt 57 marker disk inside a nuclear medicine imaging camera. Efforts by the licensee and service provider to recover the source were unsuccessful. It is likely that this very low-risk source is stuck in a shielded position within the device, resulting in no risk to health and safety of persons.

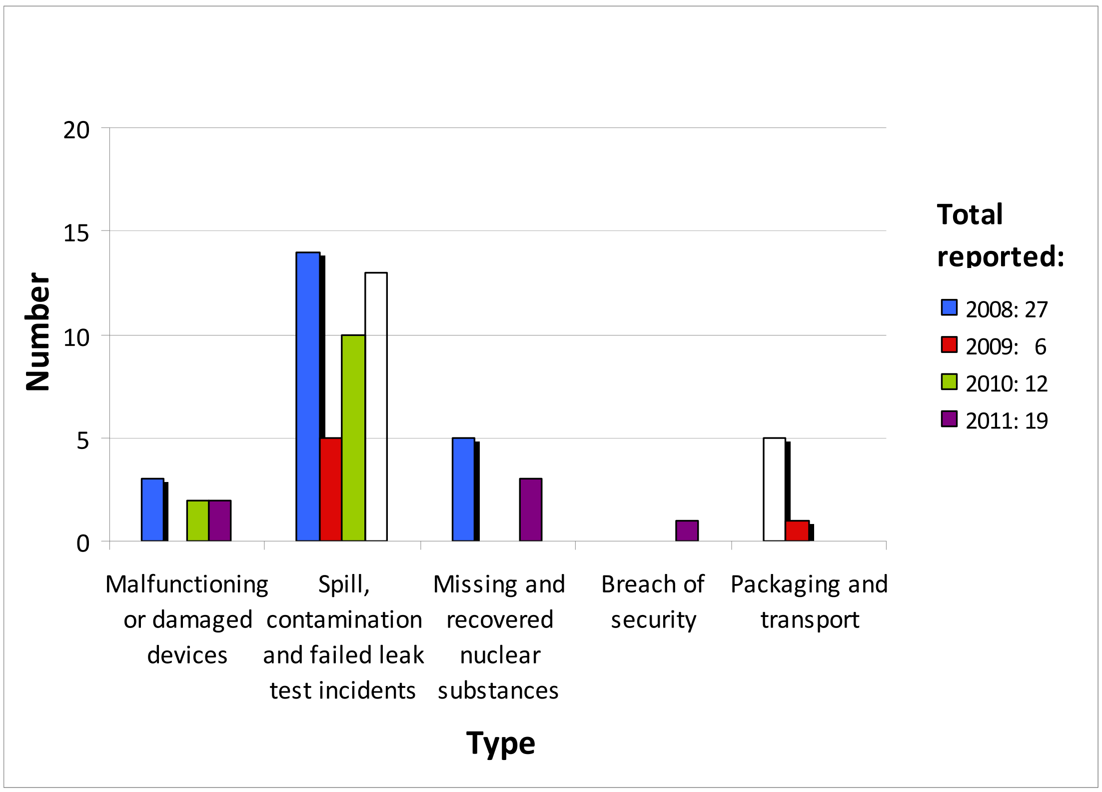
In the third incident, two low-risk 10 MBq Iodine 125 brachytherapy seeds were reported lost. These seeds have a half-life of 60 days. It is believed that the seeds may have been dislodged from the cartridge used for dispensing the seeds during the implantation and subsequently discarded with waste material following the medical procedure. The cartridge manufacturer issued a recall and made a minor design modification to its cartridges, which corrected the issue. The licensee has also provided additional training to their staff to ensure that, should such an issue occur again, seeds will not be discarded.

There was one report of a breach of security in the medical sector. While on break, staff left a nuclear medicine room unattended and unlocked. During this time, a courier from a delivery company entered the room and left a package containing 16 GBq of Technetium 99m. To prevent any reoccurrences, the licensee immediately addressed this breach of security by enforcing the importance of securing laboratory doors at all times.

In the medical sector, there were no transportation-related incidents reported in 2011.

No events reported by medical sector licensees resulted in a radiation dose to any member of the public in excess of regulatory public dose limits. In all cases, licensees implemented responses to mitigate event consequences and to limit radiation exposure to workers and the public.

Figure 19: Medical sector – Reported events and incidents



6.1.7 ENFORCEMENT ACTIVITIES – ORDERS AND MEASURES TO BE TAKEN BY THE LICENSEES

There were no orders issued in 2011 in the medical sector.

6.1.8 MEDICAL SUB-SECTORS

6.1.8.1 DIAGNOSTIC AND THERAPEUTIC NUCLEAR MEDICINE SUB-SECTOR

In diagnostic nuclear medicine, unsealed nuclear substances are administered to humans to diagnose medical problems. In therapeutic nuclear medicine, unsealed nuclear substances are administered to humans for therapeutic purposes. In this sub-sector, there were 348 CNSC licences as of December 31, 2011, comprising 61% of CNSC medical-sector licences.

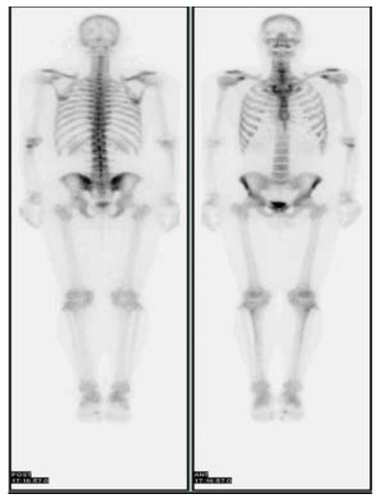


Figure 20: Nuclear medicine bone scan. Source: Wikipedia.org / Creative Commons Attribution 3.0. Retrieved June 24, 2010.

Diagnostic nuclear medicine procedures are unique in that they are used to determine both organ structure and function, whereas other imaging modalities – such as computed tomography (CT) and diagnostic X-rays – are generally limited to providing information on organ structure only. There are almost 100 different diagnostic procedures available, and every major organ system can be imaged using these techniques. In North America, cardiac imaging is the most common single procedure used in nuclear medicine.

Diagnostic procedures require the administration of a drug containing a nuclear substance, known as a radiopharmaceutical, to the patient. The most common of these are Iodine 131, Technetium 99m, Thallium 201 and Gallium 67, with activities ranging from a few megabecquerels to a gigabecquerel. Images resulting from a nuclear medicine bone scan are shown in figure 20. Depending on the body's metabolism for that chemical, radiopharmaceuticals are selectively concentrated within the body's organs, where they emit characteristic gamma radiation. This radiation is then detected externally using specialized detectors.

Therapeutic nuclear medicine requires the administration of significant amounts of nuclear substances to a patient in the treatment of both malignant and benign conditions. The most common type of treatment involves administering a drink or capsule containing Iodine 131 to treat thyroid dysfunction or malignancy. Because a large percentage of the nuclear substance is excreted from the patient's body, patients and caregivers must take special precautions to avoid the spread of radioactive contamination or unnecessary radiation doses.

Figure 21 compares inspection ratings from 2008 to 2011 of operating performance in the diagnostic and therapeutic nuclear medicine sub-sector to those of the medical sector. The figure shows the percentage of inspections meeting or exceeding requirements ("fully satisfactory" and "satisfactory" ratings). Figure 22 compares radiation protection inspection ratings during the same reporting period (2008 to 2011) for the diagnostic and therapeutic nuclear medicine sub-sector to those of the medical sector. Both figure 21 and figure 22 show a continued increase in the number of licensees that were found to be compliant in 2011 as compared to previous years. In addition, the sub-sector's performance is similar to the medical sector as a whole.

Figure 21: Medical sector vs. diagnostic and therapeutic nuclear medicine sub-sector – Comparison of inspection ratings of operating performance

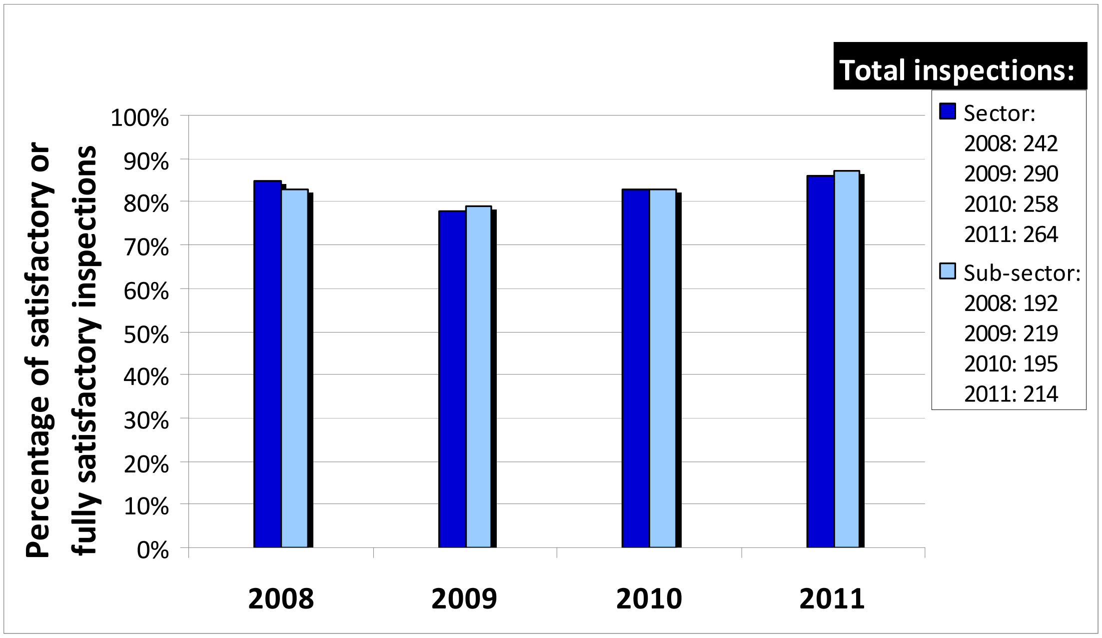
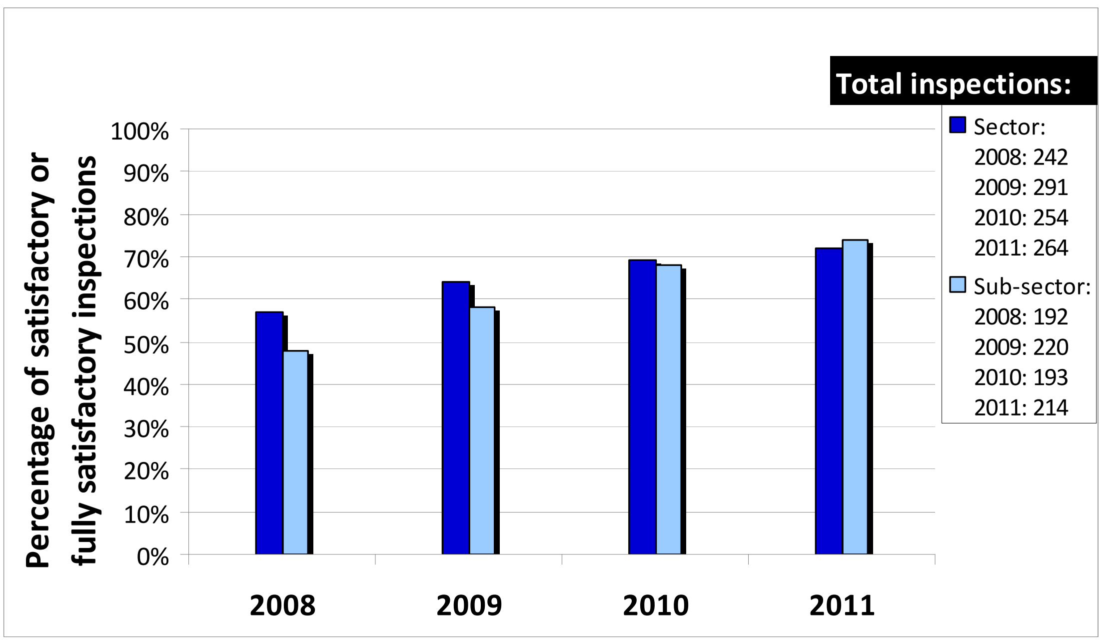


Figure 22: Medical sector vs. diagnostic and therapeutic nuclear medicine sub-sector – Comparison of inspection ratings of radiation protection



6.1.8.2 RADIATION THERAPY SUB-SECTOR

Figure 23: Medical linear accelerator.
Source: CNSC.

Medical linear accelerators are used by radiation therapists to deliver the dose of radiation prescribed by the radiation oncologists in the treatment of cancer. A medical linear accelerator is shown in figure 23.

Medical linear accelerators operate in the mega electron voltage range and are capable of inducing low-level radioactivity in some materials; therefore, they are subject to the requirements of the *Nuclear Safety and Control Act* (NSCA). Linear accelerators are primarily used to deliver high doses of radiation focused on cancerous tissue, while avoiding surrounding healthy tissue. This treatment is commonly used for breast, prostate, head and neck, and lung cancers.

All centres where these devices are installed use multiple technologies and perform several CNSC-licensed activities. There are 50 such centres across Canada licensed to operate multiple linear accelerators, brachytherapy afterloaders and other licensed activities.

Operating performance is specific to the licensed activities and includes quality control procedures, security, and emergency preparedness. As shown in figure 24, this sub-sector's performance in the operating performance safety area was below that of the sector as a whole. Furthermore, the percentage of satisfactory or fully satisfactory inspections in 2011 dropped from 2010, to the level observed in 2009.

As shown in figure 25, the radiation therapy sub-sector's performance decreased for the second year in a row. In this small sub-sector, there are a few licensees holding multiple licences. Consequently, an organisation-level non-compliance may very well impact the performance ratings of multiple licences. Corrective actions have been implemented and the CNSC is following up on them.

Figure 24: Medical sector vs. radiation therapy sub-sector – Comparison of inspection ratings of operating performance

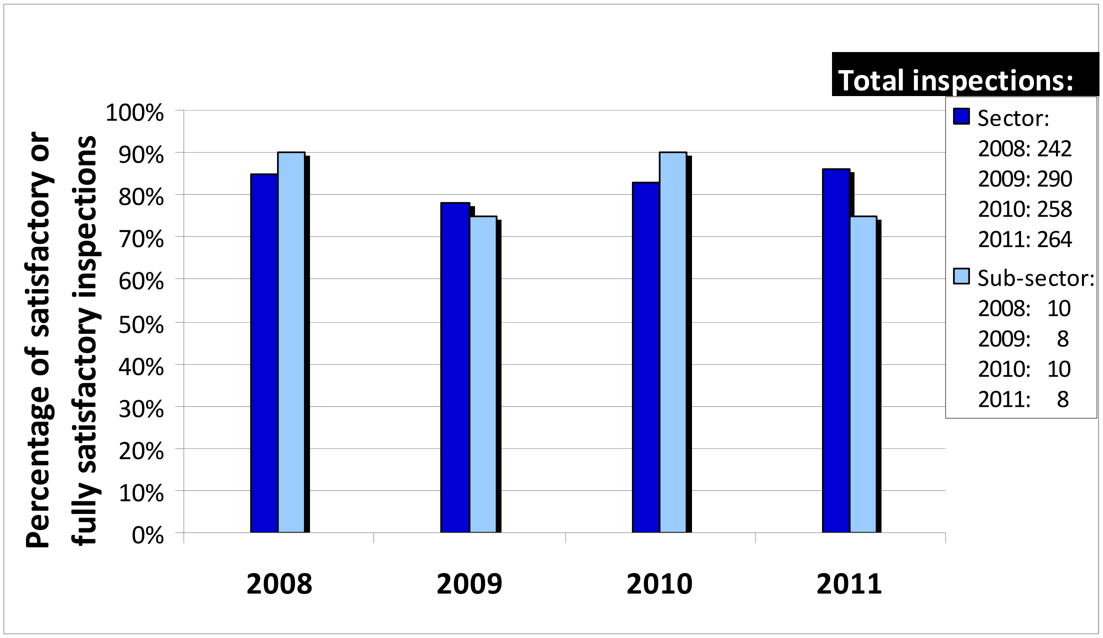
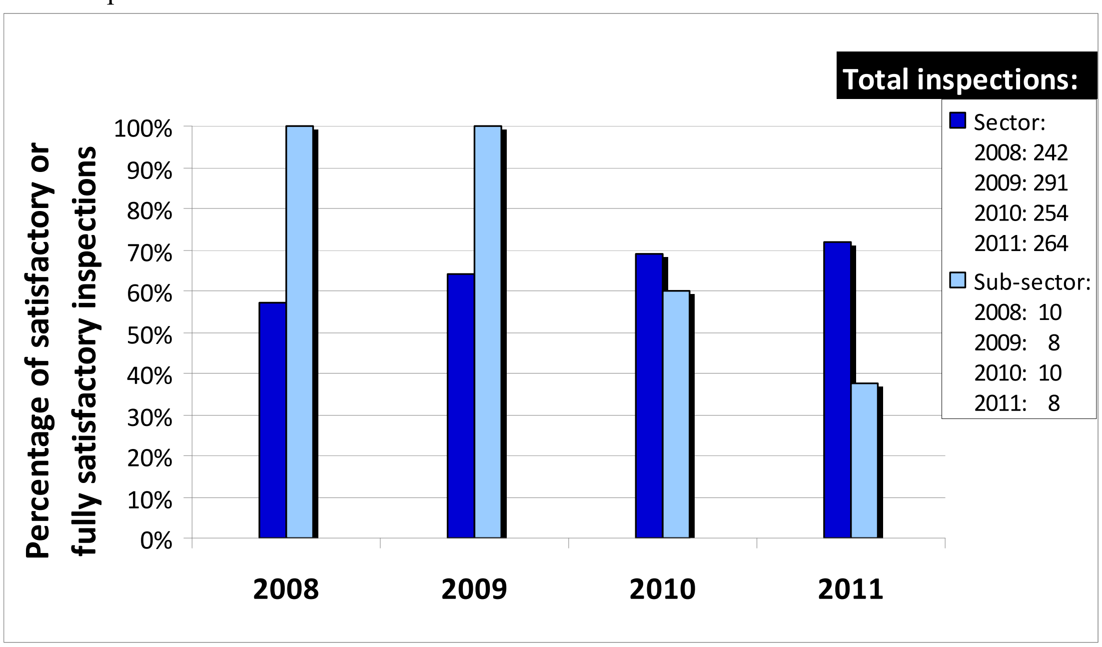


Figure 25: Medical sector vs. radiation therapy sub-sector – Comparison of inspection ratings of radiation protection



6.1.8.3 VETERINARY NUCLEAR MEDICINE SUB-SECTOR

Figure 26: Bone scan performed on a horse.
Source: Toronto Equine Hospital (with permission).

Veterinary nuclear medicine is becoming more common in Canada. Using similar techniques as those employed in human nuclear medicine, veterinary clinics across the country offer a wide range of diagnostic and therapeutic services.

Diagnostic veterinary nuclear medicine uses large doses of radiopharmaceuticals to perform bone scans on horses, as shown in figure 26. Injured animals can then be given corrective procedures to assist in their recovery.

The most common use of therapeutic nuclear medicine is to treat hyperthyroidism in cats. This procedure follows the same principles as the treatment of thyroid disorders or cancers in humans. As the thyroid gland concentrates iodine in the body, the high dose of iodine will irradiate the tissues related to the disorder.

Other therapeutic techniques are beginning to be implemented in Canada, primarily dealing with external irradiation of tissues using sealed sources or linear accelerators.

Of particular concern from a licensing and compliance aspect, is the control the licensee has over the animals once the nuclear substances have been administered. During the assessment process, licensing staff review the policies and procedures in place to ensure the animals are safely housed, segregated from other animals and staff, and released to owners only when safe to do so. These requirements are enforced through the addition of licence conditions. During compliance inspections, CNSC inspectors will verify that these conditions are being met and that the licensee's staff handles the nuclear substances and patients in a safe manner. This collaborative effort ensures a safe work environment for licensee staff, properly handled animals and maximizes the safety for the clinic clients once the animals are returned to their owner's care.

Figure 27 compares inspection ratings from 2008 to 2011 of operating performance in the veterinary nuclear medicine sub-sector to those of the medical sector. The figure shows the percentage of inspections meeting or exceeding requirements ("fully satisfactory" and "satisfactory" ratings). There has been an improvement in the inspection ratings since 2008 and the sub-sector now performs at a level very similar to the medical sector as a whole.

Figure 28 compares radiation protection inspection ratings during the same time period (2008 to 2011) for the veterinary nuclear medicine sub-sector to those of the medical sector. The figure demonstrates a consistent level of performance in the sub-sector during the reporting period that is very similar to that of the sector overall.

Figure 27: Medical sector vs. veterinary nuclear medicine sub-sector – Comparison of inspection ratings of operating performance

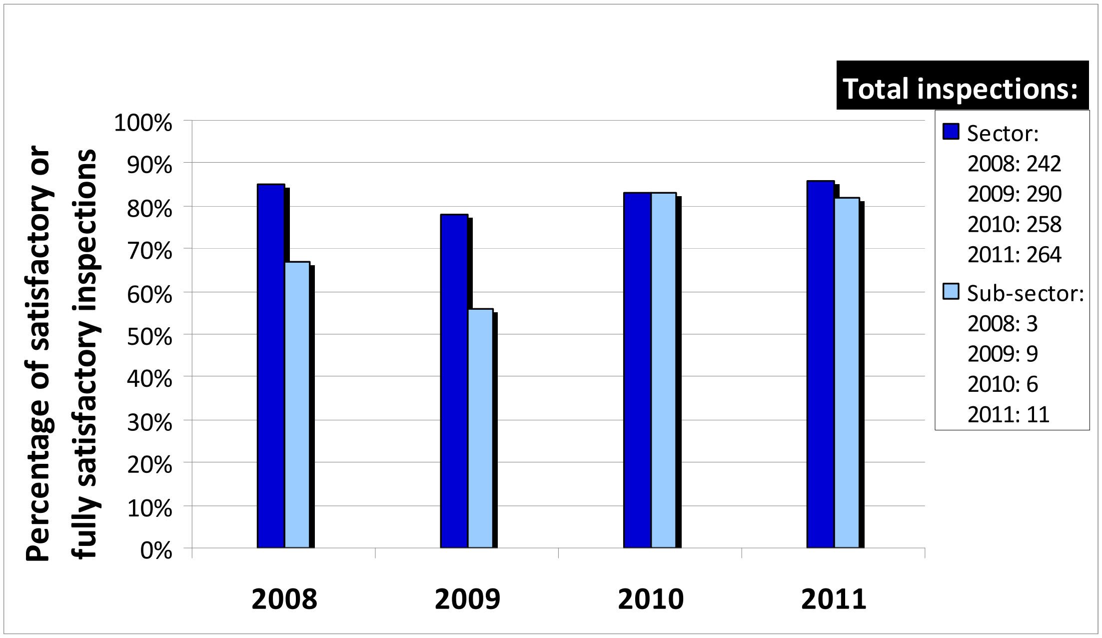
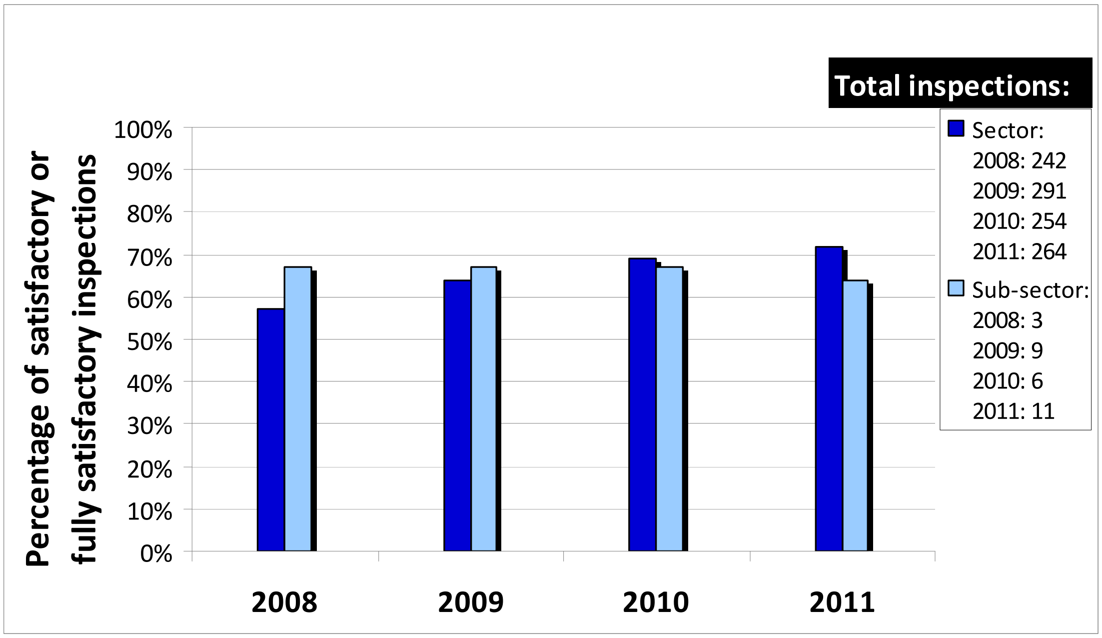


Figure 28: Medical sector vs. veterinary nuclear medicine sub-sector – Comparison of inspection ratings of radiation protection



6.1.9 MEDICAL SECTOR – SUMMARY STATEMENT

In general, the medical sector was found to be compliant. Occupational doses to workers remain low, and doses to radiation therapy workers were particularly low.

Since 2010, the radiation therapy sub-sector has shown a decline in radiation protection program inspection ratings. This is attributed to the small number of licensees holding multiple licences, where a single non-compliance may have repercussions across multiple licences. The non-compliances identified during CNSC inspections did not represent immediate safety concerns. They were addressed by using various enforcement actions such as more frequent inspections or requests for the licensees to provide regular progress reports towards resolving the non-compliances.

The number of events and incidents increased relative to 2010, due primarily to an increase in the number of reported spills in nuclear medicine laboratories and a slight increase in the number of events involving missing nuclear substances. CNSC staff continue to work with licensees in the medical sector to ensure that all incidents of skin contamination are reported. This has lead to a moderate annual increase in these types of events.

6.2 INDUSTRIAL SECTOR

6.2.1 DESCRIPTION

Licensees in the industrial sector use nuclear substances and radiation devices to perform diagnostic, quality control and characterization tasks. These licensees accounted for 1,456 licences as of December 31, 2011. Licensed activities in this sector are typically conducted in industrial production facilities, fieldwork or construction.

The industrial applications of nuclear substances are as varied as the processes to which they are applied. Specific radioisotopes are chosen based on the properties of the radiation they emit and the intended application. For example, the penetration ability of Cobalt 60 varies greatly from that of Iridium 192, and Californium 252 is used for its neutron-emitting properties. Typical applications in the industrial sector include the measurement of physical parameters such as density, moisture content and geological composition; and level and flow rate in industrial processes in areas such as oil and gas exploration, manufacturing and civil engineering.

For the purpose of this report, the following sub-sectors were identified within the industrial sector: portable gauge, fixed gauge, industrial radiography, and oil well logging. Together, these sub-sectors account for 72% or 1,052 of the 1,456 licences in the industrial sector.

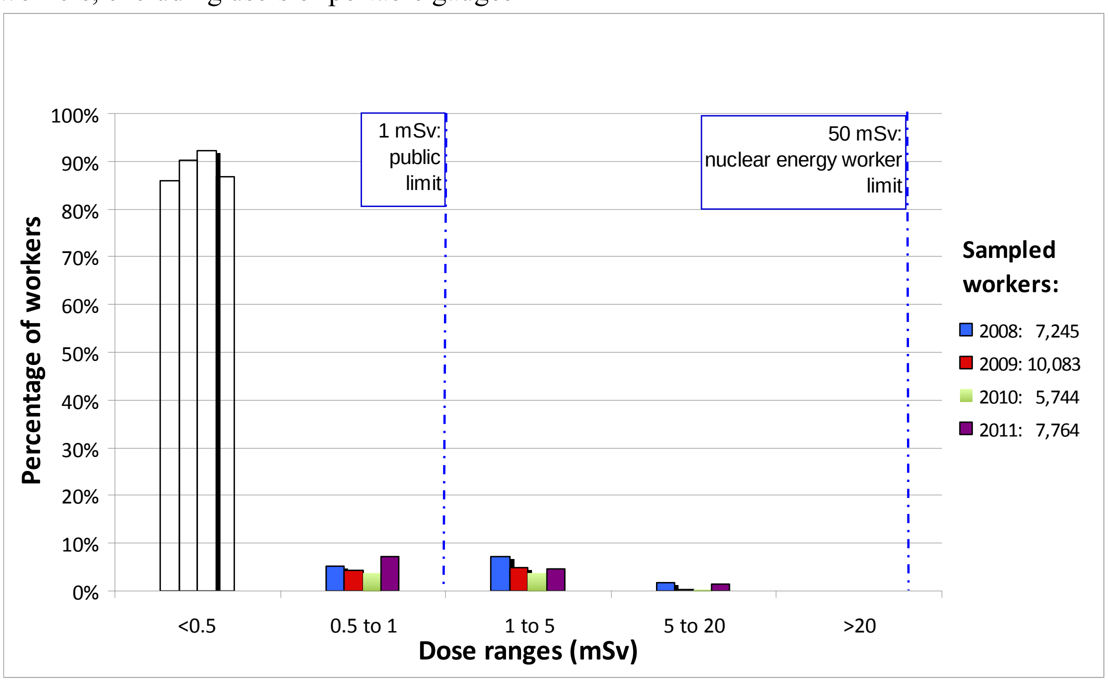
6.2.2 DOSES TO WORKERS

Licensees in the industrial sector who use nuclear substances and radiation devices have the potential to work with high-activity sources, depending on their usage. Based on the specific use of the nuclear substance, workers may not necessarily need to work in close proximity to the nuclear substance; generally, this keeps doses to workers in the industrial sector at the same level as workers in the medical and commercial sectors.

The data in this section represents the dose records of persons who may be subjected to occupational exposures to radiation while involved in CNSC-licensed activities. The data is extracted from dose reports provided by licensees in their annual compliance reports (ACRs) for the 2008 to 2011 period. For the purpose of this performance measure, CNSC staff analyzed a representative sample of worker dose records from randomly selected ACRs from licensees in each sector.

The term "sampled workers" in the figures represents the number of workers whose dose data was analyzed, of which there were 7,764 in 2011. As shown in figure 29, the average doses to workers in the industrial sector have been at approximately the same level since 2008. In 2011, 94% of sampled workers (excluding portable gauge users) received radiation doses below the public limit of 1 mSv/year. Figure 29 does not include information on doses received by workers using portable gauges. These were reported using slightly different dose ranges and are shown separately in figure 33. When including portable gauge licensees, 92.6% of workers in this sector received doses lower than the public dose limit.

Figure 29: Industrial sector – Annual whole body doses to nuclear energy workers and other workers, excluding users of portable gauges



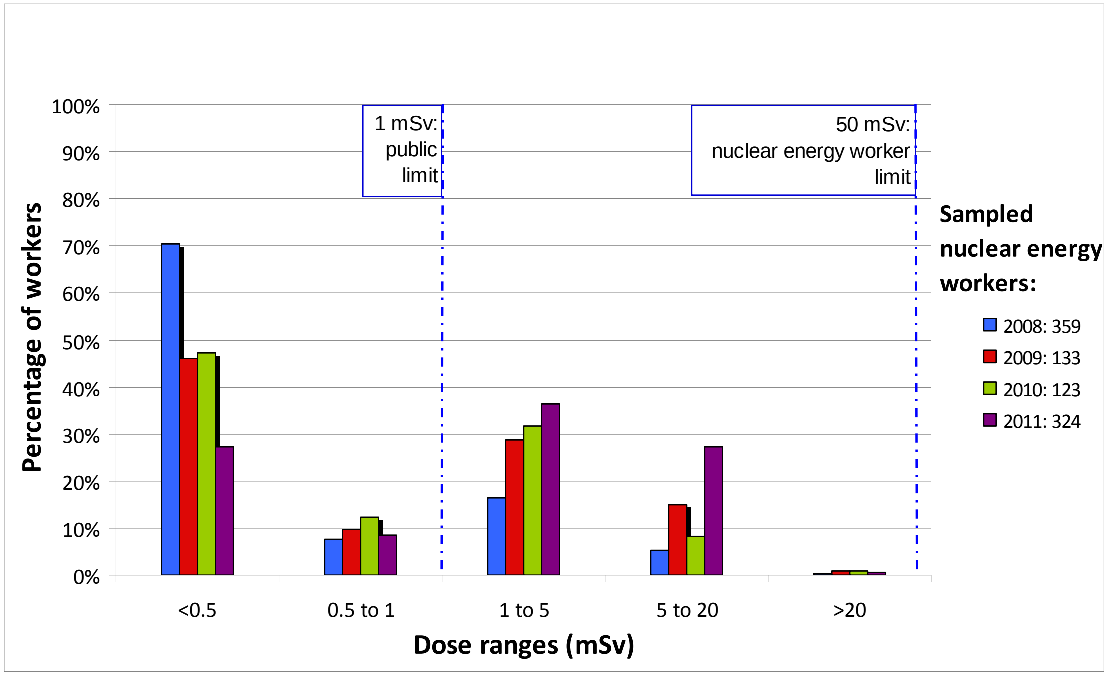
Workers in the industrial radiography sub-sector historically receive the highest radiation doses in the industrial sector. Workers in this sub-sector operate in close proximity to radiation devices that contain strong, penetrating radiation sources for non-destructive testing purposes.

In 2011, 36% of nuclear energy workers (NEWs) in the industrial radiography sub-sector received doses below the public dose limit. Less than 1% of workers were subjected to dose levels greater than 20 mSv, but all received less than the maximum annual dose limit of 50 mSv for NEWs. This information is shown in figure 30.

The doses received by workers in the industrial radiography sub-sector saw an important increase in 2011. For example, the percentage of workers receiving doses between 5 mSv and 20 mSv increased by 19% in 2011 when compared to 2010.

Based on conversations with licensees, this increase is likely due to a greater number of exposures being performed during 2011, resulting in higher worker doses being reported.

Figure 30: Industrial radiography – Annual whole body doses to nuclear energy workers



Sealed sources in oil well logging are primarily used to analyze the geological structure and composition of boreholes. In 2011, there were 37 licensees involved in these logging activities in Canada. In comparison with previous years, doses to NEWs using oil well logging and the number of NEWs receiving doses less than 1 mSv have been maintained at more than 80%. At the same time, the number of NEWs receiving doses between 5 mSv and 20 mSv has increased slightly from 0.5% in 2010 to 1% in 2011. This is likely due to an increase in the use of well logging sources, which coincides with more geological exploration. In 2011, no NEWs exceeded 20 mSv. The annual dose limit for a NEW is 50 mSv. This sub-sector's doses are shown in figure 31.

Throughout the 2008 to 2011 reporting period, the annual whole body doses to other workers have never exceeded the public dose limit of 1 mSv/yr. Doses received by other workers in this sub-sector are shown in figure 32.

Figure 31: Oil well logging – Annual whole body doses to nuclear energy workers

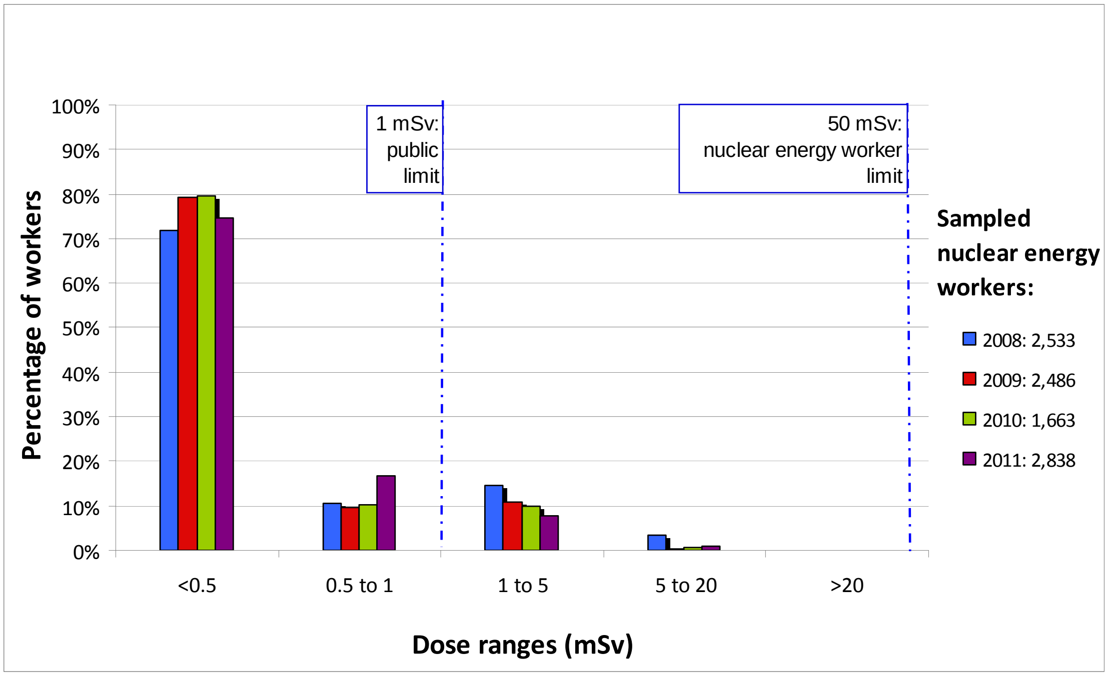
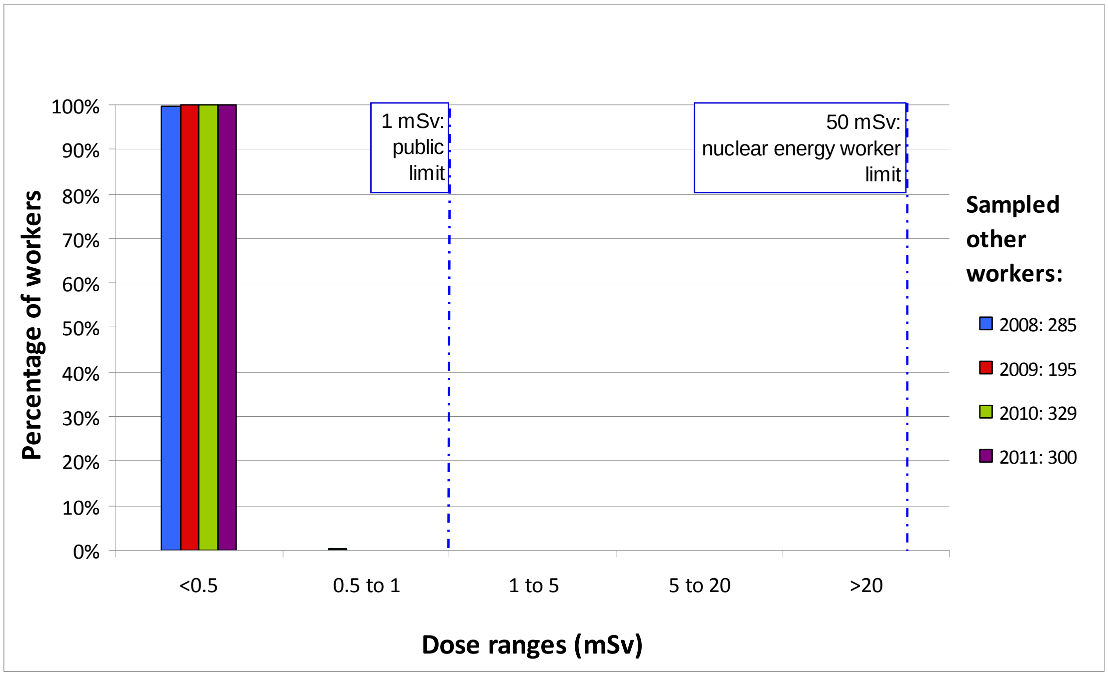
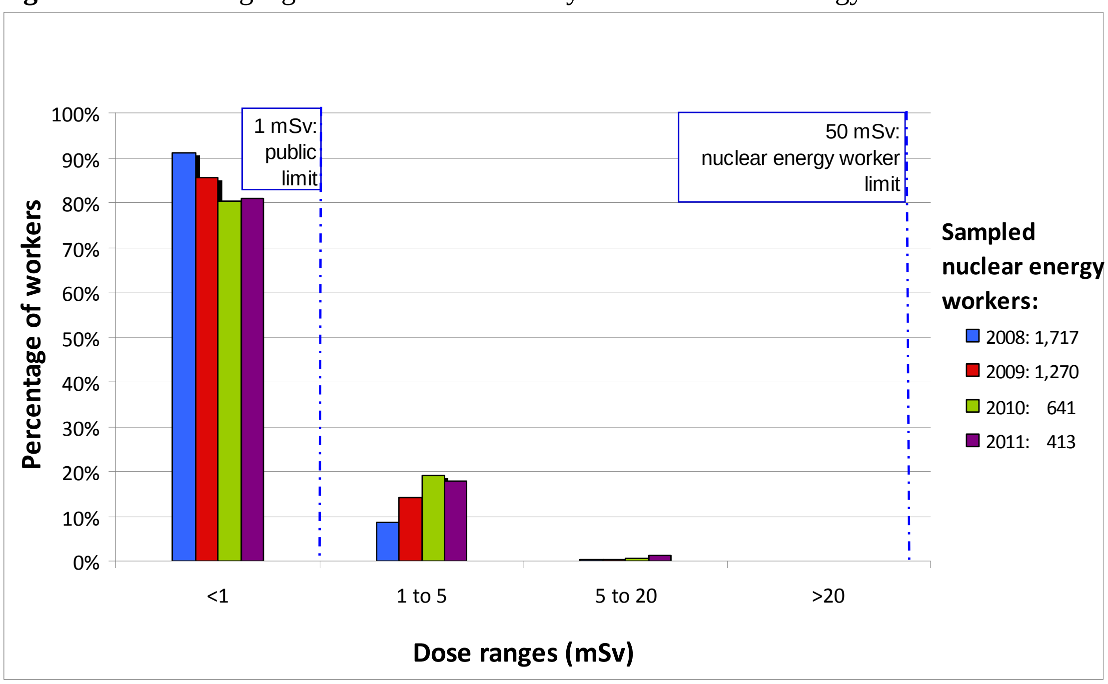


Figure 32: Oil well logging – Annual whole body doses to other workers



Doses to NEWs using portable gauges remained constant compared to those reported in 2010. Between 2008 and 2011, no NEWs exceeded the annual dose limit of 50 mSv. This sub-sector's doses are shown in figure 33.

Figure 33: Portable gauges – Annual whole body doses to nuclear energy workers



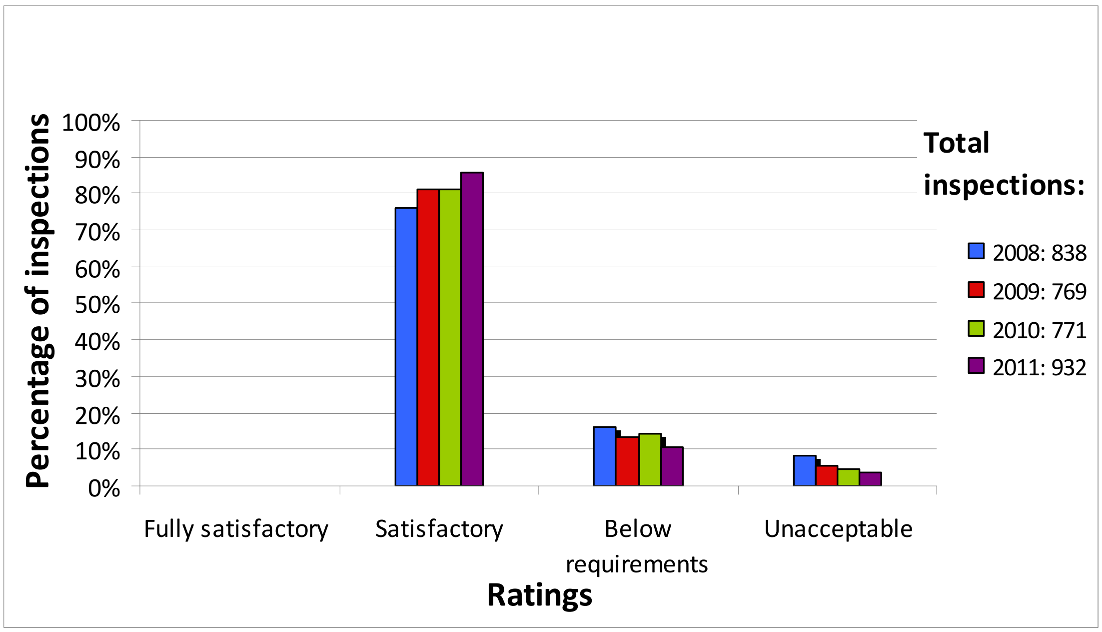
6.2.3 INSPECTION RATINGS OF OPERATING PERFORMANCE

Figure 34 shows the industrial sector's inspection ratings of operating performance. In 2011, 86% of inspected licensees were found to be compliant in this safety area. Of those found to be non-compliant, 10% had a "below requirements" rating for non-compliances that did not significantly affect safety, while 4% had non-compliances rated as "unacceptable." An "unacceptable" rating is significantly below requirements, with deficiencies that could lead to an unreasonable risk to the health and safety of workers, the public or the environment if left uncorrected.

Typical non-compliances in this safety area included failure by workers to follow licensee procedures, failure of licensees to keep appropriate training records, or failure to perform leak testing of devices at prescribed frequencies.

Since 2008, compliance of inspected licensees increased by 10% in the operating performance safety area. Consequently, the number of licensees demonstrating a rating of "below requirements" and "unacceptable" has decreased. For detailed results of inspection ratings, refer to Appendix C.3.

Figure 34: Industrial sector – Inspection ratings of operating performance



6.2.4 INSPECTION RATINGS OF RADIATION PROTECTION

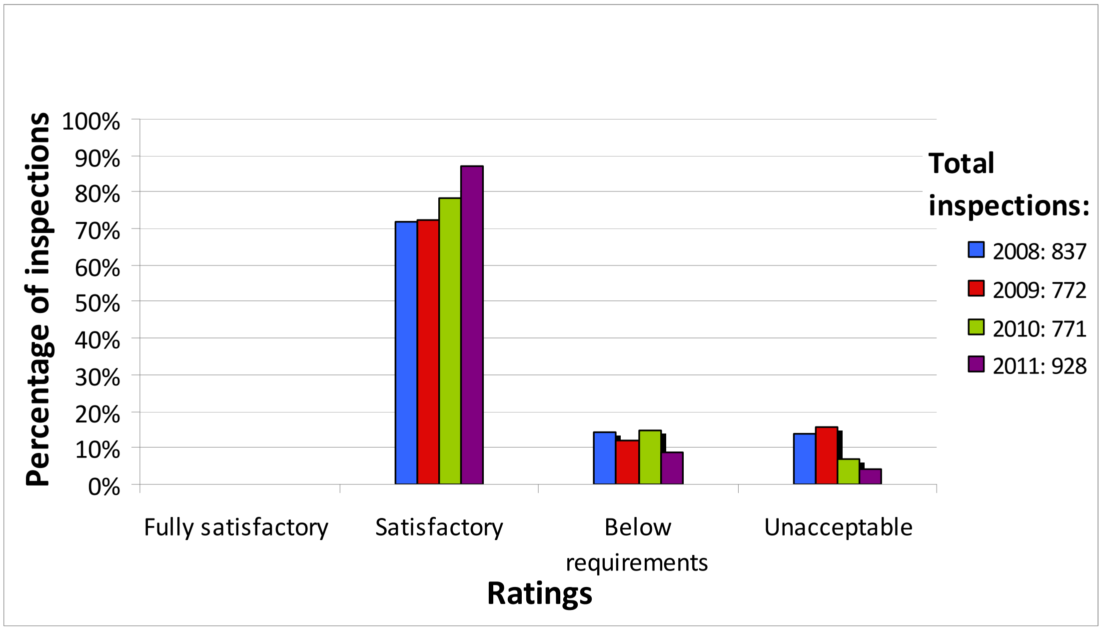
Figure 35 shows inspection ratings of radiation protection for the industrial sector. In 2011, 87% of inspected licensees were found to be compliant in this safety area. Of the inspected licensees found to be non-compliant, 9% had a "below requirements" rating for non-compliances that did not significantly affect safety, while 4% had non-compliances rated as "unacceptable."

Typical non-compliances in this safety area included inadequately labelled devices, failure to report to the CNSC that an action level was exceeded, or inability of a licensee to demonstrate that doses are As Low As Reasonably Achievable (ALARA).

The CNSC employs a graduated enforcement approach when addressing non-compliances that do not pose an immediate risk to the health and safety of workers, the public or the environment. The measures used by the CNSC to ensure licensees regain compliance include written action notices, correspondence and meetings with the licensee's senior management to discuss the issues, and acceptance of licensee plans to voluntarily shut down until operations are in compliance.

When examining compliance in this safety area between 2008 and 2011, the compliance rate of inspected licensees improved. In 2008, 72% of the inspected licensees were found to be compliant with requirements and that number rose to 87% in 2011. A more significant compliance increase was noted in the number of inspected licensees who had initially been deemed "unacceptable." In 2008, 14% of licensees were found to be unacceptable. In 2011, that number improved to 4%, which indicates overall progress in this safety area. For detailed results of inspection ratings, refer to Appendix C.4.

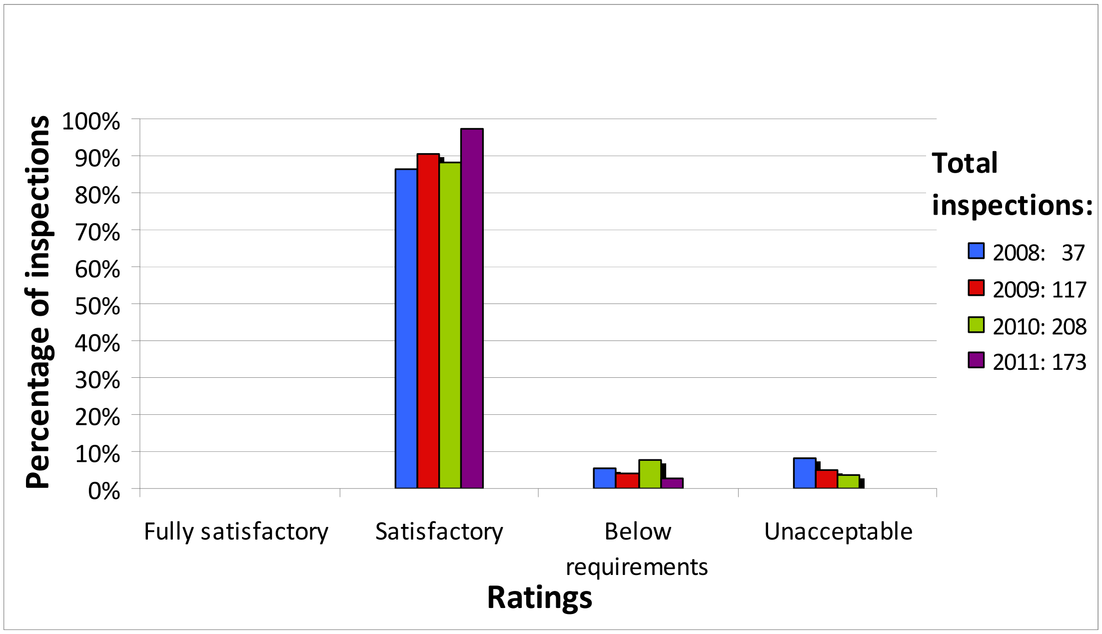
Figure 35: Industrial sector – Inspection ratings of radiation protection



6.2.5 INSPECTION RATINGS OF SEALED SOURCE TRACKING

Sealed source tracking inspection ratings for the industrial sector are shown in figure 36. In 2011, 173 inspections verified compliance against the Sealed Source Tracking System requirements and 97% of inspected licensees were found to be compliant. The distribution of inspection results for licensees appears to have improved slightly from 2008 to 2011. For detailed results of inspection ratings, refer to Appendix C.5.

Figure 36: Industrial sector – Inspection ratings for sealed source tracking



6.2.6 REPORTED EVENTS AND INCIDENTS

The number of reported events in the industrial sector is relatively high when compared to the other sectors, but this is typical of this sector's 1,456 licensees. As shown in figure 37, 83 events were reported in 2011.

The majority of incidents reported for this sector involved malfunctioning or damaged devices, many of which involved portable gauges or problems with sources stuck in exposure devices. In fact, there were 24 reported incidents involving portable gauges hit or run over by vehicles at construction sites in 2011, compared to 12 in 2010. These incidents were likely due to an increased use of portable gauges on construction sites, coinciding with an increase in infrastructure work performed across Canada in 2011. The licensees involved in these incidents implemented response procedures that the CNSC found satisfactory to mitigate the event consequences and to limit radiation exposure to workers and the public.

To address the significant number of incidents involving portable gauges, the CNSC published a special edition of the *Directorate of Nuclear Substance Regulation Newsletter*[6] in the summer of 2011, which detailed important steps to prevent and address portable gauge incidents. As a result, the CNSC has noticed a decrease in the number of crushed gauges, positive evidence that licensees took appropriate actions. Furthermore, CNSC inspectors have performed more compliance field inspections of portable gauge users in the industrial sector.

[6] Available online at http://www.nuclearsafety.gc.ca/eng/pdfs/DNSR-Newsletter/Summer-2011-Special-Edition-DNSR-Newsletter_e.PDF

The industrial sector also reported 13 incidents involving missing nuclear substances. Of these, six were reports of found nuclear substances and seven were reports of lost nuclear substances. Of the seven events of lost substances, three were recovered shortly after they were reported missing.

With respect to the other four incidents, three involved portable gauges stolen from construction sites or vehicles, and one was an analyzer reported missing, which the licensee believes may have been inadvertently shipped with scrapped metal. The latter four incidents involved low to very low-risk sources. The devices reported stolen are under investigation by local authorities and the licensee. The CNSC has also published the information on its Web site and notified the appropriate provincial and international authorities, including the International Atomic Energy Agency and United States Nuclear Regulatory Commission.

Of the six reports of found nuclear substances, one was a radiation device discovered in a metal recycling facility, and four were of nuclear substances found by members of the public. The last report involved a fixed gauge found by a mining equipment supplier while doing an inventory check of their warehouse. The gauge was originally shipped from a mine ten years earlier for disposal at the Atomic Energy of Canada Limited waste management facility in Chalk River, Ontario. It is believed that the gauge was with various mining equipment and was accidentally delivered and stored at the supply warehouse. The gauge has been returned to the mine, where appropriate measures are being taken to ensure of its disposal. The *Lost or Stolen Sealed Sources and Radiation Devices Report*[7], available on the CNSC Web site, has further information on these particular types of events.

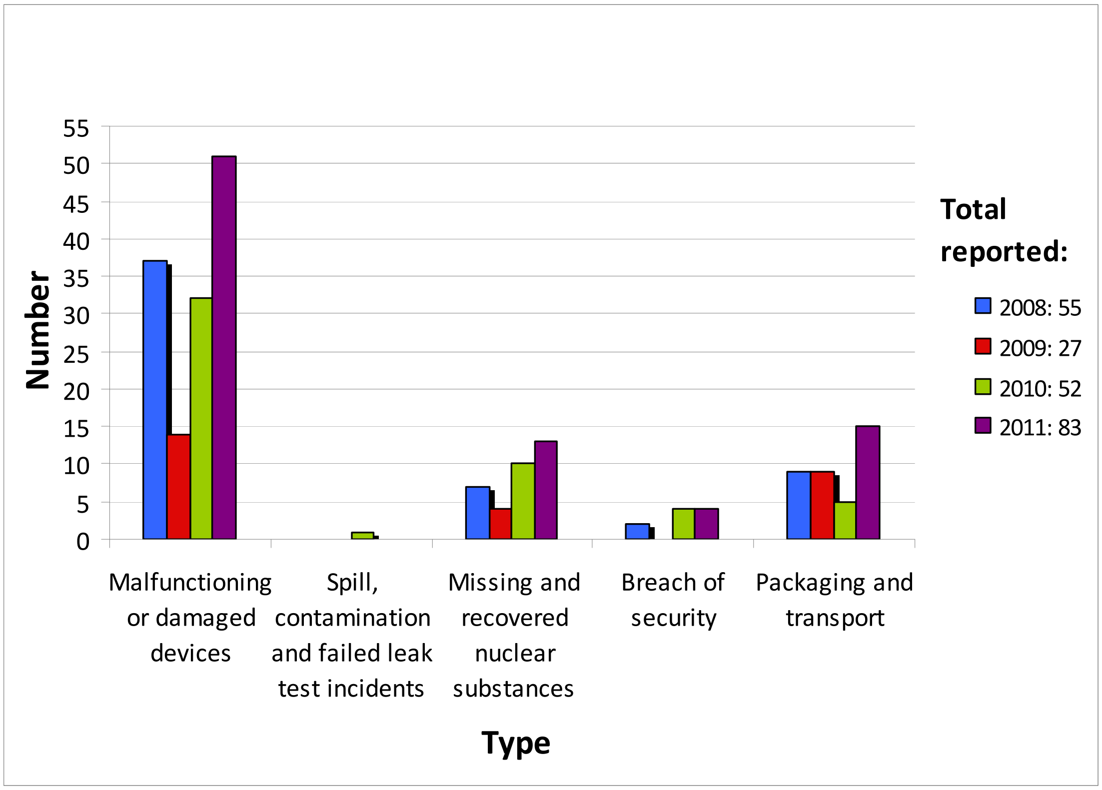
There were four breaches of security reported in 2011. In all four of these incidents, a person who was not a nuclear energy worker entered a restricted area that had been established prior to the use of an exposure device. Fortunately, in each case, the person did not receive any significant radiation dose from the device. Any doses received were well below the regulated limit of 1 mSv for a member of the public. Although these incidents were categorized as breaches of security, each resulted from a lack of control in the workplace.

In the area of packaging and transport, most of the 15 reports were of accidents involving vehicles transporting nuclear substances. In each instance, there was no damage to any of the packages. There were two reports of nuclear substances that were transported in a manner that was not compliant with the regulations. In one instance, the appropriate placards were not displayed on the vehicle, and in the other, the appropriate documentation did not accompany the nuclear substances.

None of the events reported by licensees in the industrial sector resulted in a radiation dose to a worker or a member of the public in excess of the regulatory limits.

[7] Available online at nuclearsafety.gc.ca/eng/readingroom/reports/lost_stolen_ss_rd/index.cfm

Figure 37: Industrial sector – Reported events and incidents



6.2.7 ENFORCEMENT ACTIVITIES

6.2.7.1 ORDERS AND MEASURES TO BE TAKEN BY THE LICENSEES

In 2011, CNSC inspectors issued 13 orders to licensees in the industrial sector. The orders are listed in table 1. For more information regarding these enforcement actions, readers are invited to consult the *Regulatory Action* page on the CNSC Web site.[8]

Table 1: Industrial sector enforcement activities – Orders and measures to be taken by the licensees

Licensee	Location	Date order was issued	Measures to be taken by the licensees	Date order was closed
Western Inspection Ltd. (industrial radiography)	Calgary, Alberta	April 14, 2011	Remove a certified exposure device operator from all operations involving nuclear substances until the licensee can demonstrate that the operator no longer presents a risk to the health and safety of persons.	June 3, 2011
		May 24, 2011	Amendment: Submit a training program action plan and audit results.	

[8] Available online at nuclearsafety.gc.ca/eng/lawsregs/regulatoryaction/index.cfm

Licensee	Location	Date order was issued	Measures to be taken by the licensees	Date order was closed
Stewart, Weir & Co. Ltd. (portable gauges)	Sherwood Park, Alberta	May 18, 2011	Cease the use of radiation devices and place the equipment into secure storage. Demonstrate adequate management control over work practices.	June 3, 2011
AR Geotechnical Engineering Ltd. (portable gauges)	Medicine Hat, Alberta	July 07, 2011	Place all nuclear substances and devices into secure storage until a radiation protection program has been fully implemented, with adequate training, and that all items of non-compliance observed during the inspection have been addressed.	August 29, 2011
Mistras Canada Inc. (industrial radiography)	Olds, Alberta	July 13, 2011	Remove a certified exposure device operator from all regulated activities (except transport) until the licensee can demonstrate that the operator no longer presents a risk to the health and safety of persons.	July 28, 2011
		July 21, 2011	Amendment: Provide an action plan to demonstrate that the certified exposure device operator no longer poses an unreasonable risk to the health and safety of workers and the public.	
Advance Testing Ltd. (portable gauges)	Surrey, British Columbia	August 10, 2011	Place all nuclear substances and devices into secure storage until a radiation protection program has been fully implemented, that management control over work practices has been established, and that all items of non-compliance observed during the inspection have been addressed.	August 23, 2011
EnviroGeo Testing (portable gauges)	Medicine Hat, Alberta	August 23, 2011	Keep all nuclear gauges in storage until employees have received appropriate training, and all items of non-compliance identified during the inspection have been addressed.	September 19, 2011
Pazin Geotechnical Services Ltd. (portable gauges)	Toronto, Ontario	August 26, 2011	Transfer all nuclear materials in their possession to a third party licensed by the CNSC to possess the materials.	September 29, 2011

Licensee	Location	Date order was issued	Measures to be taken by the licensees	Date order was closed
The Graff Company ULC (industrial radiography)	Brampton, Ontario	September 12, 2011	Keep all nuclear substances in storage until its employees have received appropriate training, an effective radiation protection program is in place, and all items of non-compliance identified during the inspection have been addressed.	October 24, 2011
Global Engineering & Testing Ltd. (portable gauges)	Calgary, Alberta	September 22, 2011	Keep all nuclear gauges in storage until employees have received appropriate training, and all items of non-compliance identified during the inspection have been addressed.	October 28, 2011
Stasuk Testing and Inspection Ltd. (industrial radiography)	Burnaby, British Columbia	October 5, 2011	Place the radiation device in storage, and either dispose of the device lawfully or immediately take measures to obtain a valid licence.	December 20, 2011
Recon Petrotechno-logies Ltd. (oil well logging)	Lloyd-minster, Alberta	October 19, 2011	Stop using all nuclear sources until survey meters that are calibrated and functional are made available for its operations.	October 28, 2011
Stasuk Testing and Inspection Ltd. (industrial radiography)	Burnaby, British Columbia	October 21, 2011	Limit using the accelerator and take measures to restrict access to the facility when the accelerator is in operation.	November 29, 2011

Licensee	Location	Date order was issued	Measures to be taken by the licensees	Date order was closed
Mistras Canada Inc. (industrial radiography)	Olds, Alberta	December 6, 2011	Revoke the supervisory responsibilities of a certified exposure device operator. Mistras Canada Inc. must ensure that the certified exposure device operator in question will not oversee trainees until the company can demonstrate, to the satisfaction of the CNSC, that the operator will follow proper supervisory protocol.	At the time of publication, the order is still in effect.
		January 11, 2012	Amendment: Mistras Canada Inc. shall prohibit the employee from supervising any exposure device operator trainee until such time as the company provides evidence satisfactory to the CNSC that the employee understands his duties and responsibilities as a certified exposure device operator when acting as a supervisor of an exposure device trainee pursuant to the *Nuclear Substances and Radiation Devices Regulations*.	

It should be noted that although more CNSC orders were issued in 2011 than in 2010 and 2009 (seven in each of these years), this does not necessarily indicate an increase in overall non-compliance by licensees. In fact, this is partly due to an increase in the number of field inspections being conducted. Further information on orders issued in 2008, 2009 and 2010 are found in previous editions of *Nuclear Substances in Canada: A Safety Performance Report*.[9]

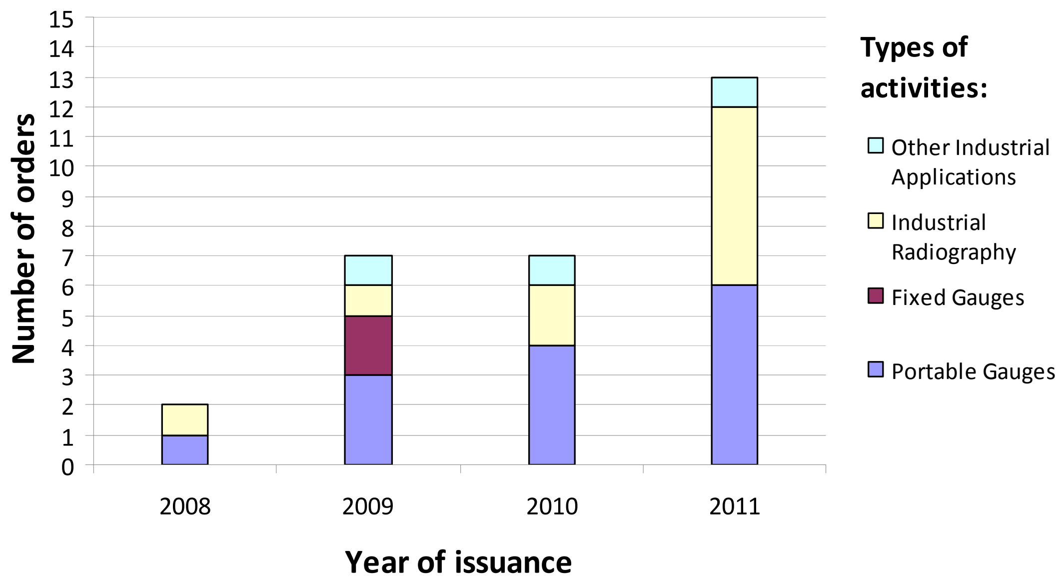
The CNSC has adopted a risk-informed regulatory program, whereby the frequency of inspection for a given licensee is based on the level of risk posed by the licensed activity. The frequency of compliance verification varies among licensees, according to the risk of the conducted activities. In the industrial sector, it varies from one year (for high-risk licensees) up to five years (for medium-risk licensees) and as required for low-risk licensees.

Inspections of low-risk licensees could be triggered by an event or an issue observed in their annual compliance report. Therefore, the CNSC may not inspect all licensees in the industrial sector each year, but all licensees must submit an annual compliance report to the CNSC for evaluation. It is therefore possible that inspectors may see many licensees requiring the issuance of an order in one year, and very few in subsequent years. Moreover, the CNSC has been issuing orders more frequently for significant health and safety issues as opposed to using alternate, less severe compliance measures.

[9] Available online at nuclearsafety.gc.ca/eng/readingroom/reports/use-of-nuclear-substances/index.cfm

A summary of the orders issued to the industrial sector between 2008 and 2011 is shown in figure 38 according to the type of licensed activities.

Figure 38: Industrial sector – Summary of orders by type of licensed activity



6.2.7.2 DECERTIFICATION OF EXPOSURE DEVICE OPERATORS

Workers who operate radiography exposure devices in Canada must be certified by the CNSC, as required under the *Nuclear Safety and Control Act*. The CNSC also has the authority to decertify these persons as required, and will do so when it has reason to believe that the certified exposure device operator has endangered the health and safety of workers, the public or the environment.

In 2011, there were no exposure device operators decertified by the CNSC. For more information on decertification of exposure device operators in 2008, 2009 and 2010, readers are invited to consult the previous editions of *Nuclear Substances in Canada: A Safety Performance Report.*[10]

[10] Available online at nuclearsafety.gc.ca/eng/readingroom/reports/use-of-nuclear-substances/index.cfm

6.2.8 INDUSTRIAL SUB-SECTORS

6.2.8.1 PORTABLE GAUGE SUB-SECTOR

Figure 39: Portable moisture density gauge.
Source: CNSC.

Portable gauges are radiation devices used to determine compaction, density or moisture content in soil. An example of a portable moisture density gauge is shown in figure 39. Some of these devices contain an Americium 241-Beryllium source that emits neutrons and allows for moisture content calculations; others may contain a Cesium 137 source, which emits gamma radiation and allows the operator to determine compaction or density; and some devices may contain both radioactive sources.

Portable gauges are typically transported for temporary use at construction job sites; users require training in radiation safety and the transportation of dangerous goods. Inspections can be performed onsite, as shown in figure 40.

Figure 40: A CNSC inspector performs an inspection of a portable gauge at a construction site.
Source: CNSC.

Figure 41 compares the portable gauge sub-sector's operating performance ratings with those of the industrial sector, and figure 42 compares inspection ratings of radiation protection. Both figures illustrate the percentage of inspections where licensees had met or exceeded requirements ("fully satisfactory" and "satisfactory" ratings). Between 2008 and 2011, the portable gauge sub-sector was found to have compliance levels essentially similar to those of the industrial sector (although slightly lower in 2011) for both performance measures.

Figure 41: Industrial sector vs. portable gauge sub-sector – Comparison of inspection ratings of operating performance

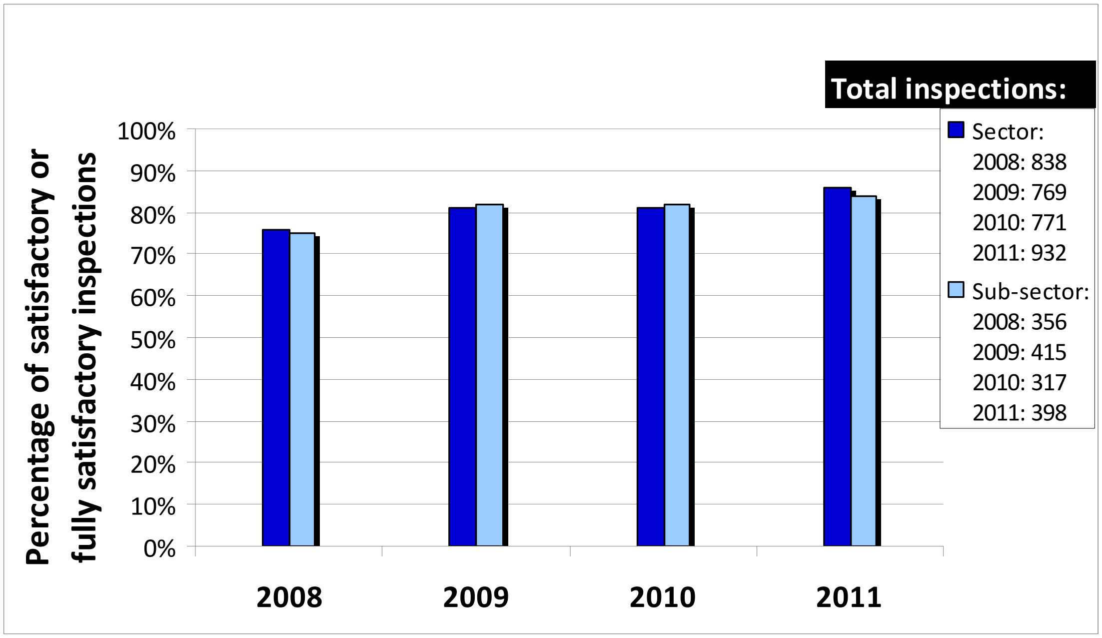
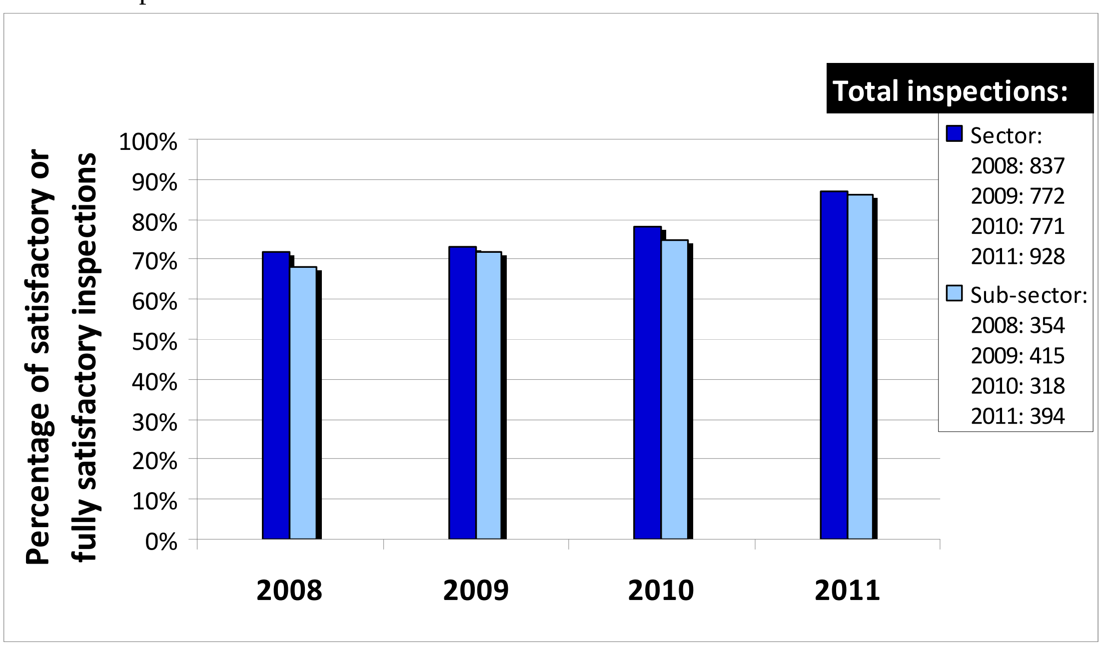


Figure 42: Industrial sector vs. portable gauge sub-sector – Comparison of inspection ratings of radiation protection



6.2.8.2 FIXED GAUGE SUB-SECTOR

Figure 43: Fixed gauge source holder. Source: CNSC.

Fixed gauges are radiation devices commonly used to determine operational parameters of an industrial process. Common parameters may include density, level and thickness. Fixed gauges contain nuclear substances with properties chosen for their specific applications and vary widely from Americium 241 to Cesium 137 to Cobalt 60. Radiation is measured using a detector, typically located on the opposite side of the source inside the gauge, which supplies feedback to a control system to adjust the process if necessary. Fixed gauges are typically mounted onto frames in an industrial facility, although vehicle-mounted mobile fixed gauges are found in the oil and gas industry. An example of a fixed gauge source holder is shown in figure 43.

Figure 44 compares the fixed gauge sub-sector's inspection ratings for operating performance with those of the industrial sector. A comparison of radiation protection inspection ratings is shown in figure 45. Both figures show the percentage of inspections that found licensees had met or exceeded requirements ("fully satisfactory" and "satisfactory" ratings). From 2008 to 2011, the fixed gauge sub-sector increased its compliance with the operating performance safety area, going from 73% in 2008 to 81% in 2011. It is still less compliant than the overall sector, which was at 86% in 2011. The sub-sector's compliance level for radiation protection ratings was better than the overall sector's in 2008, but was slightly lower in 2011 at 80% when compared to 87% for the sector.

Figure 44: Industrial sector vs. fixed gauge sub-sector – Comparison of inspection ratings of operating performance

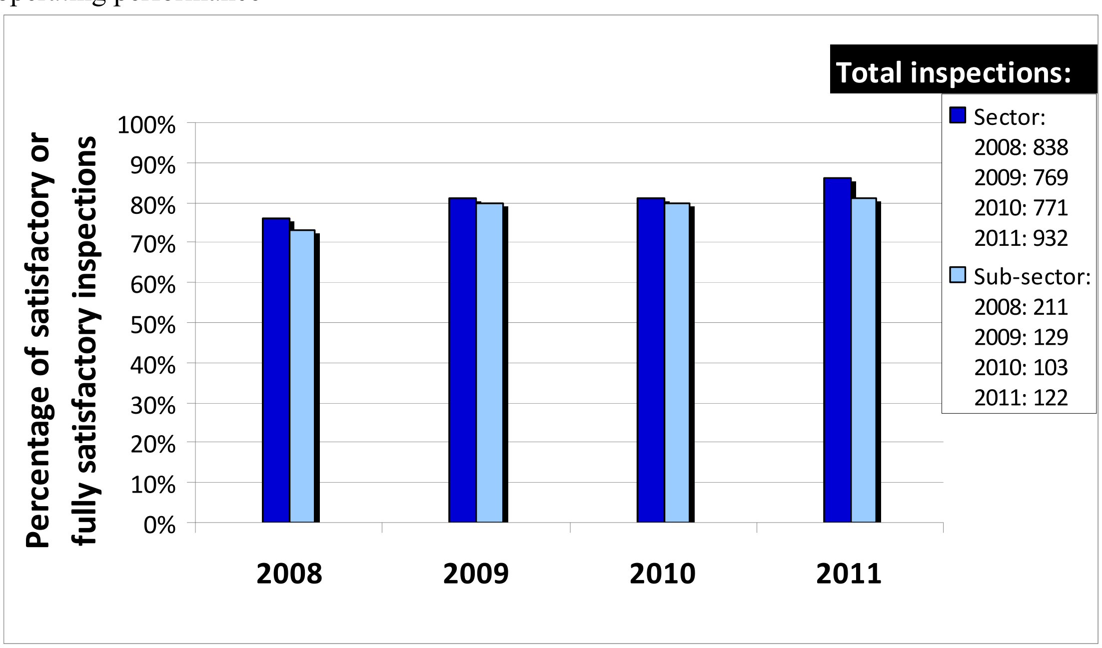
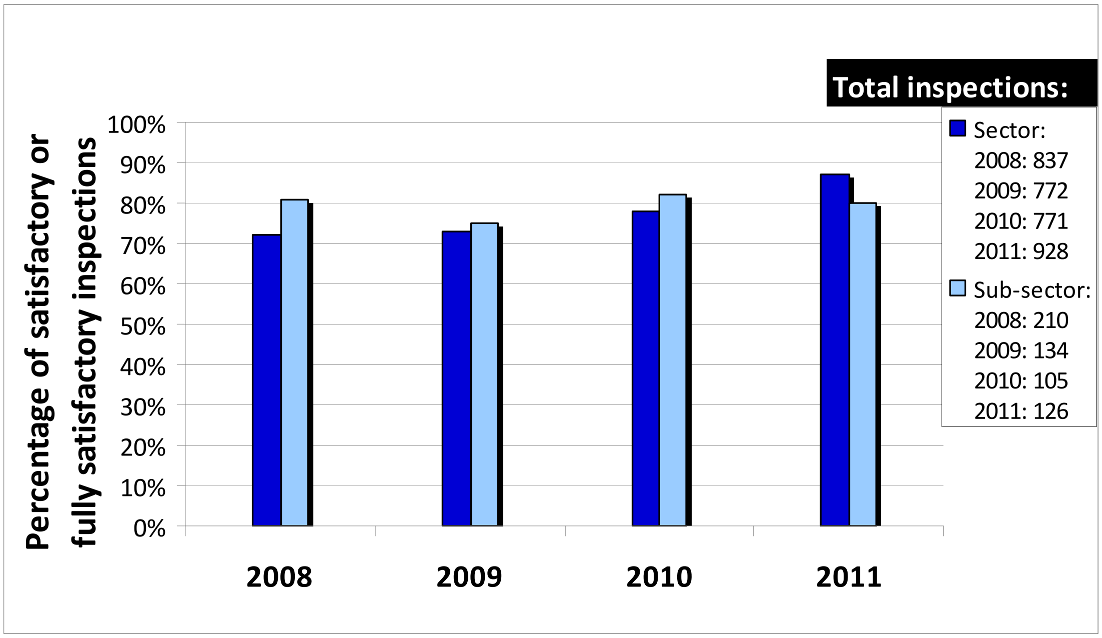


Figure 45: Industrial sector vs. fixed gauge sub-sector – Comparison of inspection ratings of radiation protection



6.2.8.3 INDUSTRIAL RADIOGRAPHY SUB-SECTOR

In industrial radiography, nuclear substances are used for the non-destructive examination of materials. Sealed radioactive sources are stored in devices (referred to as exposure devices) until they are required to be used. Exposure devices are engineered with multiple safety barriers to prevent accidental exposure of the source, and are built using dense material – such as depleted uranium – for its shielding properties. An example of an exposure device is shown in figure 46, and a typical industrial radiography set-up is shown in figure 47.

Figure 46: Exposure device.
Source: QSA Global Inc. (with permission).

Figure 47: An industrial radiography set-up.
Source: CNSC.

The CNSC certifies exposure device operators, along with the exposure devices themselves. Persons wishing to become certified exposure device operators should complete a vocational and a practical training program prior to passing the required exams. The Canadian Standards Association is planning to publish a guide on the certification of exposure device operators.

The CNSC also has the regulatory authority to decertify an exposure device operator; it will consider this enforcement action when it believes the operator's actions have caused an unreasonable risk to the health and safety of workers, the public or the environment. Further information on this enforcement option can be found in section 6.2.7.2.

The radioactivity of the nuclear substances in an exposure device is typically in the order of terabecquerels, and can be 1,000 times over the activity of a portable gauge. Nuclear substances are chosen based on the material being examined; denser and thicker materials typically require a nuclear substance with a high-energy gamma ray to allow the radiation to penetrate the material. Nuclear substances used in exposure devices usually include Iridium 192, Cobalt 60 and Selenium 75. Radiation from the nuclear substances passes through the material and allows defects in welds or composition to be recorded on photographic film or a digital imager placed on the opposite side of the object.

Figure 48 compares the industrial radiography sub-sector's ratings for operating performance with those of the industrial sector ratings, and figure 49 compares inspection ratings for radiation protection. These figures show the percentage of inspections that found licensees had met or exceeded requirements ("fully satisfactory" and "satisfactory" ratings). From 2008 to 2011, this sub-sector demonstrated better or equal compliance in the safety areas of radiation protection and operating performance when compared to other licensees in the industrial sector. This was likely due to the efforts of the joint CNSC–Industry Radiography Working Group. The CNSC has also noted that several licensees in this sub-sector are demonstrating considerable effort to be compliant. Further information on the Industrial Radiography Working Group is available on the CNSC Web site.[11]

[11] Available online at nuclearsafety.gc.ca/eng/licenseesapplicants/substancesdevices/substancesdevices/industrial_radiography_working_group.cfm

Figure 48: Industrial sector vs. industrial radiography sub-sector – Comparison of inspection ratings of operating performance

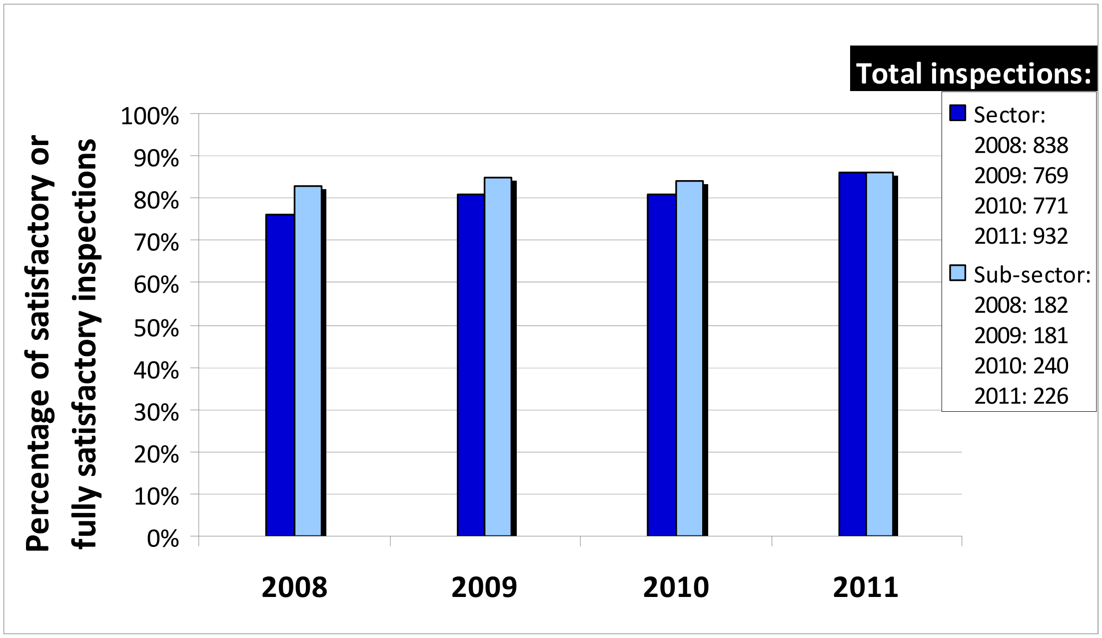
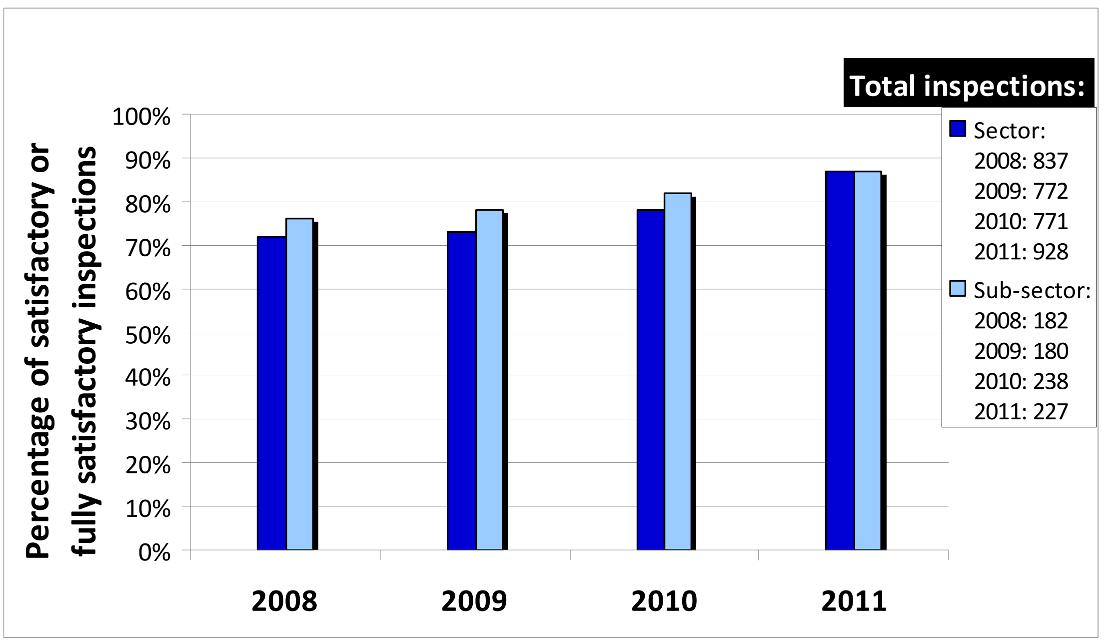


Figure 49: Industrial sector vs. industrial radiography sub-sector – Comparison of inspection ratings of radiation protection



6.2.8.4 OIL WELL LOGGING SUB-SECTOR

Figure 50: Oil well logging tool being lowered into the hole. Source: CNSC.

Sealed source oil well logging is primarily used to analyze the geological structure and composition of boreholes. The device consists of a sealed source or accelerator and detectors contained within a logging tool that is lowered into the hole, as shown in figure 50.

An electrical umbilical cord is attached and transmits the collected data to a computer. The information is then analyzed to determine geological formation characteristics such as resistivity, conductivity, fluid content, formation density or radioactivity. Typical logging tool sources used by the oil and gas industry are Cesium 137 and Americium 241-Beryllium neutron sources.

Figure 51 compares the oil well logging sub-sector's ratings for operating performance with those of the industrial sector ratings, and figure 52 compares inspection ratings for radiation protection.

These figures show the percentage of inspections that found licensees meeting or exceeding requirements ("fully satisfactory" and "satisfactory" ratings). In 2011, this sub-sector increased its level of compliance in the safety areas of radiation protection and operating performance. This increase is likely due to the CNSC having performed more detailed evaluations at the time of the licensing process, with consequent improvements in the licensees' day-to-day operations and inspection ratings.

Figure 51: Industrial sector vs. oil well logging sub-sector – Comparison of inspection ratings of operating performance

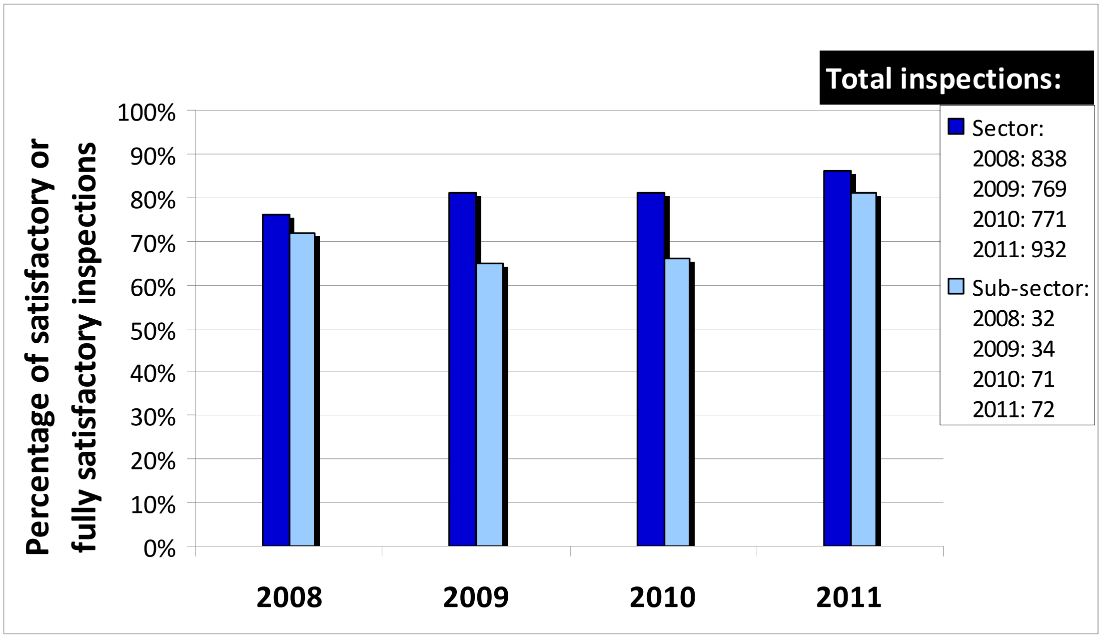
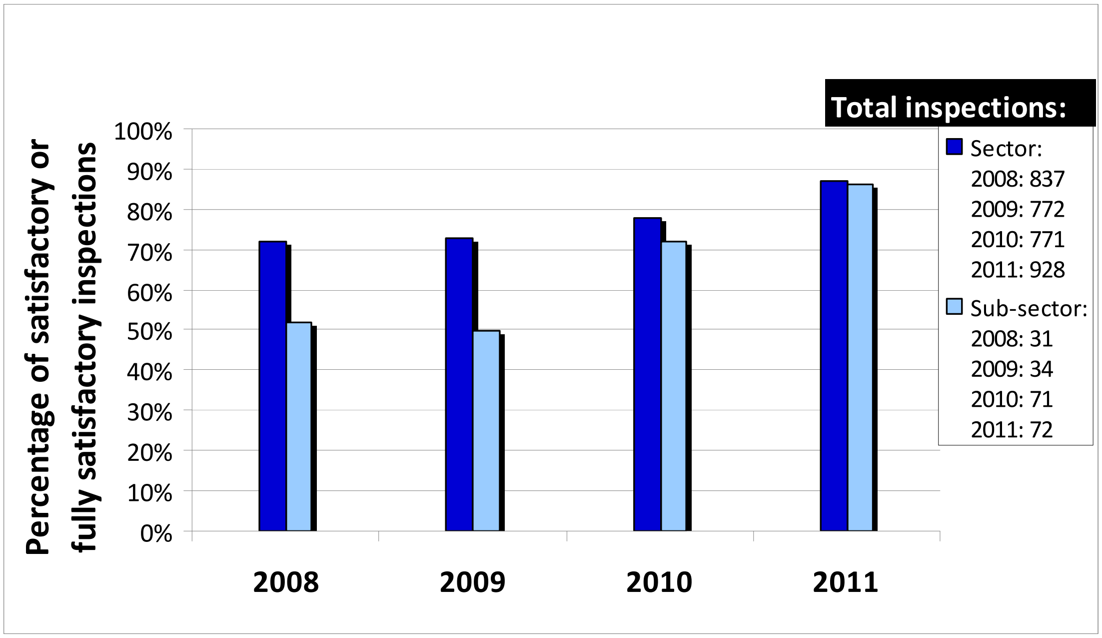


Figure 52: Industrial sector vs. oil well logging sub-sector – Comparison of inspection ratings of radiation protection



6.2.9 INDUSTRIAL SECTOR – SUMMARY STATEMENT

In general, licensees in the industrial sector remained compliant in the operating performance and radiation protection safety areas. They continued to show very good compliance with Sealed Source Tracking System requirements in 2011.

The industrial sector showed an increase in the number of reported events compared to 2010, mainly due to an increase in the number of reported incidents involving portable gauges. However, none of the events reported resulted in a radiation dose to a worker or a member of the public in excess of the regulatory limits.

The number of CNSC orders issued in the industrial sector was higher in 2011 than in 2010, partly due to an increased presence of CNSC inspectors in the field.

Doses were generally well within regulatory limits for this sector and under the dose limit of 50 mSv/year for nuclear energy workers.

6.3 ACADEMIC AND RESEARCH SECTOR

6.3.1 DESCRIPTION

Figure 53: Radioisotopes are powerful tools in biological and environmental research. Source: CNSC.

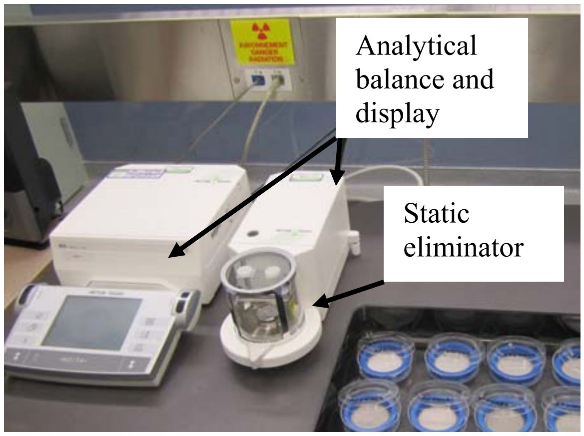
In 2011, the academic and research sector comprised 276 licences with a total of 804 licensed locations. This highly visible sector of the nuclear industry is found in universities, colleges and research labs, both private and public. Open and sealed sources, radiation devices and linear accelerators are used primarily for teaching as well as for pure and applied research. A laboratory environment where open sources could be used is shown in figure 53.

Open source nuclear substances are used in research on biological systems. Researchers can trace the metabolic fate of these compounds within living systems using nuclear substances tagged to various compounds. Although the use of open source nuclear substances has declined over the past decade and is being replaced by non-radioactive procedures, it still remains a powerful research tool.

The sub-sectors of laboratory studies and consolidated use of nuclear substances, along with the research irradiators and high-energy research particle accelerators sub-sectors, constitute 198 licences or 72% of the licences in the academic and research sector. The remaining licences include research and teaching using sealed sources. An example is the use of a static eliminator. As shown in figure 54, emission particulate samples are taken from the exhaust system of vehicles using small collection filters. A static eliminator is then used to neutralize the static on the filters prior to them being weighed using an analytical balance. The static eliminator must be used to obtain precise readings of the weight of the particulates collected on the filters; the balance is so sensitive that even weak static electric fields can affect the operation of the weighing mechanism. The static eliminator shown in figure 55 is a licensed radiation device containing Polonium 210.

Figure 54: Sample collection of emission particulate samples. Source: CNSC.

Figure 55: Static eliminator is used prior to weighing of emission particulate samples. Source: CNSC.



6.3.2 DOSE TO WORKERS

The data in this section represents the dose records of persons who may be subjected to occupational exposures to radiation associated with CNSC-licensed activities. For most sub-sectors, the dose data is extracted from dose reports provided by licensees in their annual compliance reports (ACRs) for the years 2008 through to 2011. For the purpose of this performance measure, CNSC staff analyzed a representative sample of worker dose records from randomly selected ACRs in each sector. For the two high-energy research particle accelerators, occupational dose data was retrieved from Health Canada's National Dose Registry. This data is consolidated at the sector level.

The term "sampled workers" in some of the figures represents the number of workers whose dose data, generated through sampling, was analyzed. This analysis showed that the whole body doses of sampled licensees in the academic and research sector was among the lowest reported, as depicted in figure 56. In 2011, more than 94% of workers – nuclear energy workers (NEWs) and other workers – in this sector received doses of under 0.5 mSv, which is well below the prescribed limit for the public. Furthermore, no member of this group received a dose above 20 mSv between 2008 and 2011, which is well below the prescribed limit for NEWs. The dose results for workers involved in laboratory studies and consolidated use of nuclear substances are shown in figure 57 and figure 58 for NEWs and other workers, respectively.

In 2011, all NEWs received less that 5 mSv, well below the regulatory limit. One NEW, erroneously designated as a regular worker, received a whole body dose of 2 mSv. This worker was subsequently correctly designated as a NEW and returned to work. Data for high-energy research particle accelerators is shown in figure 59 and will be discussed further in section 6.3.8.2 of this report. Doses received by workers involved in research irradiators are shown in figure 60 and figure 61. In 2011, very low doses were reported for workers in this sub-sector, as all sampled workers (NEWs and other workers) actually received less than 0.5 mSv.

Figure 56: Academic and research sector – Annual whole body doses to nuclear energy workers and other workers

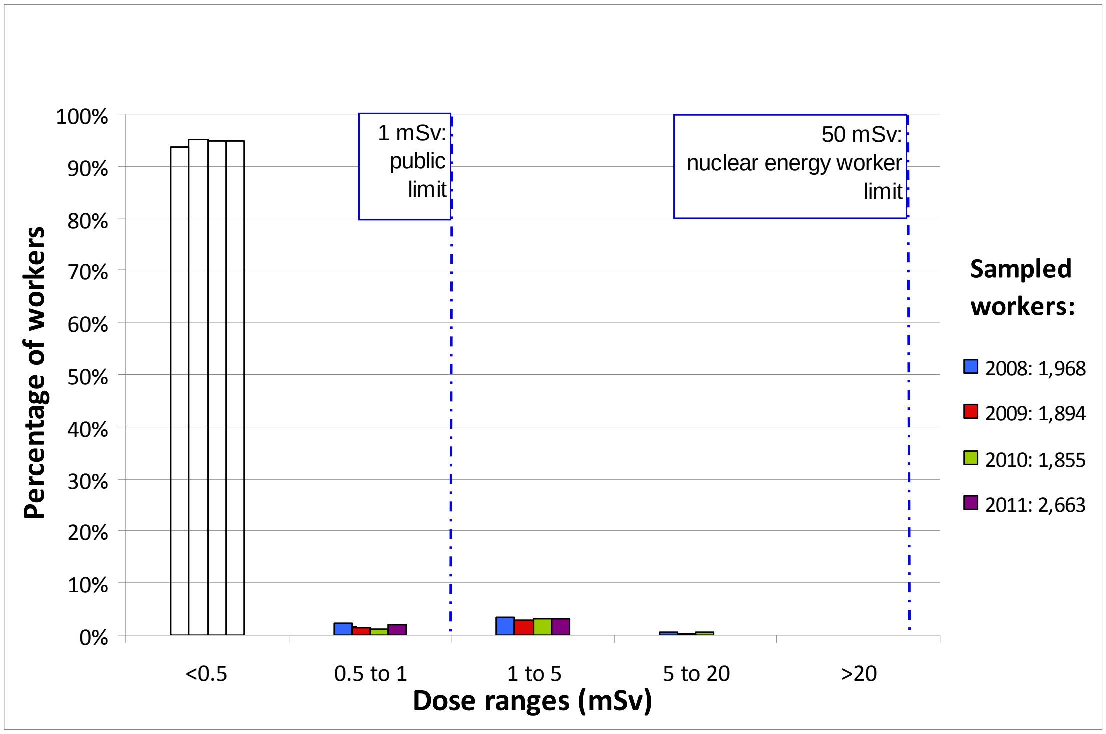


Figure 57: Laboratory studies and consolidated use of nuclear substances – Annual whole body doses to nuclear energy workers

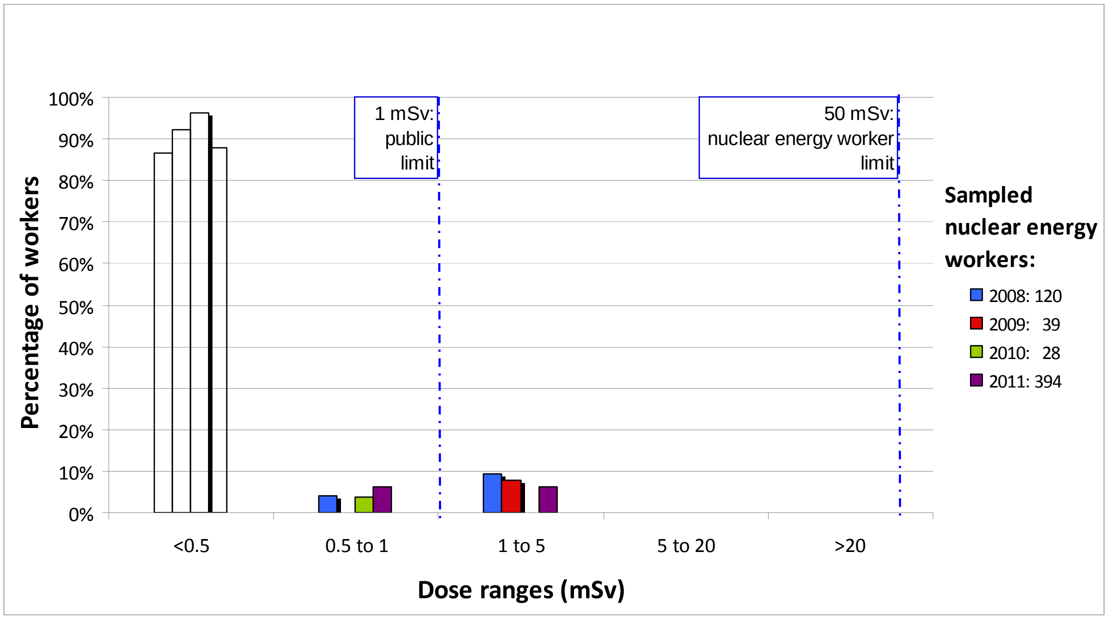


Figure 58: Laboratory studies and consolidated use of nuclear substances – Annual whole body doses to other workers

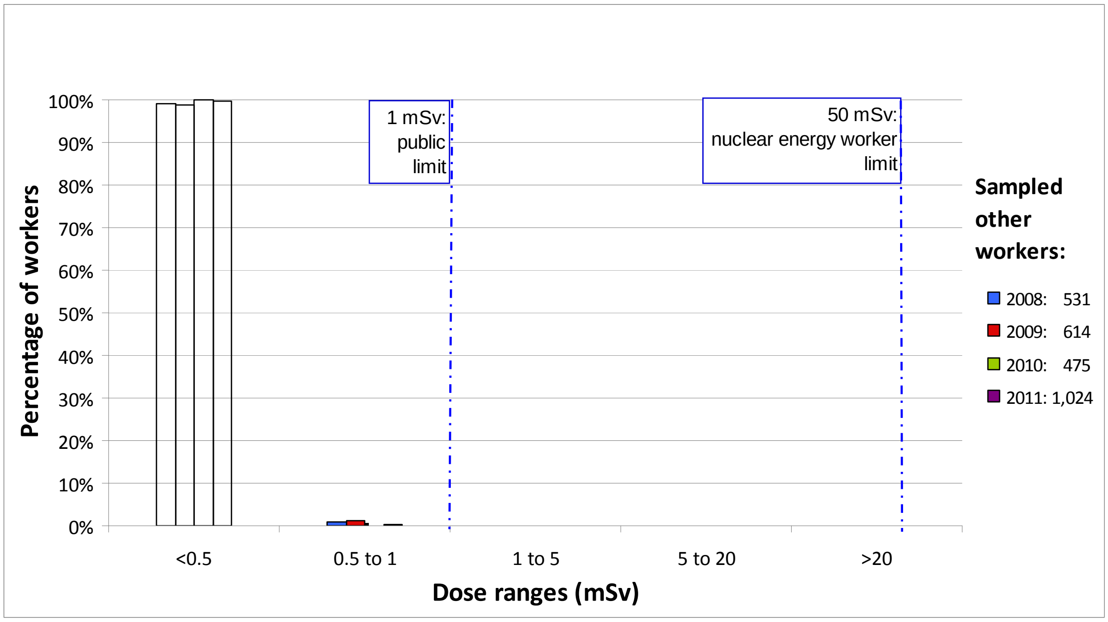


Figure 59: High-energy research particle accelerators – Annual whole body doses to all workers, including nuclear energy workers

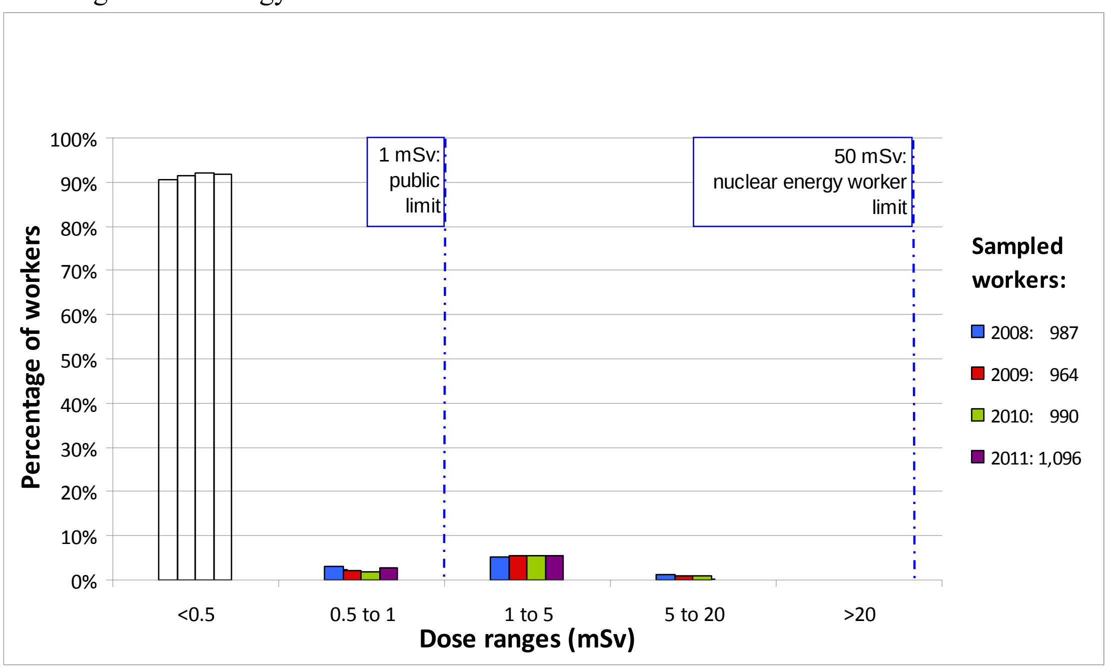


Figure 60: Research irradiators – Annual whole body doses to nuclear energy workers

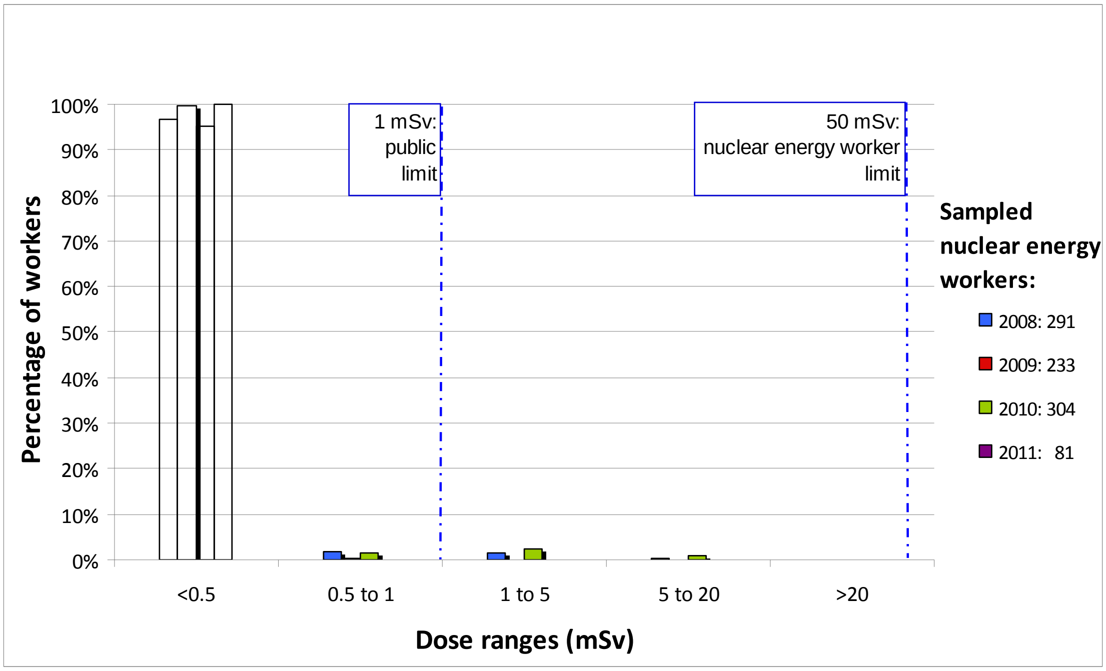
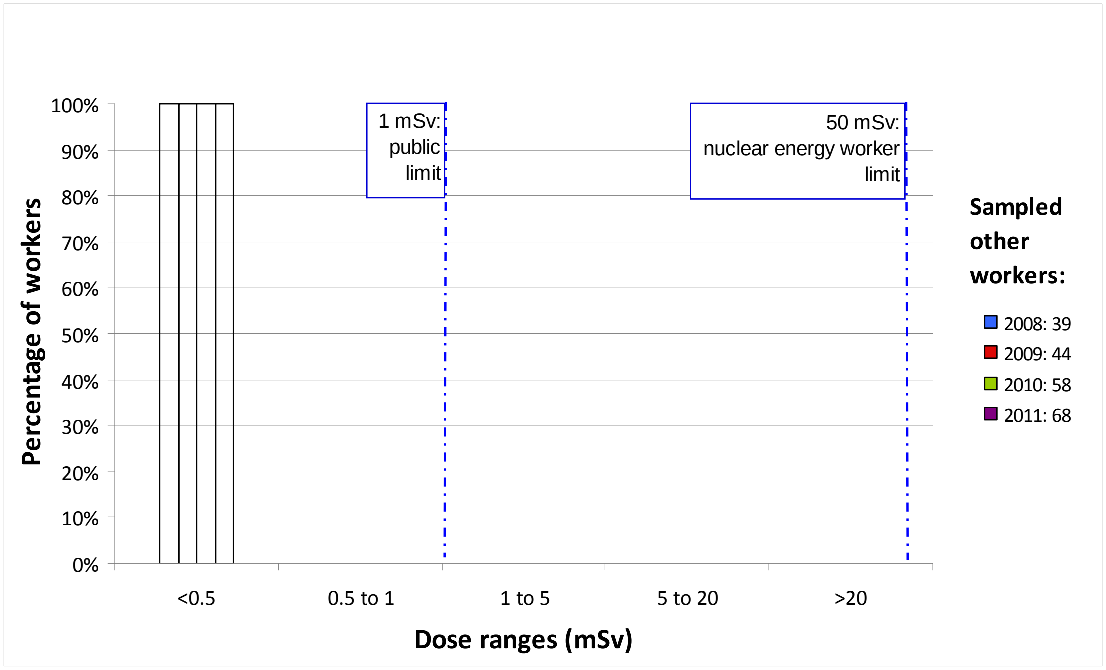


Figure 61: Research irradiators – Annual whole body doses to other workers

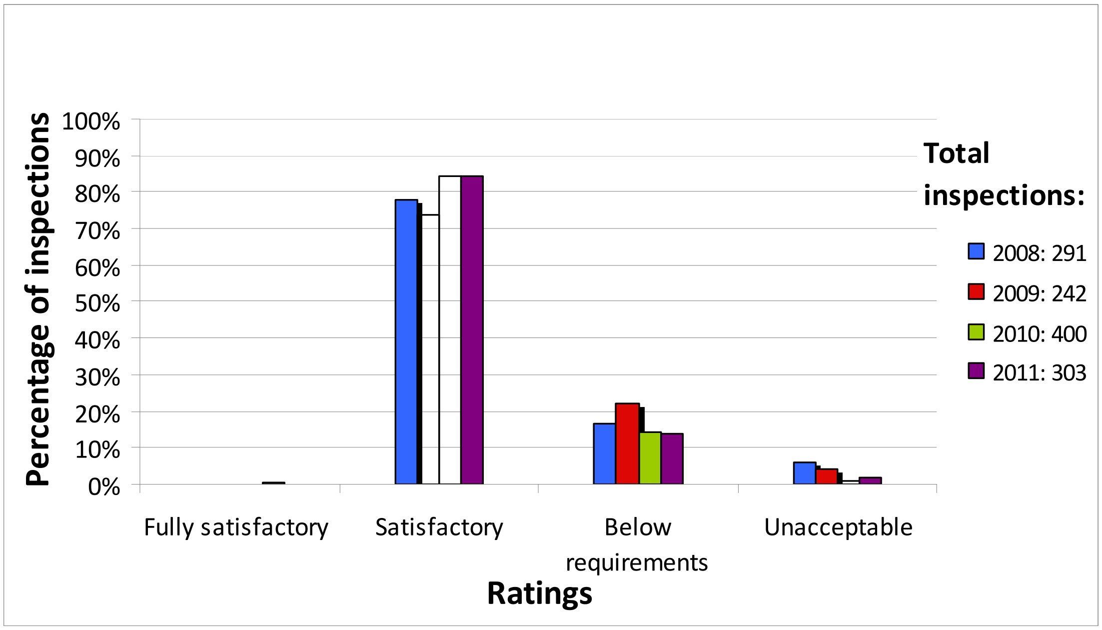


6.3.3 INSPECTION RATINGS OF OPERATING PERFORMANCE

Inspection ratings of operating performance for the academic and research sector are shown in figure 62. In 2011, 84% of the inspected licensees in this sector were found to be compliant, unchanged from 2010. Of the licensees found to be non-compliant, 14% had a "below requirements" rating for non-compliances that did not significantly affect safety, and only 2% had non-compliances rated as "unacceptable." An "unacceptable" rating is significantly below requirements, with deficiencies that could lead to an unreasonable risk to the health and safety of workers, the public or the environment if left uncorrected.

Typical non-compliances in this safety area included failure to maintain adequate training records and failure to provide current work instructions to staff. For detailed results of inspection ratings, refer to Appendix C.3.

Figure 62: Academic and research sector – Inspection ratings of operating performance

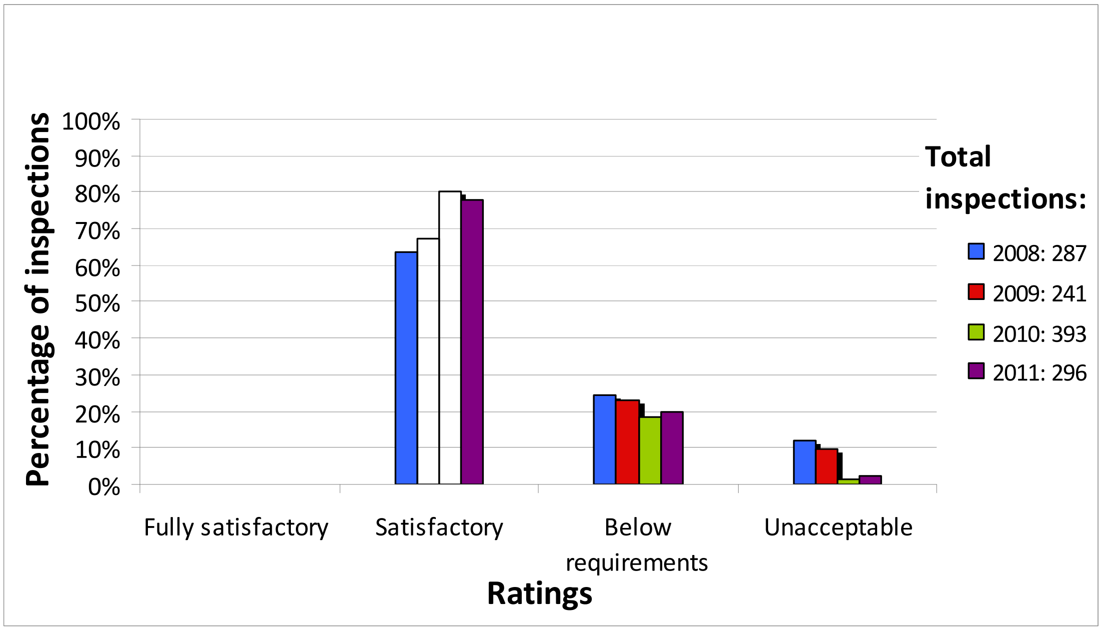


6.3.4 INSPECTION RATINGS OF RADIATION PROTECTION

Radiation protection inspection ratings for the academic and research sector are shown in figure 63. In 2011, 78% of inspected licensees were found to be compliant, consistent with the previous year. Of the inspected licensees found to be non-compliant, 20% had a "below requirements" rating for non-compliances that did not significantly affect safety and 2% had non-compliances rated as "unacceptable."

Typical non-compliances in this sector included failure to notify NEWs in writing of their doses, frivolous posting of radiation warning signs, and failure to label containers that had nuclear substances in them. For detailed results of inspection ratings, refer to Appendix C.4.

Figure 63: Academic and research sector – Inspection ratings of radiation protection

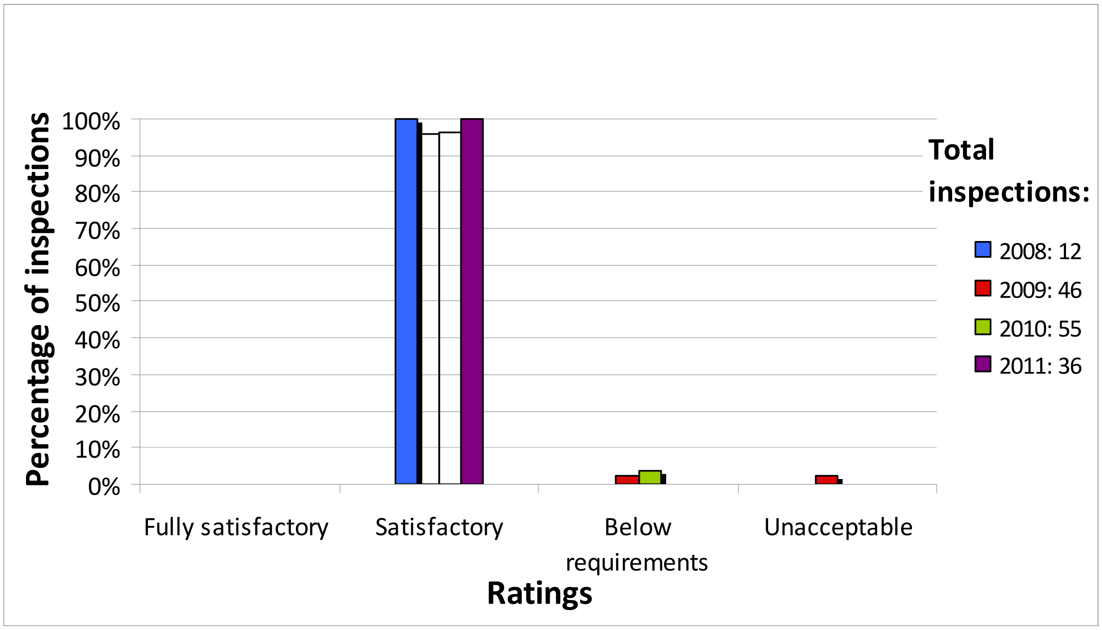


6.3.5 INSPECTION RATINGS OF SEALED SOURCE TRACKING

Sealed source tracking inspection ratings for the academic and research sector are shown in figure 64. Results show that this sector met requirements 100% of the time in 2011. Further information on the subject is available in the *National Sealed Source Registry and Sealed Source Tracking System Annual Report*, which is posted on the CNSC Web site.[12] For detailed results of inspection ratings, refer to Appendix C.5.

[12] Available online at nuclearsafety.gc.ca/eng/readingroom/reports/ssts/index.cfm

Figure 64: Academic and research sector – Inspection ratings for sealed source tracking



6.3.6 REPORTED EVENTS AND INCIDENTS

As shown in figure 65, only seven events in the academic and research sector were reported in 2011.

Two of these events involved spills or contamination. Contamination incidents mainly resulted from technicians handling nuclear substances. In both cases, licensees implemented incident response procedures to mitigate consequences.

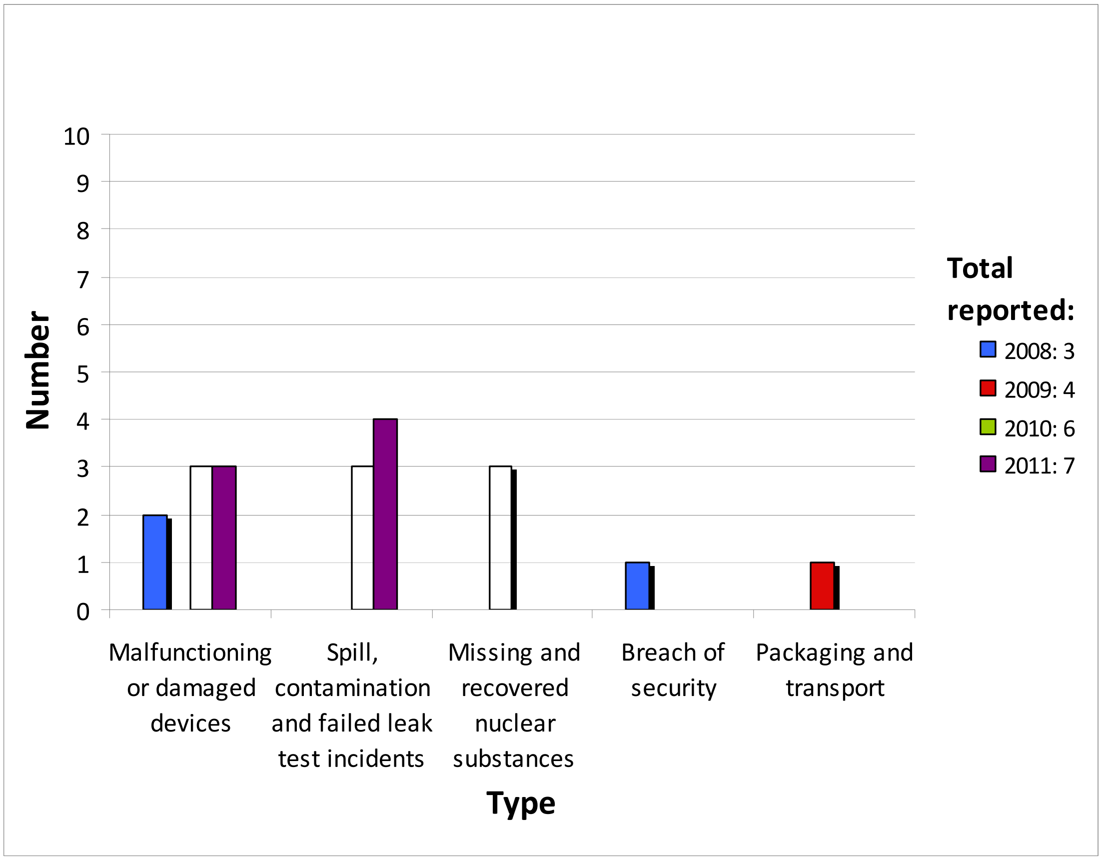
There were two leak-related events in this sector. In one instance, there was a report of a sealed source that failed a leak test in an old device that was no longer in use. There was no contamination found on the exterior of the device and the device was properly disposed of. The other event occurred in a high-energy research particle accelerator facility and is discussed in more detail in section 6.3.8.2.

There were three events reported for devices that malfunctioned or were damaged, without any radiological consequence or exposure.

None of these events resulted in any person receiving a dose in excess of the regulatory limit.

There were no reported transportation incidents, missing nuclear substances or breaches of security in the academic and research sector in 2011.

Figure 65: Academic and research sector – Reported events and incidents



6.3.7 ENFORCEMENT ACTIVITIES – ORDERS AND MEASURES TO BE TAKEN BY THE LICENSEES

One order was issued in 2011 in the academic and research sector, as listed in table 2. For more information regarding these enforcement actions, consult the *Regulatory Action* page on the CNSC Web site.[13]

[13] Available online at nuclearsafety.gc.ca/eng/lawsregs/regulatoryaction/index.cfm

Table 2: Academic and research sector enforcement activities – Orders and measures to be taken by the licensees

Licensee	Location	Date order was issued	Measures to be taken by the licensee	Date order was closed
Memorial University of Newfoundland	St. John's, Newfoundland and Labrador	September 29, 2011	Conduct review of the implementation of the radiation protection program and identify and correct systemic causes of non-compliance observed during the inspection.	November 17, 2011

6.3.8 ACADEMIC AND RESEARCH SUB-SECTOR

6.3.8.1 LABORATORY STUDIES AND CONSOLIDATED USE OF NUCLEAR SUBSTANCES SUB-SECTOR

Within the academic and research sector, the most visible licensees are those based at universities, colleges and government laboratories. Typically, these areas involve licences for laboratory studies and for the consolidated use of nuclear substances. They account for 67% or 186 of the 276 licences in the academic and research sector. This licensed community generally has well-structured radiation safety programs in place.

Pure and applied research is dominant in laboratory studies and in the consolidated use of nuclear substances in the fields of physics, biology and biomedicine; however, teaching is also a permitted use. An example of a potential application of a radiation device is shown in figure 66.

Figure 66: A laboratory worker using a liquid scintillation counter (radiation device). Source: CNSC.

Laboratory studies use open sources for research and diagnosis. Licensees are most often hospitals, private medical laboratories, universities or private research establishments. Work typically involves the use of nuclear substances as tracers in labelling studies. Common isotopes used are Carbon 14, Cobalt 57, Hydrogen 3, Iodine 125, Phosphorus 32 and Sulphur 35. Radiation activity levels range from kilobecquerel quantities to gigabecquerel quantities and more. Laboratory studies are similar to consolidated use but more restrictive in scope with the use of nuclear substances.

Consolidated licences ensure that all nuclear substances, radiation devices and activities come under the control of a single administrative body, usually a radiation safety committee. This committee controls the possession and use of nuclear substances through an internal permit system that authorizes individuals or groups of researchers to use the nuclear substances in the same way that the CNSC issues licences. These specific individuals are responsible for licensed activities within their departments, which may occur in many locations and involve numerous workers using radiation devices and a variety of nuclear substances in open or sealed form. The CNSC also requires licensees to submit annual compliance reports.

Figure 67 compares inspection ratings of operating performance in the laboratory studies and consolidated use of nuclear substances sub-sector with the academic and research sector. Figure 68 provides a similar comparison for radiation protection inspection ratings. These figures show the percentage of inspections that found licensees had met or exceeded requirements (“fully satisfactory” and “satisfactory” ratings). In 2011, this sub-sector demonstrated a compliance record in the areas of radiation protection and operating performance similar to that of the overall academic and research sector.

Figure 67: Academic and research sector vs. laboratory studies and consolidated use of nuclear substances sub-sector – Comparison of inspection ratings of operating performance

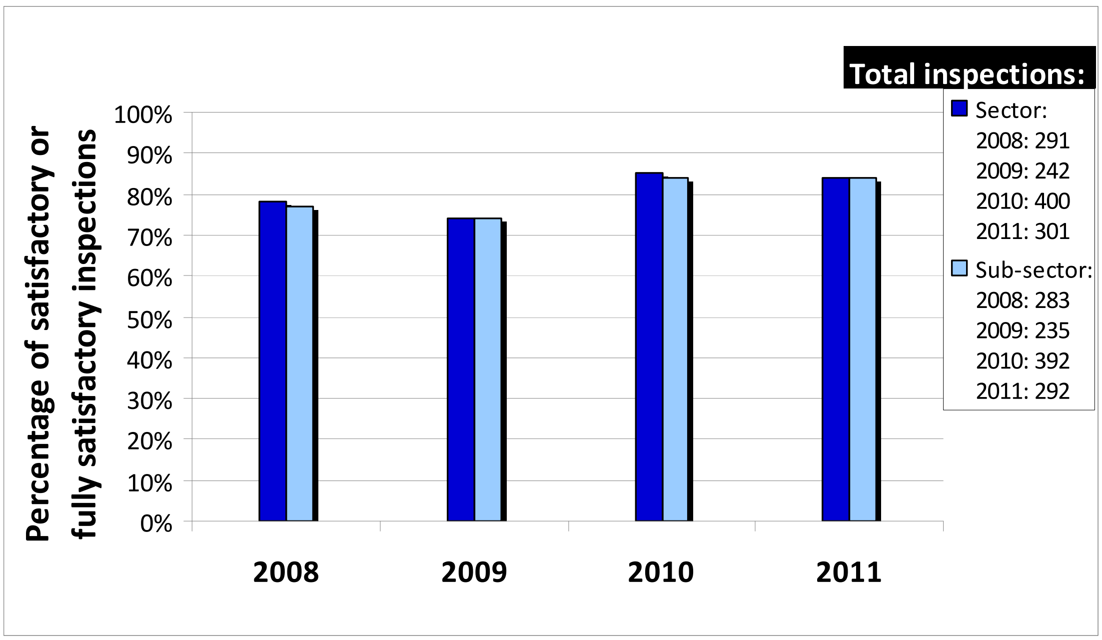
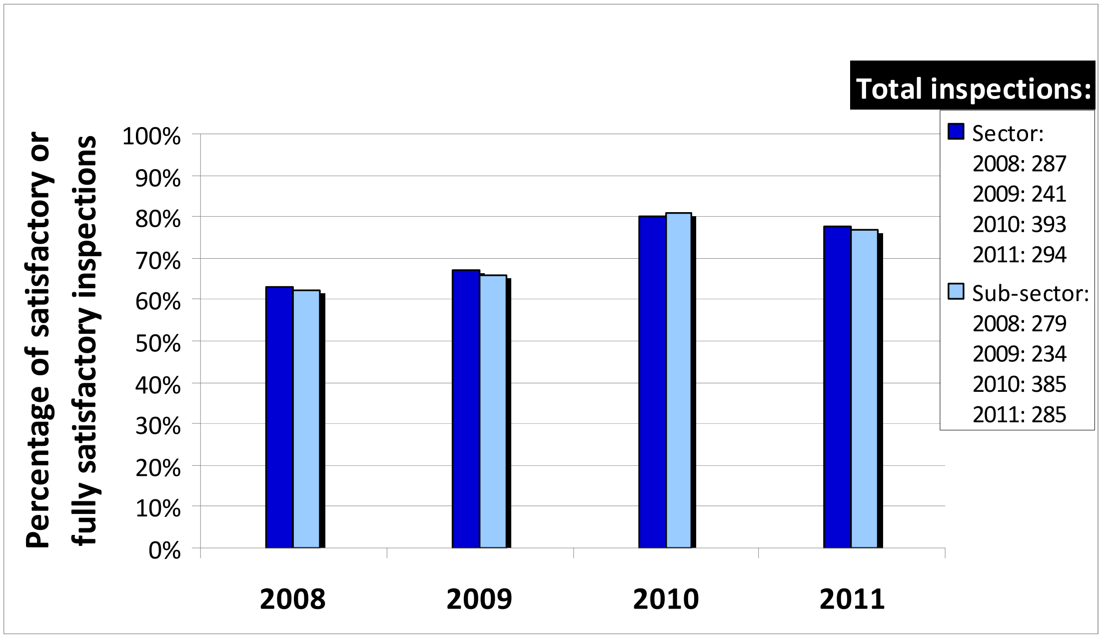
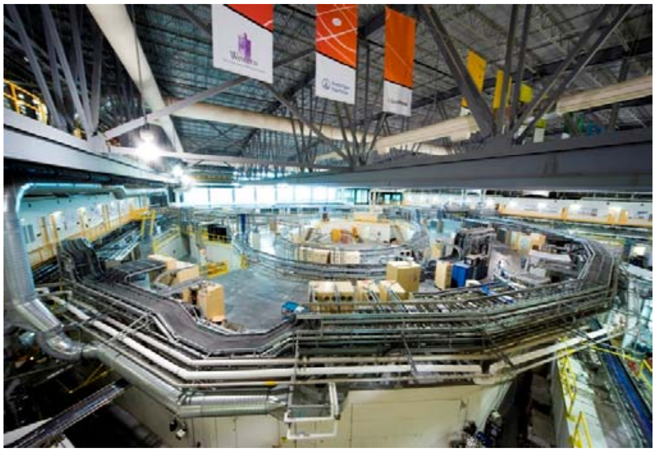


Figure 68: Academic and research sector vs. laboratory studies and consolidated use of nuclear substances sub-sector – Comparison of inspection ratings of radiation protection



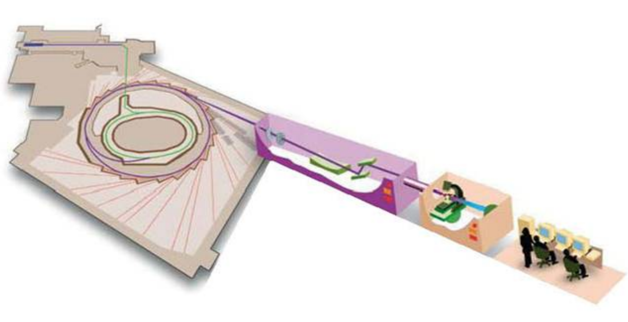
6.3.8.2 HIGH-ENERGY RESEARCH PARTICLE ACCELERATOR SUB-SECTOR

Figure 69: Canadian Light Source, a research facility located in Saskatoon, SK.
Source: Canadian Light Source Inc.



Research in this sub-sector range from pure research in astrophysics to applied research such as investigating an alternate method for medical isotopes production, identifying genetic mutations, and researching new materials used in ultra-fast electronics. These facilities provide the infrastructure and tools that would be too large and complex for a single entity to build, operate and maintain. A high-energy research particle accelerator is shown in figure 69 and a schematic diagram is shown in figure 70. These large facilities contain multiple accelerators specialized for various applications in the fields of medical and health science, nuclear and particle physics, material sciences, and environmental science. In Canada, there are two such facilities, TRIUMF in British Columbia and Canadian Light Source Inc. in Saskatchewan.

Figure 70: A schematic diagram of a research particle accelerator (not to scale).
Source: Canadian Light Source Inc.



The safety performance of these high-energy accelerators is largely consistent with other sub-sectors in the academic and research sector. As shown in figure 59, the whole body doses to workers at these two facilities were well within regulatory limits with over 91% receiving less than 0.5 mSv and all receiving less than 20 mSv. Those in the higher dose ranges are primarily involved in the periodic servicing and maintenance of activated components of the accelerator systems.

The safety performance measures outlined in section 5.1, which are used to report safety performance for other sub-sectors, are also applicable to high-energy research particle accelerators. However, due to their complexity additional performance metrics are provided for the two facilities in this sub-sector. Table 3 below summarizes the ratings for the two facilities. These ratings are derived from multiple sources including but not limited to inspection results. Note that the ratings for operating performance and radiation protection are included in the sector graphs (figure 62 and figure 63) but are repeated in the table below for completeness. Definitions for all the performance metrics are provided in Appendix B.

Table 3: Performance measure ratings for high-energy research particle accelerators

Performance measures (Safety and control areas)	Rating	
	TRIUMF	Canadian Light Source Inc.
Management system	Satisfactory	Satisfactory
Human performance management	Satisfactory	Satisfactory
Operating performance	Satisfactory	Satisfactory
Safety analysis	Satisfactory	Satisfactory
Physical design	Satisfactory	Satisfactory
Fitness for service	Satisfactory	Satisfactory
Radiation Protection	Satisfactory	Satisfactory
Conventional health and safety	Satisfactory	Satisfactory
Environmental protection	Satisfactory	Satisfactory
Emergency management and fire protection	Satisfactory	Satisfactory
Waste management	Below Requirements	Satisfactory
Security	Satisfactory	Satisfactory
Safeguards and Non-Proliferation	Satisfactory	Not applicable
Packaging and Transport	Satisfactory	Satisfactory

The only "below requirements" rating was due to deficiencies identified in the handling and disposal of low-level waste. Corrective actions were implemented to address these deficiencies. As Canadian Light Source Inc. does not conduct any licensed activities subject to safeguards obligations there is no rating associated with this particular measure.

There was one reported event among the five categories illustrated in figure 65. The event involved a small spill of a low-activity radioactive liquid inside a piece of laboratory equipment used to prepare accelerator targets. The spill was contained within the device and procedures were implemented to prevent reoccurrence of this type of event.

There were no orders issued in this sub-sector.

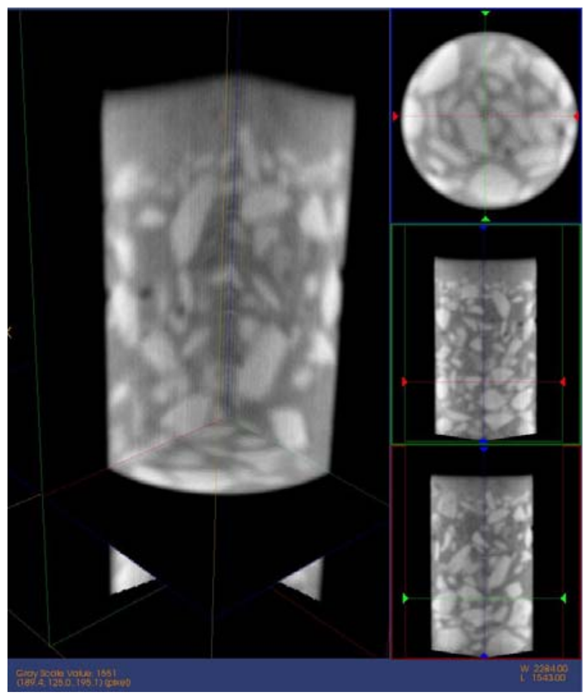
6.3.8.3 RESEARCH IRRADIATOR SUB-SECTOR

Research irradiators are used primarily for radiobiological and medical imaging research and the calibration of radiation dose measurement instruments. These devices are located in hospitals, research and private facilities.

Radiobiological research involves experimental animal studies or the irradiating of cell cultures to investigate the effects of ionizing radiation on biological systems. This research can be used to refine radiation therapy treatment protocols for cancer treatment.

Research is also conducted in the use of nuclear substances such as Cobalt 60-based 3D imaging, which produces images similar to those generated by computed tomography (CT) scanners. Access to 3D imaging in a radiation therapy treatment room gives the treatment team the ability to implement image-guided radiation therapy and more precisely deliver therapeutic doses of radiation. Successful commercialization of this technology would provide a low-cost, image-guided radiation therapy option for developing countries.

Figure 71: Cobalt 60 CT image showing uniformity of high-density aggregate in test pours.
Source: Dr. John Schreiner, Cancer Centre of Southeastern Ontario at the Kingston General Hospital (with permission).



Investigations into the use of research irradiators using nuclear substances can extend over a broad range of applications, from clinical dose delivery to clinical and applied imaging. For example, the use of Cobalt 60-based CT for image guidance during radiation treatments has been extended to a number of applied problems investigating dense materials, including verifying the integrity of high-density concrete used for facility shielding. As shown in figure 71, images of various test cylinders indicated that the high-density concrete was uniform over multiple test pours and confirmed the integrity of the concrete for shielding.

Several devices are used to calibrate radiation dose measurements. The long half-life nuclear substances contained in these irradiators, Cesium 137 or Cobalt 60, provide a reliable reference to calibrate instruments. Radiation protection and operating performance grades are not available for this sub-sector for 2011, but performance results for other metrics such as doses to workers and reported events are discussed in the previous sections.

6.3.9 ACADEMIC AND RESEARCH SECTOR – SUMMARY STATEMENT

The performance metrics for the academic and research sector indicate this sector is compliant. Non-compliance issues did not significantly affect the safety of the licensed activities.

During 2011, there was one order issued to a licensee in this sector. Ratings of operating performance and radiation protection have been stable over the last two years following an initial improving trend. Occupational doses were within regulatory limits.

6.4 COMMERCIAL SECTOR

6.4.1 DESCRIPTION

The commercial sector encompasses a number of licensed activities related to the production, processing, storage and distribution of nuclear substances, and the calibration and servicing of radiation devices for commercial gain. This sector includes isotope production accelerators, third-party service companies and organizations developing new devices. In 2011, there were 250 licences in this broad sector.

For the purpose of this year's report, two sub-sectors were highlighted within the commercial sector: isotope production and processing of nuclear substances. Together, these sub-sectors account for 11% or 27 of the 250 licences in the commercial sector. Although not large in comparison with other activities in this sector, the goal is to provide information on a variety of sub-sectors from year to year.

6.4.2 DOSE TO WORKERS

The data in this section represents the dose records for persons who may be subjected to occupational exposure to radiation associated with CNSC-licensed activities. The dose data is extracted from dose reports provided by licensees in their annual compliance reports (ACRs) from 2008 to 2011. For the purpose of this performance measure, CNSC staff analyzed a representative sample of worker dose records from randomly selected ACRs from licensees in each sector.

The term "sampled workers" in the figures in this section represents the number of workers whose dose data was analyzed (1,099 workers were sampled in 2011). As shown in figure 72, doses were relatively consistent from 2008 to 2011.

As shown in figure 73, more than 99% of the isotope production accelerator nuclear energy workers (NEWs) received whole body doses lower than 5 mSv/year in 2011, which is well below the annual regulatory limit of 50 mSv/year. Note that this sub-sector includes doses received by workers involved in the processing of isotopes produced by isotope production accelerators.

Due to the manual manipulation of instruments during radioisotope processing, occupational doses to workers' hands are also monitored. The data shows that doses received are relatively stable, and all workers continued to receive doses lower than the regulatory limit of 500 mSv/year (extremity dose limit). This information is presented in figure 74.

The doses received by NEWs in the processing of nuclear substances sub-sector are similar to those in the isotope production accelerator sub-sector and have been stable over the last four years. As shown in figure 75 and figure 76, all NEWs received less than 20 mSv/year whole body dose and all other workers received less that 0.5 mSv – both well below their respective regulatory limits.

Figure 72: Commercial sector – Annual whole body doses to nuclear energy workers and other workers

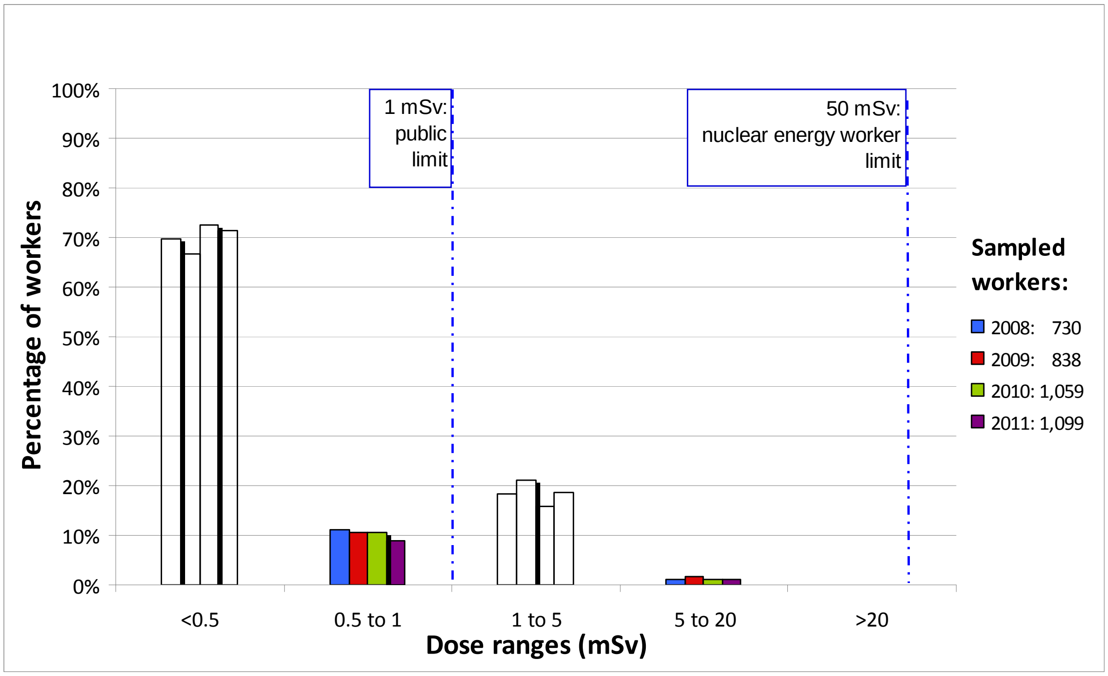


Figure 73: Isotope production accelerators – Annual whole body doses to nuclear energy workers

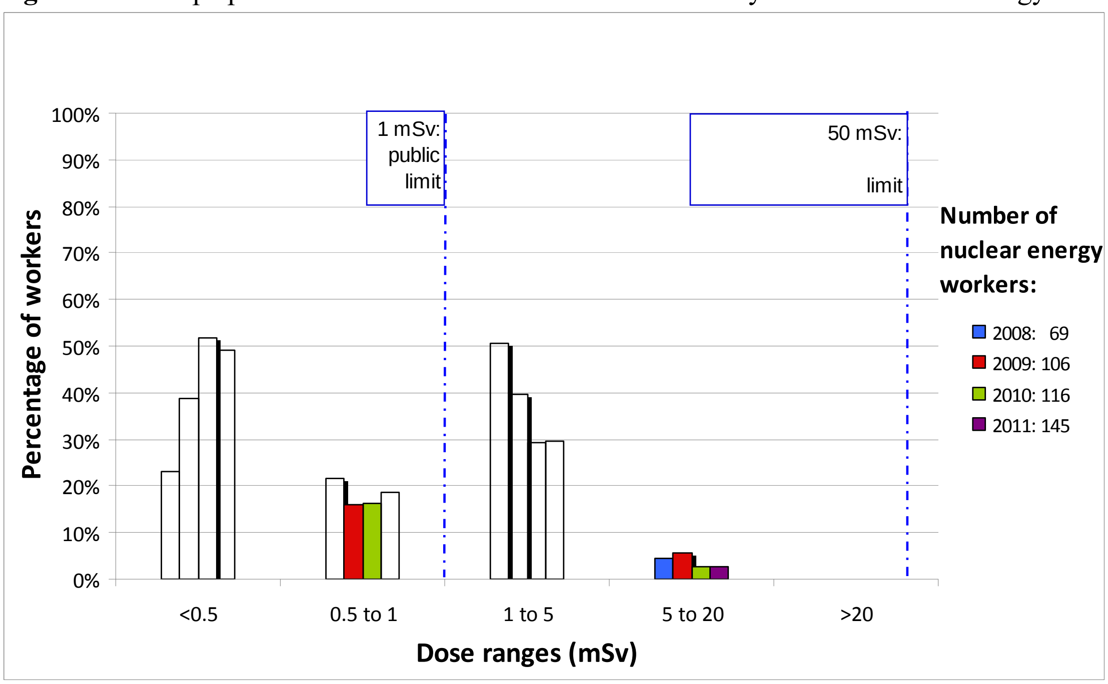


Figure 74: Isotope production accelerators – Annual extremity doses to nuclear energy workers

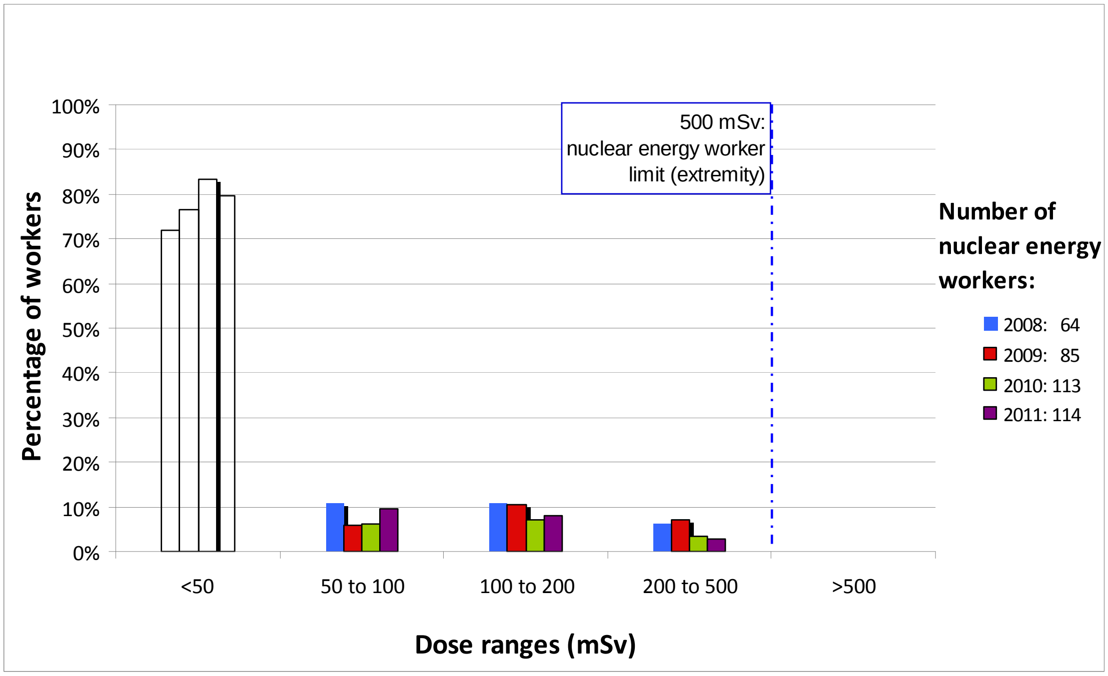


Figure 75: Processing of nuclear substances – Annual whole body doses to nuclear energy workers

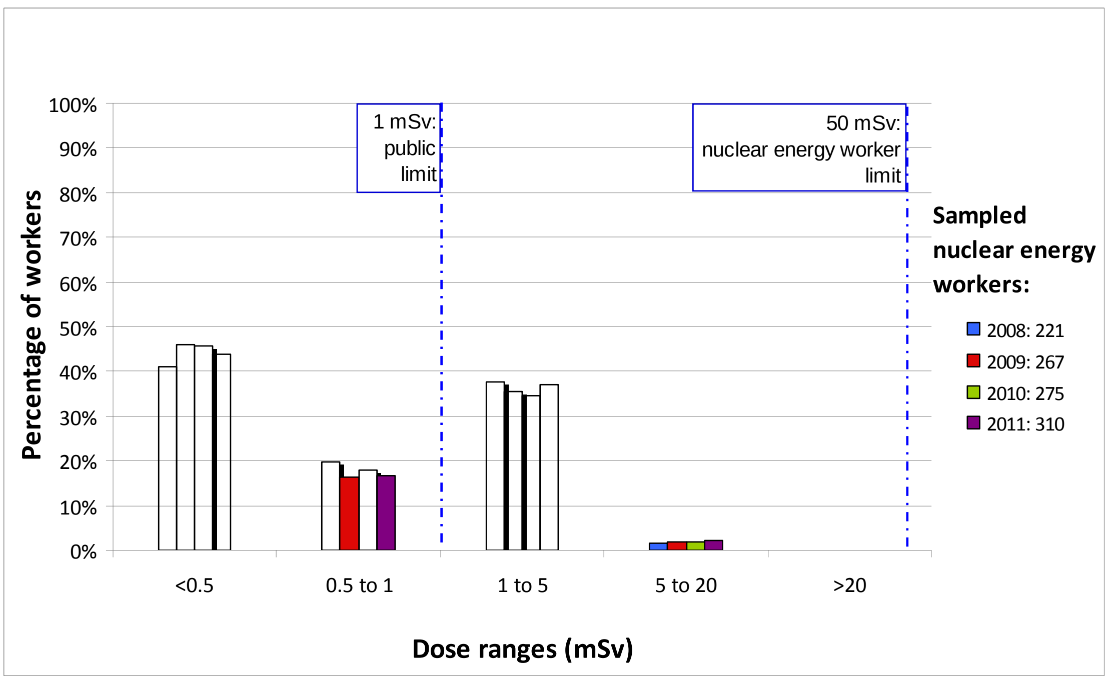
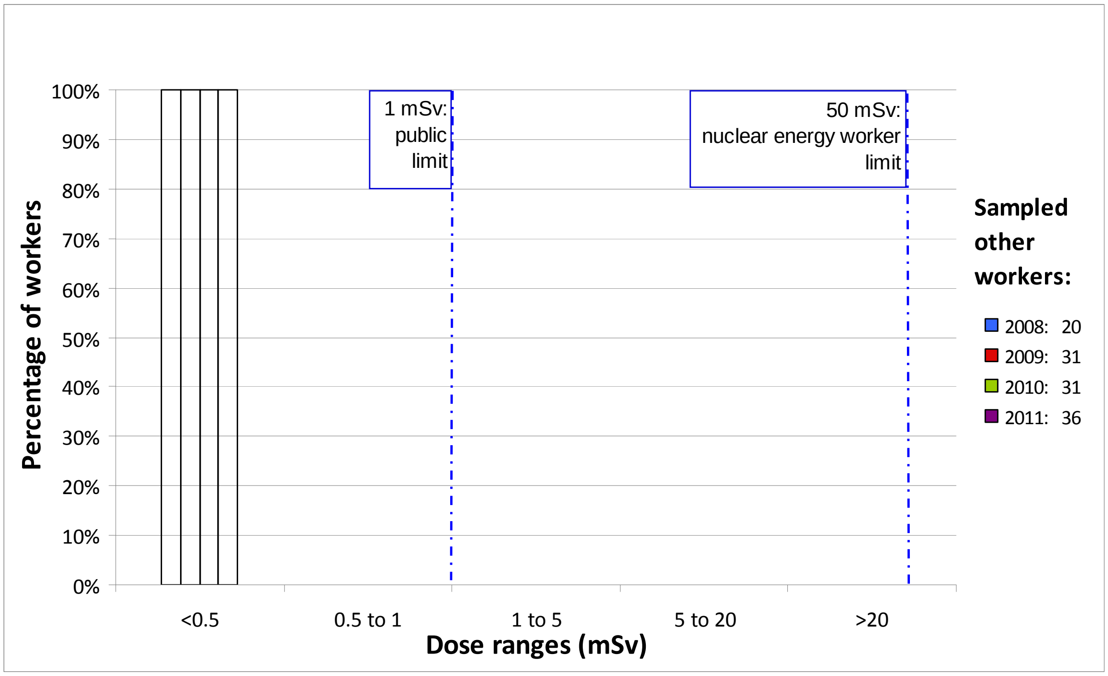


Figure 76: Processing of nuclear substances – Annual whole body doses to other workers



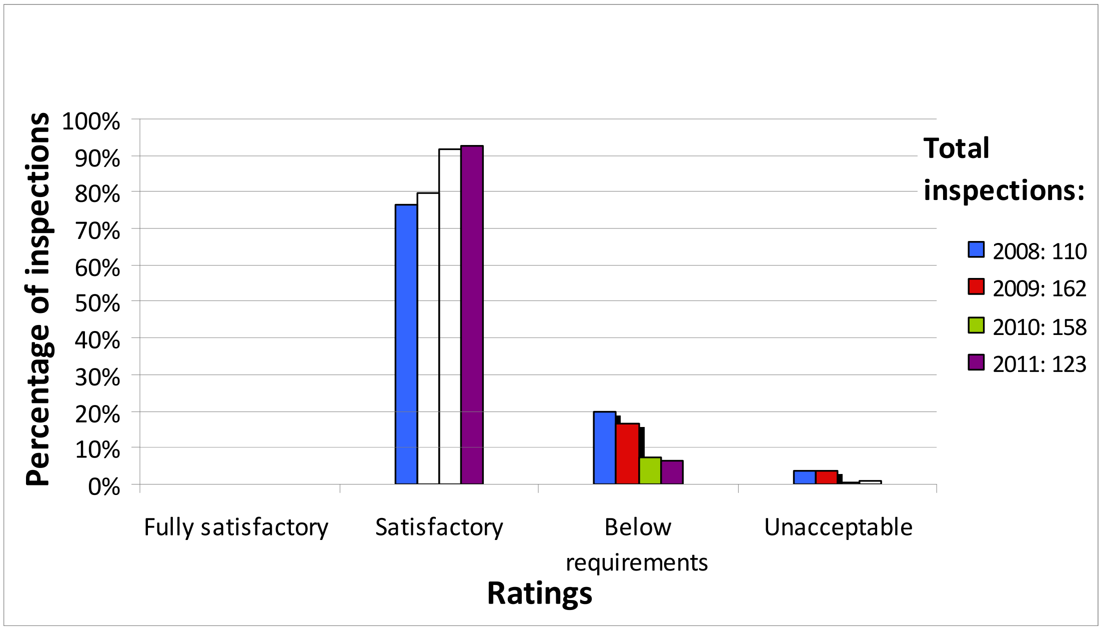
6.4.3 INSPECTION RATINGS OF OPERATING PERFORMANCE

Inspection ratings of operating performance for the commercial sector are shown in figure 77. In 2011, 93% of the inspected licensees were found to be compliant in the operating performance safety area – relatively unchanged from the previous year. Of the inspected licensees found to be non-compliant, 7% had a “below requirements” rating for non-compliances that did not significantly affect safety and 1% had non-compliances rated as “unacceptable.” An “unacceptable” rating is significantly below requirements, with deficiencies that could lead to an unreasonable risk to the health and safety of workers, the public or the environment if left uncorrected.

Typical non-compliances in this safety area included failure of workers to follow licensee procedures, failure of licensees to maintain appropriate training records, or failure to perform leak tests at prescribed intervals.

The compliance rate of commercial-sector licensees in this safety area was unchanged in 2011 compared to the previous year, suggesting robust improvements from 2007 and 2008. For detailed results of inspection ratings, refer to Appendix C.3.

Figure 77: Commercial sector – Inspection ratings of operating performance



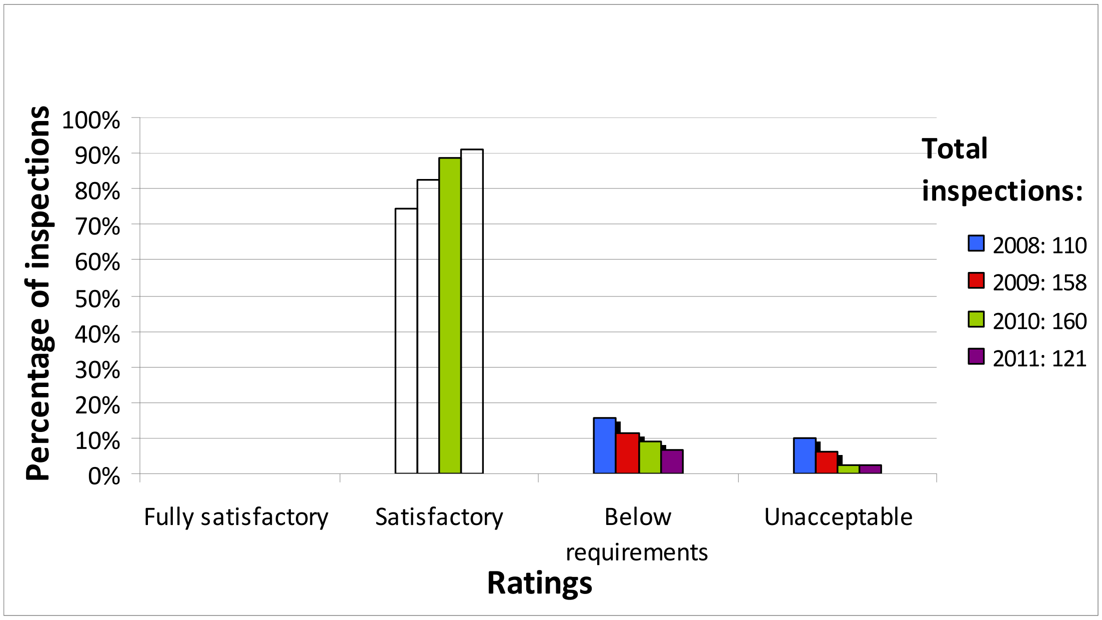
6.4.4 INSPECTION RATINGS OF RADIATION PROTECTION

Radiation protection inspection ratings for the commercial sector are shown in figure 78. In 2011, 91% of inspected licensees were found to be in compliance with this safety area. Of the inspected licensees found to be non-compliant, 7% had a “below requirements” rating for non-compliances that did not significantly affect safety and 3% had non-compliances rated as “unacceptable.”

Typical non-compliances in this safety area included inadequately labelled devices, improper storage of nuclear substances, or the inability of a licensee to demonstrate that doses are As Low As Reasonably Achievable (ALARA).

The commercial sector’s compliance level in this safety area showed modest improvement in 2011, compared to results from previous years. The number of compliant licensees increased from 75% in 2008 to 91% in 2011. The number of inspected licensees demonstrating compliance “below requirements” or “unacceptable” decreased from 26% in 2008 to 10% in 2011. For detailed results of inspection ratings, refer to Appendix C.4.

Figure 78: Commercial sector – Inspection ratings of radiation protection



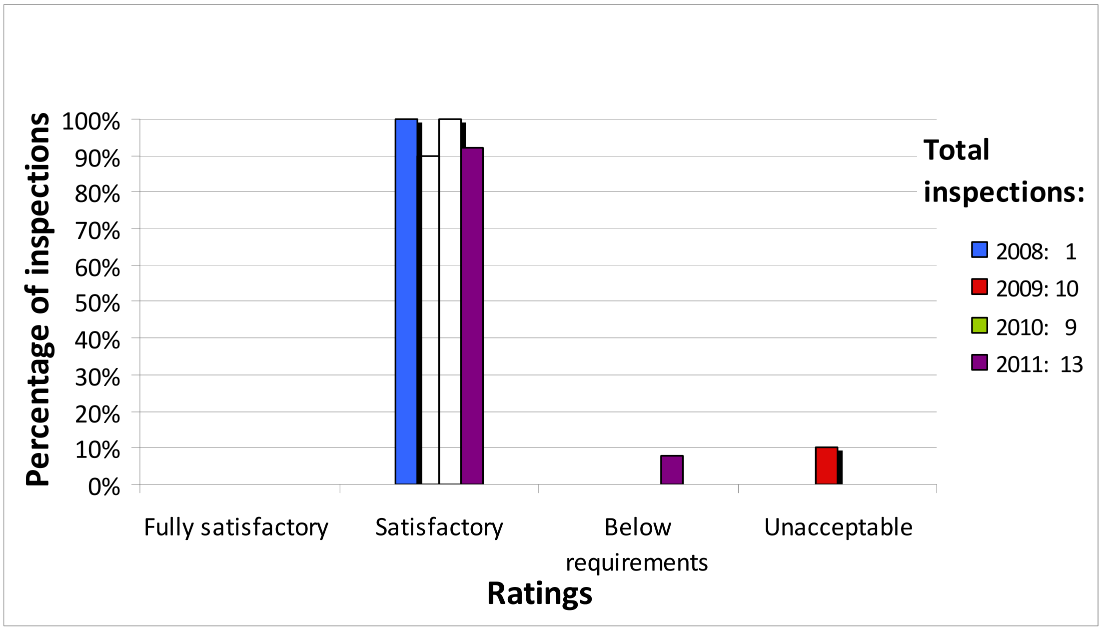
6.4.5 INSPECTION RATINGS OF SEALED SOURCE TRACKING

Sealed source tracking inspection ratings for the commercial sector from 2008 to 2011 are shown in figure 79. In 2011, as in 2009, one licensee's performance was rated "below requirements." The licensee's documented inventory of sealed sources and the inventory reported to the Sealed Source Tracking System were inconsistent with sources physically verified during inspection. The licensee has taken appropriate corrective measures to address this issue.

Further information on the subject may be found in the *National Sealed Source Registry and Sealed Source Tracking System Annual Report*, available on the CNSC Web site[14]. For detailed results of inspection ratings, refer to Appendix C.5.

[14] Available online at http://nuclearsafety.gc.ca/eng/readingroom/reports/ssts/index.cfm

Figure 79: Commercial sector – Inspection ratings for sealed source tracking



6.4.6 REPORTED EVENTS AND INCIDENTS

As shown in figure 80, there were 20 reported events in the commercial sector in 2011.

Of the 20 events, four were related to malfunctioning or damaged devices with no radiological or exposure consequences.

Seven incidents involved spills or contamination in medical isotope production facilities, one of which was caused by ruptured gas targets inside a cyclotron machine. Radiation was contained inside the devices and there were no radiological consequences or exposure to technicians or members of the public.

Spill and contamination incidents resulted mainly from technicians' handling of nuclear substances in liquid form. In all cases, licensees implemented measures satisfactory to the CNSC to mitigate the consequences and to limit radiation exposures to workers. There has been a 68% decrease in the number of spills and contamination incidents in this sector compared to 2010, likely due to measures implemented by licensees.

There were eight reported incidents in the area of packaging and transport, two of which involved damaged packages (with no loss of containment) and two that were accidents involving vehicles transporting nuclear substances (with no damage to the packages). There were also four shipments of nuclear substances that were not fully compliant with regulations. In these four cases, the non-compliances were administrative in nature.

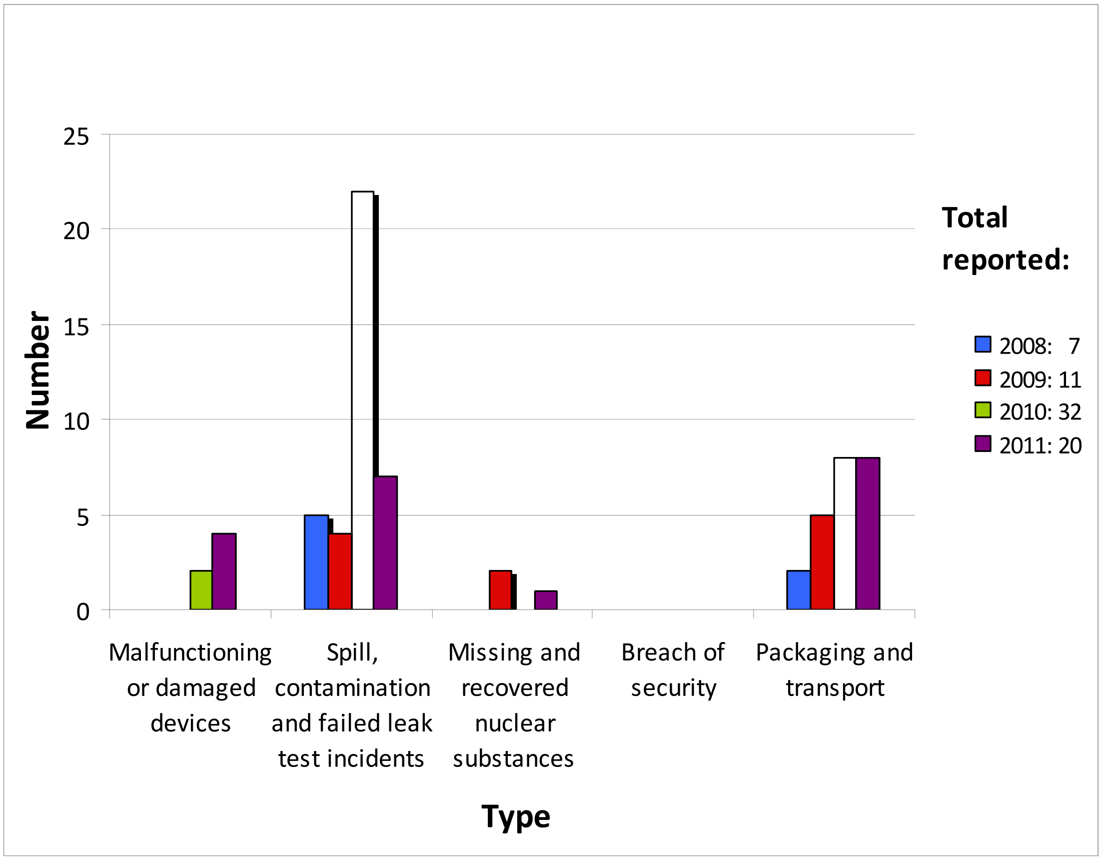
In all cases, the licensees involved implemented procedures to ensure the events would not re-occur.

The commercial sector also reported one incident of a missing nuclear substance, which was lost during transport by the carrier. Following an investigation, it was determined that the package fell off an airport trolley and was destroyed after being run over.

The debris was swept up by the janitorial crew and thrown away in the garbage, not realizing that the package and debris contained radioactive material. The nuclear substance being carried was a small quantity of Gallium 67, a short-lived medical isotope presenting no risk to health, safety or the environment. The carrier has since revised its procedures and provided all staff with the appropriate training to ensure that such an incident does not occur again.

None of the events reported by licensees in the commercial sector resulted in a radiation dose to workers or members of the public in excess of the regulatory limits and there were no reported breaches of security in 2011.

Figure 80: Commercial sector – Reported events and incidents



6.4.7 ENFORCEMENT ACTIVITIES – ORDERS AND MEASURES TO BE TAKEN BY THE LICENSEES

There were no orders issued in 2011 in the commercial sector.

6.4.8 COMMERCIAL SUB-SECTORS

6.4.8.1 ISOTOPE PRODUCTION ACCELERATOR SUB-SECTOR

Figure 81: Isotope production accelerator (cyclotron).
Source: CNSC.

The 11 isotope production accelerators licensed by the CNSC are used primarily for the production of isotopes used in medical imaging. Carbon 11 and, more commonly, Fluorine 18 are incorporated into radiopharmaceuticals used in PET imaging. A cyclotron, the most common type of isotope production accelerator, is shown in figure 81. Radiation protection and operating performance grades are not available for this sub-sector for 2011, but performance results for other metrics such as doses to workers and reported events are discussed in the previous sections.

6.4.8.2 PROCESSING OF NUCLEAR SUBSTANCES SUB-SECTOR

Figure 82: Worker processing nuclear substances.
Source: CNSC.

Nuclear substances created in an isotope production accelerator or nuclear reactor that are intended for use as a medical isotope must be processed to prepare them for therapeutic or diagnostic (imaging) applications. These radiochemical processes are typically performed in hospitals or private laboratories for use locally or at client locations. Figure 82 shows a worker processing a medical isotope in a state-of-the-art clean room facility.

As shown in figure 83, the operating performance inspection ratings for this sub-sector are essentially at par with the overall sector, with 92% meeting regulatory expectations in 2011. Typical non-compliances in this area relate to improper signage or periodic lapses in following procedures.

Similarly, figure 84 illustrates that the radiation protection ratings in this sub-sector are similar to those of the sector in 2011 – an improvement over the prior two years. Inadequate provisions to minimize contamination (for example, hand and foot monitoring) are common areas of non-compliance.

Figure 83: Commercial sector vs. processing of nuclear substances sub-sector – Comparison of inspection ratings of operating performance

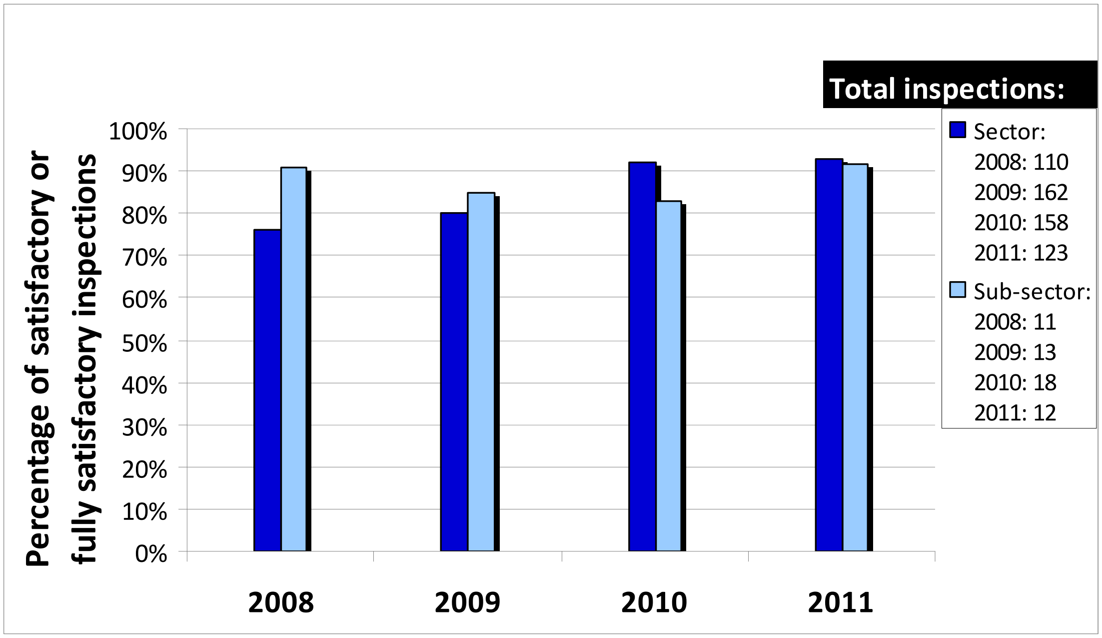
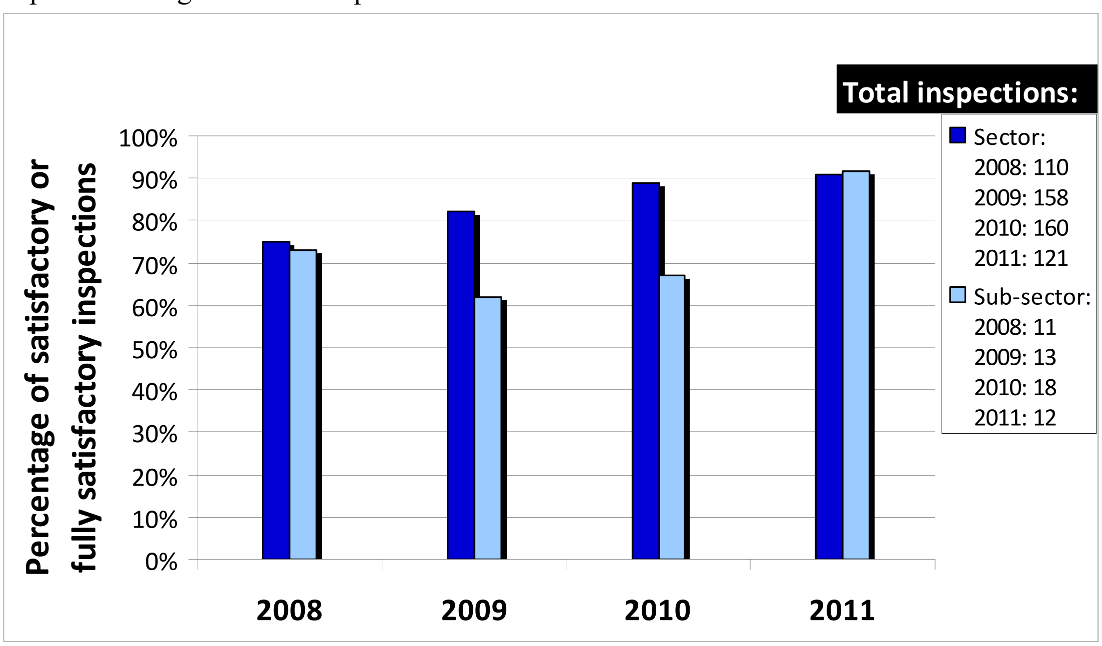


Figure 84: Commercial sector vs. processing of nuclear substances sub-sector – Comparison of inspection ratings of radiation protection



6.4.9 COMMERCIAL SECTOR – SUMMARY STATEMENT

Compared to previous years, the commercial sector showed modest improvement in its level of compliance in the safety areas of operating performance and radiation protection in 2011. Unfortunately, due to the failure of one licensee, a decline was noted in compliance with Sealed Source Tracking System (SSTS) requirements.

The total number of events reported by licensees in the commercial sector decreased substantially in 2011. The decrease was mainly due to an appreciable improvement in the area of spills, contamination and failed leak tests.

There were no orders issued in 2011 to licensees in this sector. The nuclear substance processing sub-sector demonstrated superior performance in the area of operational performance and radiation protection compared to the overall sector. Whole body and extremity occupational doses were at acceptable levels and essentially unchanged between 2008 and 2011.

7.0 CONCLUSION

In general, the 2,550 licence holders included in this report and involved in one of the four sectors exhibited positive gains in compliance in 2011. Occupational doses in all sectors were significantly lower than the regulatory limits. However, the sectors showed an increase in the number of reported events compared to 2010.

Radiation doses received by workers in 2011 remained generally constant when compared to 2010. Nuclear energy workers (NEWs) in all nuclear sectors received doses significantly lower than the regulatory limits of 50 mSv/year and 100 mSv over a five-year period, and no NEW exceeded 20 mSv in any given year.

Overall, there were 1,622 inspections performed in 2011, encompassing a review of licensees' operating performance. Licensees in all sectors showed improvement in their operating performance compliance levels when compared to the past three years.

In 2011, the CNSC performed 1,609 inspections of the radiation protection safety area with generally positive trends between 2008 and 2011. Three of the four sectors improved their compliance levels in radiation protection, the most notable increase being in the industrial sector. The only exception was the academic and research sector, which showed a very slight decrease. Although the medical sector has been showing continuous improvement in compliance since 2008, it is still lagging behind the other sectors when it comes to radiation protection inspection ratings.

With respect to the tracking of sealed sources, all sectors showed strong compliance with the CNSC's sealed source tracking requirements. In general, compliance levels were consistent with previous reporting years with the medical sector as well as the academic and research sector achieving 100% compliance.

The number of reportable events increased in 2011 to 129 from the 102 reported in 2010. This increase was more noticeable in the industrial sector due to a rise in the number of reported incidents involving portable gauges. On the other hand, the commercial sector saw a marked decrease in its number of reported events and incidents in 2011 compared to 2010.

None of the events or incidents reported to the CNSC in 2011 resulted in any person receiving a dose in excess of regulatory limits. In all cases, licensees implemented appropriate measures to mitigate the consequences and to limit radiation exposure to workers and the public.

Orders are a method for the CNSC to enforce regulatory compliance. Neither the medical nor the commercial sector had any orders issued to their licensees in 2011. However, the academic and research sector was issued its first order in four years. Of the 13 orders issued to the industrial sector, six were to portable gauge licensees, six to industrial radiography licensees, and one to an oil well logging licensee.

GLOSSARY

action level
A specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of a licensee's radiation protection program and triggers a requirement for specific action to be taken. (*seuil d'intervention*)

action notice
A written request that the licensee or a person subject to enforcement action take action to correct a non-compliance that is not a direct contravention of the *Nuclear Safety and Control Act*, applicable regulations, licence conditions, codes or standards, but that can compromise safety, security or the environment and may lead to a direct non-compliance if not corrected. (*avis d'action*)

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. (*cyclotron*)

enforcement
The set of activities associated with re-establishing compliance with regulatory requirements. (*application*)

exposure device
A radiation device 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. (*appareil d'exposition*)

fixed gauge
A radiation device attached to a structure and that enables the nuclear substance contained in it to be used for its radiation properties to measure process-related parameters (e.g., liquid flow, liquid level). (*jauge fixe*)

medical linear accelerator
An accelerator that produces high-energy photons (x-rays) for therapeutic purposes by delivering controlled doses of radiation in a collimated beam. (*accélérateur linéaire médical*)

natural background radiation
Radiation that is emitted from naturally occurring radioactive materials in the earth and from cosmic rays. (*rayonnement naturel*)

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 the person may receive a dose of radiation that is greater than the prescribed limit for the general public. (*travailleur du secteur nucléaire*)

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 health care team. (*technologue en médicine nucléaire*)

open source
A radioactive nuclear substance that is not contained in a sealed capsule or cover. (*source non scellée*)

portable gauge
A portable radiation device that enables the nuclear substance contained in it to be used for its radiation properties to measure material property (e.g., material thickness, density, moisture content). (*jauge portative*)

prescribed equipment
Equipment prescribed by section 20 of the *General Nuclear Safety and Control Regulations*. (*équipement réglementé*)

prescribed information
Information prescribed by section 21 of the *General Nuclear Safety and Control Regulations*. (*renseignements réglementés*)

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. (*appareil à rayonnement*)

radiation oncologist
A physician licensed by the appropriate provincial or territorial medical regulatory authorities who specializes in the treatment of cancer patients using radiation therapy as the main form of treatment. (*radio-oncologue*)

radiation therapist
A medical radiation technologist certified by the Canadian Association of Medical Radiation Technologists. The radiation therapist works in the field of radiation therapy and performs various duties such as planning treatment details, calculating radiation dose, positioning the patient, operating the medical linear accelerator equipment, and counselling patients on possible side effects from the treatment. (*radiothérapeute*)

radiopharmaceutical
A drug containing a radioactive substance that is used in medical imaging and cancer treatment. (*produit radiopharmaceutique*)

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. (*source scellée*)

APPENDIX A – REGULATORY PROCESS FOR NUCLEAR SUBSTANCES

The Canadian Nuclear Safety Commission (CNSC) regulates the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information in Canada. Through its licensing, certification and compliance processes, the CNSC ensures that nuclear activities are carried out safely in order to protect people, their health and the environment. The CNSC also works to ensure that Canadians and Canadian companies implement Canada's international commitments on the peaceful use of nuclear energy.

The CNSC uses a risk-informed regulatory system based on transparency, integration of effort, and a comprehensive risk-informed approach to licensing and compliance. Facilities and operations are ranked according to the health and safety risks posed by their licensed activities. The CNSC's regulatory effort, from a licensing and compliance perspective, is based on this ranking.

The basis of a risk-informed approach is that licensed activities deemed to be of high or medium risk are subject to a higher degree of regulatory control. This control includes more frequent and in-depth inspections to verify compliance with the *Nuclear Safety and Control Act*, regulations and licence conditions.

Each licensed activity is assigned a weighting factor to develop an overall risk value. A weighting factor is a coefficient assigned to licensed activities to represent their relative importance in terms of risk. Issues considered in weighting include certain aspects such as the form of the material (sealed source, open source or radiation device), where the material is used (public or controlled facility) and the history of problems with the licensed activity. Other weighting factors (e.g., compliance histories) are used in determining overall risk values for individual licensees. By using risk values and weighting factors, overall risks are calculated for each licensed activity. Generally, all high-risk licensees are inspected over a five-year period.

The risk-informed regulatory program is designed to have the following outcomes:

- a risk ranking that recognizes the influence of licensee performance
- effective administration of regulatory effort based on the risk ranking by licensed activity
- licensing and compliance activities that are effective, consistent, fully integrated, risk-informed and communicated to stakeholders

The CNSC licensing process starts with an applicant's submission for a new licence, an amendment, a renewal or a revocation of a current licence. CNSC staff assess the application for such things as completeness, radiation safety and training manuals, as well as previous reports of inspections, events and annual compliance.

Licences can be issued either by the Commission Tribunal or by designated officers who have been authorized by the Tribunal to issue, renew, amend, revoke or replace a licence, as well as to certify and decertify persons and equipment. If a decision is made not to issue a licence, the applicant has an opportunity to be heard by the designated officer or the Commission Tribunal.

A key part of the CNSC's regulatory approach is its compliance program, which monitors licensee conformance with regulatory requirements and licence conditions. This program also aims to maintain a safe nuclear sector and ensure that Canada meets its international obligations on the peaceful use of nuclear energy and materials.

Although a five-letter system is often used for operational purposes during compliance inspection, the CNSC adopted a four-level compliance rating system in 2008 for reporting purposes. The following table shows the correspondence between the two rating systems:

<table>
<tr><th colspan="2">Four Compliance Ratings Used for Reporting Purposes</th><th colspan="2">Five Compliance Ratings Used for Operational Purposes</th></tr>
<tr><td>FS</td><td>Fully satisfactory</td><td>A</td><td>Exceeds requirements</td></tr>
<tr><td>SA</td><td>Satisfactory</td><td>B</td><td>Meets requirements</td></tr>
<tr><td>BE</td><td>Below requirements</td><td>C</td><td>Below requirements</td></tr>
<tr><td rowspan="2">UA</td><td rowspan="2">Unacceptable</td><td>D</td><td>Significantly below requirements</td></tr>
<tr><td>E</td><td>Unacceptable</td></tr>
</table>

Finally, enforcement actions are required where CNSC staff identify issues of non-compliance. Enforcement measures follow a graduated approach and can include everything from a simple written notification and the requirement for remedial action to the issuance of an order, increased regulatory scrutiny, and revocation of a licence or prosecution.

Enforcement actions are selected based on the impact or potential impact of the non-compliance on the health and safety of persons, security, the environment and international obligations. Also considered are the circumstances that led to and followed the non-compliance, the licensee's compliance record, and any CNSC operational or legal constraints or risks. In all cases, the CNSC follows up on all enforcement actions until they are resolved or completed.

APPENDIX B – DEFINITIONS OF SAFETY AND CONTROL AREAS

When performing compliance inspections, CNSC staff focus their attention on a number of safety and control areas. This report covers two of them, namely operating performance and radiation protection, except in the case of high-energy research particle accelerators discussed in section 6.3.8.2. For this reason, the following table defines all safety and control areas:

Functional area	Safety and control area	Definitions
Management	Management system	Covers the framework that establishes the processes and programs required to ensure an organization achieves its safety objectives and continuously monitors its performance against these objectives and fostering a healthy safety culture.
	Human performance management	Covers activities that enable effective human performance through the development and implementation of processes that ensure that licensee staff is sufficient in number in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.
	Operating performance	This includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.
Facility and equipment	Safety analysis	Maintenance of the safety analysis that supports that overall safety case for the facility. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and considers the effectiveness of preventative measures and strategies in reducing the effects of such hazards.
	Physical design	Relates to activities that impact on the ability of systems, components and structures to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account.
	Fitness for service	Covers activities that impact on the physical condition of systems, components and structures to ensure that they remain effective over time. This includes programs that ensure all equipment is available to perform its intended design function when called upon to do so.

Functional area	Safety and control area	Definitions
Core control processes	Radiation protection	Covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations*. This program must ensure that contamination and radiation doses received are monitored and controlled.
	Conventional health and safety	Covers the implementation of a program to manage workplace safety hazards and to protect personnel and equipment.
	Environmental protection	Covers programs that identify, control and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities.
	Emergency management and fire protection	Covers emergency plans and emergency preparedness programs that exist for emergencies and for non-routine conditions. This also includes any results of exercise participation.
	Waste management	Covers internal waste-related programs that form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. Also covers the planning for decommissioning.
	Security	Covers the programs required to implement and support the security requirements stipulated in the regulations, in their license, in orders, or in expectations for their facility or activity.
	Safeguards and Non-Proliferation	Covers the programs required for the successful implementation of the obligations arising from the Canada/IAEA safeguards agreements as well as all other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.
	Packaging and transport	Programs that cover the safe packaging and transport of nuclear substances and radiation devices to and from the licensed facility.

APPENDIX C – CONSOLIDATED DATA: COMPARISON OF SECTORS

C.1 NUMBER OF LICENCES BY SECTOR

Sector	Number of licences as of December 31, 2008	Number of licences as of December 31, 2009	Number of licences as of December 31, 2010	Number of licences as of December 31, 2011
Medical	635	602	593	568
Industrial	1,703	1,540	1,482	1,456
Academic and research	325	293	290	276
Commercial	303	278	257	250
Total	2,966	2,713	2,622	2,550

C.2 DOSES TO WORKERS

C.2.1 ANNUAL WHOLE BODY DOSES TO WORKERS, 2011

Sector	Number of workers at sampled ACRs	Percentage of workers by dose range (mSv)				
		<0.5	0.5 to 1	1 to 5	5 to 20	>20
Medical	3,589	89.2%	3.3%	7.3%	0.2%	0.0%
Industrial* (without portable gauges)	7,764	86.9%	7.1%	4.5%	1.5%	0.0%
Portable gauge sub-sector	413	80.9%		17.9%	1.2%	0.0%
Academic and research	2,663	94.7%	2.1%	3.1%	0.0%	0.0%
Commercial	1,099	71.5%	9.0%	18.5%	1.0%	0.0%

C.2.2 ANNUAL WHOLE BODY DOSES TO WORKERS, 2010

Sector	Number of workers at sampled ACRs	Percentage of workers by dose range (mSv)				
		<0.5	0.5 to 1	1 to 5	5 to 20	>20
Medical	4,971	89.3%	3.5%	6.8%	0.3%	0.0%
Industrial* (without portable gauges)	5,744	92.3%	3.8%	3.6%	0.3%	0.0%
Portable gauge sub-sector	641	80.3%		19.0%	0.6%	0.0%
Academic and research	1,855	94.9%	1.2%	3.3%	0.6%	0.0%
Commercial	1,059	72.5%	10.6%	15.8%	1.1%	0.0%

* Because portable gauge licensees use a different dose reporting range in their annual compliance reports, their dose data are reported separately from those of other industrial licensees.

Note: The sum of the percentages may not add up to 100% due to rounding.

C.2.3 ANNUAL WHOLE BODY DOSES TO WORKERS, 2009

Sector	Number of workers at sampled ACRs	Percentage of workers by dose range (mSv)				
		<0.5	0.5 to 1	1 to 5	5 to 20	>20
Medical	4,775	92.2%	2.7%	4.9%	0.1%	0.0%
Industrial* (without portable gauges)	10,083	90.3%	4.2%	5.0%	0.4%	0.0%
Portable gauge sub-sector	1,270	85.6%		14.1%	0.3%	0.0%
Academic and research	1,894	95.1%	1.4%	3.0%	0.4%	0.0%
Commercial	838	66.6%	10.6%	21.2%	1.6%	0.0%

C.2.4 ANNUAL WHOLE BODY DOSES TO WORKERS, 2008

Sector	Number of workers at sampled ACRs	Percentage of workers by dose range (mSv)				
		<0.5	0.5 to 1	1 to 5	5 to 20	>20
Medical	4,230	90.6%	3.3%	6.0%	0.1%	0.0%
Industrial* (without portable gauges)	7,245	85.9%	5.2%	7.3%	1.6%	0.0%
Portable gauge sub-sector	1,717	91.1%		8.6%	0.3%	0.0%
Academic and research	1,968	93.6%	2.3%	3.4%	0.7%	0.0%
Commercial	730	69.6%	11.1%	18.2%	1.1%	0.0%

* Because portable gauge licensees use a different dose reporting range in their annual compliance reports, their dose data are reported separately from those of other industrial licensees.

Note: The sum of the percentages may not add up to 100% due to rounding.

C.3 INSPECTION RATINGS FOR OPERATING PERFORMANCE

C.3.1 INSPECTION RATINGS OF OPERATING PERFORMANCE, 2011

Sector	Total inspections	Fully satisfactory	Satisfactory	Below requirements	Unacceptable
Medical	264	0%	86%	12%	2%
Industrial	932	0%	86%	10%	4%
Academic and research	303	0%	84%	14%	2%
Commercial	123	0%	93%	7%	1%

C.3.2 INSPECTION RATINGS OF OPERATING PERFORMANCE, 2010

Sector	Total inspections	Fully satisfactory	Satisfactory	Below requirements	Unacceptable
Medical	258	0%	83%	14%	3%
Industrial	771	0%	81%	14%	5%
Academic and research	400	0%	85%	15%	1%
Commercial	158	0%	92%	8%	1%

C.3.3 INSPECTION RATINGS OF OPERATING PERFORMANCE, 2009

Sector	Total inspections	Fully satisfactory	Satisfactory	Below requirements	Unacceptable
Medical	290	0%	78%	18%	4%
Industrial	769	0%	81%	13%	5%
Academic and research	242	0%	74%	22%	4%
Commercial	162	0%	80%	17%	4%

C.3.4 INSPECTION RATINGS OF OPERATING PERFORMANCE, 2008

Sector	Total inspections	Fully satisfactory	Satisfactory	Below requirements	Unacceptable
Medical	242	2%	83%	12%	3%
Industrial	838	0%	76%	16%	8%
Academic and research	291	0%	78%	16%	6%
Commercial	110	0%	76%	20%	4%

Note: The sum of the percentages may not add up to 100% due to rounding.

C.4 INSPECTION RATINGS FOR RADIATION PROTECTION

C.4.1 INSPECTION RATINGS OF RADIATION PROTECTION, 2011

Sector	Total inspections	Fully satisfactory	Satisfactory	Below requirements	Unacceptable
Medical	264	0%	72%	24%	4%
Industrial	928	0%	87%	9%	4%
Academic and research	296	0%	78%	20%	2%
Commercial	121	0%	91%	7%	2%

C.4.2 INSPECTION RATINGS OF RADIATION PROTECTION, 2010

Sector	Total inspections	Fully satisfactory	Satisfactory	Below requirements	Unacceptable
Medical	254	0%	69%	24%	8%
Industrial	771	0%	78%	15%	7%
Academic and research	393	0%	80%	18%	2%
Commercial	160	0%	89%	9%	3%

C.4.3 INSPECTION RATINGS OF RADIATION PROTECTION, 2009

Sector	Total inspections	Fully satisfactory	Satisfactory	Below requirements	Unacceptable
Medical	291	2%	63%	17%	19%
Industrial	772	0%	73%	12%	16%
Academic and research	241	0%	67%	23%	10%
Commercial	158	0%	82%	11%	6%

C.4.4 INSPECTION RATINGS OF RADIATION PROTECTION, 2008

Sector	Total inspections	Fully satisfactory	Satisfactory	Below requirements	Unacceptable
Medical	242	3%	54%	24%	19%
Industrial	837	0%	72%	14%	14%
Academic and research	287	0%	63%	24%	12%
Commercial	110	0%	75%	15%	10%

Note: The sum of the percentages may not add up to 100% due to rounding.

C.5 INSPECTION RATINGS FOR SEALED SOURCE TRACKING

C.5.1 INSPECTION RATINGS OF SEALED SOURCE TRACKING, 2011

Sector	Total inspections	Fully satisfactory	Satisfactory	Below requirements	Unacceptable
Medical	5	0%	100%	0%	0%
Industrial	173	0%	97%	3%	0%
Academic and research	36	0%	100%	0%	0%
Commercial	13	0%	92%	8%	0%

C.5.2 INSPECTION RATINGS OF SEALED SOURCE TRACKING, 2010

Sector	Total inspections	Fully satisfactory	Satisfactory	Below requirements	Unacceptable
Medical	7	0%	100%	0%	0%
Industrial	208	0%	88%	8%	4%
Academic and research	55	0%	96%	4%	0%
Commercial	9	0%	100%	0%	0%

C.5.3 INSPECTION RATINGS OF SEALED SOURCE TRACKING, 2009

Sector	Total inspections	Fully satisfactory	Satisfactory	Below requirements	Unacceptable
Medical	16	0%	94%	6%	0%
Industrial	117	0%	91%	4%	5%
Academic and research	46	0%	96%	2%	2%
Commercial	10	0%	90%	0%	10%

C.5.4 INSPECTION RATINGS OF SEALED SOURCE TRACKING, 2008

Sector	Total inspections	Fully satisfactory	Satisfactory	Below requirements	Unacceptable
Medical	2	0%	50%	0%	50%
Industrial	37	0%	87%	5%	8%
Academic and research	12	0%	100%	0%	0%
Commercial	1	0%	100%	0%	0%

C.6 REPORTED EVENTS AND INCIDENTS

C.6.1 REPORT ED EVENTS AND INCIDENTS, 2011

Sector	Total	Malfunctioning or damaged devices	Spill, contamination and failed leak test incidents	Missing and recovered nuclear substances	Breach of security	Packaging and transport
Medical	19	2	13	3	1	0
Industrial	83	51	0	13	4	15
Academic and research	7	3	4	0	0	0
Commercial	20	4	7	1	0	8
Total	129	60	24	17	5	23

C.6.2 REPORT ED EVENTS AND INCIDENTS, 2010

Sector	Total	Malfunctioning or damaged devices	Spill, contamination and failed leak test incidents	Missing and recovered nuclear substances	Breach of security	Packaging and transport
Medical	12	2	10	0	0	0
Industrial	52	32	1	10	4	5
Academic and research	6	3	3	0	0	0
Commercial	32	2	22	0	0	8
Total	102	39	36	10	4	13

C.6.3 REPORT ED EVENTS AND INCIDENTS, 2009

Sector	Total	Malfunctioning or damaged devices	Spill, contamination and failed leak test incidents	Missing and recovered nuclear substances	Breach of security	Packaging and transport
Medical	6	0	5	0	0	1
Industrial	27	14	0	4	0	9
Academic and research	4	0	0	3	1	0
Commercial	11	0	4	2	0	5
Total	48	14	9	9	1	15

C.6.4 REPORT ED EVENTS AND INCIDENTS, 2008

Sector	Total	Malfunctioning or damaged devices	Spill, contamination and failed leak test incidents	Missing and recovered nuclear substances	Breach of security	Packaging and transport
Medical	27	3	14	5	0	5
Industrial	55	37	0	7	2	9
Academic and research	3	2	0	0	1	0
Commercial	7	0	5	0	0	2
Total	92	42	19	12	3	16

C.7 ENFORCEMENT ACTIVITIES

C.7.1 ORDERS

Sector	2008	2009	2010	2011
Medical	0	0	1	0
Industrial	2	7	7	13
Academic and research	0	0	0	1
Commercial	1	1	1	0
Total	3	8	9	14

C.7.2 DECERTIFICATION OF EXPOSURE DEVICE OPERATORS

Sector	2008	2009	2010	2011
Industrial* **	0	1	2	0

*** All certified exposure device operators work in the industrial sector – more specifically, in industrial radiography.

APPENDIX D – ABBREVIATIONS

These abbreviations are also defined when first used in the text.

ACR	annual compliance report
ALARA	As Low as Reasonably Achievable
CNSC	Canadian Nuclear Safety Commission
mSv m	illisievert
NEW	nuclear energy worker
NSCA	*Nuclear Safety and Control Act*
NSSR	National Sealed Source Registry
PET	positron emission tomography
SSTS	Sealed Source Tracking System