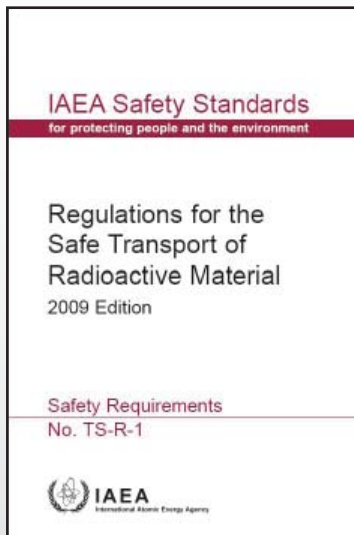




DNSR Newsletter

Review of IAEA Transport Regulations

Last year, the International Atomic Energy Agency (IAEA) initiated a review of the 2009 edition of its *Regulations for the Safe Transport of Radioactive Material (TS-R-1)*. The document had already been reviewed through consultant meetings, as well as by the IAEA's Transport Safety Standards Committee (TRANSSC), the Nuclear Safety Standards Committee (NUSSC), the Waste Safety Standards Committee (WASSC), and the Radiation Safety Standards Committee (RASSC).



The objective of TS-R-1 is to establish requirements to ensure safety and to protect persons, property and the environment from the effects of radiation during the transport of radioactive material(s). This protection is achieved by requiring:

- containment of the radioactive contents
- control of external radiation levels
- prevention of criticality
- prevention of damage caused by heat

The IAEA requested a review of the working document for TS-R-1, as well as any comments related to the following:

- Relevance and usefulness: Is the stated objective of the document appropriate, and is it met by the document?
- Scope and completeness: Is the stated scope appropriate, and is that scope adequately covered by the document?

- Quality and clarity: Do the requirements in the document represent the current consensus among specialists in the field and are they expressed clearly and coherently?

The CNSC's Transport Licensing and Strategic Support Division (TLSSD) coordinated the Canadian review of the above working document. Comments were consolidated by TLSSD and transmitted to the International Atomic Energy Agency.



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Overview of the Accelerators and Class II Facilities Division

The CNSC's Accelerators and Class II Facilities Division (ACFD) is responsible for regulating accelerators and Class II facilities in Canada. The division has 16 staff members, under the direction of Ms. Kavita Murthy.

The division is responsible for licensing, certification of prescribed equipment (e.g. radiation therapy equipment, brachytherapy equipment, etc.), certification of radiation safety officers, and the verification of licensees' compliance with the *Nuclear Safety and Control Act* (NSCA), its regulations and licences conditions. The division also regulates Class I accelerators, such as those operated by TRIUMF in Vancouver, BC, and Canadian Light Source Inc. in Saskatoon, SK.

ACFD issues five types of licences, which include a licence to construct, licence to commission, licence for normal operation, licence to decommission, and a licence to service prescribed equipment. Licence terms range from five to ten years. The division also issues certificates for Class II prescribed equipment, which are issued for a period of ten years. There are currently about 250 active licences and over 100 certificates in place. Since late May 2010, the division has also been responsible for the certification of radiation safety officers.

Among the Class II facilities under the ACFD's responsibility are cancer clinics with radiation therapy devices – such as medical particle accelerators, radioactive source teletherapy machines, and brachytherapy machines that place a radioactive source in contact with a tumour. The division also regulates particle accelerators that produce radioisotopes used in medical diagnosis and treatment. In addition, the division regulates some industrial irradiators.

ACFD uses three methods to verify the licensees' compliance: the review of annual compliance reports, and the conduct of Type I and Type II inspections.


Annual compliance reports

The licensee must complete a form containing specific questions that enable the division staff to evaluate the licensee's compliance with the NSCA and its regulations. This form is currently available in PDF format on the CNSC Web site. In the near future, the form will be available in an interactive format.

Type I inspections

These inspections are in-depth visits to facility sites. They normally take a full week, and are aimed at identifying the strengths and weaknesses of the institutions. All cancer clinics have been or will soon be visited by the division's inspectors.

Type II inspections

These are brief visits to the licensed facilities, and normally take a day or two. They focus on the verification of certain performance indicators and on situations of non-compliance with the NSCA and its regulations. These inspections are carried out mainly on small research centres and facilities with small staff complements, and follow up on Type I inspections. 




Ms. Kavita Murthy is Director of the Accelerators and Class II Facilities Division.

Industrial Radiography Working Group Update

As part of the Industrial Radiography Working Group's commitment to open communication between stakeholders in the radiography industry and the CNSC, meetings were organized in Nisku, Alberta, and Ottawa, Ontario, in May and June 2010, respectively. Both meetings were well attended, with 45 participants in Nisku and 19 in Ottawa.

Presentations covered a variety of topics, such as a review of radiography compliance performance data, event reporting, communication, and a case study. The meetings also included a session on the transportation requirements surrounding exposure devices. Attendees expressed their appreciation for the updates and for the degree of communication displayed by the CNSC and industry.

The Working Group also made a presentation to the Commission Tribunal on September 30, where CNSC staff provided an update on the implementation of the Industrial Radiography Strategy. A transcript of the presentation and the official minutes of the Commission Tribunal meeting are available on the CNSC Web site. 



Certification of Radiation Devices and Prescribed Equipment

Radiation devices (devices) and Class II prescribed equipment (equipment) are regulated under the [NSCA](#) and must be certified by the CNSC for use in Canada. These requirements are spelled out in paragraph 10(a) of the [Class II Nuclear Facilities and Prescribed Equipment Regulations](#) (CIINFPER) and subsection 11(1) of the [Nuclear Substances and Radiation Devices Regulations](#) (NSRDR).

In addition, NSRDR subsection 11(2) also prohibits the transfer of uncertified radiation devices for use by others. The only exemptions from certification are given in CIINFPER paragraph 10(b) and NSRDR subsection 11(2). These exemptions are intended for equipment and devices that are unique in that they cannot be bought “off the shelf” or marketed commercially, and they must not be used on humans. The equipment and devices covered by these exemptions are used for conducting research or for developing a product line (usually by Canadian manufacturers).

The CNSC’s goal is to ensure that the equipment and devices are safe to use. The certification process focuses on safety aspects related to workers who will operate the equipment and devices, as well as safety of the public and other personnel in the vicinity.


CNSC staff looks at the equipment or device system as a whole and evaluates the safety components that are included in it. Since the regulations only address the use of the device, the onus is on the end-user of the equipment or device, or the licensee, to ensure that it is certified by the CNSC. This does not mean that the licensee must be the owner of the certificate but rather that the licensee should make sure that the equipment or devices are certified before use or transfer for use. Certificate verification is accomplished by one of the following means:

1. visiting the CNSC Web page: nuclearsafety.gc.ca/eng/licenseesapplicants/substancesdevices/index.cfm and clicking on the link to either the “List of Certified Class II Prescribed Equipment” or the “List of Certified Radiation Devices.” These links contain all the equipment and devices that have been issued a CNSC certificate
2. contacting by phone or email the CNSC staff member responsible for the specific licence
3. sending a request to the CNSC’s info@cnsccsn.gc.ca account
4. requesting from the manufacturer a copy of a valid certificate for that prescribed equipment or radiation device

If the equipment or device being considered for use is not found on either of the above lists, or if the certificate validation period has expired, the CNSC should be contacted for further information.

For equipment or devices intended for use on humans, the manufacturer must obtain a medical device licence from Health Canada in addition to a CNSC certificate. The licensee’s process for equipment or device procurement should ensure that all regulatory approvals are in place. The purchaser should also obtain evidence from the manufacturer that the equipment or device is certified or that it is in the process of being certified by the CNSC.

A list of all medical devices that are currently licensed for sale in Canada, or have been licensed in the past, is maintained by Health Canada on its Web site, mdall.ca.


The CNSC’s certification process is complex and the service standard for CNSC staff to review applications for equipment or device certification is six months. 

Changes to the Annual Compliance Report

In the coming months, licensees will notice a change in the requested information on the Annual Compliance Report (ACR). Reporting information has been updated to better reflect the CNSC’s requirements for licensee compliance assessments.

Changes will also be made in the way reports can be submitted to the CNSC. A secure online reporting system is being developed that will allow licensees to submit their ACR electronically. Current options include submission by mail, by fax or as an attachment to an email.

This new Web-based option will allow users to update their ACR any time during the reporting period and save the document to their hard drive for future use. In addition, it will provide an efficient method of formatting and submitting inventory details.

Watch for future details on the launch of the Web-based ACR reporting system, and on how radiation safety officers and contributors can obtain authorization codes to use the system. 



Use of Multiple Dosimeters

In today's economy, it is not uncommon for people to work at two or more jobs. Questions often arise when workers are required to wear dosimeters to record the radiation doses they may receive.

Recently, the Directorate of Nuclear Substance Regulation had to answer this important question: Should an employee – typically a nuclear energy worker (NEW) – have separate dosimeters issued by each employer, or could the worker just wear a single dosimeter at all employment sites?

The simple answer is that a worker should wear the dosimeter provided by the employer while conducting work under that employer's licence and not wear the same dosimeter for each job. It is important to know where any potential radiation dose originates.

The CNSC also has the following expectations:

- When a worker is hired, their dose history is obtained for planning purposes and to assess if the employee would be at risk of reaching a dose limit.
- Each CNSC licensee is responsible for assessing the exposure potential of a worker. This way, licensees are not relying on each other to designate the person's status.

In the end, these issues may require an assessment by the CNSC on a case by case basis.

If a worker is employed by several different employers, the worker must have a dosimeter and dose record from each employer. The doses can be consolidated by the employers, to create the worker's total dose record. Each employer must ensure that the worker's dose limit is not exceeded as a result of their licensed activities. ✎

Decertification of the GammaMat M10, Certification of the M10-1

The CNSC issued a decision to decertify the GammaMat M10 exposure device on November 27, 2010. The exposure device, manufactured by MDS Nordion, was used in industrial radiography and was covered under CNSC certificate number R-434-0006.

The decision to decertify was based on a request that MDS Nordion made to the CNSC and is a result of MDS Nordion not sufficiently demonstrating that the radiation device met current applicable exposure devices standards. Read the [Decision Document \(PDF\)](#) on the nuclearsafety.gc.ca Web site.

Following an application from MDS Nordion, the GammaMat M10-1 exposure device was reviewed by the CNSC. This new device meets the applicable standards and was certified on November 26, 2010, under certificate number R-005-0008. ✎

Two Exposure Device Operators Decertified

The CNSC recently decertified two exposure device operators, for unsafe operating practices.

On May 4, 2010, the CNSC decertified Mr. Cody Hankinson of Corner Brook, Newfoundland, as a Certified Exposure Device Operator (CEDO).

The decision to decertify Mr. Hankinson stemmed from a recommendation made by the CNSC's Operations Inspection Division on February 9, 2010, as a result of a compliance inspection that took place in January 2010. It was observed that Mr. Hankinson did not use a survey meter to ensure the source was safely retracted following exposures, Mr. Hankinson knowingly made a false verbal statement to a CNSC inspector, and Mr. Hankinson did not post barriers and warning signs as required.

On June 1, 2010, the CNSC also decertified Mr. Jimmy St-Laurent, of Vanier, Québec, as a CEDO.

The decision to decertify Mr. St-Laurent resulted from a recommendation made by the CNSC's Operations Inspection Division on March 3, 2010, as a result of an investigation that was conducted in response to an incident that took place in December 2009. Mr. St-Laurent did not use a survey meter to ensure the radioactive source was safely retracted following exposures, and Mr. St-Laurent failed to wear the proper dosimeters while operating the exposure device.

Both Mr. Hankinson and Mr. St-Laurent were required to immediately return their Exposure Device Operator certificate to the CNSC. ✎



Orders Issued

The [NSCA](#) gives authority to the Commission Tribunal of the CNSC, through its designated officers and inspectors, to issue orders for the purposes of the NSCA. They may order a licensee to take any measure considered necessary to protect the environment, the health or safety of persons, or to maintain national security or compliance with international obligations to which Canada has agreed.

On June 10, 2010, the CNSC issued an order to **C.T. Soil and Materials Testing Inc.**, of Windsor, Ontario, a geotechnical engineering, geo-environmental assessment and construction materials testing company.

Following two CNSC inspections, conducted at a field location on June 10, 2010, and at the company's offices on June 11, the company was ordered to cease using radiation devices licensed by the CNSC, and to immediately put the equipment into storage. The company had to demonstrate that adequate management control over work practices has been established, and that acceptable training has been provided to its staff, so that the licensed radiation devices can be used safely and in compliance with regulatory requirements. The company complied with the order.

On June 1, 2010, the CNSC issued an order to **Elekta Inc.**, a manufacturer of medical linear accelerators based in Norcross, Georgia, USA, to immediately suspend its Canadian sales and services of the Elekta Infinity model linear accelerator. The company was ordered to submit to the CNSC, by June 2, 2010, an application for the certification of the Elekta Infinity model accelerator. Furthermore, the order required Elekta to limit its servicing activities for these accelerators to those interventions that, if not carried out, could compromise the health and safety of patients or operators.

Also on June 1, 2010, the CNSC issued an order to the **Southlake Regional Health Centre** in Newmarket, Ontario. The order required the Health Centre to submit a complete licence application by June 4, 2010, for the operation of the Elekta Infinity model medical linear accelerator. Furthermore, the order required the Health Centre to provide evidence to the CNSC, demonstrating that the operation of the Elekta Infinity does not pose a risk to the workers at the Health Centre or to patients undergoing treatment with this brand of accelerator. The CNSC required the Southlake Regional Health Centre to assume all liabilities with respect to the use of the Elekta Infinity accelerator.

Both Elekta Inc. and the Southlake Regional Health Centre complied with all the terms and conditions of the orders.


The CNSC issued a Class II Prescribed Equipment Certificate for the Elekta Infinity accelerator, and amended the licence issued to Elekta Inc. to permit servicing on the newly certified accelerator. The CNSC also amended the licences issued to the Southlake Regional Health Centre, to authorize the operation and servicing of the Elekta Infinity accelerator at this facility.

As a result of an inspection on May 27, 2010, the CNSC issued an order to **Canada Engineering Services Inc.** of Toronto, a geotechnical and environmental materials consulting company.

The order required the company to cease the use of CNSC-licensed radiation devices and to immediately put the equipment into storage. The company also had to demonstrate that an acceptable radiation safety program has been implemented, and that the workers using the radiation devices are adequately trained. The company complied with the order.

As a result of an inspection on May 10, 2010, the CNSC issued an order to **SPL Consultants Limited** of Vaughan, Ontario, a geotechnical and environmental materials consulting company.

The order required the company to cease the use of CNSC-licensed radiation devices, and to immediately put the equipment into storage. The company also had to demonstrate that adequate training has been provided to its staff, so that the radiation devices can be used safely. The company complied with the order.

The CNSC issued an order on September 23, 2010, to **Harold Sutherland Construction Ltd.** of Kemble, Ontario to cease the use of radiation devices licensed by the CNSC, and to immediately put the equipment into storage. The company was also required to implement an effective radiation protection program, corrective measures to address the regulatory non-compliances identified during the inspection, and provide training to their workers so that the licensed radiation devices can be used safely and in compliance with regulatory requirements. The company complied with the order. 

DNSR Newsletter

The *DNSR Newsletter* is a CNSC publication. If you have any suggestions on topics or issues that you would like to see covered, please do not hesitate to contact us.

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ISSN 1920-7484 (Print)
ISSN 1920-7492 (Online)

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