

RADIATION PROTECTION, CCMB

E: CCMBMPX-rayCompliance@cancercare.mb.ca

An overview of the mandatory requirements and supporting services of Radiation Protection, CCMB.

1.0 Purpose

This overview provides information for owners of X-ray equipment in Manitoba. It outlines steps for the safe and legal installation and operation of X-ray equipment in Manitoba.

2.0 Radiation Protection, CCMB

2.1 Radiation Protection, CancerCare Manitoba, is responsible to the Government of Manitoba, to provide leadership on radiation protection responsibilities that fall within the regulatory jurisdiction of the province under the authority of Manitoba Health.

2.2. The X-ray compliance group of Radiation Protection Officers are provincially appointed as inspectors with responsibility for ensuring compliance with provincial regulations. They provide expertise on all aspects of radiation safety and regulate the use of ionizing medical equipment in Manitoba bound by:

- Manitoba Regulation 341/88R, an X-ray Safety Regulation under the Public Health Act.
[X-ray Safety Regulation](#)
- Bill 37, The Radiation Protection Act.
[The Radiation Protection Act](#)
- The Radiation Emitting Devices Act.
[Radiation Emitting Devices Act](#)
- Health Canada Safety Codes provide guidance for our operations (SC 30, 35, 36).
[Health Canada Safety Codes](#)

3.0 Responsibility of the Owner of X-ray Equipment

3.1 The owner of the x-ray equipment is responsible for the radiation safety of the facility. The owner can delegate radiation safety tasks but not the responsibility. The owner must ensure that the x-ray equipment and the facility where such equipment is installed and used meet applicable legislation and regulations. In addition, the owner must comply with all recommendations to retain ministerial permission to operate x-ray equipment.

3.2 X-ray Equipment Location and Shielding Specifications

- a. When a new facility is being designed or an existing facility is being renovated, the owner (or representative) must contact Radiation Protection, CCMB to obtain approval for:
 - The location of the x-ray equipment before proceeding with installation and operation.
 - Shielding specifications required for the x-ray room prior to renovation and/or construction. X-ray facilities must be shielded such that the estimated radiation doses to occupationally exposed staff and the public will be less than 1 mSv per year.
- b. Radiation Protection, CCMB, is responsible for the determination of shielding requirements for a given facility prior to the construction and installation of X-ray imaging equipment. It is mandatory to contact Radiation Protection, CCMB, CCMBMPX-rayCompliance@cancercare.mb.ca for the following prior to construction and installation of x-ray equipment:

A *Barrier Questionnaire* form(s) must be obtained from Radiation Protection, CCMB. This form must be completed and returned to Radiation Protection, CCMB. It will require the following:

1. A floor plan of the facility to include:
 - a) Floor plan must be to scale.
 - b) Floor plan must have compass direction.
 - c) Floor plan must have areas identified beyond the walls, floor, and ceiling of the X-ray room.
 - d) Beam direction(s).

- e) Floor plan must have the location of the x-ray equipment including (but not limited to): x-ray table, vertical image holder, travel limits of the x-ray tube, control room, console, remote switches.
 2. Facility name, address, and owner of x-ray equipment.
 3. Type of x-ray equipment to include manufacturer and model name.
 4. Construction information.
 5. Completion of *Workload* form which is an estimated measure of the radiation output in one week.
- c. Once all the information is obtained, Radiation Protection, CCMB, will calculate the shielding requirements.
- Shielding is calculated so that radiation doses shall be less than 1 mSv/year for persons occupationally exposed and for members of the public. It is based on the workload and surroundings (occupancy) of the X-ray suite(s).
 - A barrier specification letter will be issued to the owner/facility indicating the required shielding for each wall, door, floor, and ceiling (if applicable). Please note: Vigilance in adhering to obtaining all the required information will minimize construction and operational delays.
 - Radiation Protection, CCMB, will also maintain records of the floor plan and shielding specifications.
- d. Shielding Inspection:
A Radiation Protection Officer will conduct an on-site shielding inspection to verify the efficacy of barriers post-installation for the specified X-ray room. Once approved, by Radiation Protection, CCMB, the walls may be covered with the desired finish.

3.5 Installation of X-ray Equipment

- a. All medical X-ray equipment (new or used) and accessories, purchased or leased in Canada must conform to the requirements of:
 - The Radiation Emitting Devices Act and Regulations [Red Act](#)
 - The Food and Drugs Act's Medical Devices Regulations for diagnostic X-ray equipment [Food and Drugs Act](#)

- b. X-ray units are considered to be a Class 3 medical device and in order for these devices to be imported or sold in Canada, they must hold a valid Health Canada Medical Device Licence as indicated by Health Canada Medical Device Regulations [Medical Devices Regulations MDALL](#) contains product-specific information on all medical devices that are currently licensed for sale in Canada. This system is designed to help those who are contemplating the purchase of a Class 3 medical device or to verify that the manufacturer has an active medical device licence.
- c. Radiation Protection, CCMB, is not responsible for the sale, resale, or licensing issues of x-ray equipment. Any licensing issues surrounding the sale or resale of X-ray-emitting devices should be directed to Health Canada. However, in support of Health Canada's Medical Device regulations, registration of x-ray equipment may be denied by Radiation Protection, CCMB, and Health Canada is to be informed.

3.6 X-ray Equipment Survey Inspection

- a. Radiation Protection surveys are inspections performed to ensure that diagnostic X-ray imaging systems and auxiliary equipment are compliant with applicable regulations and standards. Safety measures such as protective equipment and shielding are also examined to ensure that they are present and provide the required protection.
- b. Radiation Protection inspections are conducted by the Radiation Protection Officers of Radiation Protection, CCMB, and must be completed for any new installation or for equipment that has undergone substantial modifications prior to use on humans.
- c. Once the inspection is complete, Radiation Protection, CCMB, will issue a comprehensive report with details and results of the measurements carried out as well as conclusions drawn and recommendations (if applicable). Deficiencies of non-compliance must be addressed regarding the action taken to correct them within 30 days of receiving the report.
- d. Ongoing Radiation Protection inspections of existing facilities must also be carried out at regular intervals based on a guidance schedule determined by Radiation Protection, CCMB.

3.7 Personal Radiation Monitoring

- a. In Manitoba, the owner of x-ray equipment must ensure all operators of x-ray equipment and other personnel who routinely participate in radiological procedures (who are likely to receive a radiation dose in excess of 1/20th of the dose limit to radiation workers) wear a personal radiation dosimeter. For information on dose limits for radiation workers, see [Health Canada Safety Code 35](#)
- b. Personal radiation monitoring must be established with National Dosimetry Services, Health Canada. For further information and/or to apply for dosimetry services: [National Dosimetry Services](#)
- c. Not all classifications of workers will be issued with dosimeters. Only those staff that have the potential to receive a radiation dose greater than 1 mSv per year. Contact Radiation Protection, CCMB, for further information.

3.8 Provincial Registration of X-ray Equipment

- a. Within 30 days after becoming the owner, you must register all x-ray equipment (new or used) with Radiation Protection, CCMB, before it can be operated as per:
 - Manitoba Regulation 341/88 R, (12), an X-ray Safety Regulation under the Public Health Act: [Manitoba Regulation 341/88 R](#)
 - Bill 37, The Radiation Protection Act, (5), [The Radiation Protection Act \(gov.mb.ca\)](#)
- b. *Registration of X-ray Equipment* form(s) is available from Radiation Protection, CCMB, by emailing: CCMBMPX-rayCompliance@cancercare.mb.ca
- c. Once processed, a copy of the completed form will be returned to the owner, along with a *CCMB Radiation Protection X-ray Equipment Registration No.* label to be prominently posted on the corresponding X-ray unit so that it can be readily identified. It is important to note, registration relates only to the x-ray equipment and does not indicate approval of a location for its installation or operation or approval of any person to operate it.
- d. Registration will remain valid until any of the following occur, at which time a new registration request must be submitted:
 - There is a change in ownership of the equipment, or

- The equipment is relocated, or
- The x-ray generator is replaced, or
- The entire x-ray system is replaced, or
- The x-ray equipment is decommissioned and removed.

4.0 Education and Consultation

Radiation Protection, CCMB will provide in-services, or specific consultations as requested. Our goal is not only to ensure that x-ray equipment legislation and regulations are followed but to also support, offer guidance, and expertise.

CONTACT US

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