June 2, 2021

Mr. Rob Francis
Director, Strategic Policy
Ontario Ministry of Health

Consultation on Healing Arts Radiation Protection Act

Medtech Canada Submission

Dear Mr. Rob Francis,

Medtech Canada is the national association representing the Canadian medical technology industry. Our members provide technologies that save patients' lives, improve the quality of patient outcomes, reduce costs to the health care system, and create thousands of high paying jobs.

Changes to the 30+ year old HARP Act are necessary so that Ontario's patients and clinicians have access to modern medical imaging technologies that will provide improved patient outcomes and health system efficiencies. The timely update of the HARP Act to enable the use of modern medical technologies is essential to enhancing patient care, improving patient access to healthcare and enabling healthcare sustainability, while at the same time reducing surgical backlogs in Ontario.

Medtech Canada strongly supports initiatives to improve and transform the current Healing Arts Radiation Protection (HARP) Act to better enable the use and access of modern imaging technologies. Our association has developed a perspective on what we see as key principles for success in enabling todays' modern imaging technologies, and those that emerge in the future. Medtech Canada's Medical Imaging Working Group has identified the follow key challenges in the current HARP Act.*

1. **Definition and designation process for CT scanners is inappropriately burdensome for low-dose devices and other new technologies**
2. **Licensing/ testing requirements for devices that emit low-to no ionizing radiation**
3. **Definition of "owner" of an x-ray machine**
4. **Letter of Designation is required for any equipment that is defined as a CT scanner**

**** Detailed comments are provided at the bottom of this file, along with suggested changes to the legislation/regulations, and the rationales for those changes.***

Background

The Need to Modernize Existing Legislation

First passed in 1985, enacted in 1990, the Healing Arts Radiation Protection (HARP) Act was meant to reduce radiation exposure to patients receiving X-ray services in Ontario, by ensuring safe use of ionizing radiation from radiography. This legislation sets out the licensing and installation requirements and operational standards for individuals who own X-ray and CT scanners. There are also regulations in place setting requirements for registration, floor plans, barriers, shielding, worker protection, film storage, operator training and machine construction and safety features. However due to technological advancements, these same requirements do not apply to current modern medical imaging devices.

Current Barriers: Restrictions with Current Legislations and Regulations

Currently, users acquire medical imaging technologies through letters of designation, which are required for any equipment that is defined as a CT scanner. Under the current HARP Act, any X-ray machine that generates an image using a multitude of orientations is defined as a "CT Scanner", for example mammography machines equipped with digital breast tomosynthesis, interventional cone beam imaging, and 3D tomography in X-ray. Newer technologies have evolved to produce 3D images by compiling and stacking multiple 2D images. Thus, modern technologies operate at far lower doses and pose little to no risk to patients and operators, so they should not be treated the same as 3D systems. The current regulations also mandate the same facility requirements for conventional CT systems and those that operate at far lower doses. It is unnecessarily burdensome to dedicate significant floor plan space to these imaging rooms, where this spare square footage can be reassigned to other essential hospital operations. Furthermore, with radiation emissions being far less of a concern with newer x-ray imaging technologies, hospitals and healthcare facilities should be able to operate these technologies in many more areas of their institution without being subjected to additional renovation costs (such as the installation of lead lining) to meet building safety codes.

Decades later, technology and the application of the medical devices has changed. This includes mobile medical imaging units which emit less radiation. However, legislation from 31 years ago does not encompass these new technologies, thus making them unavailable to many Ontario patients and clinicians. With advances in technology, increasingly sophisticated devices that utilize non-ionizing radiation (NIR) are being introduced into clinical practice and new EAMDs have been introduced which use other forms of energy that do not include radiation. The original HARP Act was meant to reduce the variation in radiation exposure to patients, but the regulations now also limit modern technologies that have virtually no toxic emissions.

Benefits to Increasing Access to Medical Imaging Technologies

Changes to the HARP Act that encompasses modern medical imaging technologies would serve to better Ontario in the following ways:

Reduced backlogs and wait times

Under the current legislation, physicians and other clinicians are unable to acquire radiographic imaging devices to use within their practice. Having limitations on who and what locations can operate a medical x-ray device directly limits a patient's access care. By enabling more specialists to own and operate these newer technologies, backlogs and patient wait times would be reduced at hospitals and clinics as less demand would be placed on these facilities to accommodate for x-ray requisitions from specialized healthcare facilities.

For example, if physicians are having to outsource medical imaging requirements to an X-Ray clinics or hospitals, the patient is subjected to longer than necessary waits for recommendations towards a treatment plan, reduced efficiencies within the physician's practice and puts additional stress on diagnostic imaging facilities. If physicians had access to the current tools and technology available better patient outcomes can be achieved through the ability to provide expedient care.

Reduce unnecessary burden and cost for users of the technologies

Reduce costs to the health system by eliminating unnecessary construction costs associated with outdated design requirements for the implementation of new medical technologies and equipment that place additional financial barriers and burdens on Ontario's health system. Due to the HARP Act, operators and owners of medical imaging devices are subjected to undue costs based on the outdated legislation as a plan application is required which leads to the additional costs of consultation services towards facility planning, implementation of protective shielding and regulatory compliance. With present-day mobile x-ray technologies and minimal x-ray emission, the current site planning approvals and standard to operate and own a mobile x-ray imaging device is obsolete.

Improving overall care by enabling better access to minimally invasive procedures and supporting better outcomes for surgeries

By allowing physicians access to the tools needed to perform diagnosis, by reducing limitations for these devices through the HARP Act, assessment and provision of a treatment plan and the quality of patient care can be vastly improved. With the assistance of image guiding technologies, physicians are enabled to make assessments and adjust surgical plans in real-time, as opposed to post-operative imaging that may show needs of surgical revision.

There are technologies available right now that are interventional image guided systems which are being used in spinal and orthopaedic procedures. These technologies allow for surgeons to access the surgical site through a less invasive route, which in turn reduces the patient's duration of stay in the hospital as it leads to a speedier recovery. Modern technologies assist in surgical procedures by providing the physician with precise accuracy and the patient in turn will have a lower chance of ending back on the operating table.

Conclusion

Medtech Canada is committed to supporting the medical imaging technologies sector as it moves to explore new standards of innovation to provide better patient care. The revision of decades old legislations and regulations will reduce backlogs, reduce costs for users and assist in providing better access to care.

Thank you for your consideration of our recommendations. If you have any questions or would like to discuss further, please contact Nicole DeKort at ndekort@medtechcanada.org.

Sincerely,

Brian Lewis
President & CEO,
Medtech Canada

Nicole DeKort
Vice-President of Ontario & Marketing,
Medtech Canada

ADDITIONAL RATIONALE AND BACKGROUND FOR RECOMMENDATIONS

ISSUE/ CHALLENGE	DESCRIPTION	LEGISLATION OR REGULATION	PROPOSED CHANGE	RATIONALE
Definition and designation process for CT scanners is inappropriately burdensome for low-dose devices and other new technologies	Currently, any X-ray machine that generates a volumetric representation using a multitude of orientations is defined as a "CT Scanner", for example mammography machines equipped with digital breast tomosynthesis, Interventional cone beam imaging, 3D tomography in X-ray.	REGULATION Regulation 543: X-RAY SAFETY CODE *Healing Arts Radiation Protection Act (HARPA)*	Definition of "CT Scanner" and associated requirements be interpreted only as applicable to a conventional CT Scanner and specifically excluding 2D X-ray acquisition with 3D reconstruction capabilities. Specifically, we recommend revising the definition as follows: *CT scanner" means an X-ray machine that is a computerized tomography system or subsystem and that is able to generate a volumetric representation of the human body using a multitude of X-rays at a multitude of orientations, and includes any such device regardless of its common name or brand name or any other way it is referred to, including, without limiting the generality of the foregoing, a computerized tomography scanner or a computerized axial tomography scanner, but excluding 2D X-ray acquisition with 3D reconstruction capabilities*	Requiring the same facility requirements for a conventional CT system and systems that operate at far lower doses such as mammography, interventional, or C-arms is unnecessarily burdensome and poses little-to-no risk of harm to patients. Lower dose devices are covered under Medical Devices Regulations under the authority of the Food and Drugs Act to ensure their safe use and application. *See **'Appendix A'** for example using Mobile 3D C-arm™
Licensing/ testing requirements for devices that emit low-to no ionizing radiation	Current legislation groups all energy applying and detecting medical devices (EADMDs) under one definition, causing many devices that emit none to very low ionizing radiation to be captured under excessively rigorous licensing/testing requirements.	LEGISLATION Schedule 4 (1), *Healing Arts and Radiation Protection Act*. (HARPA)	Clarify that licensing/testing requirements only capture ionizing radiation devices Medtech Canada recommends documented testing of X-ray equipment according to original manufacturer's recommendations before being operated for the irradiation of a human being at any new healthcare facility. Applicable registration would take place 90 days after arriving at the facility.	With advances in technology, increasingly sophisticated devices that utilize non-ionizing radiation (NIR) are being introduced into clinical practice. The HARP Act first came into force in 1990 and was meant to reduce the variation in radiation exposure to patients receiving X-ray services in Ontario. Since then new EADMDs, and their technology, have been introduced to the market which use other forms of energy that do not include radiation.

Definition of "owner" of an x-ray machine	Common practice today for the vendor of an X-ray emitting device to supply a system to a healthcare facility on a short-term basis for demonstration purposes	**LEGISLATION** Schedule 4, *Healing Arts Radiation Protection Act (HARPA)*	Registration 4 (1) The ~~owner~~ [operator] of an X-ray machine shall not operate the X-ray machine or cause or permit the X-ray machine to be operated for the irradiation of a human being unless the X-ray machine, the location of the X-ray machine and the name and business address of the owner of the X-ray machine are registered with the Director….90 days after installation. A system located at a site for under 90 days would be exempt from registration. **Application** (2) Upon the application of the ~~owner~~ [operator] of an X-ray machine …. **Notice of change** (3) An ~~owner~~ [operator] of an X-ray machine … Furthermore, we recommend adoption of the following definition: *"owner" includes a lessee, a person in charge, a person who has care and control, and a person who holds out as having the power and authority of ownership or who for the time being exercises the power and authority of ownership.*	Despite "owning" the device in a legal sense, a vendor that has loaned a device on a short-term basis has no oversight over the operation of the X-ray machine. Such activities take place within a healthcare facility in accordance with the facility's X-ray protocols. Intent is to ensure safe operation of machine – not the manufacturing/production of equipment, which is overseen by Health Canada**.** Align requirements with other Canadian jurisdictions: Currently, Ontario is the only jurisdiction in Canada whose legislative registration requirements interprets a vendor as an "owner".
Letter of Designation is required for any equipment that is defined as a CT Scanner	Currently, any X-ray machine that generates a volumetric representation using a multitude of orientations is defined as a "CT Scanner", for example mammography machines equipped with digital breast tomosynthesis, Interventional cone beam imaging, 3D tomography in X-ray.	**LEGISLATION** H*ealing Arts Radiation Protection Act (HARPA)5* Chapter H.2 Sections 3, 23	**C.A.T. scanners:** this section should be specifically excluding 2D X-ray acquisition with 3D reconstruction capabilities. If the definition of a CT Scanner is clarified and addressed as requested above, it would also address the need for a letter of designation. 23 (1) In this section, "hospital" has the same meaning as in the *Public Hospitals Act*. R.S.O. 1990, c. H.2, s. 23 (1). **Designations by Minister** (2) The Minister may designate, (a) a hospital or facility or a class of hospitals or facilities within which it is permitted to install or operate computerized axial tomography scanners; and (b) the number of computerized axial tomography scanners that may be installed or operated in such hospitals or facilities. 1998, c. 18, Sched. G, s. 51 (8).	Requiring the same facility requirements for a conventional CT system and systems that operate at far lower doses such as mammography, interventional, or C-arms is unnecessarily burdensome and poses little-to-no risk of harm to patients. 2D imaging systems with 3D volumetric reconstruction are designed to be moved between incidents of use and should therefore be defined as a mobile X-ray equipment per Safety code 35 Section 23 of the Act creates a potential barrier to approval or adoption of these newer technologies Section 3 assist in controlling the number and hospital sites for which CT scanners can be installed, 2D imaging systems with 3D capabilities do not provide diagnostic level scans that are reported and billed to the Ministry

			Prohibition (3) No person shall install or operate or cause or permit the installation or operation of a computerized axial tomography scanner unless it is installed and operated in a hospital or facility that is designated under subsection (2) or in a hospital or facility that is part of a class of hospitals or facilities that is designated under subsection (2). 1998, c. 18, Sched. G, s. 51 (8). **Same** (3.1) No person shall install or operate or cause or permit the installation or operation of more computerized axial tomography scanners in a hospital or facility than the number designated under subsection (2). 1998, c. 18, Sched. G, s. 51 (8).	

Appendix A: Mobile 3D C-arm™

Mobile 3D C-arm™ interventional systems, based on purpose and design, aligns more closely to the categories of 'mobile fluoroscopy' and 'mobile radiographic' systems and should fall under 'Mobile equipment registration requirements'.

They are lower dose than conventional CT's and are many are designed to integrated with navigation and as such further reduce the need for imaging. Classifying mobile 3D C-arms as CT scanners solely based on the ability to create a volumetric scan vs. its function and utility, creates a situation where a hospital that is not designated for a CT scanner may be declined the ability to acquire this technology limiting access to patients, surgeons, and staff who can benefit from its unique advantages.

Scope of utilization should be considered in categorizing new technology relative to radiation exposure risk. [I.e. the O-arm is solely utilized to create images for which to navigate upon. The O-arm does not provide diagnostic capabilities but rather intro-operative guidance through transferring images to a navigation system for specific procedure types. It provides the added benefit of reduced scanning and radiation exposure.

Mobile 3D C-arm™ are not designed to be permanently used in the same space, reducing the amount of cumulative radiation one would see with conventional CT scanners. The systems are used on much less scale than conventional CT, which produce radiation 24/7 depending on CT scanners hours. The quality and detail of images is very different than a conventional CT scanner.

Classifying mobile 3D C-arms as CT scanners solely based on the ability to create a volumetric scan vs. its function and utility, creates a situation where a hospital that is not designated for a CT scanner may be declined the ability to acquire this technology. This, in turn, limits access to patients, surgeons, and staff who can benefit from its unique advantages.