

Health Quality Ontario

The provincial advisor on the quality of health care in Ontario

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Report and Recommendations on Modernizing Ontario's Radiation Protection Legislation

Let's make our health system healthier



Table of Contents

Table of Contents	2
Executive Summary	3
Introduction	6
Our Approach.....	10
Our Findings.....	11
Proposed Legislative and Regulatory Framework.....	18
Testing the Framework.....	29
Next Steps.....	30
Summary of Recommendations	33
Conclusion	36
Appendix 1 – Panel Terms of Reference	37
Appendix 2 – List of Stakeholder Groups Consulted.....	40
Appendix 3 – Summary of the Regulation of Health Professionals in Ontario	41
Appendix 4 – Documents Reviewed	43

Executive Summary

Unlike the harm experienced following a surgical error or a fall, the effects of radiation overexposure may not be immediately obvious; however, they can have serious implications. Patients are asked to place an enormous degree of trust in their care providers when they receive health services involving radiation—trust that those care providers have the training and technical skills needed to decide that a test is needed or to operate equipment; trust that the equipment is functioning properly and meets current standards; trust that facilities are safe and clean; trust that someone has considered the risks and that steps are being taken to minimize them; trust that being exposed to an intervention will benefit their care. This is the **quality contract**—an implicit obligation on the part of the health care system to ensure that patients and members of the public are not exposed to the risks associated with interventions without benefiting from that exposure.

When first enacted more than 30 years ago, the *Healing Arts Radiation Protection (HARP) Act* was meant to reduce the variation in radiation exposure to patients receiving X-ray services in Ontario. With the passing of the Act, patients and members of the public could be confident that the system had mechanisms in place to protect them from the often invisible and potentially harmful effects of radiation.

Decades later, the landscape has changed. Technologies still in their infancy when legislation was first drafted are now used as a matter of routine, new technologies apply other forms of energy to the body in novel ways and hybrid technologies that could not have been envisioned by early regulators are rapidly emerging. Applications of these technologies have changed drastically too, with new uses arising regularly in both clinical and consumer domains, requiring that providers and personnel receive increasingly focused training in order to understand or operate devices. And approaches to quality in the system have also evolved, with a focus that now extends beyond safety and radiation protection to include issues like the timeliness and effectiveness of care. A system that is relentlessly committed to person-centred care demands modern legislation capable of delivering on the quality contract within an ever-shifting landscape of health care technology.

In June 2015, Health Quality Ontario established the Expert Panel to Enhance the Safety and Quality of Energy-Appling Medical Devices in Ontario to provide recommendations to the Ministry of Health and Long-Term Care on the modernization of Ontario's radiation protection legislation. The panel was tasked with developing a framework for approaching legislation—one that provides a set of organizing principles for an increasingly complex system to allow for the nimble and forward-looking uptake of technologies. Out of scope for the panel were the specific requirements or standards that should be contained within new legislation and regulation. As part of its work, the panel undertook a rigorous process involving targeted research, environmental and jurisdictional scanning, consultations and deliberative meetings.

The first issue addressed was the scope of devices that should fall within legislation. The panel chose to extend this scope beyond that of the HARP Act to include all **energy-applying medical devices (EAMDs)**. EAMDs are devices that *apply* energy in the form of acoustic or electromagnetic radiation to the human body, or devices that *detect* energy applied to the body pharmaceutically, and are approved for use by Health Canada. Radiation exposure is not the only risk associated with EAMDs. Incorrect diagnosis or interpretation related to ultrasound services, for example, can have significant implications for the safety, effectiveness or timeliness of an individual's care. In expanding scope beyond ionizing radiation, the panel advocated a broader and more person-centred approach.

An assessment of the risks and benefits of a particular device must take into consideration not only the technology itself, but also the cohort in which it is applied—whether in the general population, in patients undergoing screening or diagnosis, with those receiving high-risk treatments or in vulnerable

populations like children and adolescents. Differentiating between various applications of a technology or device is also necessary when determining risk— for example, the risks and benefits of using computed tomography for screening an at-risk population is substantively different than using computed tomography to direct precision radiation treatments. An approach that takes into account both the application of a technology and the population in which it is applied when determining risks and benefits is essential.

Using a modern approach to the interpretation of quality in EAMD services, the panel also established a set of principles, defining the elements that are integral to an adaptable and world-leading approach to legislation. Such an approach:

- **Ensures person-centred care** by placing the needs of patients, providers and members of the public at the centre of legislation and regulation;
- **Provides strong oversight and accountability** by making responsibilities clear and providing mechanisms to hold those responsible to account;
- **Is adaptable and flexible** to respond to changes in technology and clinical practice and to accommodate a range of contexts and risk factors;
- **Is based on best evidence**, ensuring that standards and competencies are based on the best and most up-to-date evidence available;
- **Is focused on system learning**, with modern digital approaches to health care allowing data to be used to develop and drive the adoption of new standards;
- **Minimizes burden and promotes harmonization** to address gaps, overlaps and barriers in the system, reduce unnecessary burden or confusion and assure efficiency;
- **Supports transparency** through public reporting, incident notifications and other mechanisms.

Using these principles as the foundation for its work, the panel's rigorous process led to the development of six broad recommendations, as well as a number of sub-recommendations.

1. **Expand the scope of legislation for radiation protection in Ontario.** The scope should include all energy-applying medical devices, and should be capable of addressing: the existing functions of the HARP Act, its gaps and shortfalls and any anticipated or unanticipated innovations.
2. **Establish a new governance structure for quality oversight of energy-applying medical devices.** Create an oversight body and grant it clear roles and responsibilities for ensuring compliance, collecting data and engaging with stakeholders; designate an advisory committee (the Committee to Regulate Devices) to provide expert advice and to develop regulations; and require facilities to identify one individual accountable for maintaining and demonstrating compliance and ensuring ongoing quality management.
3. **Use a phased approach to introduce modernized legislation and regulation.** Strike a taskforce with the appropriate expertise to develop regulations to replace the existing HARP Act, including standards for conventional radiography (X-ray), fluoroscopy and computed tomography (CT). Use the output of this taskforce as a test case for the proposed legislative framework. Once the approach is confirmed as feasible, launch two additional taskforces to address magnetic resonance (MR) and ultrasound. When the necessary infrastructure is in place, all subsequent activities should be subsumed under the governance of the oversight body and advisory committee.
4. **On an ongoing basis, strike taskforces to develop or update regulatory requirements where indicated by the Committee to Regulate Devices.** Grant the advisory body, the Committee to Regulate Devices, the capacity and resources to continuously scan the field for issues requiring regulation. Enable this group to receive input from stakeholders and strike taskforces with the expertise required to develop and set regulations. Ensure that each taskforce considers regulations necessary for facilities, equipment, processes, professional competencies, quality management systems and mechanisms for ongoing compliance and accountability.

- 5. Continue to develop the digitally-enabled infrastructure required to drive system learning.** Data can be used to support the monitoring of facilities for compliance, but should also be applied to drive system learning, including the development of indicators and new standards. Digital and automated methods for collection are critical to support efficient and effective learning, and should be implemented wherever possible.
- 6. Develop and foster mechanisms to enhance public reporting and transparency in the system.** Approaches to greater transparency in the system include public reporting of data; making publicly available reports and recommendations of the advisory and oversight bodies; ensuring that incident reporting and disclosure requirements are clear; creating a provincial dose registry; and investing in educational interventions to promote understanding of EAMDs and support appropriateness.

Introduction

The foundation of the legislative framework

At the time of its passing in 1985, the *Healing Arts Radiation Protection (HARP) Act* was considered a world-leading example of legislation for radiation protection. The Act was motivated by careful observations published by Taylor and colleagues in 1979.¹ Under the supervision of Dr. Harold Johns, Taylor measured X-ray exposures in 30 different rooms in Toronto hospitals and found unnecessarily large variations in the doses being delivered to unknowing, trusting patients. Over the past 30 years, the HARP Act has ensured the safe use of ionizing radiation from radiography; however, the landscape has since evolved.

The increasingly rapid introduction of new technologies has challenged the prescriptive nature of the Act: clinicians now routinely use devices that were still new when the Act was first drafted; the hybridization of other technologies has added paralyzing complexity to the ways in which oversight and regulatory regimes interact.

Applications of technologies have also changed drastically. Interventional procedures are now guided by fluoroscopy, which involves continuous X-ray exposure to both patients and providers to allow procedures to be monitored in real-time; point-of-care ultrasound is relatively inexpensive and becoming widely available, requiring greater support to providers in determining when and how this technology should be used in contrast to other imaging techniques. Shifts in the field have brought radiation and imaging devices into new contexts where they are applied by a greater diversity of care providers²—ensuring these providers have the appropriate competencies and that the quality of the overall service is properly managed has become more important than ever.

This reflects a significant evolution in the public's expectations from the system in terms of quality. The focus now extends beyond safety and radiation protection to include dimensions like the timeliness and effectiveness of care. With the introduction of the *Excellent Care for All Act (ECFAA)* in 2010,³ including its more modern conceptualization of quality, the need for a new regulatory framework for radiation protection is more evident than ever. This framework must support the tenets of Dr. Johns' original work, accommodate the rapid pace of advancement in medical devices and embrace the person-centred principles of ECFAA. To address this, Health Quality Ontario established the Expert Panel to Enhance the Safety and Quality of Energy-Appling Medical Devices (EAMDs) in Ontario to develop a comprehensive, future-proof framework for legislation. Such a framework should serve as a common language for organizing the system—one that addresses an increasing degree of complexity and accommodates the depth of expertise required to navigate it.

What do we mean by quality?

There is currently no widely-accepted approach to defining the quality of health care services. This can be attributed both to the difficulty of achieving consensus in a complex and often fragmented system and to an ongoing evolution in thinking related to quality. The Institute of Medicine has articulated six dimensions of quality care: safe, effective, patient-centred, timely, efficient, and equitable. When proposed in 2001, this definition reflected a shift in focus towards the responsibility

¹ Taylor KW, Patt NL, Johns HE. (1979). Variations in x-ray exposures to patients. *J Can Assoc Radiol*, 30(1):6-11.

² Jaffray DA, Langen KM, Mageras G, et al. (2013). Safety considerations for IGRT: Executive summary. *Pract Radiat Oncol*, 3(3):167-170.

³ [Excellent Care for All Act, 2010, S.O. 2010, c. 14](#)

of the system rather than the accountability of individual providers and institutions in the quality of health care. Health Quality Ontario (HQO) has chosen to adopt this definition.⁴ While not definitive or universal, the six dimensions it articulates succinctly encompass a broad range of issues related to quality in EAMD services (e.g. Accreditation Canada dimensions of “continuity” and “appropriateness” could both be considered elements of effective care).⁵

Person-centred vs. Patient-centred

Many who are exposed to the risks associated with EAMDs are not necessarily patients—they may be individuals receiving screening; family members or caregivers who accompany patients; and providers or members of the public at risk of exposure to radiation.

To clarify the interaction between these dimensions of quality and decisions about what devices to regulate and how, the panel developed the concept of the “quality contract.” The **quality contract** is a person-centred approach to regulation that is simple to understand: any time a patient or member of the public is exposed to devices for the purpose of diagnosis or therapy, he or she should be able to expect a health benefit that outweighs the associated level of risk. The contract is implicit, and the system must uphold it. The contract is particularly essential in cases where devices or technologies cannot reasonably be understood by lay persons—this places citizens in an even more vulnerable position relative to the system and heightens its obligation to ensure they are protected and that their trust is not misplaced.

With this contract articulated, any modernized approach to legislation must be sufficiently broad to ensure the contract is upheld in the context of ever-changing technologies and evolving standards and evidence.

What do we regulate?

Rapid innovation in technology and the ongoing development of new and hybrid systems requires that the scope of legislative oversight include:

1. The function of existing legislation (i.e. ionizing radiation protection via the HARP Act);
2. Current shortfalls in oversight (e.g. insufficient regulation of hybrid devices like PET/CT scanners and of devices like ultrasound scanners);
3. Anticipated and unanticipated innovations, which legislation must accommodate nimbly.

To this end, legislation should be capable of encompassing all **energy-applying medical devices, or EAMDs**. EAMDs are defined as devices that *apply* energy in the form of acoustic or electromagnetic radiation *to the human body*, or devices that *detect* energy applied to the body pharmaceutically (e.g. radiopharmaceuticals), and are approved for use by Health Canada. “Energy-applying” devices are technologies that pose risks to members of the public, requiring specific technical knowledge or competencies in order to understand and

The Quality Contract for EAMDs

What does quality mean in the context of EAMDs? What should Ontarians reasonably be able to expect from a health care system that is committed to the safe and effective use of these devices?

When a patient lies down on the bed of a CT scanner, she should be confident that her care providers are doing whatever they can to minimize the risks associated with the use of the device, that she will benefit from receiving the scan, and that the benefits conferred will not be outweighed by the risks. The result should contribute to her overall plan of care in a manner that is timely and should involve hand-offs, where necessary, to a competent individual involved with her care.

⁴ Health Quality Ontario. (2015). [Quality Matters: Realizing Excellent Care for All](#).

⁵ Accreditation Canada. (2014). [Strategic Plan 2014-2016](#).

mitigate those risks. Patients and members of public rely on regulation to ensure they are being protected.

Further limiting devices to those requiring approval by Health Canada: 1) facilitates harmonization with federal regulations, and 2) substantially reduces the kinds of devices potentially included under the definition (e.g. low-power laser pointers, though technically energy-applying, would not be eligible for regulation).

The decision to regulate a particular class or grouping of EAMDs must proceed based on an assessment of **risk and benefit**, and the two must be weighed in relation to one another. Two additional dimensions underlying the issue of risk and benefit must also be considered. These include the **application** or embodiment of devices within a certain class, as well as the different population **cohorts** that will be exposed to those devices.

Cohorts that must be considered as part of any discussion of risk and benefit include:

1. The general population (e.g. an otherwise healthy athlete visiting a fracture clinic);
2. Patients within the diagnostic phase of care (e.g. an individual receiving image-guided biopsy following mammography);
3. Patients undergoing high-risk treatments (e.g. cancer patients receiving radiotherapy);
4. Populations that are more vulnerable to risks due to biology (e.g. children and adolescents).

For each of these cohorts, risk-benefit profiles will vary widely—determining whether to carry out CT scanning in a cancer patient receiving image-guided radiotherapy, in a member of the public undergoing screening for lung cancer or in a child with potential concussion all involve very different considerations. This balance needs to be weighed not just according to cohort, but also in relation to the medical indications for a test or treatment within a cohort. Inherent in any consideration of risk is the importance of practice guidelines and approaches for monitoring the appropriate use of EAMDs.

The **applications** of a particular device or technology are also integral to the question of associated risks and benefits. For example, point-of-care ultrasound (PoCUS) can be used in acute care settings to support catheter placement—benefits may include a reduction in infection and more effective use of resources and staff time, while risks are relatively minor.⁶ In contrast, the use of ultrasound to guide chest drain insertion has been shown to reduce failures and complications; however, the procedure is also associated with very serious and potentially fatal risks including pain, infection, hemorrhage and visceral puncture.⁷

Given these considerations, any regulatory framework must accommodate the concept of “relative risk” to ensure that the appropriate balance is struck between protecting patients and members of the public and ensuring that technological advances are being exploited across the continuum of care.

⁶ Rigby D, Housami FA. (2009). Using bladder ultrasound to detect urinary retention in patients. *Nursing Times*; 105: 21.

⁷ Havelock T, Teoh R, Laws D, Gleeson F. (2010). Pleural procedures and thoracic ultrasound: British Thoracic Society pleural disease guideline 2010. *Thorax*, 65(Suppl 2):ii61eii76.

Medical sources of radiation

Ionizing radiation has enough energy to break chemical bonds between molecules or to form charged molecules. Medical sources include but are not limited to⁸:

- *Radiography*: applies low levels of ionizing radiation (and, in some cases, contrast agent) to create images.
- *Computed Tomography*: a series of x-ray images combined to create 3-dimensional images.
- *Radiation Therapy*: cancer treatment using higher doses of radiation to destroy cancer cells.
- *Fluoroscopy*: uses X-rays to obtain real-time moving images of internal structure and function.
- *Nuclear or Molecular Imaging*: involves injection with a radiopharmaceutical and employs a scanner (PET or SPECT) to produce images and estimate concentrations within the human body.

Non-ionizing radiation does not have enough energy to break bonds between molecules, but could involve harm to patients or members of the public based on other factors (e.g. heating, excessive nerve stimulation, environmental, misdiagnosis). Medical sources include but are not limited to:

- *Magnetic Resonance Imaging*: MRI uses a large magnetic field, rapidly fluctuating magnetic field gradients and electromagnetic radiation in the form of radiowaves to create images.
- *Ultrasound*: uses high-frequency sound waves to produce images of structures in the body.
- *Electroconvulsive Therapy*: electric currents are passed through the brain, triggering a seizure.
- *Transcranial Magnetic Stimulation*: a magnetic field generator placed near the head produces small electric currents in the brain via electromagnetic induction.

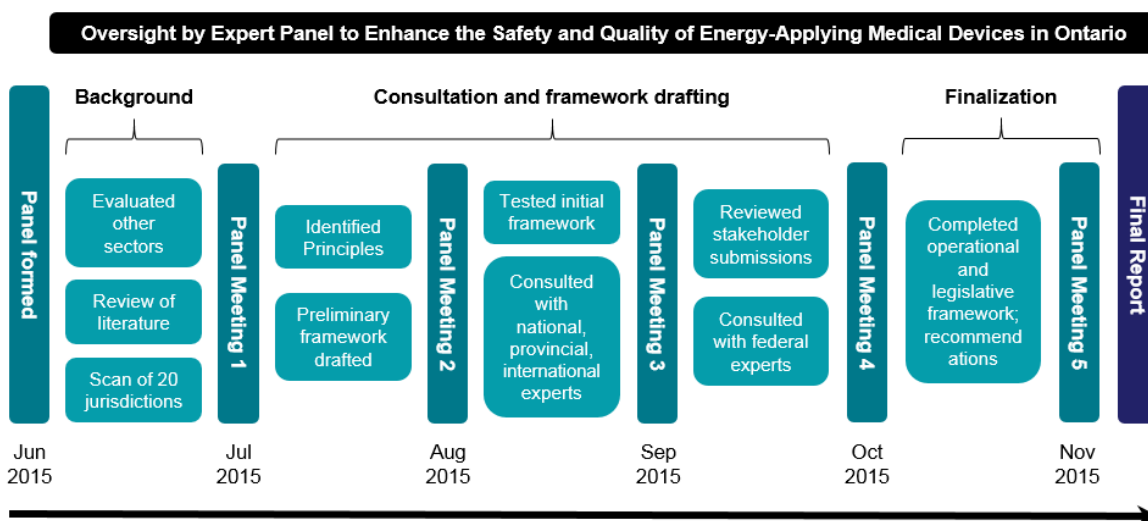
⁸ Simplified definitions are provided here to aid in distinguishing between different forms of energy only and are not intended as definitive for the purposes of regulation. In identifying specific devices, clusters of devices or subsets of devices to be subsumed under regulatory oversight, experts must approach the drafting of definitions carefully in order to avoid unintentionally including or excluding devices from scope. As an example, the HARP Act currently applies a definition for CT scanner broad enough that it could also include conventional X-ray machines that allow for the creation of 3D images after X-ray images have been captured.

Our Approach

In June, 2015, Health Quality Ontario (HQO) established the Expert Panel to Enhance the Safety and Quality of Energy-Appling Medical Devices (EAMDs) in Ontario to provide recommendations to the Ministry of Health and Long-Term Care (MOHLTC) on the modernization of Ontario’s radiation protection legislation. The panel undertook an extensive process involving research, environmental and jurisdictional scanning, consultations and deliberative meetings. The goal of this work was to develop a framework that could be used to guide the drafting of modernized legislation and regulation—out of scope was the development of specific standards to be included in that regulation.

Panel membership (complete list found in Appendix 1) included individuals with expertise in medical physics, radiology, radiation medicine, engineering, operations and administration, clinical practice and quality improvement. Members were selected for their understanding of many contexts and jurisdictions, including academic hospitals, independent health facilities, cancer services, dentistry and both local and international standards and practices. The panel’s process is depicted below.

Figure 1: Process and milestones of the expert panel



The inputs reviewed and evaluated as part of this process included:

- A scan of 20 different provincial, national and international jurisdictions, as well as an analysis of the current state of Ontario and of existing standards that may have adjacencies or implications for this work (e.g. federal regulations and codes and Ministry of Labour approaches to radiation protection);
- An investigation of the regulatory approaches of other sectors, including governance models that include delegated authorities;
- A review of the existing literature, with more than 100 documents consulted (Appendix 4);
- Presentations from and consultations with federal, provincial and international experts, including involvement from many of the experts on the panel itself;
- Submissions from more than 20 stakeholder groups and members of the public integrated into the panel’s deliberations (see Appendix 2 for list of contributing stakeholder groups);
- The results of Health Quality Ontario’s Diagnostic Imaging Quality Assurance Working Group, which served as a foundation for the panel’s perspective on quality in EAMDs. The group specifically recommended that this panel consider mandating accreditation for diagnostic imaging services.

Our Findings

Principles

Through the process described above, the panel gleaned seven principles that are integral to building a modern and adaptable legislative framework capable of upholding the quality contract. This progressive regulatory system:

- 1) **Ensures person-centred care** – The foundation of the quality contract—the needs of patients, providers and members of the public are at the centre of all we do.
- 2) **Provides strong oversight and accountability** – Accountabilities are clear, and those responsible have the tools they need to hold others to account.
- 3) **Is adaptable and flexible** – New technologies and clinical practices are responded to nimbly; the system accommodates a range of contexts and risk factors.
- 4) **Is based on best evidence** – Standards and competencies are based on the best and most up-to-date evidence available.
- 5) **Is focused on system learning** – Data is used deliberately to enable system learning; digital approaches drive the development and adoption of new standards.
- 6) **Minimizes burden and promotes harmonization** – Alignment in the system resolves gaps, overlaps and barriers, and reduces unnecessary burden and confusion.
- 7) **Supports transparency** – Public reporting, incident notifications and other mechanisms help to ensure the transparency of the system.

In reviewing approaches taken in other jurisdictions and contexts, the panel found that no single system of oversight perfectly encapsulates all seven principles or represents a “best practice.” However, pockets of excellence, particularly among jurisdictions that have recently updated their regulatory frameworks, provide illustrative examples and demonstrate trends that could be adopted as part of the foundation of Ontario’s renewed approach.

Leading national and international examples

Canada

British Columbia

Limited requirements for radiation protection nested within the *Medicare Protection Act*. Mandatory accreditation by the College of Physicians and Surgeons of British Columbia.⁹ Diagnostic Accreditation Program sets standards and evaluates practice for radiology, MRI, Ultrasound and other imaging services.

Alberta

The *Radiation Protection Act* (amended in 2013) addresses competencies, registration processes and incident notification for all X-ray equipment including analytical, industrial and veterinary devices.¹⁰ Oversight outsourced to the College of Physicians and Surgeons of Alberta, which registers equipment and monitors compliance.

Manitoba

Regulation from 1988 was replaced in 2014 with the *Radiation Protection Act*.¹¹ Regulates installation, operation and maintenance of ionizing radiation devices and requires registration. Mandates incident reporting. Oversight is carried out by CancerCare Manitoba, which also provides consultation, testing and training to facilities.

United States

Federal Requirements

The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 requires facilities that provide advanced diagnostic imaging procedures or services (e.g. CT, MRI, nuclear medicine) to be accredited by a recognized body in order to seek reimbursement.¹² Tailored accreditation programs are offered by a number of bodies (e.g. American College of Radiology, the Joint Commission).

The *Protecting Access to Medicare Act of 2014* mandates that CT scanners have features to optimize or manage doses and that physicians ordering advanced diagnostic imaging consult approved appropriate-use criteria.¹³ Penalties will be applied to Medicare reimbursement where these changes are not enacted.

Michigan – A new set of rules associated with CT were brought into effect in 2011. Provisions for personnel, equipment, quality control, event reporting and notification, and credentialing and continuing education for medical physicists.

Texas – In 2013, the Department of State Health Services issued an administrative directive with new rules for patient dose recording and dose reference levels for CT and fluoroscopy, and safety training for staff. Established protocols are reviewed every 14 months in order to ensure they are up-to-date.

California – In 2008, high-profile cases of radiation overexposure spurred the introduction of enhanced legislative oversight.¹⁴ Senate Bill 1237 (2010) added several sections to the California Health and Safety Code, requiring: CT doses to be recorded for all studies conducted/doses to be verified by medical physicists; CT sites to be accredited; reporting to take place for CT and therapy events exceeding particular criteria.¹⁵ California is also one of few jurisdictions to provide training requirements for health professionals operating high-risk fluoroscopy devices.

⁹ [Medicare Protection Act \[RCBC 1996\] Chapter 286](#)

¹⁰ [Radiation Protection Act](#)

¹¹ [Bill 37, The Radiation Protection Act](#)

¹² [Medicare Improvements For Patients And Providers Act of 2008](#)

¹³ [H.R. 4302 \(113th\), Protecting Access to Medicare Act, 2014](#)

¹⁴ U.S. Food and Drug Administration. "[Safety Investigation of CT Brain Perfusion Scans: Update 11/9/2010.](#)"

¹⁵ [Senate Bill No. 1237, Chapter 521](#)

United Kingdom

*Ionising Radiation (Medical Exposure) Regulations*¹⁶ require clinical radiology departments to develop criteria for the professionals they will accept referrals from; sufficient medical data is required before the justification for a procedure can be assessed. In England, all providers must submit diagnostic imaging data to a central repository for accreditation.

Australia

Three pieces of legislation governed by an oversight body regulate Medicare-eligible diagnostic imaging services, one of which is re-made every year.¹⁷ The complexity of the system and the lack of clear specifications for appropriateness, difficulties with access and confusion about professional requirements were highlighted as concerns.¹⁸

Opportunities for adoption

Person-centred	Many Canadian provinces rely on standards embedded in occupational health and safety regulations, but modernized examples nationally and internationally often specifically address the safety and wellbeing of patients and members of the public.
Strong oversight and accountability	The majority of the systems highlighted above have mechanisms and infrastructure to support the registration of higher risk devices; the U.S. uses Medicare reimbursement to incentivize behaviours; California sets strict training requirements for high-risk activities like fluoroscopy.
Adaptable and flexible	Modernized frameworks from B.C., Manitoba and Alberta all point to the practice of leveraging standards set by external bodies like accreditors or professional colleges—an approach that is more nimble and responsive than naming requirements directly in regulation, provided that external bodies are accountable to the overarching quality agenda.
Based on best evidence	Rather than attempting to replicate standards already developed, the federal U.S. government refers out to the standards of accrediting bodies—groups that have the right expertise and are continually updating their standards. Texas has requirements for the regular review of protocols to ensure they are up-to-date.
Focused on system learning	California legislation now requires the collection of dose records for all CT studies carried out—a wealth of data that could be used in the future to drive down exposure and reduce variation while maintaining diagnostic performance.
Minimizes burden and promotes harmonization	In updating its standards, Alberta worked closely with federal regulators like the Canadian Nuclear Safety Commission to avoid creating redundant layers of bureaucratic requirements.
Supports transparency	Most of those systems highlighted as leading examples provide standards and guidelines for public reporting and incident notification—California now requires CT dose records to be made available to patients as part of their medical charts.

Not all of the examples highlighted will be suited to the Ontario context, and not all have yet proven successful in their own right. However, they suggest a trend towards a broader view of quality in the use of EAMDs and Ontario is well-positioned, in spite of the complexity of the task, to take advantage of their learnings proactively, rather than in reaction to high-profile incidents.

¹⁶ [Ionising Radiation \(Medical Exposure\) Regulations \(2000\)](#)

¹⁷ [Health Insurance \(Diagnostic Imaging Services Table\) Regulation 2012](#)

¹⁸ Australia Department of Health. 2015. [Improving the quality and safety of Medicare funded diagnostic imaging services.](#)

Ontario's current state

Provincial legislation and regulatory bodies

The **Healing Arts Radiation Protection (HARP) Act, 1990**¹⁹ governs low-energy X-ray-emitting devices that are applied to humans. It sets out the licensing and installation requirements and operational standards for individuals who own X-ray machines and CT scanners. In addition to the Act, **Regulation 543: X-Ray Safety Code** provides detailed requirements for registration, floor plans, barriers, shielding, worker protection, film storage, operator training and machine construction and safety features.²⁰

Oversight for HARPA is carried out by the **X-Ray Inspection Service (XRIS)**, a program within the MOHLTC. The Director of XRIS has the authority to issue, refuse to issue or revoke an approval to install an X-ray machine or to change previously approved plans or specifications, and all such machines must be registered with the service. The Director or a designated inspector may also make written orders to those who own, operate or perform other functions related to X-ray machines, requiring them to take specific actions to achieve compliance or protect the health and safety of the public. In emergency cases, the Director can order individuals to cease operating devices, either permanently or for a given period of time.

In terms of the competencies required to carry out particular functions related to X-ray machines, the HARP Act and Reg. 543 permit only those professions listed in regulation and statutes to prescribe ionizing radiation and to operate scanners. Non-ionizing radiation is addressed separately within the **Regulated Health Professions Act, 1991** (see Appendix 3 for more detail), which limits who is authorized (e.g. members of certain health professional regulatory colleges) to order and apply certain forms of energy, such as MRI, ultrasound and electricity. The colleges also have by-law making powers and can set standards of practice that limit members' activities. For example, the Royal College of Dental Surgeons of Ontario sets out minimum educational requirements for Ontario dentists who wish to install and operate dental CT scanners, which is enabled under the HARP Act through a reference in regulation. Diagnostic radiation can be prescribed by a number of professions; however, to prescribe therapeutic radiation services, professional organizations and Accreditation Canada require providers to possess a Royal College of Physicians and Surgeons of Canada fellowship.

In addition to the competencies of those operating or prescribing ionizing radiation, the HARP Act also delineates the required qualifications and responsibilities of Radiation Protection Officers (RPOs). Facilities operating X-ray machines are required to have an RPO in place, and this individual establishes and monitors testing procedures, maintains records and ensures those operating equipment are qualified.

Certain provincial regulatory and oversight bodies also establish standards and provide oversight within the space of radiation protection. The College of Physicians and Surgeons of Ontario (CPSO) sets practice parameters and facility standards for X-ray, ultrasound, CT, MRI and nuclear medicine services provided in Independent Health Facilities (IHF), and conducts inspections to ensure compliance. However, this does not include specifications regarding the competency of the medical practitioners able to prescribe radiation for therapeutic purposes. This is governed by local institutional policy and reimbursement (e.g. only those qualified can bill the Ontario Health Insurance Plan for planning and delivering radiation treatment).

¹⁹ [Healing Arts Radiation Protection Act, R.S.O. 1990, c. H. 2.](#)

²⁰ [R.R.O. 1990, Reg. 543: X-Ray Safety Code.](#)

Cancer Care Ontario (CCO) and the CPSO are also currently collaborating on the development of Quality Management Partnerships, which will set out standards and guidelines, quality assurance processes and reporting and accountability structures for mammography provided at both hospitals and IHFs. CCO is also involved in the development of quality standards and guidelines for radiation treatment, along with a number of national professional bodies representing the medical and allied health disciplines that deliver treatment services.

Though not currently mandated, a number of national and international accrediting bodies have established accreditation programs for facilities operating a wide range of diagnostic and therapeutic devices. Standards address facilities, equipment, provider qualifications and other quality parameters. Accreditation is often pursued by hospitals and IHFs—either to bolster organizational reputation or as a requisite for participation in certain programs (e.g. mammography accreditation is required to participate in the Ontario Breast Screening Program).

Federal Requirements

Health Canada regulates the safety and effectiveness of all medical devices marketed and sold in Canada as per the *Medical Devices Regulation* under the *Food and Drugs Act*.²¹ Devices are placed in one of four classes according to risk, with Class II, III and IV devices requiring licenses to be imported, sold or marketed in Canada. The *Radiation Emitting Devices Act* addresses the sale, labelling and advertising of devices that emit radiation. In the case of both Acts, manufacturers or importers of devices are required to notify the federal Ministry of Health if they become aware of a device failing to comply with standards or creating risk of injury, impairment or death. Inspectors may also, with reasonable grounds, enter manufacturers' premises to examine devices and associated documents. Unless major device issues or off-label uses are identified following the point of sale, Health Canada has no jurisdiction or oversight related to the subsequent operations of devices.

Health Canada also offers a number of Safety Codes developed by the **Radiation Protection Bureau** to address environmental and workplace safety. All codes outline requirements that must be in place in order to meet their currently accepted standards of protection, as well as requirements that are advisory in nature and are recommended for implementation where possible or applicable. The Safety Codes relevant to energy-applying medical devices include those for installation and use of X-ray equipment, exposure to electromagnetic fields and radiation protection in dentistry and mammography. Safety Codes are reviewed annually, but are updated relatively infrequently and, while they are sometimes referenced as part of provincial regulations, they otherwise apply only to federal health care services (e.g. care provided by the Department of National Defence).

While Health Canada regulates medical devices at the point of sale, the **Canadian Nuclear Safety Commission (CNSC)** regulates installation and ongoing operations of a subset of these devices. The *Nuclear Safety and Control Act* and associated regulations govern the use of nuclear energy and material,²² giving the CNSC authority over all equipment capable of producing nuclear energy. This encompasses high-energy medical linear accelerators and Cobalt-60 devices, and the facilities in which they operate—hospitals and cancer centres. Through a combination of licensing, compliance and certification, the CNSC ensures that those installing and operating nuclear equipment meet requirements for facility safety standards, ongoing radiation safety programs, dose recording and record keeping and have in place worker protections such as monitoring of personal dosimetry.

²¹ [Medical Devices Regulations \(SOR/98-282\)](#)

²² [Nuclear Safety and Control Act \(S.C. 1997, c. 9\)](#)

Where Ontario falls short on the quality contract

To uphold the quality contract, patients and members of the public should not be subjected to the risks associated with EAMDs unless they can expect benefits that exceed those risks. To ensure that this is the case, clear quality standards and the appropriate oversight to enforce them must be in place. Standards established in regulation should include requirements for equipment, facilities, processes and ongoing quality management and should address the competencies required by those prescribing, operating, interpreting, servicing and ensuring quality management. Legislation and regulation should encompass all energy-applying devices for which risk is significant, and should be designed to enable the level of responsiveness required to address rapid changes in technology and clinical practice expected in Ontario's future.

The HARP Act has served an integral function in protecting the public from radiation-emitting devices, and the provincial government continues to leverage all the legislative and regulatory mechanisms at its disposal to successfully deliver on many elements of the quality contract. However, existing legislation was designed primarily to address the application of diagnostic ionizing radiation. With the rapid proliferation of technologies, therapeutic approaches, scopes of practices and evidence surrounding appropriateness, this system of oversight must be re-evaluated. When examined according to the dimensions of quality now embraced by the system, significant gaps in Ontario's approach to quality oversight emerge. It is not enough to leave individual organizations wholly responsible for certain vital aspects of quality in the delivery of EAMD services. The quality contract dictates that the system as a whole must provide centralized oversight for services that carry risks. This requires the development of a new legislative framework to replace the HARP Act—one that both replicates the successful elements of the existing Act and positions Ontario as a world-leader in terms of the provision of high quality care and the timely adoption of new and innovative technologies.

Quality dimension

Gaps identified in the current system

- Safe**
- No regulatory oversight for the operations of non-ionizing radiation devices, which carry significant risks beyond radiation exposure (e.g. misdiagnosis related to PoCUS)
 - Regulatory oversight lacking in terms of the ongoing operation and functioning of devices
 - Inspections carried out in response to suspected issues/compliance triggers; some proactive or preventative investigations, but these are limited
 - Accreditation or credentialing against exacting standards is often voluntary
 - Lack of technical competence in the oversight of safety in facilities
 - Credentialing for prescribing and applying therapeutic radiation governed predominantly by local institutional policy and OHIP reimbursement, with serious implications for appropriateness

- Effective**
- Standards are outdated; no group with the appropriate expertise is responsible for scanning the field for updates to evidence or changes in practice
 - Data collected provincially is minimal; limited opportunities to use data to drive more effective use of technologies or to develop more rigorous standards
 - Authorization to operate devices may be based on unrelated professional credentials alone and not demonstrated competency

- Person-centred**
- HARP Act addresses application of ionizing radiation to humans, but provides few mechanisms to address complex issues related to care (e.g. appropriateness)
 - No focus on helping patients to understand the risks/benefits associated with their care (e.g. personal dose records) or on education related to EAMDs
 - Current regulations contain a provision related to accident- or exposure-related incident reporting, but does not offer a definition for incidents
 - No capacity to collect or publicly report on data related to dose exposures, equipment performance or other metrics that allow for monitoring of quality in the system

- Efficient**
- Regulations often overlap, particularly for radiation protection and personal dosimetry
 - Pathways for receiving device approvals (CT vs. x-ray) are inconsistent
 - Insufficient infrastructure in place to identify and appropriately adopt or constrain new technologies or clinical applications as they arise
 - Qualifications for RPO positions are set based on credentials and not competencies, preventing otherwise qualified individuals from filling the role and, in some cases, allowing unqualified individuals to assume it

- Timely**
- Stakeholders report delays in inspections or approvals due to application difficulties that stall facility operations and increase wait times
 - Levels of oversight often require submission of duplicative information, placing additional time burdens on organizations
 - Lack of timeliness in the adoption of new technologies (e.g. hybrid technology, cone-beam CT in dentistry)

- Equitable**
- Limited data collection prevents identification and management of variation in quality (e.g. dose exposures) across different regions or patient populations
 - Limited focus on tailoring standards to vulnerable populations like children and adolescents where radiation exposure carries enhanced risk

Proposed Legislative and Regulatory Framework

Governance

The panel drew upon its defined principles, the dimensions of quality proposed by the IOM and published practices to develop and mature a governance model. This model has the following structures with clearly defined and delegated responsibilities.

Oversight Authority (OA)

With accountability to the MOHLTC, the OA carries out administrative functions associated with the framework, including:

- Ensuring compliance with legislation and regulation by issuing licenses (to be granted based on approval of applications submitted by facilities), collecting and monitoring data and conducting (or delegating) inspections;
- Setting policies related to quality management programs that align with frameworks and standards articulated in regulation and reviewing facility submissions on the basis of these policies;
- Analyzing data for the purposes of system learning and setting benchmarks and indicators;
- Engaging with stakeholder groups to ensure harmonization and alignment across the system, including liaising with federal regulators and others to reduce the burden on organizations applying for or maintaining licensing and registration;
- Producing an annual report on its activities, standards, processes and policies; submitting this report to the Committee to Regulate Devices (below); and posting it publicly.

Committee to Regulate Devices (CRD)

A body of experts, including representatives of the interests of patients and members of the public, with a mandate to provide recommendations to the MOHLTC related to the design and revision of regulations and standards, and to the Oversight Authority regarding the analysis and interpretation of data and the identification of stakeholders. Responsibilities include:

- Carrying out ongoing surveillance of the field to identify modalities requiring regulation or instances where changes to existing regulation are needed (with recommendations to be made to the MOHLTC);
- Establishing taskforces or identifying existing bodies with specific expertise (e.g. the Ontario Health Technology Advisory Committee, Cardiac Care Network, HQO), as needed, to provide the committee with unbiased recommendations on the design of regulations and standards;
- Reviewing taskforce recommendations and submitting these to the MOHLTC, with final sign-off on proposed regulations required from the committee before public posting to ensure they are consistent with the original intent;
- Receiving the annual report from the OA and reviewing its activities, standards, processes and policies to recommend changes based on new technologies and evidence;
- Advising on data analytics to be carried out by the Oversight Authority and interpreting resulting information to guide decision-making and drive the development of standards and indicators.

Applicant Authority (AA)

An individual or defined list of individuals within a facility or organization who liaise(s) with the OA. This role:

- May be held by the facility owner/Chief Executive Officer or may be delegated to the AA on the basis of necessary technical and professional qualifications;
- Acts as the point of accountability within a facility for a particular class of EAMDs. The AA must develop a quality management program that aligns with regulation and submit this to the OA in order to obtain licenses or permission to operate particular classes of devices. This quality management program must include standards related to the facility, equipment, processes and professional competencies and must align with a quality management framework outlined in regulation;
- Develops, updates and oversees the facility's quality management program on an ongoing basis (including, in some cases, the appropriate medical use of devices). Tasks may include ensuring that records and documentation are up-to-date and verifying that quality processes are operating according to standards and requirements (e.g. testing, peer review, data reporting, inspections, incident reporting);
- May involve responsibility for only a single device, for multiple devices of a single type or for many types of devices, depending the expertise required by regulations.

Figure 2 below depicts the relationships between governing bodies and the quality management processes within facilities, and the interaction between facilities and the Oversight Authority.

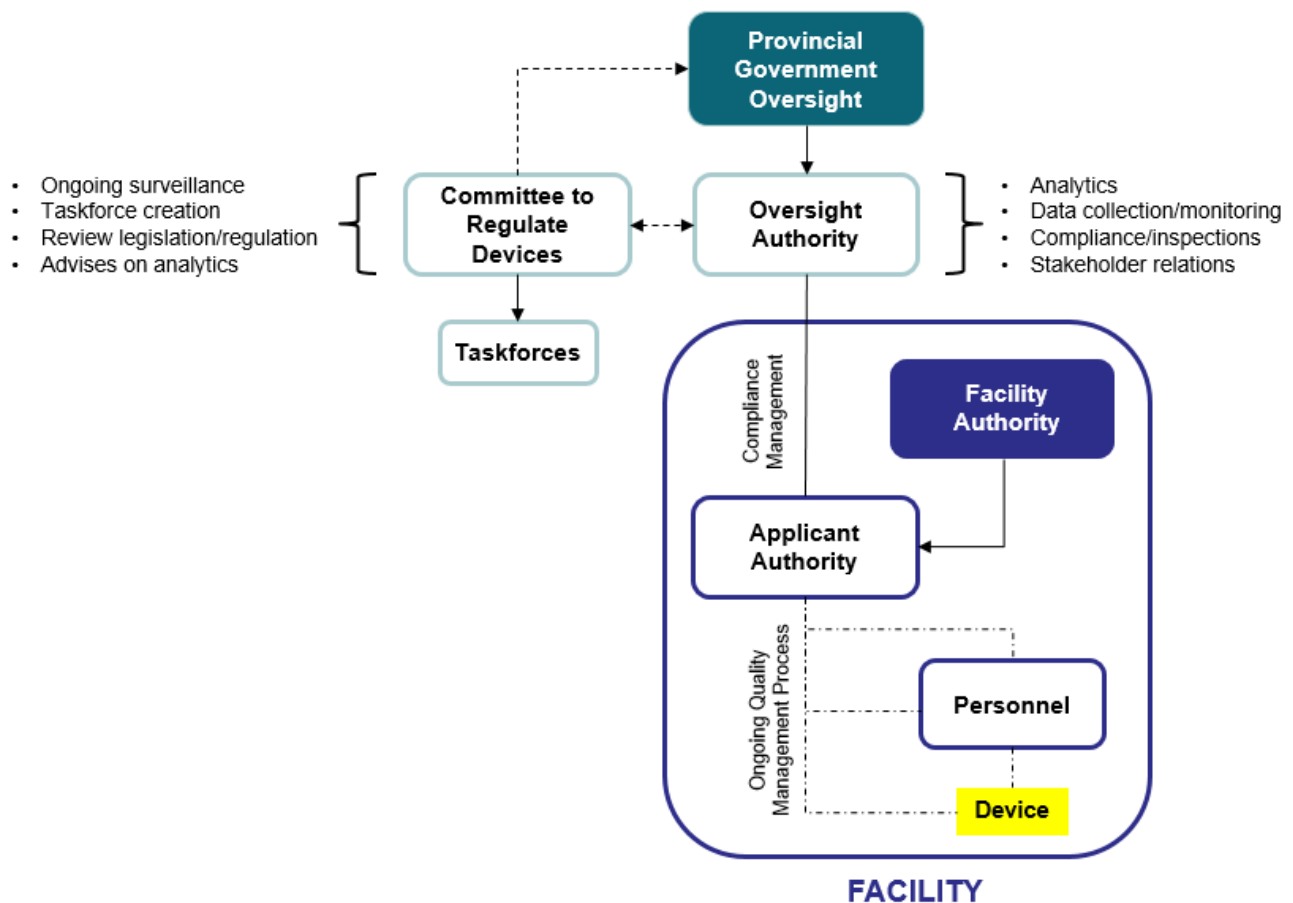


Figure 2: Proposed governance of modernized EAMD system of oversight

Regulatory requirements and standards

When the Committee to Regulate Devices identifies a device or grouping of devices that require regulation, it designates and mandates a taskforce to deliver advice to the committee related to the nature and method of regulation. This taskforce will determine the criteria that define that class of device, and identify required standards within each of the following categories: facilities, equipment, processes, professional competencies, ongoing quality management processes and compliance mechanisms. A template for regulations that is sufficiently generic to address both current and future modalities is needed. Though regulations are likely to vary widely across different device classes, the panel identified several overarching guidelines that all approaches to regulation should adhere to, wherever possible:

- Refer to external standards: given rapid changes in technology, evidence and clinical practice, regulations should attempt to refer to standards developed externally. Regulatory and accrediting bodies often have access to the expertise and infrastructure needed to update best practices nimbly and responsively. When no external standards exist, or where ongoing data collection has resulted in enough internal information to inform new standards, there must be resources and capacity in place to support standards development.
- Consider the range of facility contexts: the varying needs and resources of facilities in which devices are operated must be considered. In some contexts, requirements may not be practical (e.g. northern or remote communities may not be able to support a dedicated, on-site imaging technologist to complete one test per week) and, provided that sufficiently rigorous quality standards are still in place, mechanisms to allow for variances may be needed. The approach to variances taken by the CNSC was highlighted as sufficiently labour-intensive and rigorous to be emulated. However, variations allowed on this basis must always be balanced with efforts to prevent a tiered approach to care delivery.
- Consider the risk and benefit profile of each device or technology: in specifying performance and operational limits for devices, differential consideration should be given to the risk and benefit profiles of the cohorts in which they are applied (i.e. the general population, patients in the diagnostic phase of care, individuals receiving treatment and biologically vulnerable populations). Risks and benefits of different applications of devices must also be considered (e.g. diagnostic exposure to radiation vs. high doses of radiation received during radiation therapy; PoCUS-guided procedures carrying different levels of risk). The standards for EAMDs will need to vary according to both these dimensions in order to adequately ensure the quality contract is met.
- Enable research and innovation: the field of EAMDs is rapidly changing and innovation is constantly underway. Given that the criteria employed by local research ethics boards (REBs) are often stringent, and that oversight for clinical evaluations of new technologies is currently addressed by Health Canada through its Investigational Testing Application process, approval through such mechanisms should allow research involving new or innovative devices to move forward as it does currently. Revisions to the HARP Act should seek to proactively build innovation capacity in the province's healthcare system, while also assuring quality care.

Facility standards

The definition of “facility” is not limited to hospitals or IHFs—the term encompasses any organization where EAMDs are applied to humans as part of medical care. Facility standards should address all necessary measures to maintain a person-centred approach to the safety of the environment in which devices are operated, and may include standards for shielding and barriers, zoning and security, monitoring and alarm systems, emergency devices and signage. A person-centred approach requires consideration of the public, the patient and the worker in the development of standards. These standards should contemplate and seek to mitigate excessive cost or burden and should adapt to evolving technology, modeling accuracy and evidence regarding risk.

Equipment standards

Acceptance testing is needed to ensure that new equipment is functioning properly and ongoing functioning of devices should be monitored via regular performance evaluations. Standards may include performance specifications for image quality metrics or limitations on applied power. Requirements may also be needed for secondary or peripheral equipment. For example, reviewing a diagnostic scan on a display monitor with an inappropriate contrast resolution may result in misinterpretation, regardless of whether the device that captured the image has been correctly calibrated. Regulations should not be silent on issues like image quality or problems with equipment as these may translate to unnecessary exposures or result in misdiagnosis or mistakes during complex interventions. Standards should be clear about the equipment required to safeguard patients and providers; to read and interpret scans; to store information and data; to address emergencies; and to carry out any additional tasks that could affect the quality of service.

The significance of failures in process

During a routine visit to his primary care physician, Greg was found to have a thickening of the epididymis (a tube in the testicles).²³ Once referred for the issue, it took three months for him to be notified about an appointment with a general surgeon. During this time, he visited a walk-in clinic due to lower back pain and an abdominal mass was found. A radiologist requested urgent CT scanning to confirm a diagnosis of cancer, though discrepancies in the understanding of “urgency” led to delays.

Scans were eventually completed, but the walk-in clinic failed to inform Greg of the results. After following up, he received further diagnostic scans and a mass consistent with cancer was confirmed. He was given a referral, but the urologist’s office did not contact him and he was again forced to follow up. At this time, he learned the physician was away, and contacted the walk-in clinic to be booked with another physician. Though the surgery was completed, he experienced complications. He was unable to reach his urologist, and was forced to visit the emergency department. He was ultimately sent home to wait for an appointment, where he sadly lost consciousness and died.

Greg spent nearly 60 weeks in the health care system and experienced four significant breaks in the continuity of his care, illustrating the tremendous importance of process standards in preventing harm.

Process standards

Processes within clinics may also have serious bearing on the quality and continuity of care delivered.²³ For example, the timeframe in which certain data is read or passed on could have implications for the timeliness of an individual’s diagnosis or treatment.

When an image is read, it should enter a system and be integrated into the patient’s medical record. Standards and benchmarks may be needed in terms of the timeliness with which it is read by a qualified professional and the maximum timeframe in which results must be communicated. These standards may vary depending on the urgency of the patient’s condition or the time-sensitive nature of the test or treatment. There may also be process requirements related to communication, including confirming and documenting transfer of responsibility for patient care. Regulations should include the requirement that these standards be in place in facilities and that protocols be clearly defined for capturing and managing variances and incidents.

Professional competency standards

The panel agreed that the competencies of professionals involved in all aspects of EAMD operation can significantly affect the quality of care. Professionals prescribing procedures that involve EAMDs, operating devices, interpreting results and providing technical service to equipment are integral to ensuring the quality of the process.

²³ Health Quality Council of Alberta. (2013). [Continuity of Patient Care](#).
Health Quality Ontario

Prescribing	Operating	Interpreting	Technical Oversight and Servicing
All interventions (including diagnostic testing) are associated with risks. The ability to prescribe both diagnostic and therapeutic interventions should be granted to those with sufficient training in appropriateness, including benefits/risks.	Only those with the correct training should be permitted to operate devices. Training should include not only the operation of the device, but also its application for different purposes and in the specific populations of interest, where applicable.	To interpret images captured or to adequately comprehend interventions underway, professionals should require particular competencies to prevent misinterpretation or misdiagnosis.	Acceptance testing of newly acquired equipment and ongoing quality control must be carried out by individuals with the appropriate understanding of the technologies, and these credentials must be maintained.

According to the current regulatory system, the ability to prescribe the use of certain EAMDs or to operate equipment is granted in law to members of particular health professional colleges. Regulatory colleges may then set further restrictions on members' activities on the basis of specific educational or training requirements. This approach has a number of strengths—namely, competencies are determined by those most familiar with the training and skills of the professional group in question.

Though referencing credentials is necessary when determining the activities certain professionals are or are not permitted to carry out, it is not sufficient and cannot be a mechanism for managing all contingencies. For example, not all workers involved in operating EAMDs are associated with a regulatory college. Establishing such a regulatory body may not always be the most efficient or desirable approach to ensuring quality in these cases, particularly as the application of EAMDs and the professions associated with them continue to change.

To augment licensure or registration with particular regulatory colleges, the panel unanimously agreed that a modernized law must enable regulations to authorize specific professional activities on the basis of additional training or competencies. The skills of professionals prescribing, operating, interpreting, providing technical oversight or servicing are integral to quality. For instance, competencies to prescribe should include training in medical appropriateness—this is prerequisite to the concept of the quality contract. Modernized legislation and regulation should set the standard for all activities associated with EAMDs in Ontario, and other regulatory bodies and individuals should be held accountable to these requirements in order to ensure the quality contract is upheld. Facility AAs should be accountable for demonstrating that all professionals performing activities associated with EAMDs within their organizations meet the relevant competency and training requirements set out in standards and regulation.

The panel was adamant that the colleges should be deeply embedded in the process of determining and setting standard for competencies; however, placing competencies in regulation and beyond the purview of these regulatory bodies is one mechanism to ensure that requirements are evaluated or verified externally. This approach is reflected in California's modernized regulatory framework, which permits fluoroscopy to be administered only by qualified individuals who receive necessary certification and meet continuing education requirements.²⁴ It is also aligned with a growing trend towards core competency training (as opposed to credentialing) in medicine. For example, key organizations involved in formal accreditation for vascular and neurovascular intervention stipulate that formal education, procedural training and experience are all essential for competency.²⁵ Beyond credentialing, there are currently no regulatory levers to restrict the use of ultrasound on the basis of

²⁴ The American Registry of Radiologic Technologists. (2010). [Content Specifications for the Fluoroscopy Examination](#).

²⁵ Connors JJ, Sacks D, Furlan A, et al. (2004). Training, Competency, and Credentialing Standards for Diagnostic Cervicocerebral Angiography, Carotid Stenting, and Cerebrovascular Intervention. *American Journal of Neuroradiology*, 25;1732-1741.

its different applications, many of which vary widely in terms of associated risks and benefits. In this case, it is generally left to the health care organization itself to set additional standards for training or competency, which is insufficient to support the primary tenet of the quality contract—that the system contains mechanisms to assure the same high quality standards across all facilities.

Quality management standards

Oversight for quality within facilities will be the responsibility of the Applicant Authority. Similar in concept to the RPO role delineated in the HARP Act, this individual will be accountable for ongoing quality management and for maintaining compliance, including ensuring that facilities, equipment and processes are maintained to the standards set in regulation, that all staff meet required competencies and that quality programs like peer review, dose estimate reviews and incident reporting are also operating according to standards. The AA will be required to submit the details of their quality management program to the OA, basing the details of this program on a framework that aligns with regulation. The OA must sign off on this application for a license or permission to operate a device to be issued. This process is aligned with practices in industry and other regulatory environments like drug and medical device approval. Examples of quality management frameworks that could be adapted for the purpose of regulations abound, and are available from a number of accrediting bodies and international standards organizations.²⁶

The AA will also be held responsible for meeting data collection and submission requirements. While not all data will need to be fed into a centralized system, the AA may need to demonstrate that local data are being evaluated and used to drive standards or to allow performance reporting among clinicians.

Regulation will need to address the competencies required for individuals filling the Applicant Authority role. Where the RPO role is currently open only to members of certain professions, the panel felt that competencies should take precedence over credentials. These competencies should be linked to an understanding of the underlying technologies and their risks, as well as training on quality management. In some cases, those with the appropriate technical skills, training or continuing education credentials should be considered qualified. In others, membership within a particular college may be sufficient to be considered a candidate for the role. Regardless of the approach, the parameters of the role will need to be clearly defined for each class of devices regulated, including the deliverables related to quality management for which this individual will be held responsible and how competencies should be assessed. The certification process made available by the CNSC for radiation safety personnel is a successful model that could be emulated.

Ongoing compliance standards

Regulation will also need to delineate requirements for facilities and the AA in terms of demonstrating ongoing compliance, as well as the accountability mechanisms available to the OA.

Monitoring

Processes for monitoring the quality of facilities and their services may include regular inspections on the part of the OA or other approved or delegated regulatory bodies; notifying the OA of significant changes to equipment, facilities, processes or personnel; participating in data collection; and reporting variances or incidents. This system could also involve leveraging third-party inspecting or accrediting

²⁶ International Organization for Standardization. (2015). [ISO 9001:2015: Quality management systems — Requirements](#). Health Quality Ontario

bodies. In all cases, compliance with standards should focus on the risks associated with the technology and its applications.^{27,28,29,30}

The AA will be required to maintain documentation associated with each device or each class of devices in the facility and submit some of this data or its derivatives to the OA. This could include: date of manufacture and operating version of a specific piece of equipment (to detect obsolete technology) and records of significant changes to components or malfunctions to ensure that the integrity of the technology remains fundamentally unchanged. The degree of documentation required will vary between device classes depending on the risks associated. In some cases, the AA may only need to demonstrate documentation related the facility's quality management program. In others, more extensive documentation may be needed.

Regulations will establish the kinds of data (e.g. person-specific dose records, testing results) that facilities will be required to submit on a regular basis into a centralized data collection system maintained by the OA. Initially, simply meeting data submission requirements may be a metric of compliance. Once a more robust system of data collection is established within the OA, it could be used to identify the performance of outliers in particular areas (e.g. unusually high doses delivered via CT scanning at some facilities as compared to others; rapid improvements in image quality due to technical innovations) and target them for intervention or for propagation across the system.

When setting data collection requirements in regulations or policies, the purpose that data is intended to serve must be considered—wasteful reporting places a burden on both the regulator and the facility. Growing digitization of technology should allow for automated reporting of device operation and performance results to both local and centralized databases. Provincial regulators will have an integral role to play in driving innovations in industry by specifying requirements for data sharing functionality in products being sold and licensed.

Accountability mechanisms

Some modalities may demand more stringent mechanisms for ongoing accountability—for example, licensure of individual devices according to serial number. In other cases, individual devices may not need to be licensed (e.g. ultrasound machines), but facilities may still be required to demonstrate that they have quality management programs in place in order to purchase and operate devices of a particular class. Determination of the scope of EAMD oversight must be based on risk. While devices like ultrasound imaging systems may be technically harmless, the application

Why monitor and manage quality?

In 2006, Lisa Norris, a 15-year-old girl undergoing radiotherapy at a clinic in Glasgow, received a dose of radiation much greater than intended, causing irritation, reddening and blistering of the skin. An upgrade to the hospital's computer treatment planning system led to a data error that was not caught during subsequent checks.

In 2008, a young boy was brought to the Mad River Community Hospital in California for minor neck trauma and was mistakenly scanned 151 times in 68 minutes, reportedly as a result of a combination of human error and equipment failure.

Within the same time period, up to 260 patients undergoing CT brain perfusion imaging at Cedars-Sinai Hospital in California received up to eight times the normal radiation dose because of incorrect scanner settings.

Though contributing factors vary, these incidents all illustrate the importance of protocols, reviews and other mechanisms for monitoring and managing quality. Having quality management systems in place could mean all the difference in catching and preventing avoidable errors.

²⁷ Scottish Executive. (2006). Unintended overexposure of patient Lisa Norris during radiotherapy treatment at the Beatson Oncology Centre, Glasgow in January 2006.

²⁸ Lee CS, Lewin JS, Nagy P. (2012). Events that have shaped the quality movement in radiology. *J Am Coll Radiol*, 9(6): 437–439.

²⁹ Zarembo A. (2009). [Cedars-Sinai radiation overdoses went unseen at several points](#). *Los Angeles Times*.

³⁰ Brice J. (2009). [Custom CT protocol exposes Cedars-Sinai patients to excessive doses](#). *Diagnostic Imaging*.

involves risks when performed improperly (e.g. needle biopsy, inaccurate diagnosis). The AA will be accountable for overseeing a quality management program that involves documentation and reporting to the OA. Expectations for this program may involve registration for low-risk use of EAMDs, whereas high-risk EAMDs could require licensing and enhanced reporting.

When facilities are found to be non-compliant with requirements, a range of graduated enforcement tools should be made available to the OA, including suspending or revoking licenses, issuing sanctions, recommending corrective actions or delivering educational interventions. Based on a consideration of the risks to patients and the public (including those associated with halting certain activities without alternatives in place), the OA should determine the most appropriate action.

In some cases, educational interventions may be more appropriate, and the system of accountability must be designed to formally enable system learning. For example, if data indicates that a particular facility has a pattern of CT doses that are higher than those observed in many of its peers, this may provide an opportunity to support education and change management interventions to help that facility improve. There may be risks associated with placing the responsibility for compliance within the same body that also carries out educational or quality improvement initiatives. As such, the OA may need to implement some degree of separation between these roles, either by taking advantage of partnerships and data sharing agreements with other organizations in the system or by developing internal processes that enable rigorous enforcement while also supporting dialogue and system learning.

System learning

Data collection can be used as one tool for monitoring compliance and maintaining accountability, but to limit the use of data to this purpose alone is to neglect its capacity to drive learning at all levels of the system. The OA must be given sufficient resources to develop the infrastructure required for this purpose, with the direction of inquiry to be guided by the CRD to ensure that the approach is informed by expertise. The appropriate information technology supports to enable this system are integral to its success.

Data from across the system can be provided to facilities, allowing them to compare their own performance to that of other facilities and to identify system leaders that could be emulated or collaborated with for improvement. Support for this approach can be found within recent initiatives like that undertaken by the Canadian Partnership for Quality Radiotherapy (CPQR), which involves co-collecting and sharing incident data from centres from across Canada for the purpose of system learning.³¹

Aggregate data can also be analyzed and used in pursuit of the “as low as reasonably achievable” (ALARA) principle and the three fundamental principles of radiological protection proposed by the International Commission on Radiological Protection—justification, optimization and the application of dose limits.³² For example, with a wealth of data collected on exposure, the CRD, the OA and other system partners could collaborate to develop evidence-based standards for dose thresholds. Data can help in establishing benchmarks and indicators for the system, allowing for the identification of learning opportunities and, in the future, to incentivize behaviours. Furthermore, the success of implementing these changes can be evaluated through continued data monitoring.

³¹ Canadian Partnership for Quality Radiotherapy. [A National System for Reporting Radiation Incidents](#).

³² International Commission on Radiological Protection. (2007). The 2007 Recommendations of the International Commission on Radiological Protection.

Burden and harmonization

Burden

Existing requirements currently place an undue burden on facilities—stakeholders indicate that delays in inspections or approvals impact facility start-up and ongoing operations; administrative forms or submission requirements are sometimes duplicated between oversight bodies; regulatory guidelines often do not adapt to changing consensus around standards, resulting in confusion across the system; training or competency requirements are out-of-date and may not reflect the current environment. In some cases, burden and complexity in the system are at odds with provincially articulated targets and funding constraints—for example, the lack of timeliness in the CT scanner registration process can increase wait times and costs.

Reducing burden on both facilities and on the regulator itself should be a focus of updated legislation. Mechanisms for doing so should include:

- Clarifying all terms and categories to prevent confusion;
- Improving infrastructure available to avoid unnecessary delays in services;
- Ensuring that inspections, data submission requirements, and other mechanisms for monitoring compliance are employed effectively and strategically and that the effort associated for both facilities and regulators supplies a corresponding benefit (e.g. meaningful use of data rather than collection for its own sake);
- Offering a definitive place for facilities to go to understand requirements and regulations;
- Allowing for automated, electronic submissions wherever possible to accommodate data mining, if needed;
- Promoting a degree of self-regulation through the quality management system under the AA;
- Allowing transparent comparisons to other practices in the province (in aggregate) to drive the adoption of better practice.

Harmonization

The issue of duplication of requirements across oversight bodies can be mitigated by way of harmonization among stakeholders in the system. The federal government and many professional colleges already administer robust standards in certain domains. In collaborating with these bodies to harmonize guidelines, the gaps and overlaps in this system could be addressed.

For example, as part of their recent legislative overhaul, Alberta worked closely with the CNSC to ensure that federal requirements were not duplicated. In following a similar approach, Ontario has the opportunity to ensure that navigating both federal and provincial regulatory requirements is not an onerous process for facilities. Harmonization will also support the system in addressing current gaps, particularly for hybrid devices like PET-CT scanners, which are governed partially by federal oversight (PET-radiopharmaceutical handling) and partially by provincial oversight (CT).

Harmonization will reduce confusion and duplication for facilities and make more efficient and effective use of regulatory resources. It will also provide an opportunity to take advantage of the best examples of guidelines and standards, regardless of their source. To ensure that harmonization is pursued on an ongoing basis, the OA should be given the mandate to engage key stakeholders in the system, including: professional colleges, the federal government, other ministries or agencies that set standards (e.g. Ministry of Labour), accreditation bodies and representatives from industry.

Timeliness of approvals

One stakeholder submission received over the course of the panel's process reported wait times for CT designations of between four and ten months, after which approval of plans are still required before installation can take place. Thus, an overall timeline of one year is required for capital equipment replacement to take place at their hospital.

The ultimate effect of these delays, regardless of the cause, is to place greater burden on existing services and reduce the timeliness with which the system as a whole can provide care.

From the perspective of burden, a successful implementation of the proposed model would allow a single QMP structure and process within the Facility to satisfy both provincial and federal regulations. This single process would provide appropriate and harmonized reporting to both levels of regulation and constitute a core part of the quality management architecture in every healthcare facility in the province of Ontario.

Transparency

Provincial mechanisms

Data collection allows for accountability, not just to the OA but also to patients and members of the public through transparent reporting. The OA should work with system partners to develop and report on provincial-level indicators, promoting public confidence in the quality of Ontario's EAMD services. Provider- and facility-level reporting can also be used to help support local improvement. The OA should seek out partnerships with organizations like Health Quality Ontario to determine how this data can be used and reported most effectively to drive improvement and efficiency.

Efforts to ensure transparency should also extend to the OA and the CRD and its taskforces. As a lever for ensuring that the OA remains accountable to these expert bodies, all recommendations developed by these expert bodies as well as the OA's annual report should be made publicly available.

Transparency may also involve broader educational interventions for patients and providers regarding the risks and benefits of EAMD services. The panel recognizes appropriateness as a difficult issue to legislate, but one that has a powerful impact on the quality of services. Being subjected to unnecessary or excessive testing and interventions can heighten a number of risks—among them, exposure to radiation and incorrect diagnoses resulting from false positives. However, determining when a medical service or intervention is inappropriate depends on many factors, including the prescribing provider's training, the competencies of those carrying out the procedure and the willingness of patients themselves to advocate for certain services after deciding that the perceived benefits outweigh the risks. In addition, efforts need to be made to educate the public on the value of appropriately prescribed tests. A patient that declines an appropriate test due to unfounded fears regarding acceptable levels of radiation exposure would demonstrate the system's failure to deliver on its commitment to a person-centred approach. Campaigns like Choosing Wisely, Image Gently and other educational initiatives should be evaluated, supported and enhanced in order to promote understanding among both providers and the public, helping them to make more informed decisions regarding the value and appropriateness of EAMD use.^{33,34}

Incident reporting

Facilities and the providers they employ also have a duty to be transparent with individuals who receive screening or interventions with EAMDs. A number of national and international jurisdictions have moved towards firmly establishing requirements for incident reporting in legislation and regulation, and Ontario should follow suit.

While both the HARP Act and the *Public Hospitals Act* stipulate that incidents be disclosed to patients or their representatives, the definition of incident in the PHA requires that serious injury or harm has occurred. This definition may be limiting when applied to EAMDs, where the extent of the injury or harm is not always immediately clear. What qualifies as an incident and to what level it should be

³³ Choosing Wisely Canada. [Radiology: Five Things Physicians and Patients Should Question](#).

³⁴ Alliance for Radiation in Pediatric Imaging. [Image Gently: Educational Materials](#).

escalated is important to articulate in order to provide clarity in accountability. For example, Alberta's legislation requires notification when overexposures (or incidents that could result in overexposure) occur, and the process for notification is outlined clearly. Similarly, California legislation names specific circumstances in which reporting must take place, including when CT is unintentionally repeated, an incorrect body part is irradiated or certain CT dose thresholds are exceeded. Though flaws exist in both of these systems, with the aid of progressive data collection and system learning Ontario has an opportunity to pursue dose thresholds that minimize exposure and to ensure that patients are kept informed.

There are recognized challenges in engaging clinicians and administrators in the uptake of incident reporting, but there is an opportunity in Ontario's current environment to leverage legislative changes and initiatives currently underway related to critical incidents, including a planned legislative update to the Quality of Care Information Protection Act and an initiative underway at HQO to establish a provincial repository for sharing recommendations from incidents. Regulations should clearly establish when and how incidents should be reported into a central repository to support system learning, and in what cases incidents should be managed locally, including when disclosures should be made to patients and their families. Furthermore, relevant learnings should be rapidly shared with all licensees to minimize the likelihood that the incident will be repeated within Ontario.

Dose registries

A number of stakeholder submissions received as part of the panel's process were in favour of establishing a provincial dose registry, which could be used to support quality improvement at facilities and inform best practices provincially.

Collecting such a significant data set will increase opportunities for transparency in the system. A number of jurisdictions do this already, including the U.S. (via the Food and Drug Administration and the American College of Radiology) and the United Kingdom. California is at the forefront of initiatives to provide greater public transparency, and has recently introduced requirements that total effective CT doses be recorded for all studies conducted and added to interpretive reports. This has led to questions regarding how dose exposure values are interpreted by both referring physicians and patients who access them. Determining what values should be reported in order to ensure that they are not misinterpreted is an issue—approaches to reporting doses vary, and the calculation of an accumulated dose will differ depending on whether radiation has been applied to a limb or to the abdomen. Simply providing doses without additional context and to those without appropriate training could even result in individuals opting against necessary interventions or tests out of misplaced concern.

However, transparency regarding doses could drive greater awareness of the risks associated with EAMDs and ensure accountability to patients. While many of California's requirements were introduced reactively to manage issues in the system, Ontario is in a position to investigate all the issues surrounding dose reporting and make a strategic decision about how this could be best executed such that it promotes confidence and does not inspire fear unnecessarily. A provincial dose registry could accommodate not just CT-related dose, but also with other forms of ionizing radiation. Given that all medical imaging is digital, in future it may be possible to mine metadata as part of a variety of other quality improvement initiatives, including those involving appropriateness.

Testing the Framework

In order to assess the proposed framework, the panel tested its parameters against each of the principles identified as integral to quality oversight.

	Current System	Proposed System
Person-centred	<ul style="list-style-type: none"> ○ Few mechanisms for transparency ○ Limited or variable support for campaigns to educate patients and providers on issues like appropriateness ○ No recognition of differences in risks/benefits across cohorts 	<ul style="list-style-type: none"> ✓ Opportunities for public reporting and transparency ✓ Greater transparency to individual patients via dose reporting ✓ Clear and well-understood approaches to incident reporting ✓ Approach based on risks/benefits; recognizes cohort differences
Strong oversight and accountability	<ul style="list-style-type: none"> ○ No provincial oversight for non-ionizing radiation devices ○ Standards for ongoing operations unclear or lacking ○ A focus on credentials vs. competencies ○ Infrastructure and resources for monitoring compliance limited 	<ul style="list-style-type: none"> ✓ Roles and accountabilities for quality clearly articulated ✓ Stronger compliance monitoring capabilities through data ✓ Greater infrastructure to support oversight bodies ✓ Strong mechanisms for holding facilities accountable
Adaptable and flexible	<ul style="list-style-type: none"> ○ Limited infrastructure to address new technologies 	<ul style="list-style-type: none"> ✓ Regulations refer to external standards that continually update ✓ CRD scans the field for gaps and opportunities ✓ Support for current, emerging, and hybrid technologies
Based on best evidence	<ul style="list-style-type: none"> ○ Standards are not maintained and refer to outdated sources ○ Lacking groups with expertise to scan the field and update 	<ul style="list-style-type: none"> ✓ Expertise embedded in the regulation development process ✓ Regulations leverage up-to-date standards and existing resources to ensure Ontario remains on the leading edge
Focused on system learning	<ul style="list-style-type: none"> ○ No opportunities to use data to drive learning and improve standards 	<ul style="list-style-type: none"> ✓ Robust data collection system to drive learning and improvement ✓ Opportunities to focus on key initiatives like appropriateness and dose thresholds
Minimizes burden and promotes harmonization	<ul style="list-style-type: none"> ○ Patchwork of provincial and federal legislation, accreditation and regulatory oversight operates in the space ○ Duplicative information often required via submissions ○ Definitions are unclear, creating confusion in the field 	<ul style="list-style-type: none"> ✓ Oversight authority works closely with other regulatory bodies to ensure alignment and harmonization and reduce duplication ✓ Expert involvement in regulation development to reduce confusion and improve clarity of requirements ✓ Aligned with emerging quality management approaches
Supports transparency	<ul style="list-style-type: none"> ○ Limited support for incident reporting ○ No capacity to collect or publicly report on data to monitor quality in the system 	<ul style="list-style-type: none"> ✓ Data collection provides opportunities for public reporting ✓ Clarification of incident reporting guidelines supports facilities ✓ Potential for dose registries and individual-level reporting

Next Steps

Phased Approach

The Ministry should begin by establishing a taskforce to develop the regulations and standards for conventional radiography, fluoroscopy and CT, and should use the output of this work to test the legislative model proposed above.

The infrastructure required to support ongoing operations of the proposed system will take time to establish. In order to prevent unnecessary delays in the execution of modernized legislation, the work of this first taskforce should begin immediately. Efforts to establish the Oversight Authority and the Committee to Regulate Devices can be carried out in parallel. This phased approach would allow for work to begin immediately, would provide the opportunity to confirm the feasibility of the proposed approach and would contribute to a validated roadmap that could be used by future taskforces. Once infrastructure related to the OA and CRD are firmly established, ongoing activities could be folded into this structure.

The panel saw no reason that the legislative framework and the regulations for CT and X-ray (radiography and fluoroscopy) could not be finalized within two years.

Priorities for regulation

Among the devices and technologies considered by the panel, X-ray and CT were seen as obvious starting points given that any modernized legislation would need to address the devices currently regulated by the HARP Act. The HARP Act currently has many strengths and addresses many of the dimensions of quality articulated above, and it may be the case that many of its components can be adopted and embedded in new legislation. Fluoroscopy was also considered a high priority. It involves continuous X-ray exposure as part of real-time monitoring of procedures (e.g. placing a stent in the body), and it can result in relatively high radiation doses and acute side effects. Ensuring that the necessary standards and professional competencies are in place is imperative. Developing regulations for this modality would work to mature the competency component of the proposed regulatory model as well, and approaches from jurisdictions like California could be investigated further in support of this.

As the criteria for MR are relatively straightforward and the technology does not involve some of the same exposure risks as CT or X-ray, the panel saw this stream of activity as an opportunity to test the new framework with a modality that has never been regulated previously. Ongoing advancements in MR, including the move to higher field strengths (from 3T to 7T) and its emerging use in guiding high-risk, life-saving treatments, also support the need for regulation.

Finally, ultrasound was seen as a difficult technology to regulate, but also a high priority for oversight. There is an absence of high-quality evidence related to the standards for ultrasound; its use is extremely heterogeneous in health care settings, with applications that increasingly include point-of-care and unregulated community settings. Though ultrasound imaging technology itself carries few risks of direct harm, the risks associated with misinterpretation may be significant, particularly in cases where it is used to guide procedures or to make significant decisions regarding care. Greater oversight related to training, particularly in appropriate use and interpretation, was seen as a high priority.

Beyond the technologies listed above, future taskforces should also address nuclear medicine and PET/CT, among others as the need arises. In future, there may be cause to employ the framework in regulating novel or emerging applications of energy or medical applications like electroconvulsive therapy and transcranial magnetic stimulation.

Challenges and Opportunities

Though the panel was clear in their recommendation that this work be undertaken quickly, a number of challenges will need to be overcome to ensure that this new legislative framework is successful. Regulators should also be mindful of the opportunities that a renewal of legislation presents in order to take advantage of these.

The role of the medical physicist

From 2004 to 2007, more than 1000 treatments were delivered to 620 patients at the Ottawa Hospital Cancer Centre using inaccurate data to calculate radiation dose and to program the centre's radiation therapy unit. As a result, 326 patients received a potentially clinically significant under-dosage (as much as 17% less than the dose prescribed by their physicians).

After reviewing the issue, an expert panel concluded that the radiation unit was improperly calibrated following relocation from another campus. Root cause analysis revealed that staffing shortages and extreme resource limitations affecting the centre's medical physicists contributed significantly to the error. To prevent similar incidents in the future, the panel stressed the criticality of medical physics for the safety and quality of services involving large doses of radiation.

Competencies

In addressing the competencies of professionals in new legislation, regulators must confront the insufficient degree of oversight for particular professions within the existing system. Medical physicists are currently unregulated, despite the fact that they serve a de facto mandatory role in terms of the commissioning and quality oversight of EAMDs (including X-ray systems, CT and MR scanners, as well as radiotherapy systems), a role that is necessary to achieving optimal image quality with the minimum dose applied, delivering safe radiation treatments and ensuring radiation protection of patients, providers and the public.³⁵

Similarly, there are no regulatory bodies ensuring competencies for ultrasound or providing oversight for sonographers. In some cases, this vacuum in oversight may be addressed through means beyond regulation—for example, in response to a request from the MOHLTC, the Health Professions Regulatory Advisory Council (HPRAC) released a series of reports recommending that diagnostic sonographers be regulated as part of the profession of medical radiation technology.³⁶ However, in others, establishing such a regulatory body may not always be the most efficient or desirable mechanism to

ensure quality, particularly as the application of EAMDs and the professions associated with them continue to change. Any new regulations developed will need to grapple with this issue and determine how best to identify and enact standards related to competencies.

Worker protections

Currently, the HARP Act encompasses the application of ionizing radiation to all human beings and is not explicitly focused on those receiving care. It provides standards for shielding and whole-body-dose-equivalent limits for both members of the public and X-ray workers. The worker protections

³⁵ Dunscombe P, Lau H, Silverthorne S. (2008). [The Ottawa Orthovoltage Incident: Report of the Panel of Experts convened by Cancer Care Ontario.](#)

³⁶ [Health Professions Regulatory Advisory Council. Diagnostic Sonography: Recommendations for Regulation under the Regulated Health Professions Act, 1991](#)

offered by the Act are further supplemented by those established under the **Occupational Health and Safety Act**, which include dose equivalent limits and dosimetry requirements.³⁷

If the HARP Act is repealed, the OHSA will continue to address issues of radiation exposure for workers; however, if any gaps should arise as a result of the Act being removed, those must be identified and addressed.

Capacity and resources

A number of stakeholder submissions received by the panel named delays in receiving approval for installation as a barrier, and suggested that inspections are often relatively limited. If the mandate of the existing program were to be scaled up—not only to encompass new devices, but also to inspect with an eye to broader issues of quality—resources would similarly need to be invested to enhance the capacity of this oversight structure.

To address the need for additional resources, the work of the many organizations currently acting in the space of EAMD oversight should be leveraged wherever possible. In some cases, programs currently operated by provincial bodies like the CPSO and CCO already provide significant quality oversight, and facilities operating under those programs may only need to meet a few additional requirements to be in compliance with updated legislation. Similarly, bodies like the Canadian Association of Radiology and the American College of Radiology provide world-leading accreditation services that should be leveraged to prevent duplication in effort.

Regardless of challenges and resource limitations that may arise, there is currently widespread readiness within the field to push the EAMD quality agenda forward. Almost all stakeholders who submitted feedback as part of this process expressed broad support for modernization of legislation. Recent reviews of diagnostic imaging quality in Ontario undertaken by expert panels at HQO were also highly aligned with the innovative and adaptable approach the panel has suggested. This is an ideal moment to capitalize on growing support for a modern approach to quality in EAMDs. Although investments may be required upfront to achieve this modernized system, the framework suggested here is integral to providing more streamlined, appropriate and rationalized care in the future. Failure to undertake these changes will ultimately incur greater costs to the system in the long-term.

Industry

Industry partners have a key role to play, both in helping to operationalize components of the quality contract and in developing innovations that promote even greater quality in the delivery of care. Device manufacturers can support automation of certain requirements laid out in regulation; for example, integrating doses into patient records or collecting and submitting data. Modernized regulations can also support industry by enhancing collaboration between regulators in the system, thereby reducing the burden on vendors to understand and adhere to requirements. Recognizing and supporting industry stakeholders as key partners in this work will be integral to designing innovative and future-focused legislation.

³⁷ [R.R.O. 1990, Reg. 861: X-Ray Safety](#)

Summary of Recommendations

Recommendation 1: Expand the scope of legislation for radiation protection in Ontario

1.1	Undertake a process to expand the scope of legislation to include all energy-applying medical devices, establishing a framework that addresses: the existing functions of the HARP Act, its gaps and shortfalls and anticipated and unanticipated innovations.
1.2	Define energy-applying medical devices as devices that <i>apply</i> energy in the form of acoustic or electromagnetic radiation to the human body, or devices that <i>detect</i> energy applied to the body pharmaceutically (e.g. radiopharmaceuticals), and are approved for use by Health Canada.
1.3	When determining what devices to subsume under regulation and how those devices should be regulated, dimensions of risk and benefit should be taken into account, including both a device's specific applications and the patient cohorts in which it will be applied.

Recommendation 2: Establish a new governance structure for quality oversight of energy-applying medical devices

2.1	Establish an Oversight Authority with the mandate and resources to establish policies, ensure compliance, collect and analyze data and engage with relevant stakeholder groups to harmonize requirements.
2.2	Establish a Committee to Regulate Devices, an independent body of experts tasked with a mandate to identify gaps in regulation, establish taskforces, conduct annual reviews of policies and standards and advise on analytics and system learning.
2.3	Within facilities, require an Applicant Authority to be designated with the necessary qualifications to be accountable for developing, updating and overseeing the facility's quality management program and maintaining compliance with regulations for EAMDs.

Recommendation 3: Use a phased approach to introduce modernized legislation and regulation

3.1	Immediately strike a taskforce to develop regulations for conventional X-ray radiography, fluoroscopy and CT.
3.2	Select taskforce members representing a range of clinical practice, geographic and facility contexts, with competencies/expertise in a variety of issues related to quality in EAMDs.
3.3	Support the taskforce in consulting with stakeholders and help them to identify externally developed standards that can be leveraged locally to reduce duplication of efforts.
3.4	Test X-ray and CT regulations and standards against existing standards in the HARP Act to ensure that gaps and overlaps have been addressed.

3.5	Within new regulations and standards developed, assure the practice of medical physicists be advanced as a necessary component of the safety and quality of EAMD operations.
3.6	As soon as the feasibility of this legislative approach is confirmed, launch two additional taskforces to develop regulations for MR and ultrasound, using lessons learned from the first phase to inform the next phase of work and achieve standardization in design.
3.7	Repeal the HARP Act and enact new legislation.
3.8	Once the infrastructure of the Oversight Authority and Committee to Regulate Devices is established, fold all ongoing and future work under this structure.
3.9	Require the Oversight Authority to work collaboratively with stakeholders across Ontario and Canada to promote harmonization in standards and best practices.

Recommendation 4: On an ongoing basis, strike taskforces to develop or update regulatory requirements where indicated by the Committee to Regulate Devices

4.1	Provide the CRD with the authority and resources to scan the field for changes in technology and practice and to identify devices requiring regulation and instances where changes are required to regulation.
4.2	Require the CRD to carry out annual reviews of the policies and standards of the Oversight Authority, with an annual report on its activities to be submitted to the committee.
4.3	Provide the CRD with the mandate to create or designate taskforces with the necessary expertise to develop regulations for EAMDs identified as requiring regulation.
4.4	Allow taskforces to establish the specific characteristics that will define the device class within regulations.
4.5	Require each taskforce to consider regulations for facilities, equipment, processes, professional competencies, mechanisms for ongoing compliance and accountability and the quality management framework, following a standardized approach informed by previous taskforces and other regulatory efforts.
4.6	Provide the CRD with the necessary resources to identify standards or best practice documents that could be leveraged to promote harmonization in the system; also provide the resources to develop or adapt these documents where existing examples are lacking.
4.7	Require taskforces to identify standards for the competencies of professionals prescribing services, operating devices, interpreting device outputs, providing technical servicing, ensuring radiation protection and acting in the role of the Applicant Authority.
4.8	Permit taskforces to build mechanisms to accommodate variances from regulation, provided that the process to apply is sufficiently rigorous and that the applications themselves are reviewed by individuals with the appropriate expertise.
4.9	Require sign-off by the CRD on all draft regulations before they are posted to ensure they align with the original intent of taskforce recommendations.

Recommendation 5: Continue to develop the infrastructure required to drive system learning

5.1	Provide the Oversight Authority with the resources and digital infrastructure to support a robust system of data collection and analysis.
5.2	Give the CRD the mandate to guide the direction of data analysis and require reports to be returned to the committee regularly.
5.3	Use aggregate data to drive system learning and to inform the development of benchmarks, targets and indicators.
5.4	Identify opportunities to use centrally reported data to drive local improvement, including by allowing facilities to compare their own performance against their peers.

Recommendation 6: Develop and foster mechanisms to enhance public reporting and transparency in the system

6.1	Use data collection infrastructure to develop a public reporting strategy to support transparency and promote confidence in the quality of EAMD services in Ontario.
6.2	Make all recommendations of the CRD and its taskforces and the annual report produced by the OA publicly available.
6.3	Establish clear requirements in regulations related to when incidents should be reported and shared, and when incident disclosures are made to patients.
6.4	Invest in campaigns and educational interventions among both patients and providers to enhance appropriateness and to support the system in working towards the As Low As Reasonably Achievable principle.
6.5	Investigate the possibility of creating a provincial dose registry that would allow patients and members of the public to make more informed decisions related to their care.

Conclusion

Ontario's radiation protection legislation and infrastructure has long served as a safeguard, helping to mitigate risks to patients and members of the public as they undergo testing or receive therapy. As technologies, clinical practices and approaches to analytics in the field have evolved, so too have expectations of quality in the system. The quality contract demands a new regulatory infrastructure with the mechanisms necessary to keep Ontarians safe, to drive learning and improvement, to reduce duplication and confusion in the field and to position the province for growth and innovation.

The elements that ensure quality in EAMD services are often invisible to patients—from the dose of radiation received during CT scanning to the technical servicing of equipment and the credentials of individuals providing services, patients rely on the assumption that someone is accountable for verifying and monitoring their quality.

This new system proposes making this quality contract explicit, ensuring that all of the factors that contribute to quality and risk in a service are appropriately regulated and that the accountability for complying with regulations is clear. Furthermore, this model goes beyond ensuring that quality processes are in place behind the scenes. It also seeks to increase the transparency of the system to allow patients and members of the public to make more informed decisions about their care.

Revisiting the Quality Contract

Under this new system of oversight, a patient undergoing a CT scan can expect:

- That the facility where she receives treatment is licensed and that one person is responsible for the quality of her care;
- That her health care providers are fully trained in the risks and benefits of the procedure and that someone has considered whether she really needs the scan;
- That she is receiving the minimum dose of radiation needed to allow her physicians to understand her condition and make decisions about her care.

Appendix 1 – Panel Terms of Reference

MANDATE

To provide recommendations / advice to Health Quality Ontario (HQP) on the modernization of the *Healing Arts Radiation Protection Act* (HARP Act) in order to:

- Enhance patient, provider and public safety in energy-based imaging and therapeutic modalities, contemplating risk for general use, therapeutic use, and use with vulnerable (e.g., pediatric) populations; and,
- Promote quality in their application to medical practice.

To achieve these goals, the panel will prepare a legislative/ regulatory framework for safety and quality.

RESPONSIBILITIES

The panel will achieve its mandate by Spring 2016.

In undertaking its responsibilities, the Panel will consider best available scientific evidence, best practices and any similar legislation in other jurisdictions.

Panel activities will include the following:

1. Identify and agree upon the principles of quality and safety underlying the use of energy-based imaging and therapeutic modalities in medical practice.
2. Assess the gaps that have been identified during stakeholder consultation. See, for example, foundational briefing deck: *Modernizing the Healing Arts Radiation Protection Act* (HARP Act) (slides 7 to 10).
3. Develop a unifying, adaptive legislative quality framework that can accommodate any type of energy-applying medical devices (EAMDs). Devices which may require new, amended, additional or harmonized standards and monitoring based on the framework include but are not limited to:
 - Ionizing radiation emitting devices / X-ray machines (e.g., computed tomography (CT) scanners)
 - Nuclear radiation devices (e.g., nuclear medicine and radiation therapy)
 - Non-ionizing radiation devices (e.g., magnetic resonance imaging scanners and ultrasound)
 - Mobile / portable / handheld medical radiation devices
 - Hybrid/combination systems (e.g., guided high-intensity focused ultrasound and positron emission tomography / computed tomography devices)
 - Therapeutics and image-guided procedures
 - Devices used for personal non-medical purposes such as lasers
 - Devices used for research and experimental purposes (does not include protection of workers in the field of veterinary medicine)

In developing the framework, the panel is asked to make recommendations in areas including but not limited to:

- a) Compliance with safety and quality standards in the context in which devices are operated;
 - b) Professional practice standards (e.g., ordering tests using EAMDs, operating EAMD equipment). Other issues for consideration include: delegating EAMD activities, interpreting images taken with EAMDs, reviewing image interpretation, IT, record management, appropriateness;
 - c) Roles and responsibilities, including responsibilities of device manufacturers, testers, owners/ licensees and radiation protection officers (RPOs); and,
 - d) Reporting, compliance monitoring, oversight mechanisms and approaches to determining device inclusion over time (e.g., risk-based assessment mechanism).
4. Compare the framework with current HARP Act requirements to identify gaps, overlap and duplication.
 5. Test the framework and its application to various modalities, specifically evaluating the legislative, regulatory and operational gaps, overlap and duplication in accountabilities and responsibilities of stakeholder organizations including the MOHLTC, other provincial ministries, the federal government, regulatory colleges and other radiation protection organizations.
 6. Provide recommendations for next steps in implementing a new framework for oversight of EAMDs, including governance structures and timelines for implementation.

FINAL PRODUCTS

Panel products will be determined in consultation with Panel members.

SCOPE

The scope of the committee's work is to undertake analysis and provide advice necessary to modernize legislation, regulations and operational policy. Unless later specified by HQO, it does not include advising on funding.

MEMBERSHIP

Panel co-chairs are:

- Tim Dowdell, Radiologist-in-Chief, St. Michael's Hospital
- David Jaffray, Executive VP of Technology and Innovation, Medical Physicist and Senior Scientist, University Health Network

Panel members are:

- Paul Cornacchione, Clinical Director, Joint Department of Medical Imaging; Medical Radiation Technologist, University Hospital Network
- Julian Dobranowski, Provincial Head, Cancer Imaging, Cancer Care Ontario; Senior Consultant, Strategic Quality Initiatives Diagnostic Imaging, St. Joseph's Healthcare, Hamilton
- Lee Fairclough, VP, Quality Improvement, HQO (ex-officio)
- Neville Fairclough, Patient Representative
- Sophie Foxcroft, Director, Operations, Radiation Medicine Program, Princess Margaret Radiation Medicine Program, University Health Network
- Michael Gardner, Manager, Quality Assurance, Royal College of Dental Surgeons of Ontario
- Bruce Gray, Medical Radiologist, St. Michael's Hospital

- Dawn-Marie King, Administrative Director, Laboratory Medicine and Medical Imaging, St. Michael's Hospital
- Ting Lee, Medical Physicist and Senior Scientist, Robarts Research Institute
- Michael Milosevic, Radiation Oncologist and Clinician Scientist, University Health Network, and Chair, Canadian Partnership for Quality Radiotherapy
- David Price, Director of Diagnostic Services, Queensway Carleton Hospital
- Murray Rice, Clinical Engineer, University Health Network
- Tony Seibert, Professor of Radiology, UC Davis Medical School
- Manohar Shroff, Radiologist in Chief, The Hospital for Sick Children
- Colleen Taylor, Board Member, Independent Diagnostic Clinics Association

ACCOUNTABILITY / REPORTING

The Panel Co-Chairs report to the President and Chief Executive Officer of HQO. HQO reports to the MOHLTC.

ACCESS AND PRIVACY

All information pertaining to the panel, including notes written by individual members, is subject to the provisions of the *Freedom of Information and Protection of Privacy Act* and may be subject to disclosure in accordance with this Act.

CONFLICT OF INTEREST

Any actual, potential or perceived conflict of interest arising in regard to any matter under discussion by the Panel must be disclosed to HQO.

ADMINISTRATIVE, RESEARCH AND CONSULTATION SUPPORT

Support for the Panel will be provided by HQO.

HQO will provide administrative support, which will include drafting of meeting minutes, preparation of meeting materials and agendas and maintaining all records relevant to the Panel.

HQO will conduct consultations requested by the Panel to support its activities.

DECISION-MAKING PROCESS

Decisions of the Panel will, as much as possible, be made by consensus. If consensus is not possible, a simple majority of members present will suffice, in which case the vote will be recorded and significant objections noted.

Appendix 2 – List of Stakeholder Groups Consulted

Stakeholder submissions from the following organizations were reviewed and considered as part of the panel's process:

- Canadian Dental Hygienists Association
- Canadian Organization of Medical Physicists
- Canadian Memorial Chiropractic College
- College of Chiropodists of Ontario
- College of Dental Hygienists of Ontario
- College of Medical Radiation Technologists of Ontario
- College of Nurses of Ontario
- College of Physicians and Surgeons of Ontario
- College of Physiotherapists of Ontario
- Hamilton Health Sciences
- MEDEC
- Nurse Practitioners' Association of Ontario
- Ontario Association of Medical Physicists
- Ontario Association of Medical Radiation Sciences
- Ontario Chiropractic Association
- Ontario Dental Hygienists' Association
- Ontario Hospital Association
- Ontario Physiotherapy Association
- Ontario Podiatric Medical Association
- Registered Nurses' Association of Ontario
- Royal College of Dental Surgeons of Ontario

The following groups were also consulted as part of the panel's efforts to understand different regulatory and jurisdictional approaches:

- Canadian Nuclear Safety Commission
- Health Canada
- Ministry of Health and Long-Term Care

Appendix 3 – Summary of the Regulation of Health Professionals in Ontario

In Ontario, health professionals and the activities they can perform are regulated through a number of mechanisms, including:

- The *Regulated Health Professions Act, 1991* (RHPA);
- The health regulatory colleges;
- The various health professions acts;
- Other regulations and statues that limit or enable particular activities (e.g. *Laboratory and Specimen Collection Centres Licensing Act, Healing Arts Radiation Protection Act, Public Hospitals Act*).

The **RHPA** establishes the system of self-governance for 27 health professions under 26 health regulatory colleges. It also contains a blanket prohibition on the performance of 13 controlled acts (namely, health care services that would pose significant risk of harm if performed by unqualified individuals) unless certain conditions apply. The conditions include membership in a particular health regulatory college or delegation of the task by such a member. Regulated health professionals and some non-regulated individuals may be exempted from the blanket prohibition under the Controlled Acts Regulation.

The **health regulatory colleges** established by the RHPA are self-governing and self-financing bodies that are responsible for regulating their respective health professions in the public interest. They have regulation and by-law making powers that allow them to carry out registration, investigations, complaints and discipline and quality assurance. As part of their responsibilities, the colleges set standards of practice and establish requirements related to continuing education and professional development.

The **health professions acts** (e.g. *Medicine Act, 1991, Nursing Act, 1991*) require individuals to be members of health regulatory colleges in order to practice and identify themselves as members. These establish each profession's scope of practice, controlled and authorized acts and protected titles.

The HARP Act itself also deals with dental assistants, as no external college is responsible for regulating them. Under the RHPA, the Health Professions Regulatory Advisory Council contains a mechanism for updating the list of professions included in legislation. However, they may only undertake such an update if the minister refers them, in writing, to conduct a review. This is done at variable frequencies, at the discretion of the minister.

In terms of the governance of EAMDs, the RHPA prohibits individuals from: “applying or ordering the application of a form of energy prescribed by the regulations under this Act,” unless authorized. Forms of energy included are electricity, electromagnetism (MRI) and soundwaves. The application of X-ray and radiation is controlled by the HARP Act, which contains a number of requirements related to professionals. The following table provides a comparison of the two pieces of legislation and their applications:

Governance Area	RHPA	HARPA
Authorizing individuals to order and apply x-ray radiation for health care purposes	X	✓
Authorizing individuals to order and apply other forms of energy for health care purposes	✓	X
Setting educational requirements/ qualifications for health care professionals	✓	✓
Requirements for ongoing competence for health professionals	✓	X
Premises	X	✓
Equipment	X	✓
A mechanism dedicated to regularly integrating new technologies into professions' practice	X	X

Appendix 4 – Documents Reviewed

All website links active as of February, 2016.

1. Accreditation Canada. (2013). [Diagnostic Imaging Services](#).
2. Accreditation Canada. (2014). [Strategic Plan 2014-2016](#).
3. Alliance for Radiation in Pediatric Imaging. (n.d.). [Image Gently: Educational Materials](#).
4. American Registry of Radiologic Technologists. (2010). [Content Specifications for the Fluoroscopy Examination](#).
5. Australian Department of Health. (n.d.). [Diagnostic Imaging under Medicare](#).
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