MODERNIZATION RECOMMENDATIONS

On the

HEALING ARTS RADIATION PROTECTION ACT

And its

REGULATIONS

INTRODUCTION

The Healing Arts Radiation Protection Act (HARPA) was world leading patient safety legislation in 1980 and was put into place to address the excessive ionizing radiation that patients were receiving from medical diagnostic imaging procedures, particularly fluoroscopy studies but also issues related to appropriateness – duplication of exams in particular. CT was in its infancy. Ultrasound was not as sophisticated as it now is. MRI was in initial development.

Patients now face potential risk of harm from other forms of energy such as MRI, Ultrasound, lasers. There is no substantial legislation in place to protect patients from risk of harm from non-ionizing radiations. Further, the ionizing radiation environment has become even more a patient safety and risk management issue with the increasing CT doses, increasing cardiac investigation fluoroscopic doses, interventional radiology investigation procedures and the increasing ordering of all Diagnostic Imaging examinations as well as treatment planning and delivery imaging (“on board imaging”). Lastly, despite regulations and guidelines at the Federal level concerning Nuclear Medicine and Radiation Therapy, there are gaps that provincial legislation needs to close.

Expert Imaging, detection, diagnosis and treatment: with care!
The issue with medical “radiations” is that unlike pharmaceutical errors by drug companies, pharmaceutical errors that occur at administration, water pollution impacts, the effects of medical radiations often don’t manifest themselves for years.

The Government’s “Excellent Care for All Act, 2010”, and the Minister’s “Ontario Action Plan for Health Care” focuses on better access, better quality, and better value. Modernizing the HARPA or developing new appropriate legislation fits into these healthcare system issues. Without the appropriate legislation in place, lives may be saved, but future healthcare issues and demands, such as unintentionally induced cancers, birth defects and diseases, may be a result if medical energies in the electromagnetic spectrum are not controlled and / or applied appropriately. A modernized HARPA, or its equivalent, will contribute to the Minister’s objective of high quality care, and will reduce the stress on the economy and thus tax payers in addressing the matter of ordering of examinations, acquisition and maintenance of DI and radiation therapy equipment, and help integrate Ontario’s healthcare system related to Interprofessional education and practice.

We were asked to look at contributing to the review, in advance, centering on:

- What can be done through policy
- What needs to be in legislation
- What needs to be done in regulations.

Below we provide our view points on the three areas noted above.

**POLICY - GENERAL**

Patients in Ontario will receive high quality and safe care through the lowest exposure possible to medical radiations as determined by internationally established best practices, ordered by only competent professionals and administered by appropriately certified practitioners, at the lowest possible cost.

To reduce the potential of future cancers, birth defects and diseases.

The government of Ontario will assure patient safety from medical radiations, quality improvement, and economies of scale through an oversight body responsible for the monitoring of patient radiation safety.
POLICY DEVELOPMENT

We are suggesting the following policy development topics and potential objectives:

- That legislation and regulations regarding “radiation” safety to patients encompass both ionizing and non-ionizing radiations for medical purposes – essential now with hybrid technology
- That medical radiation safety be harmonized and subsequently coordinated concerning the patient, worker, and the public – to address issues related to the OH&SA
- That the “As Low As Reasonably Achievable” (ALARA) principle is the primary accountability reference for the ordering and application of all medical radiations no matter the source – universally-accepted internationally, ionizing radiation is classified as a carcinogen
- That only those who have received the proper training, experience and are properly certified be allowed to order and operate Diagnostic Imaging and radiation therapy equipment – this means a change from the present Act; that by virtue of a protected title you do not have the automatic authority. As an example, just because one is a physician, or a nurse, it doesn’t automatically qualify them
- That all ionizing radiation exposure to the patient be recorded according to the best practices internationally – ICRP refers
- That the legislation and regulations model be a flexible and easily amended one to adapt to best practices in radiation protection, changes in technology, and changes in medical and related practices – technology and practice is evolving at light speed
- That anyone who operates medical imaging or radiation therapy equipment must be certified through an accredited program – to prevent the situation that exists now with people operating equipment because of loop holes in the HARPA. Operation of the primary and components of equipment directly affects the dose the patient receives, the image quality and clinical outcomes. Proof of both training and experience is essential, especially in the situation where operation of the equipment and its system components is limited. Delegation of operating DI and radiation therapy equipment is unsafe and undermines patient care
- That accountability mechanisms are in place for those authorized to order medical imaging procedures – presently a weak area in the HARPA, and must dovetail with the RHPA and individual scopes of practices
- That a comprehensive compulsory quality control program is in place for each medical imaging and radiation therapy facility to include control, monitoring, reporting and accountability mechanisms to assure patients that the medical imaging and radiation therapy equipment is indeed operating safely – this is a critical element. History has shown the XRIS cannot get to all facilities. Presently there is no requirement for a comprehensive compulsory program. The HARPA regulations are still based on the 1970’s environment and thus is not adequate for today
The Radiation Protection Officer (RPO) is any individual who has taken a certified, recognized course to qualify themselves as an RPO – a long standing and universal issue that needs resolving. Just because one is a radiologist, it doesn’t mean they make a good RPO as history has proven.

The RPO is given full authority to execute any evidence-based decisions concerning patient safety for the facility including its satellite sites if they exist. Each satellite facility of a large hospital needs to have its own dedicated Quality Control individual or assistant RPO – very important especially if a non-physician is the RPO, such as an MRT, Sonographer or Medical Physicist. There have been issues where the RPO has only addressed the DI department, but is actually responsible for all Medical Imaging (MI) equipment no matter the location in that facility. Responsibilities need to be very clear. In the case of facilities with satellite sites, we suggest the title be “Corporate RPO”.

That a provincial inventory be established of all medical imaging and radiation therapy equipment and a sub-inventory of hybrid and combined technology equipments – there is no comprehensive inventory. DI equipment is costly; there are cries for equipment replacement (recent CCO mammography issue as one example). Equipment acquisition and replacement needs to be objective vs. emotive.

That physical inspection of facilities is essential by a branch of the Ministry designed and qualified to do audits to ensure the QC Programs in place are doing their job – this will still be essential, but by qualified, knowledgeable inspectors are needed with clear, concise policies, directives and procedures. The auditing needs to be done to ensure compliance and potential political embarrassment and that it is in concert with the measurement frameworks that are being put into place related to accountability. This will need to be done in collaboration with vendors and third party QC companies to facilitate the auditing process.

That an oversight organization, such as a Commissioning / Advisory Board / Council / Institute, be established to address issues relating to medical radiant energies and that this be a made up of experts in the medical radiant energy field with representation from OTHAC, MOL, and Health Canada, Radiation Protection division – with the HARP Commission’s retirement, there is a gap where coordination and collaboration is needed among provider groups related to medical radiant energies to reduce silo mentality and activity.

THE ACT

As we have suggested, the Legislation needs to include all medical radiant energies that are applied to patients, being that it is a patient safety and risk reduction document. With the changes in technology, and particularly the coupling of various technologies (CT/MR, CT/Ultrasound, SPECT/CT, PET/CT, MR/PET, etc.) called “hybrid technology” legislation is needed if the ultimate goal of reducing the risk to patients is to be achieved.
We recommend that the Legislation be a core document with elements that are not likely to change over time.

We suggest that the following be in the Legislation:

- Definitions – especially defining what an “operator” is or isn’t. This whole section needs a re-write
- Powers of the Minister
- Listing of authorities within the Ministry
- Clause on the ALARA principle
- Clause on the fact that the Legislation is based on evidence-based international, national, and provincial best practices
- Clause on who can own medical imaging and radiation therapy equipment
- Clause on who can order medical imaging and radiation therapy examinations / tests / treatments and the appropriate tool(s) to do this that do not compromise the Act or the intent of it
- Clause on who can administer medical radiant energies
- Clause establishing that every facility and satellite facility, which has medical imaging, must have an Radiation Protection Officer (RPO) to have oversight on ionizing and non-ionizing DI equipment
- Clause that requires every facility and satellite facility, which has a medical imaging or radiation therapy equipment, have a mandatory comprehensive Quality Control program overseen by a qualified individual certified for the equipment of that facility
- Requirement for accountability related to acquisition, installation, ongoing monitoring, and auditing (fits into the mandatory QC Program)
- The making of Regulations, fees, etc.
- Establishment of the oversight body.

**REGULATIONS**

In our view much of what is in the HARPA should go into Regulations one way or another.

We are suggesting that the Regulations include a general regulation or Code, and a series of specific regulations.

The Regulations should reflect the best standards, so where the standard is accepted such as those of the ICRP or Health Canada, they would be inserted into the Regulations rather than make up our own.

The Code, as we are calling it, would include those items that are common to all providers that could include:

- Definitions specific to the Code
• General registration, inventory recording, and approval requirements for the acquisition and installation of equipment – Ministry, vendor, site/facility
• Inspection / audit process
• Cease and desist orders
• Appeal process
• Appointment, qualification, and responsibilities, and accountabilities of RPOs
• Appointment, qualifications, and accountabilities of those responsible for the QC Program in a site/facility/department
• The role of the X-ray Inspection Service, or the agency that will on behalf of the government be responsible to ensure the accountabilities are adhered to
• Linkages with other relevant legislation
• Qualifications of operators
• Appropriate ordering of examinations and tests

Regulations specific to:
• Dentistry
• Podiatry
• General Radiology including Interventional Radiology(IR)
• Radiation Therapy – need to address gaps that the Canada Nuclear Safety Act doesn’t cover or to re-affirm key requirements in that Act
• Nuclear Medicine - need to address gaps that the Canada Nuclear Safety Act doesn’t cover or to re-affirm key requirements in that Act
• Medical Sonography / Ultrasound – there are no requirements to have any kind of QC on ultrasound equipment, who can operate them, and the education and training to operate them. There also is no handle on how many, who owns and/or controls them, and the type of ultrasound units in the Province which is a cost and appropriateness issue
• CT – present regulation is problematic for the DI community, XRIS and 3rd Party groups. The 3D interpretation has caused a lot of stress, confusion and frustration in the DI community regarding installation approvals. There is nothing related to QC on CT equipment in the present Regulations, which is causing DI facilities to struggle with image quality vs. dose, and QC programs for CT are not required and need to be
• MRI – there are no regulations anywhere to address MRI
• Hybrid equipment – there is nothing in the present Act or regulations addressing the combining of technology such as PET/CT, SPECT/CT, etc.
• Lasers
• Chiropractic
Within these specific regulations would be

- Definitions
- Responsibilities
- Accountabilities
- QC requirements of the equipment and any imaging chains and recording systems – each piece of the imaging chain needs to have mandatory QC especially. An example is monitors whose specifications need to be monitored for drift, compression rates checked, etc., as subtle clinical information can be missed leading to a misdiagnosis
- RPO duties
- Qualification of those operating the equipment
- CQI requirements
- Government compliance requirements specific to the Regulation.