



Ontario Association of Medical Physicists

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www.oamponline.net

300 March Road, Suite 202
Kanata, ON
K2K 2E2 CANADA
Tel: (613) 599-3491
Fax: (613) 595-1155

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Mr. Grant Crack, MPP, Member of the Provincial Parliament
Parliament Buildings,
Room 1405, Whitney Block
Queen's Park, Toronto, ON M7A 1A2

Dear Mr Crack,

The Ontario Association of Medical Physicists (OAMP) appreciates the opportunity to provide comments to the Standing Committee on General Government regarding Bill 160, an *Act to Amend, Repeal and Enact Various Acts in the Interest of Strengthening Quality and Accountability for Patients*.

The OAMP represents medical physicists in Ontario. Through the application of our education, skills, and technical expertise, medical physicists assure the safe and effective delivery of energy to achieve a diagnostic or therapeutic result. Medical physicists are employed in Ontario in research institutions and industry, and in hospitals and cancer centres.

The majority of our members are *qualified medical physicists (QMPs)* who have been certified by professional colleges (the Canadian College of Physicists in Medicine, the American Board of Radiology, or the American Board of Medical Physicists) to be competent to provide independent clinical physics services. There are 180 QMPs practicing in hospitals, cancer centres, and other health care facilities in the province. In diagnostic radiology, the medical physicist is a key member of the Imaging Team, as endorsed by the Canadian Association of Medical Radiation Technologists, Canadian Association of Radiologists, Canadian Association of Nuclear Medicine, and Canadian Interventional Radiology Association (www.imagingteam.ca), and in radiation oncology, medical physicists are responsible for maintaining the medical devices and software systems used in radiation oncology.

Qualified medical physicists are not a regulated healthcare profession in any jurisdiction in Canada; as part of our scope of practice, we do not apply energy directly to patients. However, our expertise and activities in quality assurance of energy-applying and detecting medical devices (EADMDs), and in the protection of the public from ionizing radiation, necessitates our interest in Bill 160.

As an organization, we support the repeal of the existing Healing Arts Radiation Protection Act (HARPA), an outdated piece of legislation which no longer meets the required regulatory framework of the fast-evolving EADMDs landscape. Current and future technology and medical practices of diagnostic imaging and radiation therapy have greatly exceeded the scope of the existing act, so introduction of a new quality and safety paradigm is timely. We believe the *Strengthening Quality and Accountability for Patients Act, 2017* can provide the regulatory infrastructure needed to keep Ontarians safe and ensure exceptional quality of care. Our comments pertain to Schedule 9, Oversight of Health Facilities and Devices Act, 2017.

(1) Framework for Quality Oversight:

The recent Health Quality Ontario (HQO) publication *Report and Recommendations on Modernizing Ontario's Radiation Protection Legislation* (2016) made a number of recommendations that are relevant to Bill 160, particularly Schedule 9. Co-chaired by a radiologist (Dr. Tim Dowdell) and qualified medical physicist (Dr. David Jaffray), the report detailed an evidence-based approach to modernize and strengthen the legislation for radiation protection in Ontario. The OAMP provided written comments to the committee during the preparation of the report.

The HQO Report outlined a governance framework for quality oversight of EADMDs (Figure 2 in the report). While the oversight authority ('Executive Officer', Section 2 of the Bill) is established and its roles and responsibilities are clearly defined in Bill 160, the other key component of this framework - the "Committee to Regulate", to advise the oversight authority in licensing and inspecting EADMDs with respect to their safe operation and optimal performance and ongoing regulatory review of these devices, is not established. The OAMP recommends that the structure of the Committee to Regulate Devices be included in Schedule 9 to ensure the quality oversight of EADMD. The proposed system suggested that the oversight authority (filled by Executive Officer) would work closely with an advisory/operational committee to regulate EADMD on an evidence based approach. The committee would consist of healthcare professionals including physicians, qualified medical physicists, medical radiation technologists, and others with expert knowledge of EADMD applications, functionality, theory of operation, and safety. It would provide critical guidance and technical expertise so that the Executive Officer would be able to make policy decisions and regulatory changes for protection of the public in a fiscally responsible manner.

The OAMP further recommends that Committee to Regulate Devices refer to contemporary guidelines and methods regarding protection of the public from ionizing radiation. For example, the X-ray Safety Code (HARPA Regulation 543) refers to guidance documents (*e.g.*, Health Canada Safety Code 20A: *X-ray equipment in medical diagnosis part a: recommended safety procedures for installation and use*) that are dated and not applicable to modern ionizing radiation-emitting devices, such as CT scanners. Further, the application of these dated guidelines increases the construction costs of new and renovated facilities. The Committee to Regulate should have the authority to identify guidelines and standards which are evidence-based and provide economic cost-benefit analysis for the current and future medical device environment in Ontario.

(2) Safety Officer:

We commend the inclusion of an assigned 'Safety officer' (section 30 of the Bill) for quality oversight of EADMDs at the local level. We recommend that Bill 160 requires that this individual has certified training and expertise in the technical understanding of the function and safe operation of these EADMD (*e.g.*, a radiation safety officer certified by Canadian Nuclear Safety Commission, with certified expertise in the healthcare setting), rather than membership of a regulated healthcare profession. Only a quality assurance program for EADMDs managed by an appropriately trained safety officer will achieve maximum protection of the public in Ontario.

The OAMP is pleased that the government is modernizing the regulation of energy-applying and detecting medical devices in the province, and we stand ready to provide our expertise for the benefit of patients and the public in our province.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Stephen L. Breen'.

Stephen L. Breen, PhD, MCCPM
President, OAMP