EXPERT PANEL TO ENHANCE THE SAFETY AND QUALITY OF ENERGY-APPLYING MEDICAL DEVICES IN ONTARIO ("THE EAMD PANEL")

MANDATE

To provide recommendations / advice to Health Quality Ontario (HQO) 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 Fall/Winter 2015.

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 and tanning beds
    - Devices used for research and experimental purposes (may 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

Health Quality Ontario will appoint Panel members with expertise in the following areas:

- Biomedical engineering
- California's radiation protection legislation
- Ex-officio members: HQO
- Facility administration (including large hospitals and smaller community-based facilities)
- Industry/ informatics
- Medical diagnostic, medical therapeutic (including interventional radiology, dental, applications of EAMDs)
- Medical radiation technology
- Medical physics (covering non-ionizing, ionizing and nuclear radiation, as well as diagnostic and therapeutic applications of EAMDs)
- Patient experience
- Radiology

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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.