Consultation Follow Up Letter to Dental Suppliers and Testers

Dear Stakeholder,

Thank you for your interest and engagement on consultations on the *Healing Arts and Radiation Protection Act* (HARPA).

Background

As part of the Spring 2021 Red Tape Reduction Package, the Ministry of Health (ministry) committed to formally consult technical and radiation safety experts, technology users, and sector industry representatives to identify opportunities under HARPA to better enable the use of emerging technology.

In June 2021 the ministry invited manufacturers, sector technical and safety experts, hospitals, industry associations, and professional colleges to submit written feedback on potential changes. The consultation sought out recommendations that would meet the following criteria:

- Better enable innovation and the use of new technology, or improve clarity and implementation of the legislation
- Can be implemented within the existing HARPA framework
- Are within the scope of the provincial government
- Do not compromise safety and quality standards

The ministry received 28 submissions with a total of 53 recommendations. The ministry completed a thorough review of these recommendations, which included virtual consultation sessions with a wide variety of stakeholders, partners and experts. The ministry is proceeding with four targeted actions under HARPA that will better enable the use of emerging technology while continuing to protect the safety of patients, workers and the public in the use of X-ray devices.

Targeted Actions

The ministry's actions include a regulatory amendment as well as policy changes and clarifications.

To better enable the use of emerging technology:

- A proposed amendment to Regulation 543 on shielding design methods to reference include more modern standards (NCRP 147) and safety codes (Health Canada Safety Code 35 which replaced Safety Code 20A) while maintaining the same dose limits. This is intended to align Ontario's requirements with modern shielding safety standards and would also be more cost effective for the sector. This regulatory change is now posted on the regulatory registry for public comments and feedback and, if approved, would be implemented in 2022.

- Additionally, updated and clarified guidance is being implemented to streamline the computerized tomography (CT) designation process for hospitals, create certainty for approval timelines, and eliminate unnecessary requirements. The ministry will be targeting a reduction in the approval timeline for new designations by 60% and creating a streamlined application for replacement CTs. This streamlined process will make it easier for technology users to purchase and implement new technology. This will be implemented in fall 2021.

To improve clarity and implementation of the legislation the following policy changes are being implemented in fall 2021:

- The ministry will update public-facing forms and pamphlets to clarify the definitions surrounding “owner” and “operator”. This will include a new guidance document to provide clarification regarding the responsibility of operating devices solely for demonstration purposes. Clearer guidance on administrative responsibilities will support industry vendors in supplying technology.

- The ministry will also clarify existing guidance documentation regarding floor plan submission requirements for mobile devices. Clearer guidance on administrative responsibilities will make applications easier for health facilities with mobile devices.

Additionally, the ministry is conducting a review to update and enhance existing guidance documents for the dental sector to further clarify current HARPA testing requirements and related responsibilities of owners and operators of dental x-ray machines.

These targeted changes will make it easier for technology users to purchase and implement new technology. The standards will be more efficient/cost effective and are expected to support industry vendors and health facilities navigating the administrative requirements. The proposed changes also uphold the ministry’s commitment to maintaining the safety of patients, workers, and the public.

The ministry appreciates these actions do not reflect the full suite of recommendations received through this consultation. Some of the recommendations (e.g. changing the CT definition and exempting floor plan submissions for in-kind devices) are not currently proceeding because they would have a patient safety impact that could not be sufficiently mitigated within the current HARPA framework. Other issues could not be addressed due to conflicting regulations (i.e., protective lead garment specifications must align with the *Occupational Health and Safety Act*) or were already sufficiently addressed within existing legislation/regulations and existing public-facing pamphlets (e.g. photographic QC for digital systems).

The ministry will keep these recommendations on file for consideration as part of any potential future modernization of HARPA (e.g., clinical standards and scope of practice, expanding imaging modalities covered by HARPA).

The ministry remains committed to ongoing engagement with stakeholders to determine the best path forward on future HARPA modernization. Should you wish to meet with us regarding any of the above, please contact Rob Francis at Robert.Francis@ontario.ca. We’d like to thank you again for your time and encourage you to share updated contact information for future engagement opportunities.

Thank you,

Rob Francis