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Sent: February 24, 2022 11:13 AM
Subject: Summary of consultation responses on proposed regulatory requirements for laser devices

Thank you for participating in Health Canada's consultation on proposed changes to the regulatory requirements for lasers, outlined in Schedule II of the *Radiation Emitting Devices Regulations* (REDR).

The consultation, conducted online between June 30, 2021, and August 30, 2021, solicited feedback from stakeholders on proposed changes aimed at enhancing the safety of laser devices that are imported, sold, leased, or advertised in Canada. All interested Canadians and stakeholders were invited to provide feedback; in particular, manufacturers, importers and retailers of laser devices, trade associations; test/certification labs; standards development organizations and groups or individuals (e.g., organizations, professionals) that use laser devices. Feedback was sought for all proposed changes. Further details are available here:
Notice to interested parties – Consultation on potential amendments to the Radiation Emitting Devices Regulations (Laser Devices): Closed Consultation - Canada.ca

Health Canada received submissions from 18 organizations that included:
- Importers/distributors/manufacturers
- Academic/research groups
- Professional associations
- Industry associations
- Individuals

Specific areas of feedback:

- **Incorporation of existing international standards:** Overall, respondents were supportive of a regulatory approach that includes the incorporation of sections of IEC 60825-1:2014, with one respondent suggesting recognition of compliance with the US Food and Drug Administration's Title 21 Code of Federal Regulations as an accepted alternative to the IEC standard.
- **Record-keeping:** There was overall recognition for the importance of record-keeping to support regulatory compliance and enforcement, as well as traceability in cases where a product lot/batch/series of devices are found to be non-compliant. Respondents did not object to the requirement for records but questioned the logistics of locating physical records in Canada. In addition, one respondent did not agree that record-keeping was necessary for Class 2 or 3R lasers due to lower risk. There were also requests to consider digital storage/safekeeping, harmonize with US record-keeping requirements, and clarify exactly *whom* should be responsible for the retention of such records.
- **Labels and user Information:** With respect to introducing bilingual labelling, unique identification code/manufacturer information, and user information, most respondents were supportive. However, some expressed uncertainty over information requirements on the product identification label as well as concern regarding limited space. Specifically, some respondents noted potential challenges with proposed warning label requirements, especially with small devices that do not have an appropriately sized surface area to apply a label, or devices used in sterile or hazardous environments where the label material itself may be hazardous or reduce sterility. A few respondents suggested the use of digital labels via QR codes.

- **Scope of products:** Some respondents requested additional clarification regarding which laser products would be subject to, or exempt from, the proposed regulations, such as componentry, devices modified for own use, and resale.
- **Potential costs:** When asked about additional costs stakeholders may face to comply with the proposed regulations, respondents cited record-keeping, translation (for Official Languages compliance) and printing of user information. A few respondents expected minimal costs due to their familiarity with the IEC standards, with some citing no additional costs, as they do not import, sell, manufacture, or distribute laser devices as part of their core operations. Respondents noted translation costs for proposed bilingual labels/user information as one of the highest costs for compliance, however the IEC standard is available in both French and English (including descriptive wording, explanatory statements, and additional warnings).

Other Feedback:
Some comments received were outside the scope of the regulatory proposal and the *Radiation Emitting Devices Act*. For example, concerns were expressed related to the impacts of the proposal on the possession of existing laser devices in Canada, the use of lasers in occupational settings, or medical device lasers. The proposed changes deal with requirements applicable to the importation, sale, lease, and advertising of laser products and do not address requirements pertaining to the use of laser products in Canada. Furthermore, laser devices incorporated into medical devices under the *Medical Device Regulations* are exempt under this proposal.
Some responses suggested misinterpretation of proposed changes. For example, the IEC standard requires manufacturers to provide (i) instructions for assembly, maintenance, safe use, and warnings, (ii) information to select eye protection, (iii) a description of the radiation emission pattern, and (iv) a list of controls, adjustments, and procedures. However, it is the responsibility of the manufacturer to decide which additional information is "applicable" and therefore provided. To reduce such subjectivity on relevance, Health Canada proposed that four of the twelve IEC user information requirements (8.1a, 8.1c, 8.1f, 8.1i) would apply to Class 3B and Class 4 devices only. In addition to clarifying the applicability of these user information requirements, Health Canada's intention was to reduce the overall compliance burden (e.g., translation and printing costs) for devices that present a lower risk of injury. No comments were received regarding the proposed adoption of eight remaining user information requirements detailed in IEC 8.1 (b, d, e, g, h, j, k, and l).
Finally, many stakeholders provided feedback in support of possible class and/or wavelength limits on laser products, including toys and laser pointers. While none of the respondents were opposed, there was a broad range of suggestions for setting these limits. Class and/or wavelength limits for types of products will be given further consideration in the development of future regulatory proposals regarding laser products in Canada.

Health Canada would like to thank all respondents for providing comments, which will inform recommendations for next steps. Interested parties and stakeholders can stay informed on the progress of this regulatory proposal by consulting Health Canada's Forward Regulatory Plan.

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