# Consultation with MedTech - Proposed Change to the List of Recognized Standards for Medical Devices

The Medical Devices Directorate (MDD) is planning to change the way we publish the List of Recognized Standards (LORS), and is looking to get feedback from MedTech for an early perspective on the industry response to the proposed plan. For reference, the current list can be accessed at the following link:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/standards/list-recognized-standards-medical-devices-guidance.html>

Proposed Plan:

MDD is planning on removing editions and publication years from the LORS for most of the standards listed. Where no edition or publication year is listed for a given standard in the LORS (eg. ISO XYZ), the most recent version of that standard would be the officially recognized version, with a three-year transition period from the date of publication, during which the previous version would also remain recognized.

Where an edition or publication year is displayed for a given standard (eg. ISO XYZ:2021-Ed.2.0), only that specific version of the standard would be officially recognized. This would occur in one of three scenarios:

* If MDD decides not to recognize a new version of a standard, the edition and/or year of the accepted older version would be displayed with the standard designation number. Only the specified version would be considered as officially recognized.
* If a new version of a recognized standard contains new information that MDD deems necessary to support safety and effectiveness, the edition and/or year of the new version of the standard would be displayed with the standard designation number. Only that newest version would be recognized and the three-year transition period from the previous version would not apply.
* If a section of a standard is not recognized, this would be detailed in a note under the standard in question according to current practice, but would include the year and/or edition to which the note applies, if applicable.

Header Note

To explain the details to external stakeholders accessing the LORS, a notice will be published at the start of the LORS with the following proposed wording:

***Scope***

*This notice applies to all standards listed on Health Canada's List of Recognized Standards for Medical Devices*

***Notice – Version Recognition for Medical Device Related Standards***

*Recognised standards are displayed by Standards Developing Organization and Standard Designation Number, either without specifying the edition and year, or with an edition and/or year specified.*

*For standards listed without an edition and year, the latest version of that standard is recognised. However, a three (3) year transition period from the date of publication by the Standards Developing Organization will apply. During this transition period, Health Canada recognizes both the most recent version of the standard and the one prior version.*

*For standards listed with an edition and/or year, only that specific version of the standard is recognised. If the edition/year displayed is not the latest version of the standard, newer versions are not recognised. If the edition/year displayed is the latest version of the standard, the transition period does not apply to that standard and only the latest version is recognised.*

Guidance document:

The [guidance document](https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-recognition-use-standards-under-medical-devices-regulations.html) currently on the HC website would not be altered and would still apply to the proposed method of displaying the List of Recognized Standards. As such, the following statement would still apply:

*Conformance with recognized standards is voluntary for manufacturers. A manufacturer may choose to demonstrate conformance with a recognized standard or may elect to address the relevant issues in another manner.*

*If a standard is recognized, a manufacturer applying for a licence for a device to which that standard applies must either:*

1. *meet the standard; or*
2. *meet an equivalent or better standard; or*
3. *provide alternate evidence of safety or efficacy*

*In case the manufacturer chooses option (b) or (c), detailed information must be submitted with the device licence application. If the manufacturer does none of the above, a licence will not be issued.*

Rationale:

The rationale for the proposed change is the need to improve the timeliness and predictability of updates to the LORS, including the predictability of transitions to new editions of currently recognized standards. This involves the need to reduce the internal administrative and technical resource burden that the current system places on the directorate, as well as the need to decouple updates to recognized standards from the internal publication pathways and competing publication priorities to the extent possible. The current resource burden and publication timelines are at a level such that it is not possible to maintain an up to date list for currently recognized standards and to add relevant new standards to the list. The proposed plan should result in a more current and up-to-date LORS that better matches the state of technology in medical devices, as well as improve the predictability of transition to new editions of recognized standards, to the benefit of both the MDD and industry.

We would appreciate your general feedback on the plan, potential pros and cons of the plan, and on the proposed wording of the notice.