ALBERTA HEALTH REUSABLE & SINGLE-USE MEDICAL DEVICES STANDARDS SUMMARY OF CHANGES

The Alberta Health *Reusable & Single-Use Medical Devices Standards* (the "Standards") replace the *Standards for Single-Use Medical Devices: As Applied to Critical and Semi-Critical Medical Devices* (2011), and the *Standards for Cleaning, Disinfection and Sterilization of Reusable Medical Devices for Health Care Facilities and Settings* (2012). These revised Standards will serve as a valuable resource in any facility or setting where health services are provided and where a single-use or reusable medical device may be used or reprocessed. This includes privately operated community-based health care settings, home-based businesses and private clinics.

The Standards were updated to reflect current best practices and updated technical content as set out by the Canadian Standards Association (CSA). Additionally, the Standards were edited for clarity and auditability. This makes the Standards more user friendly and will help to facilitate ongoing compliance with the Standards.

The policy shifts in the revised Standards are highlighted below:

In the Introduction and Definitions

- **Modified definition for "manufacturer" (p. 12)**
  - The definition for "manufacturer" has been modified to include persons or departments who develop or modify a medical device for use within the organization (but not for resale). This will better support the requirement for MDR areas to reprocess in accordance with validated manufacturers' instructions for use.

In S1: Single-Use Medical Devices (p. 18)

- **The revised standards no longer include a definition or standard for 'single-client-use medical devices'**
  - The CSA Z314-18 *Canadian Medical Device Reprocessing* standards are directed toward reprocessing reusable medical devices that are shared between clients and do not address single-client-use medical devices.
  - No corresponding reference to this category of devices was found in Health Canada *Medical Devices Regulations* or on the Health Canada website.
  - A review of practices revealed inconsistencies with respect to the definition and application of this category of devices.
  - By remaining silent, Alberta Health is not creating a definition or introducing a standard that cannot be supported with literature from the CSA, Accreditation Canada or other key resources.
- **Commercial reprocessing of single-use medical devices will be permitted**
  - With the introduction of the revised standards, commercial reprocessing of single-use medical devices is no longer expressly prohibited by the Alberta Standards. This aligns with current practice in British Columbia, Saskatchewan, Manitoba, and Ontario and eliminates existing red-tape with respect to management of single-use medical devices in Alberta for those organizations that may wish to employ this option.
  - The new standard requires that commercial reprocessing of single-use medical devices be done in compliance with Health Canada's requirements and regulations.

- A definition for ‘commercial reprocessor’ has been developed to provide clarity around the types of facilities that are permitted by Health Canada to conduct this activity.

In S2: Environmental and Structural Requirements for an MDR Area (p. 20)

- **Introduction of appropriate environmental and structural requirements for existing smaller, community-based health care facilities or settings**
  - The revised standards provide alternate paths to compliance for smaller community-based health care facilities and settings (such as a dental or physician’s office) to meet appropriate minimum environmental and structural standards.
  - The standards allow practical and safe solutions for requirements related separation of MDR areas, sink requirements, and multi-use MDR areas.
- **Standards that establish the minimum requirements for storage of clean, disinfected, and sterile medical supplies have been added**
  - These standards reflect what should be existing practice, but allow for the practice to be audited.
- **Removal of standards for specific air change, temperature and humidity requirements**
  - Standards with requirements to meet specific air change, temperature and humidity requirements have been removed. These standards are recognized as best practices, rather than as minimum standards, so they exceed the scope of these standards.

In S7: Disinfection of Reusable Medical Devices (p. 32)

- **Improved focus on key principles to achieve disinfection**
  - Several standards have been added to this section that set out minimum requirements required to achieve disinfection.
  - The standards reflect what should be existing practice, but they were not explicitly stated in the 2012 standards.
  - This includes standards for documentation requirements and added clarity around the minimum standards related to thermal disinfection and pasteurization practices.

In S8: Sterilization of Reusable Medical Devices (p. 38)

- **Improved focus on key principles to achieve sterility**
  - Several standards have been added to this section that reflect what should be existing practice and set out minimum requirements required to achieve sterilization.
  - The standards reflect what should be existing practice, but were not explicitly stated in the 2012 standards.
  - Having appropriate minimum standards that can be monitored for compliance may prevent IPC failures in the future.
- **New direction with respect to the use of immediate-use steam sterilization**
  - The 2018 CSA standards permit the use of immediate-use steam sterilization for implantable medical devices in unavoidable, emergency situations, and the revised Alberta Standards have been drafted to reflect this.
- **Updated requirements for sterilizers**
  - The CSA Z314-18 standards indicates that cycle documentation provided by a printer is now considered essential quality assurance information. The revised Alberta standards will required that all sterilizers used in Alberta health care facilities

and settings come equipped with a printer that records cycle parameters effective three years to the date of the standards being implemented.

In S10: Education and Training (p. 49)

- **Revised for readability and to provide reasonable paths to compliance for community settings**
  - Certification requirements for personnel working exclusively in MDR are unchanged.
  - Reasonable paths to compliance with education and training requirements have been provided for privately operated community-based settings that have different reprocessing needs than large organizations like Alberta Health Services and Covenant Health.

In S11: Quality Management Systems (p. 51)

- **Standards for quality management systems**
  - The 2011 single-use medical device standards included "Written Policy" and "Monitoring and Compliance" sections. The 2012 medical devices reprocessing standards included a "Policy and Procedure" section. These sections have been brought together into a single, unified "Quality Management Systems" (QMS) section.
  - Standards in the QMS section set out clear requirements for a formalized quality management system that will guide an organization's ability to meet the requirements of applicable standards and legislation, provide assurance and quality control, and support client safety.
- **New standard requiring policies that mandate the use of clean or sterile sheaths on ultrasound transducer probes that come into contact with the mucous membrane**
  - The requirement to use a clean or sterile sheath on these probes complements existing requirements that semi-critical medical devices shall, at a minimum, be cleaned and undergo high-level disinfection according to the manufacturer's instructions for use.

Sections from the 2012 standard have been removed

- **The sections in the 2012 medical device reprocessing standards that focused on specific standards for endoscope reprocessing have been removed**
  - Describing the very specific requirements of reprocessing flexible endoscopes is beyond the scope of these minimum standards. Instead, the revised draft standards require organizations who reprocess devices that present unique and complex challenges for reprocessing, like flexible endoscopes, to develop specific, detailed standard operating procedures as appropriate.
  - Organizations should refer to standards and guidelines established by the CSA and other applicable organizations when developing standard operating procedures for reprocessing of complex medical devices.
- **The sections in the 2012 medical device reprocessing standards occupational health and safety have been removed**
  - Alberta's *Occupational Health and Safety (OHS) Act* and the corresponding *OHS Regulation* and OHS Code provide legislated OHS requirements for health care workers. Removing this section from these standards in no way reduces or minimizes the requirements of OHS legislation. Certain standards related to OHS remain embedded throughout the revised standards.