**Report to CAMDR on CSA Activities & Conference 2020 Update**

**CSA Activities:**

CSA Technical Committee (TC)met in person September 30 and October 1, 2019 in Toronto. There was great discussion over the proposed new edition to Z314-18 and recognized there are new trends that will require consideration during the review process e.g. ERCP scopes, mobile systems, robotics, Performance quality and load testing.

Review process of Z314-18 started in October 2019 - TC was divided into 6 working groups:

- WG 4,5,6,7,8,10 Clauses lead by Donna Moore (T. Herd, C. Williamson, B. Smith, Diana Johnson, Dianne Trudeau)
- WG 11, 14 Clauses lead by Colleen Landers (R. Rieve, Rod Parker, Audrey Wall, Anne Augustin)
- WG 9, 17 Clauses lead by Katie Flynn (Tammy Bernardo, Ian Pequegnat)
- WG 12, 13 Clauses lead by Sandy Saioud/Tim Muller (Merlee Rodway, S. Savoie, P. Labrie)
- WG 15, 19, 20 Clauses lead by Rob Nightingale (Nancy Aelick, Garry Bassi, Sylvie Dufresne, Raphael Nishida)
- WG 16 & 18 Clauses lead by Atila Nozari (Laurie Buist, Andy Sun, Nita Muzurat, Chris Swayze)

Several teleconferences were held to review the various clauses of Z314-18 from October/November 2019 into 2020 and made recommendations for which the whole TC is currently reviewing.

Due to Covid-19 travel restrictions meetings will be held virtually & have been happening to review the suggested changes to Clauses 4-18 made by the various Working Groups (WG) . It has been strongly suggested that in person meetings are vital to the success of the 'proposed new edition' however, this isn't possible in 2020.

It is discussed that the various WG's take into consideration the following examples of where there is confusion and an improvement is required:

- Clauses 10.2.5.9; 10.2.5.14; 17.2.2; Users are still challenged with the intent of 'External shipping containers'. Proposed change to read - "External shipping material/container (or device) shall not be used to store sterile medical devices or supplies".
- Add definition for External shipping container
- BI PCD for table top sterilizers - currently there is not a commercially available PCD for all table top sterilizers. This puts the user in a difficult position as the wording has been removed for the Z314-18 version. Proposed - to putting the wording back in to assist the user when there has not been a BI PCD validate for the sterilizer.
- Annex A 'Difficult to clean Medical Devices' formerly in Z314.8-14 appears to be missing in Z314-18. Proposed adding it into Z314-18
- Annex E ' Liquid Chemical Disinfectants formerly in Z314.8-14 appears to be missing in Z314-
- 18. Proposed - adding it into Z314-18

<u>Post-cleaning testing - endoscopy and other medical devices</u>

- Suggested there is a need to look at studies being done
- Stated MIFU's aren't being fully followed, CSA members need to look at steps required for improvement

- Research is taking place on the effectiveness of enzymatic or lack of it

High Level Disinfection

- Reported that FDA has made recent recommendations on ERCP scopes
- DIN no longer applicable but Health Canada has extended the deadline to March 2021
- Discussed should we continue to address pasteurization?

Transport between sister sites

- Discussed transfer of medical devices between sister sites without reprocessing if a Health Care Facility (HCF) has strong processes? Does this count as a loaner?
- Some sister sites do not reprocess - CSA TC will need to clarify in new edition of Z314

Mobile MDR Units

- CSA TC discussed the need to provide specific requirements or, acknowledge the existence of mobile MDR units. This is a community issue and are unclear if this is acceptable because some are using devices that appear like 'Instapots'

Clarification of peel pack packaging requirements

- Discussed frequency of Operational Qualification (OQ) & Performance Qualification (PQ)
- ISO draft is under development - can monitor direction & duplicate for FAQ or Z314 revision
- Peel pouches are widely used in the community settings e.g. self-seal, rolls and tape shut - need for FAQ

Suggested CSA FAQ topics

- Need more detail for OQ & PQ
- CSA Personnel Certification - can there be a departmental certification where inspectors would do audits and certify?
- Temp and Humidity information: Z317.2 Table 1 has 20-23 for MDR storage but clean utility is 22-24. Z314 does match tables in clauses 10.1 & 17.1
- Clause 12.4.3 - timely reprocessing of endoscopes - still situations where endoscopes are being left overnight and aren't being cleaned by certified MDR technicians. WG needs to look at the wording covering frequency (within one hour), transit times, & prolonged soaking
- Clause 12.5.4 - clause currently allows an endoscope shelf life of 7 days but new cabinets are validated for up to 21-30 days - this needs to be reviewed and revision made to reflect.

**ISO Standards:**
Last ISO TC 198 WG & Plenary meetings were held in South Korea in December 2019.
Due to Covid-19 travel restrictions any ISO meetings scheduled for 2020 will be held virtually.

**CAMDR 2020 Conference:**
It is with mixed emotions that we postponed the in person conference however we are excited to offer a 'virtual conference' scheduled for February 25-28, 2021. The conference agenda may change slightly in light of the pandemic and need for updated information, stay tuned conference agenda will soon be available.

Stay Safe & Healthy
Respectfully submitted by:
Dianne Trudeau, CAMDR CSA Liaison & Conference Director September 15, 2020