

Information Update CSA, Health Canada and MEDEC  
July 2007

As a member of the C.S.A. Technical Sterilization Committee, the following information is from the meetings held last week in Halifax, Nova Scotia. Please visit the website links for the complete documents available at this time.

A special thanks to Colleen Landers for her input and her AAMI report from the meetings she attended.

See you all at the conference!

Lorna Coutoulas  
President C.S.A.O.

CSA Document Z17664

Health Canada have Issued a Guidance document on information to be provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices. Facilities need to report any issues around medical devices, be it processing, sterilization etc. to Health Canada. They will compile the reports and investigate any duplicate complaints as they come in. We all need to respond to any issues. There is a form available so that the information we give is generic and when Health Canada receive these they will send a report to the manufacturer to investigate the issues and ask for compliancy documents. Form is posted on the website and draft document posted on the website.

CSA Document Z314.2 Effective sterilization in health care facilities by the steam process, and CSA Document Z314.3 Effective sterilization in health care facilities by the ethylene oxide process are out for public review. Visit CSA website at ([https://review.csa.ca/opr/opr\\_list.asp](https://review.csa.ca/opr/opr_list.asp)) and scrowl down to Z314.2 and Z314.3 and send any comments. After public review and the editorial period, they should be available for purchase by the end of March 2008.

CSA Document Z314.8 Decontamination of Reusable medical devices is in the final editorial stages. We will vote in September providing everything is ready and it will be published January 2008.

CSA Document Z11138-1 Sterilization of Healthcare products Biological indicators and CSA Document Z11140-1 Sterilization of Healthcare products Chemical indicators parts 1 and published and available to purchase at CSA.ca (<mailto:sales@csa.ca>)

We are currently working on the following documents:

Z314.15.03 Warehousing, Storage and Transportation of Reusable Medical Devices.

Z314.14.04 Selection and use of rigid sterilization containers

Z314.10 Selection, use, maintenance and laundry of reusable textile wrappers, surgical gowns and drapes for Health care facilities/care and maintenance of reusable textiles and single use packaging

I also attended the joint meeting with Scientific Advisory Panel (SAP) and Canada's Medical Device Technology Companies (MEDEC) and members of the CSA Sterilization Technical Committee (STC)

This meeting contains all of the above experts and gives us a direct line to Health care device Manufacturers.

Ontario Hospital Association also attended and out of this meeting I have joined a user group including OHA to look at some of the issues.

Please read the attached Guidance Document for humidity in sterile storage areas and action plan to handle this situation. This was developed at the CSA meeting last week when Humidity hit the headlines in hospitals across Canada.

See the AAMI Report submitted by Colleen Landers and her comments on the recommended sterilization cycles.

Any comments and questions please contact me at [coutoulasl@smh.toronto.on.ca](mailto:coutoulasl@smh.toronto.on.ca). I am really enjoying the chance I have been given to be a part of this information and sit around the table with the experts across Canada. The most important part is getting the news out to you as soon as possible to help with our daily issues at work. I will continue to communicate as soon as I can.

We hope everyone is coping with the heat this summer and truly hope you will attend the CSAO conference September 16<sup>th</sup>, 17<sup>th</sup>, 18<sup>th</sup> 2007.

### **Extended Cycle Information**

The USA have developed a TIR 31 on PCD's which addresses set extended cycles for manufacturer's to develop PCD's. The cycles being balloted are Pre Vac 270 degrees F 10 and 20 minutes and gravity 250 degree F for 40 minutes. Once the TIR is finished being balloted then Canada has agreed to accept these as extended cycles so there is harmonization for North America. This does not eliminate other cycles but the manufacturer will have to validate these cycles outside of these ranges with their own developed PCD's. It is hoped that manufacturer's would validate their medical; devices with regular hospital cycles or one of these cycles. The PCD's being developed will be for a solid load and a hollow load. If a hospital has medical devices that meet both categories then they will require one of each PCD. Work is starting but it will take time to Develop these PCD's and get them to market.

Keep posted for developments on the CSAO website.

Regards,  
Lorna Coutoulas,  
President C.S.A.O.