OPENING PLENARY AGENDA

1. Opening, introductions, and notice of Antitrust Statement (see ATTACHMENT A)
   - Approval of the agenda (Doc. STN139)
   - Approval of the minutes of the 14 April 2014 AAMI Sterilization Standards Committee meeting (Doc. STN138)

2. Introductory remarks

3. Review of relevant FDA activities and other regulatory/government matters (FDA staff)

4. Update on changes to the Sterilization Standards Committee meetings and structure (Joe Lewelling/Carol Herman)

5. Brief reports of individual working groups:
     - Plans to revise TIR14, TIR15, TIR16 and TIR28
     - Update on status of ISO work on TS for EO sterilization in a flexible chamber
     - Status of ISO 11137-3 and plans to adopt as a revision of ANSI/AAMI/ISO 11137-3
     - Proposal to revise AAMI TIR35
     - Proposal to develop new AAMI TIR on "Sterilization of health care products – Radiation sterilization - Guidance on the determination and use of alternate SALs when using VDmax to substantiate the dose"
     - This group will not meet and has no active work items.
     - Update on revision of 11138 series documents
     - Status of BI reduced incubation period document
  ▪ Update on revision of ISO/TS 11139 as an international standard and plans for U.S. adoption
  ▪ Plans for future participation in ISO/TC 198/WG 5, Terminology

• Report of the AAMI Chemical Indicators Working Group/U.S. Sub-TAG for ISO/TC 198/WG 6 [ST/WG 06]
  (Co-chairs: Richard Bancroft and Kristen Singleton)
  ▪ Status of 11140-1, 18472, and 11140-6

  ▪ Discussion of the proposed revisions of ANSI/AAMI/ISO 11607-1, ANSI/AAMI/ISO 11607-2, and AAMI/ISO 16775
  ▪ Discussion of the ASHRAE’s change in recommendation for humidity levels and its implications

  ▪ Review status of AAMI TIR53, Effectiveness testing for antimicrobial agents incorporated into medical devices and combination products
  ▪ Update on the status of the AAMI reaffirmation and overview of initial revisions needed in ISO 11737-2, Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

  ▪ Overview of revisions to ISO 13408-1 (general requirements), and possible revisions to ISO 13408-2 (filtration), and ISO 13408-6 (isolator systems)
  ▪ Discussion on ISO/TS 11139, Sterilization of healthcare products – Vocabulary

  ▪ This group will not meet and has no active work items.

  ▪ This group will not meet and has no active work items.

  ▪ Plans to adopt revision of ISO 17664 as a revision of ANSI/AAMI ST81

  ▪ This group will not meet.

• Report of the Steam Sterilization Hospital Practices Working Group [ST/WG 40] (Co-chairs: Ramona Conner and Cynthia Spry)
  ▪ Review of comments on the second working draft of ANSI/AAMI ST79, 3ed.
  ▪ This group will not meet and has no active work items.

• Report of the Hospital Steam Sterilizer Working Group [ST/WG 43] (Co-chair: Mark Smith)
  ▪ This working group will not meet.

• Report of the Ethylene Oxide Sterilization Hospital Practices Working Group [ST/WG 60] (Co-chairs: Jackie Daley and Phil Schneider)
  ▪ This working group will not meet.

  ▪ Review of first draft of new TIR, Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals in healthcare facilities

• Report of the Hospital Ethylene Oxide Sterilizer Working Group [ST/WG 62]
  ▪ This working group will not meet.

  ▪ This working group will not meet.

• Report of the AAMI Reusable Surgical Textile Reprocessing Working Group [ST/WG 83] (Co-chair: Linda Slone)
  ▪ This working group will not meet.

• Report of the Endoscope Reprocessing Working Group [ST/WG 84] (Co-chairs: Nancy Chobin and Mary Ann Drosnock)
  ▪ Review of ballot results and comments on AAMI ST91/CDV-1, Comprehensive guide to flexible and semi-rigid endoscope reprocessing in health care facilities

  ▪ Review of ballot results and comments on AAMI TIR55, Human factors engineering for processing medical devices

  ▪ Review of second draft of AAMI ST90, Processing of health care products — Quality management systems for processing

• Report of the AAMI Sterility Assurance Level (SAL) Working Group [ST/WG 90] (Co-chairs: Trabue Bryans and Vicki Hitchins)
  ▪ Review of the results of the ballot of new ISO work proposal to develop a TS on "Guidance on aspects of a risk-based approach to assuring sterility of terminally-sterilized, single-use health care products"
  ▪ Discussion of the plans for revision of ST67: a) adding aseptic information back in, b) adding reprocessed devices, and c) adding an informative annex about assurance of sterility to include all applications
  ▪ Report of the task group that was to meet with PDA/USP to discuss collaboration on ST67
  ▪ Discussion of a possible webinar on ST67 and assurance of sterility
  ▪ This working group will not meet.

  ▪ Report of the meeting with FDA regarding extended cycles.
  ▪ Discussion of the perception of devices that are most challenging and requires extended cycles from AAM users
  ▪ Discussion of whether new work item is needed for the Round Robin work for setting a “Gold” standard for extended cycles

• Report of the Cleaning of Reusable Medical Devices for Reprocessing Working Group [ST/WG 93] (Co-chairs: Steve Goldstine and Vicki Hitchins)
  ▪ This working group will not meet.

  ▪ Review of ballot results and comments on AAMI TIR63, Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection

• Report of the Water Quality for Reprocessing Medical Devices Working Group [ST/WG 95] (Co-chairs: Jackie Daley and Emily Mitzel)
  ▪ This working group will not meet.

• Report of the Qualification of Materials to be Sterilized Working Group [ST/WG 96] (Co-chairs: Byron Lambert and Jeff Martin)
  ▪ This working group will not meet; a task group will meet to work on the revision of TIR17.

6. General discussion
   • Common themes/overlap within working groups
   • New scientific research or publications affecting sterilization standards

7. Future ISO/TC 198 meetings

8. Sterilization Standards Committee program of work
   • Any proposed changes to the work program of the Sterilization Standards Committee will be considered

9. ISO/TC 198 programme of work
   • Is there a need for the U.S. to propose any changes to the current ISO/TC 198 work program?

10. ISO/TC 198 liaisons (only matters not yet discussed)

11. Review of standard setting activities by other groups in the U.S. and Canada

12. General announcements
   • Anyone with information on forthcoming technical meetings on sterilization or disinfection, including international meetings, is requested to share this information.
13. Upcoming meetings of the AAMI Sterilization Standards Committee and affiliated working groups
   - 27-30 April 2015, Historic Inn, Annapolis MD
   - 19–23 October 2015, Double Tree by Hilton, Silver Spring MD

14. Other business

15. Adjournment

---

CLOSING PLENARY AGENDA

1. Opening, introductions, and notice of Antitrust Statement (see ATTACHMENT A)

2. Introductory remarks

3. Welcome to new co-chairs

4. Highlights of individual working group meetings
   - New projects
   - Major issues
   - Completed documents
   - Other

5. Other business

6. Adjournment