Cochairs Jeffrey Martin and Jonathan Bull led the meeting. Cliff Bernier served as recording secretary. The report of the previous meeting was approved. Introductions were made (see attached attendance list).

AAMI TIR74, Change summary for ISO 11135:2014 and TIR14, Contract sterilization using ethylene oxide had been published. Complimentary copies would be distributed to Working Group members.

The results of the ballot on AAMI TIR15, Physical aspects of ethylene oxide sterilization unanimously supported approval. The Working Group reviewed the comments and provided responses to each one. The Working Group agreed that the document, as revised in Bethesda, could proceed to final 15-day committee review.

The results of the ballot on AAMI TIR16, Microbiological aspects of ethylene oxide sterilization supported approval, however 3 negative votes had been received. The Working Group reviewed the comments and because of extensive proposed changes, agreed that the TIR16 Task Group should consider the comments and submit a revised document to AAMI by the end of January 2017 for a second Committee Draft ballot, results to be considered at the March 2017 WG 1 meeting.

The results of the ballot on AAMI TIR56, Guidance for the development, validation and routine control of an ethylene oxide sterilization process utilizing flexible bag systems for the sterilization of medical devices supported Reaffirmation. The Working Group reviewed the comments and agreed to hold them for the next revision. The Working Group agreed that the document should proceed to final 15-day committee review.

Regarding a review of unexpected BI positive survey results, the Working Group proposed a meeting with AAMI ST/WG 4, Biological indicators to address EO BI concerns at the next AAMI meeting. A call for participation would be sent.

AAMI TIR28, Product adoption and process equivalence for ethylene oxide sterilization would be circulated for final 15-day review.

As no leader had come forward and no action had been taken on a New Work Item Proposal for a new Technical Information Report on EO validation, the WG agreed to abandon the project.

The ISO New Work Item Proposal for a Technical Specification on parametric release had been approved and a Working Draft would be reviewed at the October 2016 Berlin meeting of ISO/TC 198/WG 1.

ISO/TS 19572, Guidance on the application of ISO 14937 to the sterilization of medical devices using ethylene oxide in a flexible sterilization chamber would be further developed at the October 2016 Berlin meeting of ISO/TC 198/WG 1.

German comments on small lot release Amendment to Annex E of ISO 11135:2014 and ISO Convener responses were reviewed. The comments would be considered at the October 2016 Berlin meeting of ISO/TC 198/WG 1.

Peter Strain had been appointed ISO/TC 198/WG 1 Convener, succeeding Arjan van Drongelen.


The next meeting of the Working Group would be held in conjunction with the next AAMI sterilization standards meetings, 20-23 March 2017.
<table>
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<tr>
<th>Attendance</th>
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<td>Clifford Bernier</td>
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Brief report of AAMI/ST/WG2, Radiation sterilization working group
19 October 2016
Bethesda, MD

The meeting was led by cochairs Emily Craven and Pat Weixel. Colleen Elliott was the recording secretary. Introductions were made (see attached attendance list). Mr. Weixel asked attendees to review the anti-trust statement, patent policy and code of conduct. The agenda was approved. The report of the April 2016 meeting was approved.

Update on TIR 35 (Ed.2)

Mr. Weixel provided an update on TIR35 (Ed.2): the document has been published and Ms. Elliott provided a copy to committee members in August.

Update on ISO 13004

Mr. Weixel provided an update on the systematic review and reaffirmation ballots of ISO 13004 and ANSI/AAMI/ISO 13004, respectively. The result of the ISO systematic review ballot was to reconfirm the document. The result of the AAMI ballot was to reaffirm the document. Trabue Bryans stated that VDmax 15 and 25 should be added into the document. She will prepare a draft ISO NWIP for review and approval by ST/WG2. Upon approval, it can be submitted via ANSI to ISO.

Update on ISO/NP 11137-1/Amd 1

Ms. Craven provided an update on ISO/NP 11137-1 Amd 1. The draft NWIP that was discussed at the ST/WG2 meeting in April was originally circulated to ST/WG2 to approve submission on behalf of the US. It was approved with no negative votes. The ISO NWIP resolution was circulated on 2016-07-27. The US voted in favor since approval was already established.

On 2016-09-08, Ms. Craven and Mr. Weixel were informed that there was an objection to how the NWIP was worded, so it was withdrawn so that it could be revised. The replacement ISO NWIP resolution was circulated on 2016-09-22 with an end date of 2016-11-21.

Regarding a full revision of 11137-1, Mr. Winters will work with the TG agreed upon in April to provide a draft for comment to be circulated to ST/WG2 in January.

ISO 11137-4 Update

Ms. Craven reported that progress on ISO 11137-4 is underway. Ms. Craven briefly reviewed the outline of the draft.

Update on Draft 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

Gerry O’Dell stated that a TG has been working on developing a TIR for alternative SALs since 2013/2014. She stated that the group had hit some road blocks in attempting to provide equations to help users figure out the correct value. John Kowalski developed an interactive spreadsheet to make the calculations simple for users. The committee emphasized the importance of validation. AAMI will work on incorporating this new format into the TIR.
Reaffirmation decision on AAMI TIR40/Ed.1, Sterilization of health care products - Radiation - Guidance on dose setting utilizing a Modified Method 2

Ms. Craven informed the committee that TIR40 was due for reaffirmation. The committee agreed to reaffirm the document. Lisa Foster also stated that the document could benefit from a revision to simplify it. A revision will be initiated, with a call for comments circulated in mid-November.

Survey of Experience with VDmax
Joyce Hansen would like to circulate a survey similar to the ones done for Methods 1 and 2 to determine if there are situations where VDmax is problematic and possibly contraindicated. There was a suggestion that the survey be extended beyond VDmax, to focus on bioburden. Ms. Craven agreed and stated that she would work with Ms. Hansen to develop survey questions.

ASTM Liaison report
On behalf of John Logar, Ms. Craven provided an updating about ASTM activating and upcoming events.

IMRP Liaison report
Mr. Winters stated that IMRP would take place November 7-11, 2016 in Vancouver. He stated that there was a healthcare strand with four sessions and encouraged committee members to attend.

Other business
The committee observed a moment of silence for valuable past committee members who recently passed away, Craig Herring and James Whitby.

Ms. Elliott stated that she pursued publication of the position paper and was told there was no appropriate avenue for publication. The committee asked that she follow up again.

A concern was raised about NIST and their ability to support dosimetry calibrations for radiation sterilization of medical devices. It was agreed that iia was the best avenue to pursue this. Ms. Craven will take the lead.

The next ISO/TC 198 meeting will take place April 24-28, 2017. The location has not yet been announced.

Ms. Craven reviewed the current roster of US Experts: Denise Cleghorn, Joyce Hansen, Lisa Foster, Pat Weixel and John Logar. The WG agreed that these are appropriate experts at this time.

Wendy Wangsgard noted that Martell Winters received the Jeanne C. Mowe Distinguished Service Award. The WG recognized him for this accomplishment.

Next meeting
The next meeting of ST/WG2 will be held in conjunction with the Spring Sterilization Standards Week in Baltimore, MD on 20-23, 2017.

With no further business, the meeting was adjourned at 10:20 am.
The meeting of AAMI ST/WG 4 was chaired by Tony Piotrkowski and Craig Wallace and opened at 9 a.m. Attendees introduced themselves (see below).

The Cochairs referred the attendees to the AAMI statements for anti-trust, code of conduct and patent policy. These had been circulated with the agenda prior to the meeting.

Cliff Bernier gave an update on the status of the ISO 11138 series of standards (Sterilization of health care products – Biological indicators – Parts 1 to 5). The ISO FDIS ballots would start on 22 October 2016 and the documents would be circulated to the ST/WG 4 as Action Items for review. As the US had voted to accept the DIS texts, a US position of Affirmative on the FDISs would be proposed.

The Working Group reviewed the ballot results on ISO/CD 16342, Sterilization of health care products - Biological indicators - Method for validation of incubation time for a biological indicator and the comments that had been submitted on the Option A and Option B proposals. A roll call vote of members who had not voted was taken which resulted in a valid return for US adoption. Comments were resolved and the Working Group agreed to support Option A. The FDA agreed to provide more clarity on the comments they had submitted that were not accepted for submission to ISO.

The Working Group agreed to vote Affirmative on the redesignation of ISO 16342 as ISO 11138-6 in order for it to join the 11138 series.

The Working Group reviewed the ballot results on ISO/CD 14161, Sterilization of health care products - Biological indicators - Guidance for the selection, use, and interpretation of results and the comments that had been submitted. A roll call vote of members who had not voted was taken which still did not result in a valid return for US adoption. Comments were resolved and the Working Group agreed to submit a vote of Affirmative with Comments to ISO, submitting all comments received.

The Working Group agreed to submit to Argentina all comments received on the Argentine LTSF D-value proposal.

Ballot results on the ISO New Work Item Proposal for a new H2O2 processes standard were reviewed. The US had submitted a Negative vote and the final ISO tally narrowly supported approval. However, substantive comments had been submitted and the results and comments would be considered at an interim ISO/TC 198/WG 4 meeting and a recommendation would be forwarded to TC 198 for consideration.

Cochair Craig Wallace reported on activity in AAMI/ST/WG 1, Industrial ethylene oxide sterilization, on unexpected BI positives. A survey had been conducted and further data would be solicited. Based on the data received, WG 4 could be involved in discussions with WG 1 when the survey was complete, possibly at the March 2017 meeting.
US delegates to the December ISO/TC 198/WG 4 Orlando meeting were identified: Craig Wallace (Convener), Tony Piotrkowski, Krissy Singleton, Kurt McCauley, Cesar Perez, Joel Gorski, Matt Roybal (Invited Expert), and Tricia Cregger (Observer).

The Working Group agreed to meet in conjunction with the next AAMI Sterilization Standards Committee meeting, during 20-23 March 2017 in Baltimore, MD.

Attendance
Jenny Berg, Sterilucent
Suzanne Butler, Boston Scientific
Tim Carlson, Becton Dickinson
Liza Chenette, Avista Pharma Solutions
Tricia Cregger, STERIS
Kim Darnell, CR Bard
David Dominguez, Becton Dickinson
Paul Fioriti, PF Quality Consulting
Marga Foster, Medline Industries
Deborah Havlik, Hospira
Julie Hoover, Johnson & Johnson
Satu King, Spectranetics
Garrett Krushefski, Mesa Labs
Patrick McCormick, Bausch & Lomb
David McGoldrick, Abbott Labs
Mike Padilla, Sterigenics
Susan Pelton, Getinge
Cesar Perez, FDA
Tony Piotrkowski, STERIS
Matt Roybal, Johnson & Johnson
Andrew Sharavara, Propper
Krissy Singleton, Getinge
Krisy Vogt, ADA
Craig Wallace 3M
Stacy Wiehle, Boston Scientific
Jon Wilder, Quality Processing Resource Group
Dennis Wildes, St. Jude Medical

Observers
Jennifer Metch, Johnson & Johnson
Paul Littley, Nelson Labs
Randall Eveland, STERIS
Linnette Cocharles, Medtronic
Denise Carey, Medtronic
Veronica Falkevitz, HIGHPOWER Labs
Lori Patzner, Cook Medical
Ketura Marion, Cook Medical
Samantha Freeman, Cook Medical
Leslie Tavares, WUXI Apptec
Sean Colwell, WUXI Apptec
Greg Crego, IUVO Bioscience
Jacob Killian, IUVO Bioscience
Robbie Gidney, Midwest Sterilization
Kurt McCauley, Mesa Labs
Eric Sisk, Midwest Sterilization
Jon Van Dyk, Getinge
Paul Newman, 3M

Elizabeth Gonzalez, FDA
Catherine Rocco, ASP
Joe Smith, Belimed
Lindsey Brown, Key Surgical
Vin Caputo, ETC
Jennifer Asleson, BSL
Robert Bradley, Mesa Labs
Adrian Pone, Caltech
The meeting was led by cochairs Lena Cordie and Phil Cogdill. Cliff Bernier, AAMI staff, served as recording secretary. Ms. Cordie drew the committee members’ attention to the Antitrust, Code of Conduct, Patent Policy, and Conflict of Interest Statements. Introductions were made. Attendance is noted below.

The Working Group reviewed outcomes from the September ISO/TC 198/WG 5 meeting where draft rules of engagement for terms and definitions were developed.

Further discussion concerned the role of AAMI WG5 in AAMI sterilization standards and whether there was a need for a similar terminology document to capture terms and definitions for AAMI-only sterilization standards.

There was general agreement from cochairs that this would help in the development of the section 3s in their standards.

The next meeting would be held in March 2017 in conjunction with the next meeting of the AAMI Sterilization Standards Committee.

Attendance
Suzanne Butler
Tim Carlson
Phil Cogdill
Lena Cordie
Paul Fioriti
Bill South
Stacy Wiehl
Nancy Fellows

Observers
Richard Shule
Mary Ann Drosneck
Cliff Bernier
Jack LeClair
Anna Lim
Amy Karren
Richard (Bud) Weisman
Carolyn Braithwaite
Anthony Piotrkowski
Trisha Avasthi
Kurt McCauley
Dennis Wildes
Susan Pelton
Angela Brightwell
Ralph Basile
Ken Gordon
Jennifer Asleson
1. Opening and roll call of members, review of Antitrust Statement/Code of Conduct

The 20 October 2016 meeting of the Microbiological Methods working group was chaired by Martell Winters and Carolyn Braithwaite. Members introduced themselves and an attendance list can be found in Attachment 1.

2. Approval of agenda (N 163)

The agenda was approved with the following modification:

- Addition of discussion on TIR53

3. Approval of the 19 April 2016 meeting minutes (N 160)

The meeting minutes from the 19 April 2016 were approved without modification.

4. Update from the June 2016 meeting of ISO/TC 198/WG 8

   a. New work item proposal on Sterilization of health care products—Microbiological Methods --Guidance on sterility and bioburden and testing of biologics and tissue-based products

Carolyn Braithwaite reported that the new work item proposal had been shared with Dr. Hummell. He provided the following feedback:

   The NWIP does not include a guidance related to the testing of intracellular microorganisms (e.g. mycoplasma, small colony variants g- or g+ bacteria), protozoa and cyanobacteria. All these microorganisms could be present in cell based health care products. Bioburden and sterility testing methods as described in ISO 11737-1 and -2 are not appropriate.

As a result of the feedback, the proposed scope has been modified to include biologics-based, cell-based or tissue-based products.

   One member raised a concern that the proposed work is different enough from the AAMI TIR that was used as the base document that it may require users to conduct two separate tests, one for human tissue and one for animal tissue. Martell Winters pointed out that this document would fill gaps and point to existing documents in instances where there is already a good test. Following discussion, it was determined that there is a need for such a document but there will be an effort to not duplicate any requirements that are found in other documents.

5. Technical discussion of issues related to “Product Sterility Test: To Test or Not to Test, That is the Question”

Elaine Daniell gave a presentation that was based on an article that was published in the Industrial Sterilization Supplement to BI&T in the summer of 2016. The article will be posted on the working group website. See Attachment 2 for the presentation slides.


   a. Agree to U.S. position on the draft document and which comments to submit to ISO

Members agreed to accept those comments that the cochairs noted as strictly editorial in order to allow time for discussions on the technical comments. Following discussions, members agreed to submit a vote of approval with comments as indicated on the comment form (to be circulated).

7. Revision of 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

Carolyn Braithwaite reported that ISO 11737-2 is going to be revised and that it will be circulated again for comment from this group. The plan is to review the comments submitted at the March meeting in advance of the ISO meetings in April.
8. TIR 53 Discussion

It was noted that the rough draft of the TIR was circulated for comment. Debbie Havlik noted that the task group would consider the comments received and a revised document will be considered at the March meeting. There was some general discussion around one members concern that the content of the document has little to do with the scope. The question was also raised as to whether or not the document is needed any longer given the revision of ISO 11737-1.

Members agreed that it contains useful information but that it should be published as a paper in BI&T. That would provide additional flexibility as to what is in the document and it could still be used as a reference. Staff will deactivate the project and notify the AAMI Standards Board that the project is no longer under development within this working group.

9. Revision of ANSI/AAMI ST72, Bacterial endotoxin - Test methods, routine monitoring and alternatives to batch testing

Carolyn Braithwaite provided an update on the work that the task group has done. See Attachment 3 for more detailed information on the task groups and the timeframe for the revision work. It is anticipated that an initial draft would be circulated to the working group for review and comment.

10. Liaison reports:

a. USP

Carolyn Braithwaite reported that USP is in the process of developing a natural occurring endotoxin (NOE) source that could potentially be used as a more stable source of endotoxin for extraction studies.

b. IEST

Gordon Ely indicated that there is not a lot to report from IEST. A few documents are under development in their related ISO committee and there will be a boot camp regarding how to apply the recently published versions of – ISO 14644-1 and ISO 14644-2.

c. PDA

It was noted that the PDA meeting is the week of October 24 and an update can be provided to this working group following those meetings.

11. Nomination of experts to the spring 2017 meeting of ISO/TC 198/WG 8

The following individuals were nominated to attend the April 2017 meeting of ISO/TC 198/WG 8:

Martell Winters, Nelson Laboratories
Carolyn Braithwaite, Spectranetics Corporation
Gerry O’Dell, Gerry O’Dell Consulting
Joyce Hansen, Johnson & Johnson
Debbie Havlik, Hospira, a Pfizer Company
Kim Darnell, CR Bard

It was noted that Trabue Bryans is the convenor of the ISO group and does not need to be nominated.

12. Plans for the next meeting

Members agreed to meet in conjunction with the next Sterilization Standards Week, March 20-23 2017 in Baltimore, MD. Future meeting dates are:

October 16-19, 2017
March 19-22, 2018
October 22-25, 2018

13. Adjournment

There being no further business, the meeting adjourned at 1:30 pm.
Co-chairs Nancy Chobin and Ralph Basile opened the meeting. Attendees introduced themselves (Attachment A). Ms. Chobin called attention to the Antitrust Statement/Code of Conduct.

The agenda and the meeting reports N71 and N80 were approved as written.

Kathleen Stanton, Chair of ASTM D12 presented on ASTM's effort to develop standardized test methods for evaluating detergents intended to clean medical devices.

ISO/TC 198/WG 12 had met in Arlington, VA 8-9 September 2016. Comments on ISO/DIS 17664, Sterilization of medical devices - Information to be provided by the device manufacturer for the processing of reusable medical devices had been reviewed and resolved. No major technical changes had been made. The document would proceed to FDIS. The responses to the US comments were reviewed.

Don Tumminelli reported on progress of the Task Group developing the first draft of a proposed new Annex for TIR12: Standardized Cleaning Programs for Medical Devices. The Task Group had held an ad hoc meeting in April and had developed groupings of medical devices and 2 categories - manual and mechanical – of cleaning methods. ISO 17665 would be reviewed for its categorization of instruments for sterilization. Answers to the questionnaire (doc.N86) were reviewed. The Working Group agreed to develop the Annex. The Task Group would consider the comments and revise the draft Annex in time to circulate for comment to be discussed at the next meeting. The Working Group also agreed that TIR12 should be revised once sufficient progress has been made on the Annex.

Ralph Basile, Lena Cordie, Nupur Jain, and Steve Turtill would attend the ISO/TC 198 April 2017 meeting. Marcia Frieze, Don Tumminelli, Emily Mitzel, and Sarah Friedberg expressed interest in attending.

The Working Group agreed to meet in conjunction with the next AAMI Sterilization Standards Committee meeting, 20-23 March 2017.
Attachment A - Attendance

Ralph Basile, Healthmark                              Mike Neilson, CR Bard
Greg Baumgardner, Zimmer                              Greg Crego, IUVO Bioscience
Nancy Chobin, Sterile Processing U.                  Sean Hodges, user
Christina Cloutier, Case Medical                     Susan Pelton, Getinge
Ramona Conner, AORN                                    Erica Rifat, NAMSA
Lena Cordie, Qualitas Professional Services          Kate Segars, FDA
Jackie Daley, Sharp Metropolitan Medical Campus       Keisha Findley, FDA
John Erickson, U. of Iowa Hospitals & Clinics         Karroll Cortez, FDA
Marga Foster, Medline                                    Allison Rodriguez, FDA
Sarah Friedberg, Stryker                               Bryjn Fontier, QPRG
Marcia Frieze, Case Medical                           Nancy Kaiser, STERIS
Nicole Grant, Medtronic                                Jeffrey Marx, STERIS
Shani Haugen, FDA/CDRH                                Andrew Van De Weghe, Becton Dickinson
Julie Hoover, Johnson & Johnson                       Brian Davis, Stryker
Nupur Jain, Intuitive Surgical                      Don Socha, Getinge
Sue Klaclik, IAHCSSM                                      Mary Wen, FDA
Kaumudi Kulkani, Healthmark                           Scott Jelly, DePuy/Synthes, J&J
Natalie Lind, IAHCSSM                                   Don Rotter, Ecolab
Elan Lopezcuba, Becton Dickinson                              Myra Smith, FDA
Emily Mitzel, Nelson Labs                               Jack Leclair, Memorial Herman Hospital
Alpa Patel, Nelson Labs                                      Richard Bancroft, STERIS
Michael Quin, Johnson & Johnson
Mike Schoene, Bausch & Lomb
Richard Schule, STERIS
Rose Seavey, Seavey Healthcare Consulting
Barb Smith, Getinge USA
Richard Sparano, Medtronic
Joan Spear, B Braun of America
Larry Talapa, 3M Healthcare
Thomas Lynne, STERIS
Angie Thornton, NAMSA
Don Tumminelli, HIGHPOWER
Steven Turtit, FDA/CDRH
Dave Vogel, Smith & Nephew
Bryan Worwa, Boston Scientific
Cliff Bernier, AAMI

Observers
Kathleen Stanton, American Cleaning Institute
Denise Carey, Medtronic
Akira Ozaki, Olympus
Shigeyuki Baba, Olympus
Damien Berg, St. Anthony Hospital
Seth Handee, UMMC
Catherine Rocco, Johnson & Johnson
Mike Cain, Getinge
Jon Weeks, FDA
Poulani Nandy, FDA
Aparajita Garg, FDA
John Whelan, U. of Michigan
David Dominguex, Becton Dickinson
Megan Walsh, Medline
Holger Bieting, Consultant
Kristy Vogt, ADA
Leslie Tavares, Wuxi Apptec
Mara Tafoye, Wuxi Apptec
Annie Sitkiewitz, oneSource
Graham Witherby, NuVasive
1. Opening and roll call of members, review of Antitrust Statement/Code of Conduct

The 19 October 2016 meeting of the Washer Disinfectors working group was chaired by Pat McCormick and Emily Mitzel. Members were asked to review the code of conduct and antitrust statement that was attached to the agenda. Members then introduced themselves and an attendance list can be found in Attachment 1.

2. Approval of agenda (N 157)

The agenda was approved without modification.

3. Approval of the 20 April 2016 meeting report (N 150)

The April meeting report was approved without modification.

4. Update from the 26-27 May 2016 meeting of ISO/TC 198/WG 13 in Arlington and WebEx meetings

   a. Work to develop ISO 15883-5, Washer-disinfectors – Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy

   Ralph Basile reported that ISO 15883-5 is still a working draft. It is expected that all of the open action items will be submitted to the ISO convener, Vivienne Christ, who will incorporate the information into the next draft. It is expected that all action items will be due in November and that a revised draft document will be circulated around that time. This document gives guidance on selecting and using test soils. A lot progress has been made on this document.

   There was a question as to whether or not the collaborative immersion testing study would be part of the normative document or provided for information. Brian Wallace noted that the biggest challenge with making it normative is that the acceptance criteria haven’t been established.

   Pat McCormick also raised the issue of biofilm and the concerns that have come from the FDA on this issue. Mr. McCormick anticipates that this will become a bigger issue with washers given the volume of water that is used and the complexity of washer design. It has the potential to become very complex issue and developing a model for it will likely be the next big challenge after the cleaning methods and limits have been firmly established.

   b. Status update on ISO/DIS 15883-4, Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

   The draft international standard ballot (DIS) closed on 5 August 2016. It was reported that over 400 comments had been submitted on the document and that the process to address the comments has just started.

   There will be another WebEx meeting held on 22 November 2016 and an interim in-person meeting held in 6-8 February 2017 in Europe.

5. Update on starting the revisions of ISO 15883-1 and ANSI/AAMI ST15883-1

It was noted that the US had submitted some comments for consideration during the revision of part 1. It was also reported that work on revising part 1 has been sidetracked by the work needed on -5 and -4.
6. Nomination of experts to the interim meeting in February 2017 and the spring 24-28 April 2017 meeting of ISO/TC 198/WG 13

The following individuals were nominated to attend the interim meeting of ISO/TC 198/WG 13 in February:

Ralph Basile, Healthmark  
Emily Mitzel, Nelson Laboratories  
Brian Wallace, Intuitive Surgical

The following individuals were nominated to attend the plenary meeting of ISO/TC 198/WG 13 in April:

Ralph Basile, Healthmark  
Emily Mitzel, Nelson Laboratories  
Brian Wallace, Intuitive Surgical  
Krissy Singleton, Getinge

7. Other business

a. Discussion regarding the discrepancy in test soil formulation between ISO 15883-1 and HTM2030

Pat McCormick raised a concern with a disconnect between the 100 mL defibrinated sheep blood vs. 10 mL defibrinated sheep blood referenced in ISO 15883-1. Richard Bancroft indicated that it was a typo and it should be 10 mL. Mr. McCormick noted that this should be raised with ISO in order to be corrected or resolved in some manner.

b. Other

It was also noted that the Germany delegation on ISO/TC 198/WG 13 would like to reduce the amount of test soil used from <6.4µg/cm² to <3µg/cm². Pat McCormick has a concern that establishing a test soil level based on the capability of the washer as opposed to something that is clinically relevant. There needs to be more research or compilation of current results from different devices before changing the current acceptance criteria.

c. Work taking place in WG 12

Ralph Basile raised a concern that has come up in WG 12 on an issue related to standardized cleaning cycles. This need to include the standardization of washer cycle parameters. This is going to be difficult due to all of the manufacturers of washer/disinfectors and the differences in the cycles as well as the differences in water quality and chemistries used in each machine and in different parts of the world.

8. Plans for the next meeting

Members agreed to meet at the next Sterilization Standards Week in March of 2017.

9. Adjournment

There being no further business, the meeting adjourned at 1:45 pm.
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The meeting was cochaired by Byron Lambert and interim cochair Trabue Bryans. Attendees introduced themselves (see Annex A). Attention was drawn to the Antitrust, Code of Conduct, Patent Policy, and Conflict of Interest Statements.

The agenda was approved with the modification of adding review of N170 to item 4 and the movement of item 7 to after item 3. The minutes of the last meeting were approved as written.

Vicki Hitichins was recognized for her contributions to the development of SALs.


Comments on the revision AAMI/WD-3 ST67 were reviewed and responses were drafted. Resolutions from the meeting will be posted to Kavi.

The next meeting of ISO/TC 198/WG 15 would be held 25-26 October 2016 in London, UK. The Working Group reviewed the international comments on ISO/TS 19930 to give the US delegates guidance on the US position going into the meeting. US participation would include Byron Lambert, Trabue Bryans, and Joyce Hansen.

The Working Group agreed that a Drafting Group including Byron Lambert, Trabue Bryans, and Joyce Hansen would determine requirements that could be harmonized with ISO/TS 19930 and clean up the ST67 draft. Sopheak Srun was recruited to address risk assessment issues and volunteers were requested to round out the small group. The revised draft is to be sent to AAMI by mid-January 2017 for distribution to the Working Group for comment to be due by the end of February 2017 for discussion at the March 2017 meeting.

Two nominations for Non-Industry cochair had been received. The nominations would be circulated to the Working Group for comment, then sent to the AAMI Standards Board for review and the President of AAMI for appointment.

The next meeting would be held in conjunction with the next AAMI Sterilization Standards Committee meeting, 20-23 March 2017 in Baltimore, MD.
Annex A - Attendance

Jenny Berg, Sterilucent
Carolyn Braithewaite-Nelson, Spectranetics
David Brodersen, LexaMed
Trabue Bryans, BryKor
Suzanne Butler, Boston Scientific
Tim Carlson, Becton Dickinson
Phil Cogdill, Medtronic
Emily Craven, Nordion
Kim Darnell, CR Bard
Ely Gordon, MiMedx Group
Veronica Falkevitz, HIGHPOWER
Niki Fidopiastis, Sterigenics
Doug Harbrecht, Sterility Assurance
Nicole Jackson, Ecolab
Satu King, Spectranetics
Byron Lambert, Abbott Laboratories
Nichole McLees, 3M
Gerry O’Dell, Gerry O’Dell Consulting
Dave Parente, Ecolab
Nichole Pasquino, Case Medical
Kimberly Patton, Becton Dickinson
Matt Roybal, Johnson & Johnson
Michael Sprague, Ethide Laboratories
Sopheak Srun, Quality Tech Services
Wendy Wangsgard, Nelson Laboratories
Stacy Wiehle, Boston Scientific
Martell Winters, Nelson Laboratories

Observers
Deborah Havlik, Hospira
Bran McEvoy, STERIS
Jody Rupert, WL Gore
Jeff Martin, SQS Consulting
Liza Chenette, Avista Pharma Solutions
Kerry Pearson, Industry
Angela Brightwell, Medtronic
Charles Taylor, Medtronic
Jacob Killian, IUVO Bioscience
Leisel Masson, Stryker Orthopaedics
Mike Graybill, 3M
Terra Kremen, Nelson Labs
Vu Le, Abbott
Laxmi Smith Sreedasyam, Boston Scientific
Jami McLaren, Boston Scientific
Greg Bush, Alcon
Jocelyn Faraoe, Ethide Labs
Crystal Fenton, Terumo BCT
Aimee Ravgiala, Terumo BCT
Andrew Porteous, Baxter
Paul Newman, 3M
Brian Davis, Stryker
Dennis Wildes, St. Jude Medical
Richard Weisman, Fresenius
Christophe Deneux, Becton Dickinson

MarJean Boyter, Fresenius
Chris Anderson, Johnson & Johnson
Myra Smith, FDA
Sean Hayes, Sean Hayes Consulting
Linnette Cachares, Medtronic
Lori Peters, FDA/CDBER
The 18 October 2016 meeting of AAMI/ST/WG 40 was chaired by Ramona Conner and Cynthia Spry. Amanda Benedict served as the recording secretary. There were approximately 87 individuals in attendance. The agenda and minutes from the 15 August 2016 WebEx meeting were approved as written. An amendment to the 17 and 21 June 2016 WebEx meeting minutes was approved.

The working group reviewed and discussed remaining inputs, small task group work, and other outstanding matters to resolve comments from the CDV-1 ballot for ST79. Nancy Chobin requested to change her vote on the ballot to affirmative. The working group accepted the FDA’s proposed table top sterilizer table with an amended title “Examples of...”. The proposed renderings of sterilizer cart loads will be edited to remove busy backgrounds and reduce identifiability of specific manufacturers’ products and the title will include “Examples of...”. Donna Swenson gave a presentation on “Thermal Comfort in the Decontamination Room” related to proposed changes to the HVAC content in ST79. The proposed Annex Q will be revised to include some additional relevant information. Table 1 (HVAC parameters) will be removed from the next iteration of the draft, the HVAC task force members will draft additional language by November 30th including references to ASHRAE 170 and FGI, and language will be made consistent throughout the document. Table D.3 was proposed with generic categories and generic terminology for the tests and tables D.1 and D.2 will be similarly revised by a small task group by November 30th. The working group decided against adding new language to 13.2 about recording changes to the equipment. The working group discussed instrument air in the context of concerns about facilities needing additional piping to deliver it to the SPD and arrived at the conclusion that how the air is made is not within the scope of ST79. A reference for quality of air standard ISO 8573-1: 2010, Compressed air -- Part 1: Contaminants and purity classes, will be added but the delivery will not be addressed in ST79.

The remaining edits and small task group work will be added to create a next iteration draft for ballot and public review. These next steps are anticipated to launch by 31 December 2016.

There being no further business, the meeting was adjourned at 11:23 AM EST.
1. Opening and roll call of members, review of Antitrust, Code of Conduct, Patent Policy, and Conflict of Interest Statements

The 20 October 2016 meeting of the AAMI Hospital Steam Sterilizers was chaired by Sue Klacik. Amanda Benedict, AAMI staff, served as recording secretary. Ms. Klacik called attention to the Antitrust statement, Code of Conduct, Patent Policy, and Conflict of Interest Statement. Attendees introduced themselves [ATTACHMENT A].

2. Approval of agenda

The agenda was approved as written following a motion by Gary Benning and a second by Mark Smith.

3. Approval of the minutes of the last meeting (Doc. STwg43N106)

The minutes of the 20 April 2016 meeting were approved as written following a motion by Mark Smith and a second by Michael Bacik.

4. ST8

Attendees discussed whether to open ST8 for revision. Input submitted by email for consideration by Chip Moore and Jonathan Wilder regarding was reviewed and discussed, along with additional points was in the discussion. Points considered included whether to align portions of ST8 with EN285 and relevant revisions to ST79, issues with extended cycles, using the language “cleared cycles”, whether references to “unwrapped loads” should be revised to “packaged loads”, whether content on steam quality should be added, adding UDI considerations, inclusion of synthetic wrap for validation.

Following discussions, the majority of attendees agreed that ST8 should be revised. The published document will be circulated for comments for specific proposed revisions for six weeks and the comments will be reviewed and resolved at the March 2017 Sterilization Standards Week. A small task group consisting of Michael Blacik, Richard Bancroft, Mark Smith, Jay Upchurch and Anthony Powell will work on a proposed harmonization of selected areas of ST8 to EN 285.

5. Other business

There was no other business.

6. Plans for the next meeting

Members agreed to meet during the next Sterilization Standards Week in March 2017.

Adjournment

The meeting adjourned at 9:47 a.m.
In attendance:

Michael Blacik, Steris
Richard Bancroft, Steris
Gary Benning, Midmark Corp.
Tim Carlson, Becton Dickinson
Fiona Collins, ADA
Michael D’Onofrio, Presage Health
Christopher Dugard, FDA
Nancy Fellows, ASP/J&J
Sue Klacik, IAHCSMM
Jack Leclair, Memorial Hermann
Tania Lupu, Case Medical
Kathleen McMullen, APIC
Anthony Powell, Getinge
Mark Smith, Getinge USA
Myra Smith, FDA
Andy Sun, SciCan
Dawn Tomac, APIC
Jay Upchurch, Belimed
Dean Wellman, Midmark
The WG 61 Committee met (attendance was as noted in ATTACHMENT A) and reviewed the two active TIRs:

**TIR 67 Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals in healthcare facilities.** The CDV-1 was submitted for ballot prior to the meeting but fell short of the required ballot returns. The ballot has been extended to October 28, 2016. All comments submitted with received ballots were reviewed and resolved. If additional comments are submitted with remaining ballots, a conference call will be scheduled to review and resolve. Following final ballot results, resolution of any additional comments or negative votes, it is intended that the document will be finalized and submitted for approval.

**TIR 68 Low and intermediate level disinfection in healthcare settings for medical devices, patient care equipment and sterile processing environmental surfaces.** Comments to the WD-1 for this new TIR were reviewed and resolved. A new task group was formed to develop content for the section on environmental cleaning for device reprocessing areas consistent with the scope of the document and the initial NWIP. WD-2 will be provided for comment prior to March 2018 meeting.

Geetha Jayan had stepped down as co-chair prior to this meeting due to a job change within FDA. Nominations are being accepted from the committee for a non-industry co-chair.

Respectfully submitted,

Janet Prust

Co-chair WG 61
Attendees:

Jennifer Bangle
Marcia Benedict
Nancy Chobin
Fiona Collins
Ramona Conner
Jacqueline Daley
Mary Ann Drosnock
Christopher Dugard
Susan Flynn
Nancy Kaiser
Terra Kremer
Jean-Luc Lemyre
Elaine Mayhall
Gerald McDonnell
Emily Mitzel
Alpa Patel
Janet Prust
Catherine Rocco
Matthew Roybal
Laxmimsita Sreedasyam
Jon Van Dyk
Jonathan Wilder
Minutes from WG 84 meeting regarding updating ST91

**Brief report of ST/WG 84, Endoscope Reprocessing Working Group [Co-chairs: Mary Ann Drosnock, Nancy Chobin]**

Co-chairs Mary Ann Drosnock and Nancy Chobin called to order the 19 October 2016 meeting of ST/WG 84. Amanda Benedict, AAMI staff, served as recording secretary. Attention was called to the Antitrust statements, Code of Conduct, Patent Policy and Conflict of Interest statement. Attendees introduced themselves.

The agenda was approved as written by a motion by Rose Seavey, seconded by Jon Fish. The minutes from the previous meeting were approved as written following a motion by Rose Seavey, seconded by Jon Fish.

Inputs from three task groups (critical devices, repairs, and microbial surveillance methods) were presented and discussed; a fourth task group (audits) had not yet submitted its work but that proposal will be circulated when received. Additional comments were requested on the new repair content, to be synthesized by the co-chairs; comments were to be entered into the comment template and emailed to Amanda Benedict within two weeks to be compiled and forwarded to the co-chairs. Jackie Daley will provide language about contracting with a lab to do testing of sampling to fit into the microbial surveillance methods new content; additional proposals for edits to this content can be submitted as comments to the working draft.

Attendees began reviewing and resolving comments for proposed edits. An additional four WebEx meetings will be held in December and January to finish the review of comments. A working draft will be circulated to ST/WG 84 members by February 3rd and comments will be due by March 3rd. Amanda Benedict will provide information to help commenters determine whether their comments are editorial, technical or general.

The working group’s next in-person meeting will be during March 2017 Sterilization Standards Week.

There being no further business, the meeting was adjourned by 4:49 PM following a motion by Kathleen McMullen, seconded by Steve Kovach.
Minutes from WG 84 meeting regarding updating ST91

ATTACHMENT A

Attendees:

Susan Adams
Marcia Benedict
Melinda Benedict
Damien Berg
Lindsay Brown
Denise Carey
Nancy Chobin
Linda Condon
Lena Cordie
Jacqueline Daley
Alicia Diaz
David Dominguez
Mary Ann Drosnock
John Erickson
Nancy Fellows
Jon Fish
Marga Foster
Sarah Friedberg
Brent Geiger
Zory Glaser
Allan Guan
Shanil Haugen
Regina Hammond
Julie Hoover
Nupur Jain
Susan Klacik
Dan Klein
Natalie Lind
Elan Lopezcuba
Alisha Loy
Tania Lupu
Viktoriya Lusignan
Elaine Mayhall
Kathleen McMullen
Masuzo Nagasaki
Navid Omidbakhsh
Janet Prust
Michael Quin
Catherine Rocco
Allison Rodriguez
Rose Seavey
Barb Smith
Joseph Smith
Mark Smith
Minutes from WG 84 meeting regarding updating ST91

Joan Spear
Mara Tafoya
Leslie Tavares
Lynne Thomas
Dawn Tomac
Richard Warburton
Sharon Van Wicklin
Graham Witherby
Stephen Kovach
Chris Strafaci
Suzanne Stefanik
Cynthia Spry
Bryan Worwa
Alpa Patel
Seth Hendee
M. Bieviny
Larry Talapa
John Whelan
Mitchell McCorty
Jason Simon
Robert Reich
Erica Rifar
Don Socha
Angela Thornton
Angela Lewellyn
Lawayne Perkins
Pat McCormick
Michael Schoene
Akina Ozaki
Joelle Glass
Perdita Patrick
Jennifer Asleson
Gary Benning
Dean Wellman
Don Tumminelli
Marcy Konja
Susan Pelton
Anthony Powell
Hyung Lee
Sunny Park
Rich Sparans
Marcia Frieze
Sharon Hadley
Stephen Loes
Richard Schule
Shireyoshi Baba
Klaus Roth
Stephanie Teat
Minutes from WG 84 meeting regarding updating ST91

Michael Blaskiewicz
Tricia Creggis
Clifford Gaine
Fred Alston
Kaumudi Kulkarni
Scott Jelley
Don Rotter
Damien Berg called the 17 October 2016 meeting of ST/WG 86 to order at 1 PM. Kelly Hunget, AAMI staff, served as recording secretary. Attention was called to the antitrust statement, patent policy, code of conduct and conflict of interest statement. Attendance is noted in ATTACHMENT A.

The agenda was approved following a motion by Rose Seavey, seconded by Joan Spear.

The previous meeting minutes were approved following a motion by Joan Spear, seconded by Rose Seavey.

Review of comments on the CDV-1 ST90 ballot opened with discussion of the editorial/terminology comments from Lena Cordie. Lena stated that many of her comments were based on the ISO/TC 198/WG 5 terminology standard work. Going forward, they want to figure out how to address Section 3 of the standard. The terminology comments were withdrawn, and the working group agreed to address on the definitions.

There were two negative votes on the CDV-1 ST90 ballot. The working group reviewed the objections submitted with 3M’s negative vote. Following resolution of these comments, 3M changed their vote to affirmative.

The other negative vote was from Intuitive Surgical, whose primary representative (Nupur Jain) was not present. The objection submitted with the vote proposed a change to the scope, which was considered but not considered persuasive by the working group. It was decided to move forward with the scope as is, with the agreement that the co-chairs would speak with the representative to try to encourage her to change Intuitive Surgical’s vote to affirmative.

The remaining comments were discussed and resolved. Lena Cordie will be updating Annex D figures to incorporate comments received during the meeting; work is to be completed by 29 November. Those in attendance were very pleased with the current document with many questions asked about next steps for assistance with implementing and training for users. The draft is currently out for public review which is scheduled to close November 29th. Any comments received from public review will be addressed, The document will then be finalized, sent to the AAMI Standards Board for review, then to ANSI for approval as an American National Standard.

A question was raised about whether it is required for hospitals to comply with ST90 once published? The co-chairs indicated that the document is a recommended practice; only in New Jersey is it required.

Provided that the public review and finalization of the document proceed without issue, it is not anticipated that WG 86 will need to meet during March 2017 Sterilization Standards Week.

There being no further business, the meeting was adjourned following a motion by Rose Seavey, seconded by Silas McAghon.
Attendees:

Richard Bancroft
Ralph Basile
Damien Berg
Angela Brightwell
William Brodbeck
Denise Carey
Thomas Chandler
Sean Colwell
Lena Cordie
Christophe Deneux
John Erickson
Becky Gilsdorf
Regina Hammond
Seth Hendee
Sean Andre Hodges
Susan Klacik
Jack Leclair
Angela Lewellyn
Stephen Loes
Alisha Loy
Jeff Marx
Leisel Masson
Silas McAghon
Jennifer Metch
Kerry Pearson
Susan Pelton
Cesar Perez
Lawayne Perkins
Michael Quin
Allison Rodriguez
Don Rotter
Marta Santana
Richard Schule
Rose Seavey
Joan Spear
Cynthia Spry
Donna Swenson
Larry Talapa
Lynne Thomas
Sharon Van Wicklin
Kristy Vogt
John Whelan
Bryan Worwa
The meeting of AAMI ST/WG 91 was chaired by Kurt McCauley and Don Tumminelli and opened at 2 pm. The attendees introduced themselves.

The cochairs referred the attendees to the AAMI statements for anti-trust, code of conduct and patent policy. These had been circulated with the agenda for the meeting.

The agenda and the minutes of the last meeting were approved as written.

Kurt McCauley and Richard Bancroft reviewed the Tampa Brief Report. Comments received on the CD ballot had been reviewed and resolved and ISO 18472 had been approved for DIS balloting. Richard Bancroft discussed considering EO concentration as well as temperature in the EO diagram. The ISO 18472 DIS text had been issued by ISO and would be distributed to AAMI ST/WG 91 for voting and commenting. Based on the US ballot results, a conference call to develop the US position would be scheduled to be held in January 2017 if needed.

An informal Argentine proposal for a method for determination of D value for LTSF biological indicators was discussed. The proposal pertained more to resistance determination of biological indicators and at this stage was viewed as not appropriate for further discussion in ST/WG 91.

The next meeting was tentatively agreed to be held in conjunction with the next AAMI Sterilization Standards Committee meeting, 20-23 March 2017.

The following were in attendance:

Richard Bancroft, STERIS
Jonathan Bull, Johnson & Johnson
David Dominguez, Becton Dickinson
Veronica Falkevitz, HIGHPOWER
Garrett Krushefski, Mesa Labs
Viktoriya Lusignan, Getinge
Elaine Mayhall, FDA
Kurt McCauley, Mesa Labs
Patrick McCormick, Bausch & Lomb
Tony Piotrkowski, STERIS
Matt Roybal, Johnson & Johnson
Mike Schoene, Bausch & Lomb
Krissy Singleton, Getinge
Don Tumminelli, HIGHPOWER
Craig Wallace, 3M
Jon Wilder, Quality Processing Resource Group

Leslie Tavares, Wuxi Apptec
Paul Newman, 3M
Adrian Ponce, Caltech
Greg Crego, IUVO Bioscience
Jacob Killian, IUVO Bioscience
Paul Littley, Nelson Labs
Fiona Collins, ADA
Rod Parker, Stryker
Shobha Puntambekar, Chrome
Jennifer Metch, Johnson & Johnson
Satu King, Spectranetics
Robert Bradley, Mesa Labs
Beth Ridgeway, Mesa Labs
Stephen Loes, Steriliucent
Andrew Porteous, Baxter

Observers
Jennifer Bangle, 3M
Cochair Karl Hemmerich led the meeting. Colleen Elliott served as recording secretary. Mr. Hemmerich asked committee members to review the anti-trust, code of conduct, patent policy and conflict of interest documents. The agenda was approved. The report of the last meeting was approved. See attached list for attendance.

Mr. Hemmerich led the committee in a review of the comments received on the ballot of TIR17. See STWG96Nxxx. All of the comments were resolved and the document will proceed to publication. Mr. Hemmerich thanked the committee members for helping to bring the document to completion.

The next meeting will take place in conjunction with Spring Sterilization Standards Week in Baltimore, MD on March 20-23, 2017.

With no other business, the meeting was adjourned at 2:25 pm.