AAMI ST/WG 15, Assurance of Sterility Working Group
Draft Agenda
AAMI Center for Excellence, Arlington, VA

Meeting date/time:       Tuesday        17 March 2020     8:00 AM to 12:00 PM EDT

1. Opening and roll call of members, review of Antitrust, Code of Conduct, Patent Policy, and Conflict of Interest Statements (ATTACHMENTS A-D)

2. Approval of agenda

3. Approval of the report of the last meeting (doc. STWG15N224)

4. Review of co-chair term dates
   - Current co-chairs:
     - Bryans, Mrs. Trabue: 7/1/2017 – 12/31/2020 (special appointment)
     - Lambert, Dr. Byron: 12/9/2015 – 12/31/2021
   - No action needed at this time

5. Discussion of comments on AAMI WD-1 TIR100, End-to-end Microbiological Quality and Assurance of Sterility (docs. STWG15N227, STWG15N2XX)
   - Next steps

6. Other business

7. Plans for the next meeting

8. Adjournment
ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION

Antitrust Statement

The Association for the Advancement of Medical Instrumentation ("AAMI") and its Board of Directors are committed to the activities of the Association, including meetings held for the purpose of:

1. Promoting the common interests of its members and the general welfare of the healthcare and patient communities through lawful activities.

2. Performing, in a lawful manner, such civic, commercial, industrial, professional and social events and activities to promote or foster the advancement of medical technology.

3. Preparing and disseminating among its members and others accurate and reliable information concerning the medical technology community, including standards, other publications, education and other services.

4. Participating in international, foreign and national standards activities to promote the welfare of the business, professional and patient care community.

5. Participating in scientific, consensus and educational activities and other lawful endeavors for the advancement of the public’s and members’ interests.

However, AAMI recognizes that in the process of these lawful activities, opportunities may arise that could result in violations of antitrust laws. Violations of antitrust laws are serious, criminal and civil violations, which are punishable by jail terms, fines and treble damage penalties. Therefore, all AAMI members and guests are reminded that AAMI meetings cannot be used, in violation of antitrust laws, to:

1. Discuss pricing, pricing policies, or any marketing policy with an indirect effect on pricing.

2. Confer about division or allocation of sales territories or customers.

3. Establish blacklists or boycotts of suppliers, purchasers, or competitors.

4. Coerce members or others to implement particular programs or policies.

5. Resolve problems in an arbitrary or unreasonable manner or based solely on the needs of a single party or a small, select group.

If you believe a potential antitrust problem has arisen or is occurring during this meeting, please immediately contact the person(s) chairing the meeting or an AAMI staff person.

Approved November 30, 2007
by the AAMI Board of Directors
# AAMI Consensus Body Member Code of Conduct

This AAMI Consensus Body Member Code of Conduct (Code) is adapted from the ISO Code of Conduct for the technical work. The goal of this Code is to facilitate AAMI’s standards development work—work that is carried out in a multi-stakeholder environment. The Code is also intended to ensure that consensus body deliberations are conducted in a respectful and professional manner by all parties. It applies to anyone who chooses to participate on an AAMI consensus body. The Code is an obligation for participation.

As participants in AAMI’s standards program, we acknowledge the responsibility and value of participating in the development of standards and technical information reports. We therefore adhere to this Code in accordance with the terms below.

<table>
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<tr>
<th>Work for the net benefit of the healthcare community</th>
<th>We recognize that the development of standards is for the net benefit of the healthcare community, over and above the interests of any individual or organization. We are committed to advancing standards within their agreed scope and we will not hinder their development. We support AAMI’s goal of advancing patient safety and medical technology.</th>
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<tr>
<td>Uphold consensus and governance</td>
<td>We will uphold the key principles of AAMI’s standardization: consensus, due process, honesty, openness, transparency, fairness, effectiveness, relevance, and coherence.</td>
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<tr>
<td>Agree to a clear purpose and scope</td>
<td>We are committed to having a clear purpose, scope, objectives, and will work to ensure the timely development of standards and technical documents.</td>
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<tr>
<td>Participate actively and manage effective representation</td>
<td>We agree to actively participate in standards development projects. We will make our contributions to the work according to the AAMI Standards Department Policies and Procedures.</td>
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<td>Escalate and resolve disputes</td>
<td>We will identify and escalate disputes in a timely manner to ensure rapid resolution. We will uphold the agreed dispute resolution processes.</td>
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<tr>
<td>Behave ethically</td>
<td>We will act in good faith and with due care and diligence. We will avoid collusive or anticompetitive behavior. We will promote a culture of fair and ethical behavior.</td>
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<td>Respect others in meetings</td>
<td>We are committed to respecting others and the professional culture of standards development. In meetings we are committed to:</td>
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<td></td>
<td>• conducting ourselves in a professional manner</td>
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<td>• respecting others and their opinions</td>
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<td>• accepting group decisions</td>
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<td>• ensuring that the views of all are heard and understood</td>
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3.1 ANSI patent policy - Inclusion of Patents in American National Standards

There is no objection in principle to drafting an American National Standard (ANS) in terms that include the use of an essential patent claim (one whose use would be required for compliance with that standard) if it is considered that technical reasons justify this approach.

Participants in the ASD/ANSI standards development process are encouraged to bring patents with claims believed to be essential to the attention of the ANSI-Accredited Standards Developer (ASD).

If an ASD receives a notice that a proposed, revised or approved ANS may require the use of such a patent claim that is not already covered by an existing assurance, the procedures in this clause shall be followed.

3.1.1 Statement from patent holder

The ASD shall receive from the patent holder or a party authorized to make assurances on its behalf, in written or electronic form, either:

   a) assurance in the form of a general disclaimer to the effect that such party does not hold and does not currently intend holding any essential patent claim(s); or

   b) assurance that a license to such essential patent claim(s) will be made available to applicants desiring to utilize the license for the purpose of implementing the standard either:

      i. under reasonable terms and conditions that are demonstrably free of any unfair discrimination; or

      ii. without compensation and under reasonable terms and conditions that are demonstrably free of any unfair discrimination.

Such assurance shall indicate that the patent holder (or third party authorized to make assurances on its behalf) will include in any documents transferring ownership of patents subject to the assurance, provisions sufficient to ensure that the commitments in the assurance are binding on the transferee, and that the transferee will similarly include appropriate provisions in the event of future transfers with the goal of binding each successor-in-interest.

The assurance shall also indicate that it is intended to be binding on successors-in-interest regardless of whether such provisions are included in the relevant transfer documents.

3.1.2 Record of statement

A record of the patent holder’s statement shall be retained in the files of both the ASD and ANSI.

3.1.3 Notice

When the ASD receives from a patent holder the assurance set forth in 3.1.1.b above, the standard shall include a note substantially as follows:

NOTE – The user’s attention is called to the possibility that compliance with this standard may require use of an invention covered by patent rights.

By publication of this standard, no position is taken with respect to the validity of any such claim(s) or of any patent rights in connection therewith. If a patent holder has filed a statement of willingness to grant a license under these rights on reasonable and nondiscriminatory terms and conditions to applicants desiring to obtain such a license, then details may be obtained from the standards developer.

3.1.4 Responsibility for identifying patents

Neither the ASD nor ANSI is responsible for identifying patents for which a license may be required by an American National Standard or for conducting inquiries into the legal validity or scope of those patents that are brought to their attention.