AAMI BE/WG 11, Allowable Limits for Leachable Substances
Skype Meeting

Agenda

Meeting date/time: Tuesday 15 January 2019 11:00 am to 1:00 pm EST

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 brief report of the last meeting (doc. BEWG11N040)

4. ISO 10993-7:2008/Amd 1, Ethylene oxide sterilization residuals – Amendment 1
   a. Project timeline
   b. Status
   c. Proposed revision of ISO 10993-7

5. ISO/DTS 21726:2018 Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of extractable substances from medical devices
   a. Project timeline
   b. Overview of ISO/TC 194/WG 11 discussion on methods for derivation of non-cancer TTC thresholds

6. ISO/NP 10993-17, Biological evaluation of medical devices - Toxicological risk assessment of medical device constituents
   a. Project timeline
   b. Overview of ISO/TC 194/WG 11 discussion on new content and revision of proposed content and discussion on toxicological equivalence

7. Overview of ISO/TC 194/WG 11 discussion on application of quantitative risk assessment method for sensitizers and dermal sensitization threshold to medical device extractables

8. Overview of ISO/TC 194/WG 11 discussion on interdisciplinary approach when executing ISO 10993-1, -18, and -17

9. Other business

10. Plans for next meeting

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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<tbody>
<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>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<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>
</tr>
<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>
</tr>
<tr>
<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>
</tr>
<tr>
<td></td>
<td>• conducting ourselves in a professional manner</td>
</tr>
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| • respecting others and their opinions  
| • accepting group decisions  
| • ensuring that the views of all are heard and understood |
AAMI (ANSI) Patent Policy

The AAMI Standards program follows the current ANSI Patent Policy (reproduced below from the 2014 ANSI Essential Requirements: Due process requirements for American National Standards)

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.

If an ANSI-Accredited Standards Developer (ASD) receives a notice that a proposed ANS or an approved ANS may require the use of such a patent claim, 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.

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.

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CONFLICT OF INTEREST STATEMENT

This conflict of interest statement is designed to help directors, officers, the management team, and members of certain committees of the Association for the Advancement of Medical Instrumentation ("AAMI") identify situations that present conflicts of interest or potential conflicts of interest and to provide AAMI with a procedure which, if observed, will allow a transaction to be treated as valid and binding even though a director, officer, management team person or committee member has or may have a conflict of interest with respect to the transaction. This statement is intended to comply with Virginia law. If there is an inconsistency between the requirements and procedures prescribed herein and Virginia law, Virginia law shall control.

1. Definitions.

a. A "Covered Person" is any person serving as an AAMI director, officer, management team person, or as a member of an AAMI Board or Governance committee.

b. A "Family Member" is a spouse, domestic partner, or dependent child of a Covered Person.

c. A "Material Financial Interest" in an entity is a financial interest of any kind, which, in view of all the circumstances, is substantial enough that it would, or reasonably could, affect a Covered Person's or Family Member's judgment with respect to transactions to which the entity is a party. This includes all forms of compensation.

d. A "Conflict of Interest" is any circumstance described below:

(i) A contract or transaction between AAMI and a Covered Person or Family Member except routine, incidental transactions, conducted in the normal course of AAMI business (e.g., payment of membership dues, purchases of services or publications at regular rates; customary honoraria for courses or seminars; travel reimbursement for volunteer services).

(ii) A contract or transaction between AAMI and an entity (A) in which a Covered Person or Family Member has a Material Financial Interest or (b) of which a Covered Person or Family Member is a director, officer, agent, partner, associate, trustee, personal representative, receiver, guardian, custodian, conservator or other legal representative.

(iii) A Covered Person competing with AAMI in the rendering of services or in any contract or transaction with a third party.
(iv) A Covered Person's having a Material Financial Interest in an entity that competes with AAMI in the provision of services.

(v) A Covered Person's serving as a director, officer, employee, agent, partner, associate, trustee or personal representative of an entity that competes with AAMI in the provision of services. (Legal counsel has expressed an opinion that serving on governing bodies of other standards developing organizations could be a conflict of interest. Serving on the Board of another standards developing organization will be a conflict of interest if the association engages in competitive activity.)

(vi) An AAMI contract or transaction that involves a Covered Person when a reasonable person, with knowledge of all relevant facts, would question the impartiality of the Covered Person with respect to such contract or transaction.

2. Procedures.

a. Prior to board or committee action on a contract or transaction involving a Conflict of Interest, a director, officer, management team person or committee member having a Conflict of Interest or potential Conflict of Interest and who is in attendance at the meeting shall disclose all facts material to the Conflict of Interest. Such disclosure shall be reflected in the minutes of the meeting.

b. A director, officer, management team person or committee member who plans not to attend a meeting at which he or she has reason to believe that the board or committee will act on a matter in which the person has a Conflict of Interest shall disclose to the chair of the meeting all facts material to the Conflict of Interest. The chair shall report the disclosure at the meeting and the disclosure shall be reflected in the minutes of the meeting.

c. A person who has a Conflict of Interest shall not participate in or be permitted to hear the board's or committee's discussion of the matter except to disclose material facts and to respond to questions. Such person shall not attempt to exert his or her personal influence with respect to the matter, either at or outside the meeting.

d. A person who has a Conflict of Interest with respect to a contract or transaction that will be voted on at a meeting shall not be counted in determining the presence of a quorum for purposes of the vote. The person having a conflict of interest may not vote on the contract or transaction and shall not be present in the meeting room when the vote is taken, unless the vote is by secret ballot. Such person's ineligibility to vote shall be reflected in the minutes of the meeting.
e. Covered Persons who have a Conflict of Interest with respect to a contract or transaction that is not the subject of board or committee action, shall disclose to the chair or the chair’s designee any Conflict of Interest that such Covered Person has with respect to a contract or transaction. Such disclosure shall be made as soon as the Conflict of Interest is known to the Covered Person. The Covered Person shall refrain from any action that may affect AAMI’s participation in such contract or transaction.

f. If it is not entirely clear that a Conflict of Interest exists, the individual with the potential conflict or any other person who becomes aware of the potential conflict may disclose the circumstances to the Executive Committee of the Board of Directors, who shall determine whether there exists a Conflict of Interest that is subject to this statement. The Executive Committee, working with staff and legal counsel, will also advise Board members on the interpretation of this statement.

g. Statements pertaining to disclosures of conflicts of interest may either be submitted to the Chair of the Board or the President. Such statements will be made available to the Board as necessary for the implementation of this Statement.

3. Confidentiality. Each Covered Person shall exercise care not to disclose confidential information acquired in connection with such status or information the disclosure of which might be adverse to the interests of AAMI. Furthermore, a Covered Person shall not disclose or use information relating to the business of AAMI for the personal profit or advantage of the Covered Person or a Family Member.


a. Each new Covered Person shall be required to annually review a copy of this statement and to be reminded of the obligation to conform to it.

b. Each Covered Person may annually complete a disclosure form identifying any relationships, positions or circumstances in which the Covered Person is involved that he or she believes could create a Conflict of Interest. Such relationships, positions or circumstances might include service as a director of or consultant to a nonprofit organization that competes with AAMI, or ownership of a business that might provide goods or services to AAMI. Any such information regarding business interests of a Covered Person or a Family Member shall be treated as confidential and shall generally be made available only to the Executive Committee, except to the extent additional disclosure is necessary in connection with the implementation of this Statement.
c. This statement shall be reviewed annually by the Board of Directors and management team. Any changes to the statement shall be communicated immediately to all Covered Persons.
AAMI Conflict of Interest Information Form

Name: ______________________________ Date: ___________________________

Please describe below any relationships, positions, or circumstances in which you are involved that you believe could create a Conflict of Interest (as defined in AAMI’s Statement on Conflicts of Interest).

I hereby certify that the information set forth above is true and complete to the best of my knowledge. I have reviewed the statement on conflict of interest of AAMI that is currently in effect.

Signature: __________________________________________________________

Date: _____________________________________________________________

Updated June 2010