AAMI/PB, Protective Barriers Committee

Joint meeting with ASTM F23.40

Bethesda Marriott
Bethesda, MD

Meeting date/time: Tuesday 19 April 2016 9:00 pm to 5:00 pm


2. Approval of agenda (N77)

3. Approval of report of October 2015 meeting (N76)

4. Questions and further discussion of the newly issued CDC guidance document on PPE and Ebola

5. Discussion of clinical use and testing of isolation gowns, with objectives outlined on page 2

6. Discussions of possible revisions to PB70 to address new requirements in the guidance document: Inclusion/exclusions re. “isolation gown”; other health care protective attire, e.g., decontamination gown; design requirements; additional content relative to barrier levels.

7. Refinement of the proposed ASTM isolation gown standard based on new requirements in the guidance document

8. Discussion of comments received on revision of TIR11

9. Update on ISO/TC 94/SC 13, Protective clothing

10. Plans for next meeting

11. Other business

Adjournment
Discussion Objectives

1. Objective: To understand how the clinical use of surgical and isolation gowns has changed with the development of new technologies and terminology.
   a. What are the clinically relevant performance parameters?
   b. What exposure are gowns subjected to?
   c. Are manufactures and/or health care industry moving to a one-size-fits-all product line? If so do variable exposure conditions matter?

2. Objective: To determine if the current performance standards are adequate. If not, what are the appropriate, clinically relevant metrics for the current use paradigm?
   a. Are the current performance tests appropriate for the intended use of the gowns?
      · AATCC 42 and 127
      · ASTM 1670 and 1671
   b. Surgical vs. non-surgical/isolation gowns
   c. Should there be a review of all testing labs?
   d. Discuss current variability of test results.

3. Objective: To determine if the current sampling, validation, and monitoring ensures that existing performance standards are met or should measure be taken to improve compliance, and if so, what can be done to improve that compliance?
   a. Are the current sampling strategies prescribed in the standard(s) adequate?
   b. Testing performed on the fabric and not on the finished product.
   c. Testing performed in the design or production validation stage. Is there value in continuous or periodic testing post production phase?
   d. Are the current AQL of 4% and RQL of 20% adequate?

4. Objective: Determine if there is a need to revise the definition of an isolation gown.
   a. Should open back gowns be included in the definition?

5. Objective: Determine if there is a need to add other types of health care protective attire to the document, e.g. decontamination gown.
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>Term</th>
<th>Description</th>
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<tr>
<td>Work for the net benefit of the healthcare community</td>
<td>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.</td>
</tr>
<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 <em>AAMI Standards Department Policies and Procedures</em>.</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>
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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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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 proposedANS 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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