AAMI ST/WG 12, Instructions for Reusable Device Reprocessing
Hyatt Regency–Baltimore Inner Harbor
Baltimore, MD

Meeting date/time: Wednesday 18 October 2017 12:00 p.m. – 3:00 p.m. ET

1. Opening and roll call of members, review of Antitrust Statement/Code of Conduct

2. Approval of agenda (N 97)

3. Approval of the 23 March 2017 meeting report (N 89)

4. Update on projects within ISO/TC 198/WG 12:
   a. ISO/FDIS 17664, Sterilization of medical devices - Information to be provided by the device manufacturer for the processing of reusable medical devices (undergoing identical adoption to replace AAMI/ST81)
   b. ISO/NP 22913, Processing of health care products -- Information to be provided by the medical device manufacturer for the processing of medical devices -- Part 2: Medical devices not intended for direct patient contact

5. Revision of AAMI/TIR12, Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
   a. Review comments received on N 96, Document for comment: Proposed annex on standardized cleaning protocols [comments to be posted]
   b. Review comments received on N 94, AAMI WD-1 TIR12 for comment [comments to be posted]

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>
<thead>
<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>
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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>• 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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