AAMI RENAL DISEASE AND DETOXIFICATION COMMITTEE
(US Sub-TAG for ISO/TC 150/SC 2/WG 5,
Renal replacement, detoxification and apheresis and IEC/SC 62D MT20,
Hemodialysis equipment)

PROPOSED AGENDA
Dress Business Casual

9 AM – 5 PM, 17-18 April 2015
Coronado Springs Resort
Orlando, FL 32830

1. Opening and roll call of members, review of Antitrust Statement
2. Approval of agenda
3. Approval of minutes of last meeting [RDN604]
5. Status of article to support US deviation to ISO dialysis fluid standards
7. Review of ballot results and resolution of comments/development of US position on Systematic Review of ISO 8637:2010, Cardiovascular implants and extracorporeal systems -- Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators
11. Review and resolution of comments/development of US positions on Amendment to IEC 60601-2-16, ed.4 (haemodialysis, haemodiafiltration and haemofiltration equipment) and Amendment to IEC 60601-2-39, ed.2 (peritoneal dialysis equipment)
12. Review and resolution of comments on AAMI TIR72, *Dialysis fluid chemical composition* and determination of next steps

13. Review and resolution of comments on draft AAMI TIR, *Safe use of equipment for hemodialysis and related therapies* and determination of next steps

14. Review and resolution of comments on draft AAMI TIR, *Sorbent-Based Regenerative Hemodialysis Systems* and determination of next steps

15. Review of draft TIR on use of AAMI standards for clinical applications and determination of next steps

16. Report on Alarms Committee activity

17. Update on CMS activity

18. Discussion of contingency plans for alternate meeting spaces/ASN connection

19. Other business/next meeting

Adjournment

NOTE Please bring copies of the documents listed above to the meeting, as extra copies will not be available on site.
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