

AAMI: What is it and how does it impact the biomedical Technician?

TECHNICAL LEADERS

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Objectives

You will be able to do the following when done with this presentation:

- ❖ Define what AAMI is
- ❖ Discuss what aami does
- ❖ Discuss how AAMI develops recommendations
- ❖ Discuss how aami impacts the biomedical technician

AAMI: Association for the advancement of medical instrumentation

- ❖ Nonprofit organization founded in 1967.



Fifty years ago, AAMI's founders, which included (left to right) **John Post, Warren (Zeph) Lane, Arthur C. Beall, and Bob Allen**, realized that without effective standards, appropriate regulation, education, and support, medical devices would never achieve their full potential. Today, AAMI continues to work to ensure the promise of emerging healthcare technologies.



AAMI:

Association for the advancement of medical instrumentation

- ❖ Diverse community of nearly 7,000 professionals united by one important mission: the development, management, and use of safe and effective healthcare technology.
- ❖ Provides recommendations that the centers for Medicare & Medicaid services (CMS) has regulated
 - ❖ Associated V-tags within the regulations relate to AAMI guidelines

AAMI:

Association for the advancement of medical instrumentation

Sets standards for:

- ❖ Contaminant levels in water used for preparing dialysate and concentrates (13959)
 - ❖ Periodic Analysis
 - ❖ Action and allowable limits for bacteria and endotoxin cultures
- ❖ Concentrates For Hemodialysis (13958)
 - ❖ Solute concentrations
 - ❖ Bacteriology and Endotoxin Levels
 - ❖ Labeling

AAMI:

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- ❖ Water treatment equipment (26722)
 - ❖ Requirements
 - ❖ Labeling
- ❖ Reprocessing of hemodialyzers (RD47)

AAMI:

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- ❖ Hemodialysis Medical Electrical equipment Part 2-16 (60601-2-16)
 - ❖ Requirements for the basic Safety and essential performance of hemodialysis equipment
 - ❖ Protection against electrical hazards
 - ❖ General requirements for tests and guidance for alarms systems
 - ❖ Requirements For me equipment (Hemodialysis) and me systems used in the home environment

AAMI:

Association for the advancement of medical instrumentation

- ❖ How are they developed?

- ❖ AAMI provides a unique and critical forum for a variety of professionals including clinical and biomedical engineers, technicians, physicians, nurses, hospital administrators, educators, scientists, manufacturers, distributors, government regulators, and others with an interest in healthcare technology.

- ❖ Who issues these standards?

- ❖ AAMI standards program consists of over 100 technical committees and working groups that produce Standards, Recommended Practices, and Technical Information Reports for medical devices.

How does AAMI impact the Biomed?

- ❖ AAMI is a resource for biomedical technicians and the manufacture to set guidelines for equipment they use
- ❖ CMS and Some states use AAMI to set rules and regulations for:
 - ❖ Water treatment
 - ❖ Operation
 - ❖ Monitoring
 - ❖ Cleaning and disinfection
 - ❖ Culture standards
 - ❖ Determines when action must be taken
 - ❖ Equipment
 - ❖ Machines
 - ❖ Concentrate
 - ❖ Cleaning and disinfection
 - ❖ Monitoring

AAMI: in summary

- ❖ Professional organization composed of health care professionals, manufacturers, and federal agencies to develop guidelines and recommendations for medical products and procedures.
- ❖ AAMI (www.aami.org) serves as a primary resource for the industry, the professions, and government for national and international standards. Created by its various committees, these standards help those managing dialysis clinics to control costs, and keep the renal team informed of new technology and policy developments.
- ❖ What is the best way for biomedical technicians to understand aami and the important role it plays in their job responsibilities?

How can the biomed and NANT affect AAMI Decisions?

- ❖ Committees
- ❖ Manufacturers
- ❖ Standards
- ❖ Nant: how do they influence these decisions?
 - ❖ Workgroups

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Baxter Healthcare Corporation
AWAK Technologies Pte Ltd.
Rockwell Medical Inc.
Fresenius Medical Care North America
Medtronic Inc.
MarCor Purification
B Braun of America, Inc.
Reprocessing Products Corp
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STRENGTH THROUGH DIVERSITY!