



Keeping Your Program in Alignment

AAMI and AORN Updates

Presented by Erika Wilson



Erika Wilson

Area Manager

Speaker info

- B.S. in BioMolecular Engineering, Milwaukee School of Engineering
- Joined Phigenics in August of 2018 as an Account Manager
- Certificate from the ANSI Certified *Sustainable Comprehensive Water Management Programs for the Built Environment* Course
- Has two and a half years of experience developing and operating water management programs to achieve water safety

Learning Objective

1. Understand the objectives of AAMI TIR34 and the AORN Guideline for Instrument Care and Cleaning
2. Evaluate key considerations for the integration of Medical Device Reprocessing (MDR) into existing water management programs
3. Understand the recommended water quality monitoring parameters for different water sources in medical device reprocessing

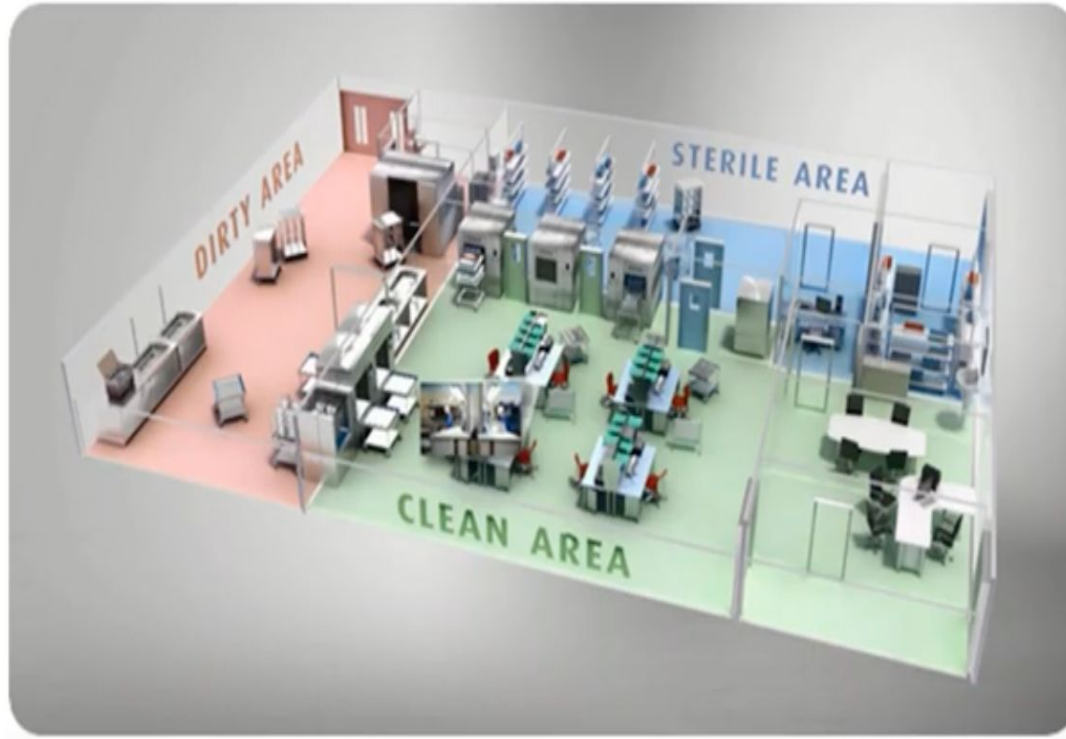
This content is based on a review of AAMI TIR34 and the AORN Guideline; content presented represents information that was reviewed by Phigenics as important for consideration water management teams.

Phigenics chooses to be **independent** from profiting on the sale of water treatment products and services which conflict with our only bias:

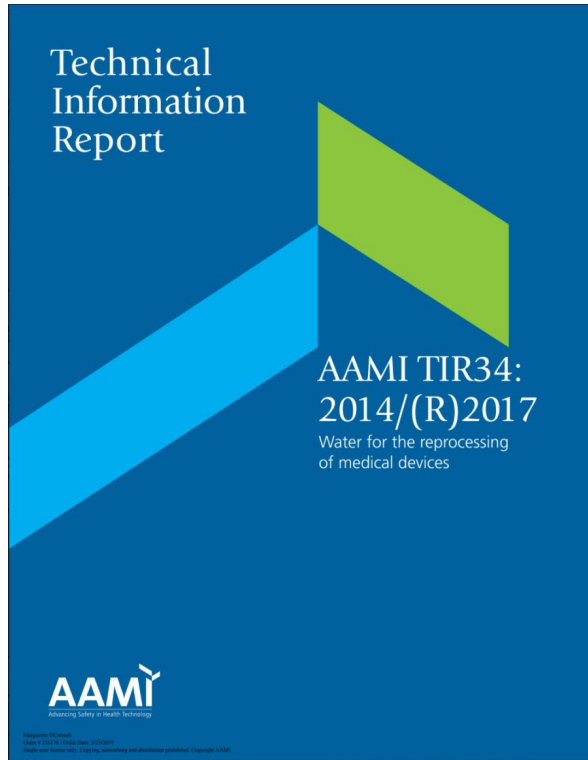
Work with facility owners and managers to achieve defensible, data driven water management programs which **verify** and **validate** their building water systems are safe, efficient and cost-effective.

Water Quality in Medical Device Reprocessing (MDR): Interpretation of Industry Guidance

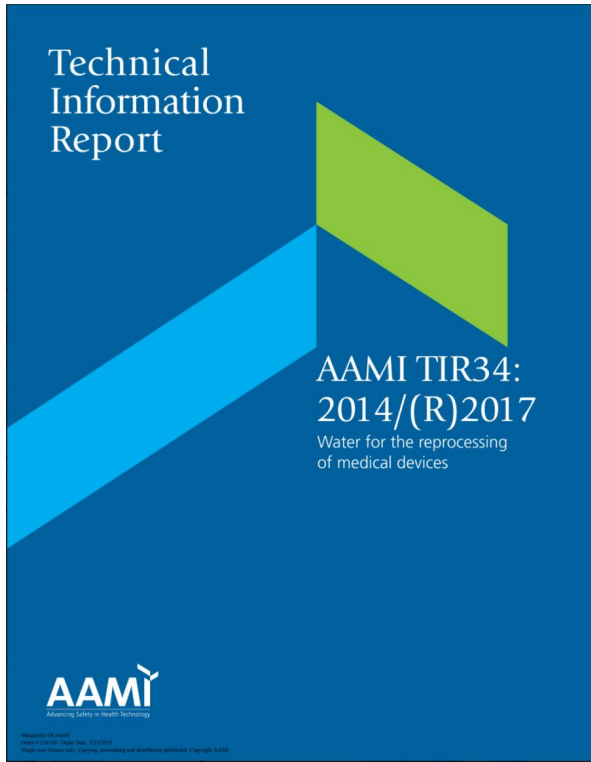
What is Medical Device Reprocessing



Industry Guidance for Water Quality in MDR



What is the goal of these guidelines?

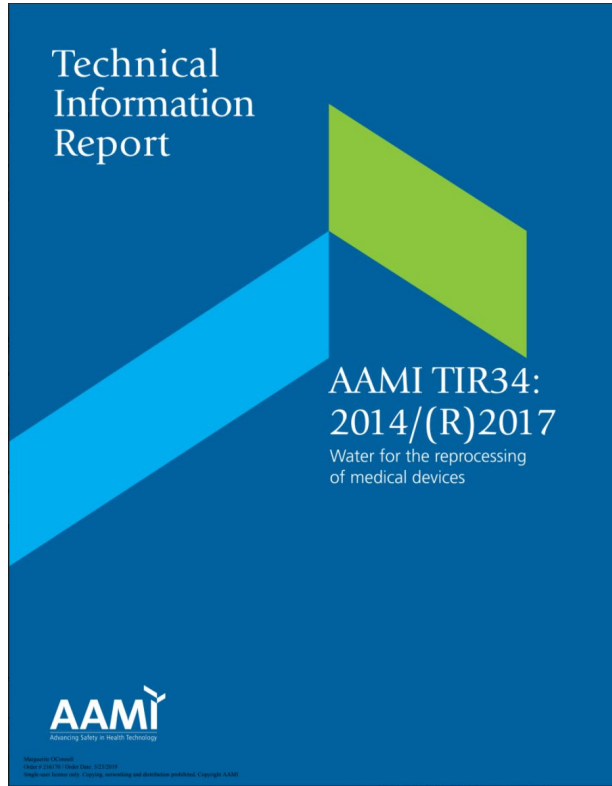


Implement **prevention** methods to minimize the impact of water on:

1. Life of medical instrumentation
2. Effective functioning of instrumentation
3. Risk of adverse patient outcomes arising from contaminated medical devices



Industry Guidance for Water Quality in MDR



1. AAMI is committed to updating this document every three years (i.e. 2017 revision)
2. Normally there would be a 2020 - now they decided to produce a standard ST108
3. AAMI is soliciting support from industry experts in order to produce this standard
4. The goal of the standard is to come to a consensus around water management practices and water quality goals for medical device reprocessing
5. The annexes of this document discuss a process that is already vetted by ASHRAE Standard 188: developing a water management program

Industry Guidance for Water Quality in MDR



1. Normally writes guidance for surgical services - this is the first time we are seeing them step into the space of water quality
2. This guideline is in parallel with AAMI TIR34
3. AORN makes an effort to call out the need for a Water Management Program and Team in the body of the document
4. It is our understanding the regulatory bodies (TJC, DMV, etc.) listen when AORN and AAMI release guidance of this nature

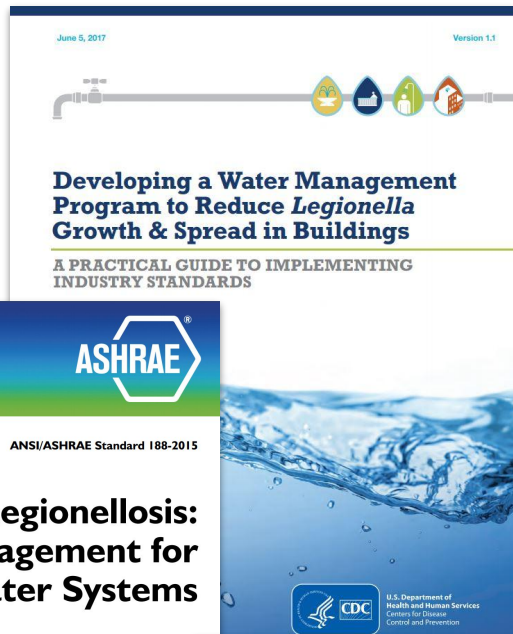
What are the issues?



1. Device malfunction during a patient procedure (corrosion, breakage, hindered mechanical movement)
2. Toxic effects and tissue irritation resulting from residuals on a device or implant that was reprocessed using water of inadequate quality (endotoxins)
3. Patient infection resulting from the use of contaminated devices (salt, organic deposits or microorganisms)
4. Ineffective cleaning/disinfection because of chemical integration with water contaminants.
5. Increased rejection rate = increased operational cost
6. Asset preservation of cart washers, tray washers, medical devices etc.

Incorporate in your Hospital's Water Management Program

- Facility should already have a water management program in place
- Include the Sterile Processing Department in the existing program
- Allows for streamline decision making when issues occur



THE 7 STEPS OF A COMPREHENSIVE & DEFENSIBLE WATER MANAGEMENT PROGRAM (WMP)

1. Form a Team

2. Develop Program Goals

3. Describe Water Systems

4. Analyze Water Systems for Safety & Efficiency

5. Specify Control Locations, Control Limits, Monitoring and Corrective Actions

6. Develop Verification Strategy

7. Develop Validation Strategy



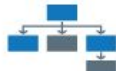
INCORPORATING MEDICAL DEVICE REPROCESSING INTO A WMP



1) Integrate MDR stakeholders into WMP Team



2) Develop water safety & quality goals for MDR



3) Develop process flow diagrams for utility, critical water and steam systems



4) Analyze systems for safety, quality & efficiency



5) Specify control locations, control limits, monitoring and corrective actions



6) Develop Verification Strategy



7) Develop Validation Strategy

Overview of Recommended Water Quality and Monitoring

Two Categories of Water Quality



1. AAMI Utility Water

Water as it comes from the tap that might require further treatment to achieve the specifications. This water is mainly used for flushing, washing, and rinsing.

2. AAMI Critical Water

Water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, DI, and RO or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water. This water is mainly used for the final rinse or steam generation.

Water Quality for Medical Device Reprocessing

Parameter	Unit	AAMI Utility Water	AORN Utility Water	AAMI Critical Water	AORN Critical Water	Type of Testing	Testing Frequency
Bacteria	cfu/mL	< 10*	n/a	< 10	< 10	Heterotrophic plate count	Monthly
Endotoxin	EU/mL	< 20*	n/a	< 10	< 10	LAL Test	Quarterly
Total Organic Carbon	mg/mL	< 1	< 1	< 1	< 1	TOC Test	Monthly or Quarterly
pH	n/a	6 - 9	6 - 9	5 - 7	5 - 7	pH Meter	Monthly
Hardness	mg/L	< 150	< 150	< 1	< 1	Colorimetric Dipsticks	Annually
Conductivity	µS/cm	< 500	<500	< 10	< 10	Conductivity Meter	Daily

*Only monitor if high level disinfection occurs

Water Quality for Medical Device Reprocessing

Parameter	Unit	AAMI Utility Water	AORN Utility Water	AAMI Critical Water	AORN Critical Water	Type of Testing	Testing Frequency
Chlorides	mg/L	<250	< 250	< 1	< 1	Chloride Test	Annually
Iron	mg/L	n/a	n/a	< 0.2	< 0.2	Iron Test	Annually
Copper	mg/L	n/a	n/a	< 0.1	< 0.1	Copper Test	Annually
Manganese	mg/L	n/a	n/a	< 0.1	< 0.1	Manganese Test	Annually
Color / Turbidity	n/a	Colorless, clear, no visible residues	Colorless, clear, no visible residues	Colorless, clear, no visible residues	Colorless, clear, no visible residues	Visual Inspection	Daily
Temperature	°F	Downstream Equipment Requirements	Downstream Equipment Requirements	Downstream Equipment Requirements	Downstream Equipment Requirements	Thermometer	Daily

Identifying Sample Locations

1. Source Water (Monitoring)

- a. Filters, Softeners, RO Unit, DI Tanks, etc.
- b. Referred to by ASHRAE Standard 188 as **Verification**
- c. Definition: implementing the program as designed through monitoring activities



2. Point of Use (Testing)

- a. RO or DI Water Faucet, Critical Water Storage Tank, Sample Port before Equipment, etc.
- b. Referred to by ASHRAE Standard 188 as **Validation**
- c. Definition: ensuring that the water management program is producing water that meets the set goals



Steam Considerations

1. Types of Steam

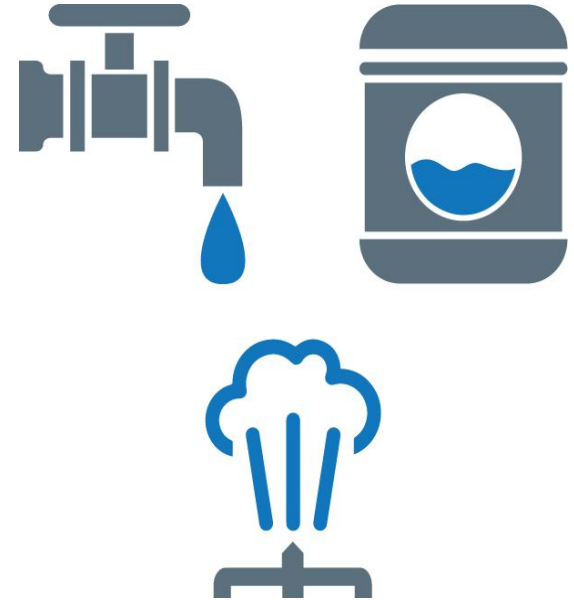
- a. Plant Steam - split from building boiler system
- b. Clean Steam - localized steam generation and distribution

2. Testing Steam Condensate

- a. Poor representation of overall steam quality

3. Focus on:

- a. Proper steam trap operation
- b. Steam Filtration and Steam Separators
- c. Boiler water treatment
- d. Asset management



Q & A