

Water Quality

A Critical to Quality Driver in Cleaning, Disinfection,
and Sterilization

The Passion to Protect.
The Power to Prevent.

Disclaimer

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Learning Objectives – The WHAT

01

Water quality as a critical-to-quality factor in cleaning, rinsing, disinfection, and sterilization of reusable medical devices.

02

Risk-based evaluation of water control points across the processing cycle: Utility Water, Critical Water, and steam.

03

How chemical, microbial, and physical water parameters affect processing outcomes, equipment performance, and patient safety.

04

Key concepts of ANSI/AAMI ST108:2023 — water categories, monitoring expectations, and multidisciplinary program responsibilities.

05

Practical tools and strategies to develop, assess, monitor, and continuously improve a water quality management program.

The Passion to Protect. The Power to Prevent.

Conversation Flow – The HOW



Stand Up

If you have a question, stand up — we will stop and answer questions.



Ask As We Go

We'd rather answer in the moment than save everything for the end.



Bring Your Reality

Your facility's water, constraints, and risks make this conversation better.

Conversation Leads – The WHO

Why these two voices, together

- Sarah Frank, BS — **frames the risks**: where device design and sterile processing practices break down, and what that means for cleaning, disinfection and sterilization outcomes.
 - Co-chair, AAMI WG-61 Chemical Sterilants Hospital Practices; J&J voting member for most AAMI standards groups focused on device processing.
- Terra Kremer, PhD, BS — brings the **industry research behind those risks**, studying microbial contamination control across the entire supply chain, from pharmaceutical and medical device manufacturing all the way to patient use.
 - Co-chair, AAMI WG-95 Water for Reprocessing; U.S. ISO expert (WG12, WG13); ASTM/AAMI/ISO and PDA TR70 contributor; PhD Microbiology, 20 years of lab and standards work.

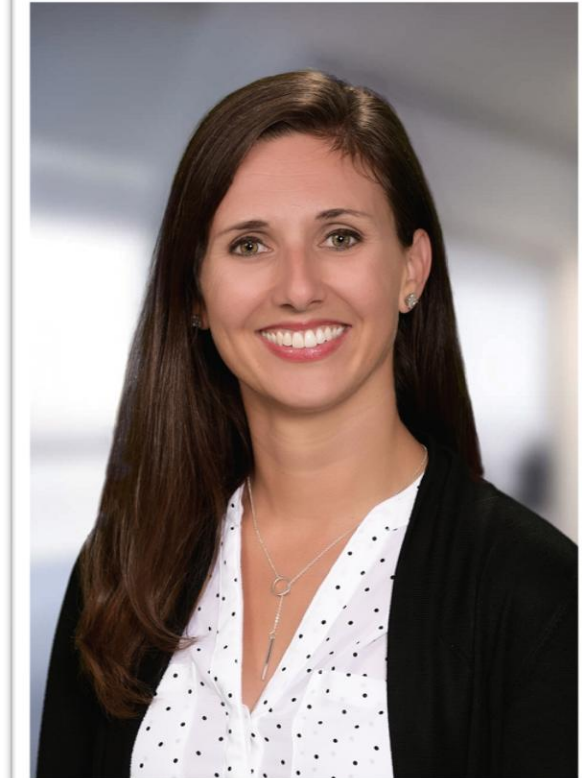
Sarah Frank

Manager, Device Processing



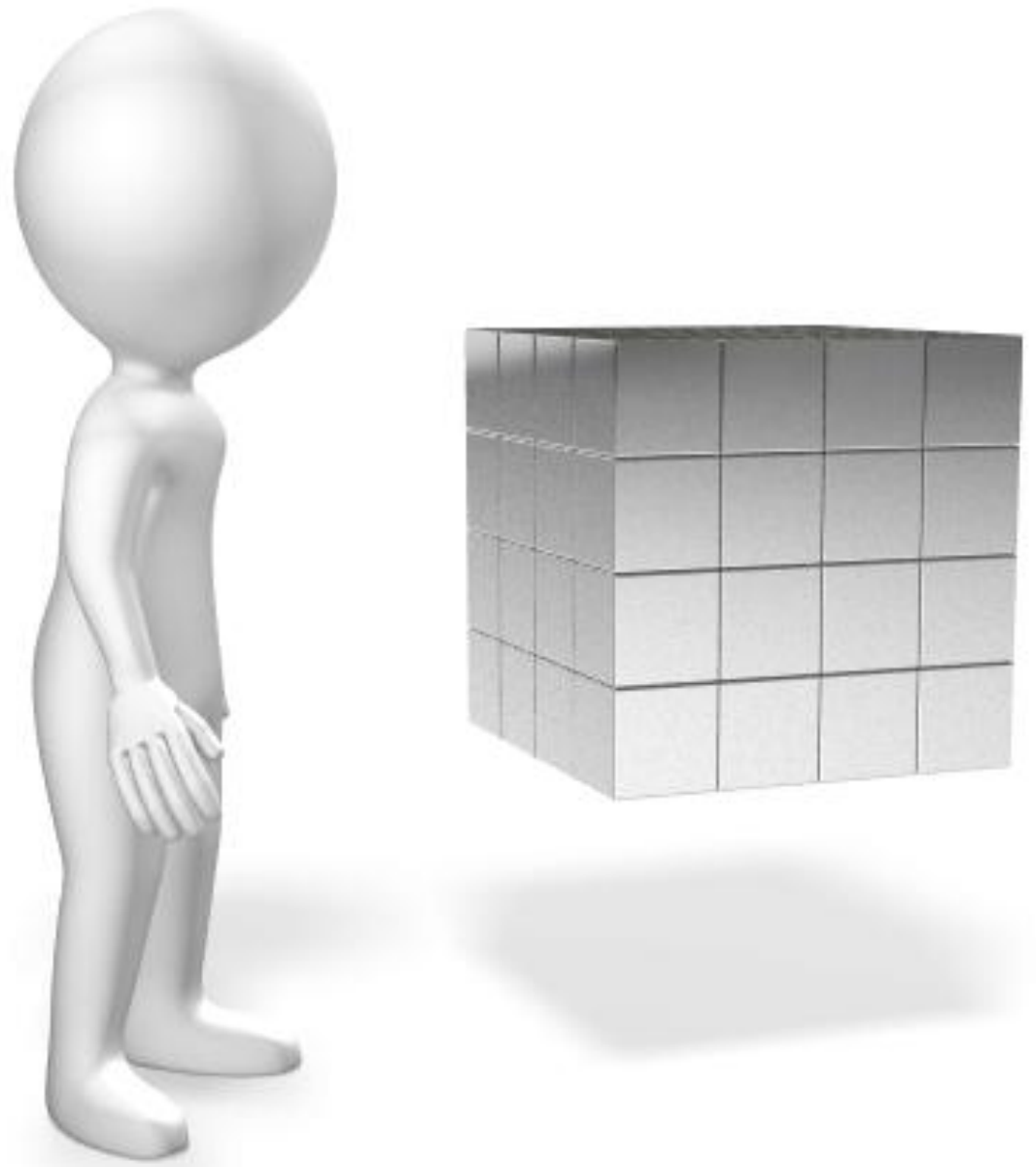
Terra Kremer

Director of Microbiological Quality



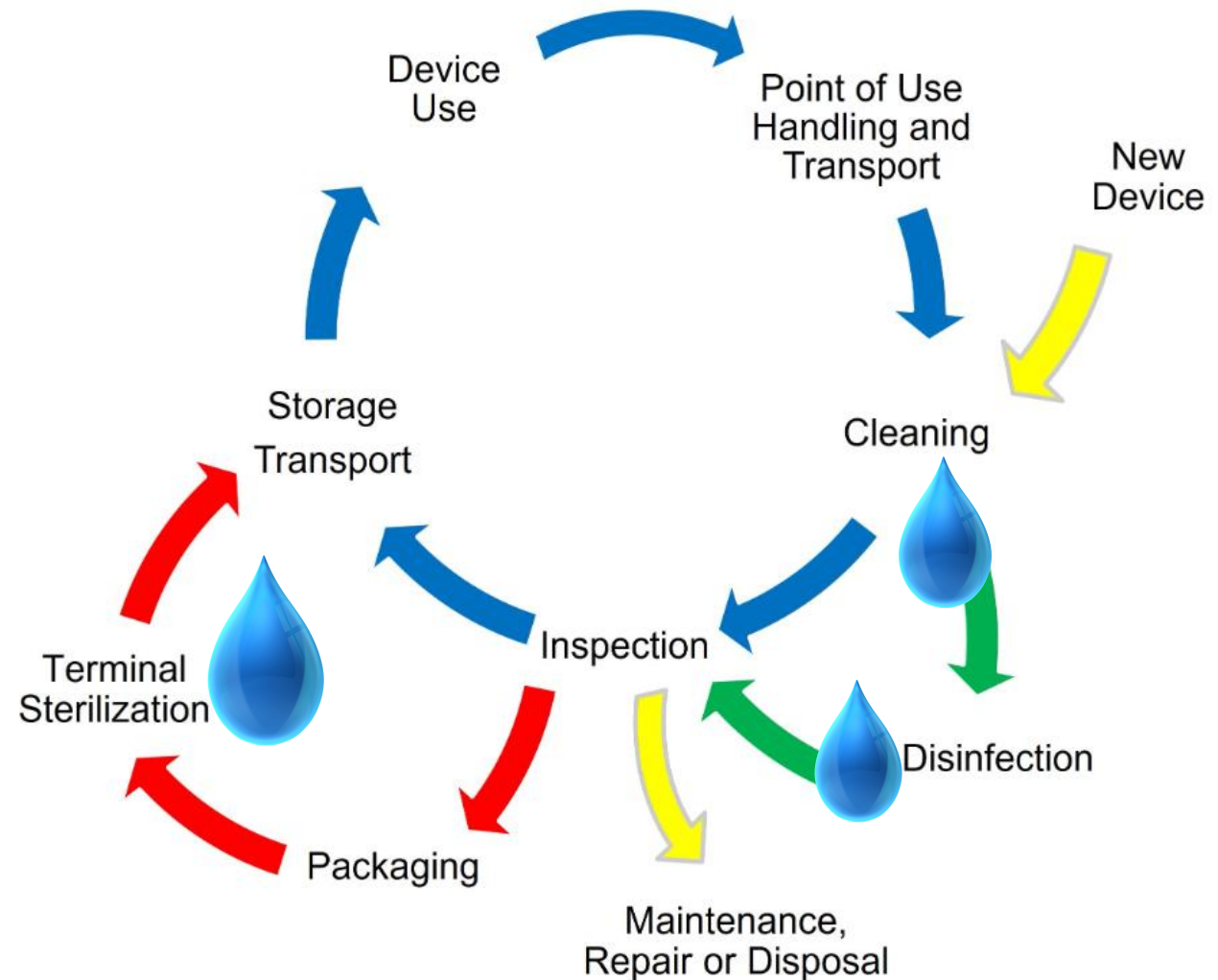
01

Water quality as a critical-to-quality factor in cleaning, rinsing, disinfection, and sterilization of reusable medical devices.



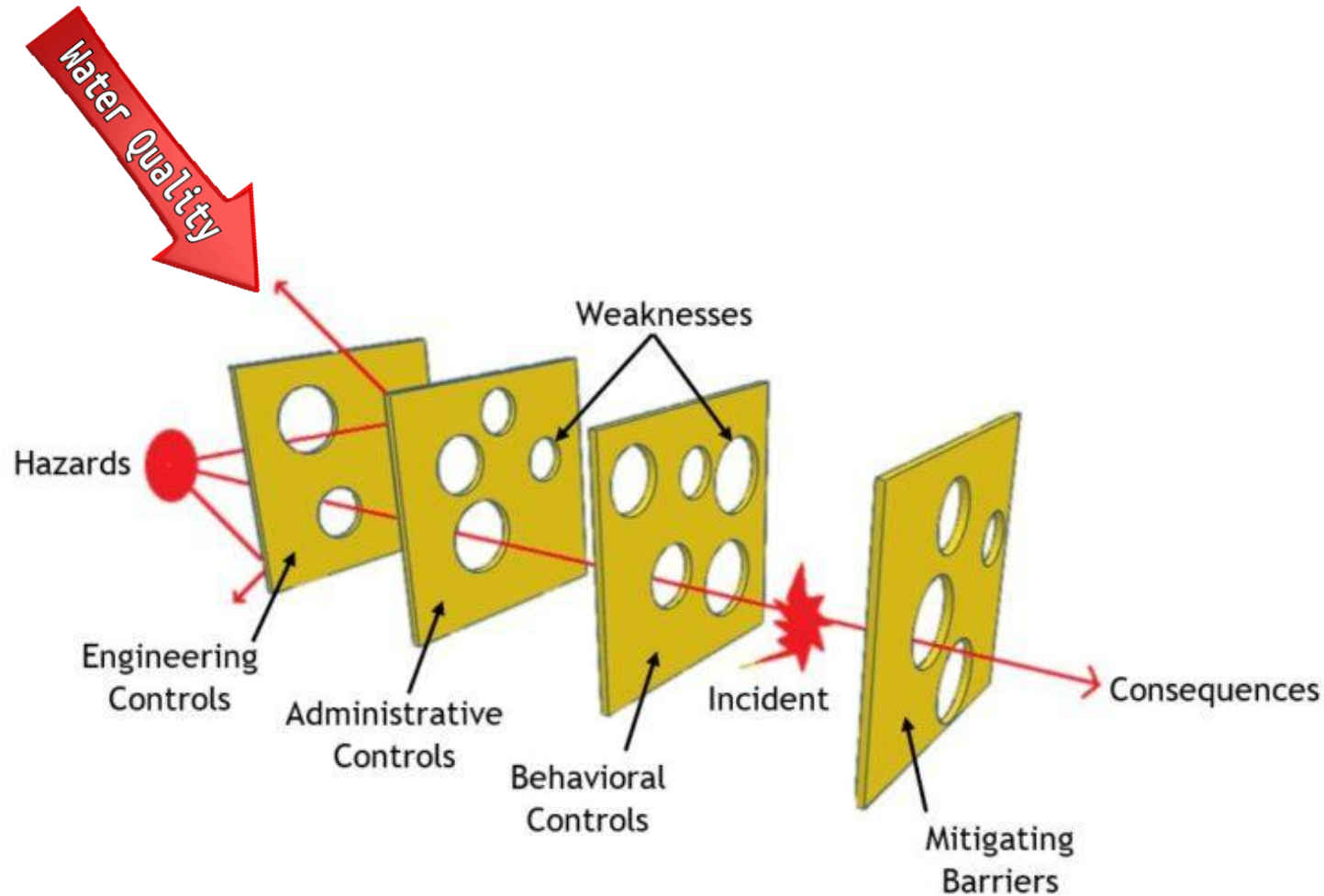
Water for Device Processing

- Required for device processing
- Water quality can impact processing outcome
 - Cleaning agent performance
 - Detergent residuals



Swiss Cheese Model – The RISK

No single barrier catches everything — water quality is one of the layers.



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Understanding the “Swiss Cheese Model” and Its Application to Patient Safety

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The Theory of Active and Latent Failures was proposed by James Reason in his book, *Human Error*. [1] According to Reason, accidents within most complex systems, such as healthcare, are caused by a breakdown or absence of safety barriers across four levels within a sociotechnical system. These levels can best be described as Unsafe Acts, Preconditions for Unsafe Acts, Supervisory Factors, and Organizational Influences. [2] Reason used the term “active failures” to describe factors at the Unsafe Acts level, whereas the term “latent failures” was used to describe unsafe conditions located higher up in the system. [1]

Today, most people refer to Reason’s theory as the “Swiss Cheese Model” because of the way it is typically depicted (See Figure 1). For example, each level within the model is often shown as an individual layer or slice of cheese. [3] Absent or failed barriers at each level are represented as holes in the cheese (hence the cheese is “Swiss”). When holes across each level of the system line up, they provide a window of opportunity for an accident or patient harm event to occur.

The Swiss Cheese Model is commonly used to guide root cause analyses (RCAs) and safety efforts across a variety of industries, including healthcare. [4–12] Various safety and RCA frameworks that define the holes in the cheese and their relationships have also been developed, such as the Human Factors Analysis and Classification System (HFACS; see Table 1). [2, 4–8] The Swiss Cheese Model and its associated tools are intended to help safety professionals identify holes in each layer of cheese, or level of the system, that could (or did) lead to an adverse event, so they can be addressed and mitigated before causing harm in the future. [2]

Wiegmann DA, Wood LJ, Cohen TN, Shappell SA.
Understanding the “Swiss Cheese Model” and Its Application to Patient Safety. J Patient Saf. 2022 Mar 1;18(2):119–123. Doi: 10.1097/PTS.0000000000000810. PMID: 33852542; PMCID: PMC8514562.

Consequences of Poor Water Quality

- **INEFFECTIVE** cleaning / disinfection because of chemical integration with water contaminants
- Steam **PURITY** with water contaminants
- Device **MALFUNCTION** during a patient procedure
- **TOXIC** effects and tissue irritation resulting from residuals
- **Patient INFECTION** resulting from the use of contaminated devices



Risk Management Lives Inside the Quality Management System (QMS)

ANSI/AAMI ST90:2024 — Quality management systems for processing in health care facilities

“Risk concepts shall be applied throughout the planning process.” Risk management is not a side activity — ST90 requires it to be established, documented and maintained within the facility's quality management system, reviewed at least annually and re-assessed whenever a significant change occurs.

1

Risk identification

Review processes, observe practice, use inspection findings, complaints, recalls and incident reports.

2

Root cause

Break each risk down to its causal event — focused on process and procedure, not human failure.

3

Assessment

Score probability × severity against predefined risk levels; plot on the risk matrix to judge acceptable vs. unacceptable.

4

Mitigation

Close the gap between root cause and risk; document controls and watch for new residual risks.

5

Monitoring

Scheduled review of risks and controls — the assessment controls risk, monitoring measures whether controls work.

What is a Critical to Quality Element?

A Critical to Quality (CTQ) element is any input or process step that, if not controlled, **directly changes whether the device is safe for the next patient.**

It is the point where quality is built in — not inspected in. In device processing, water is a CTQ element: it is the most-used “ingredient” in cleaning, rinsing, disinfection and steam sterilization.



Impacts the outcome

A change in this element changes cleaning efficacy, disinfection, sterilization or device integrity — and therefore patient risk.



Measurable and controlled

It has defined limits, a monitoring method and an action plan — chemical, microbial and physical water parameters per ANSI/AAMI ST108.

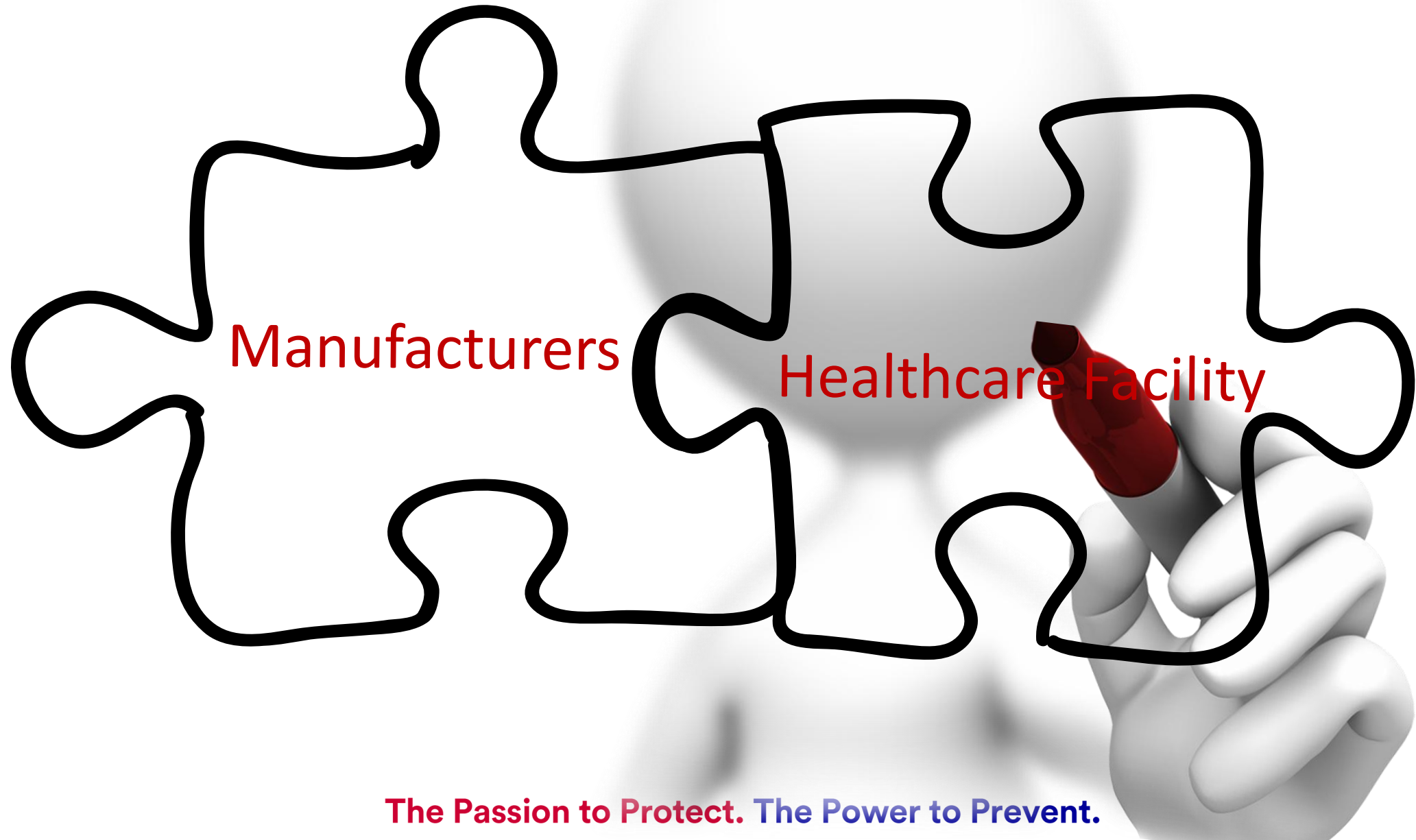


Built in, not tested in

Control is demonstrated across the process, not proven by a single end test — quality cannot be tested into the product.

If water quality fails, every downstream control — cleaning, disinfection, sterilization — is working against a compromised starting point.

Device Performance Responsibility



Manufacturers

Healthcare Facility

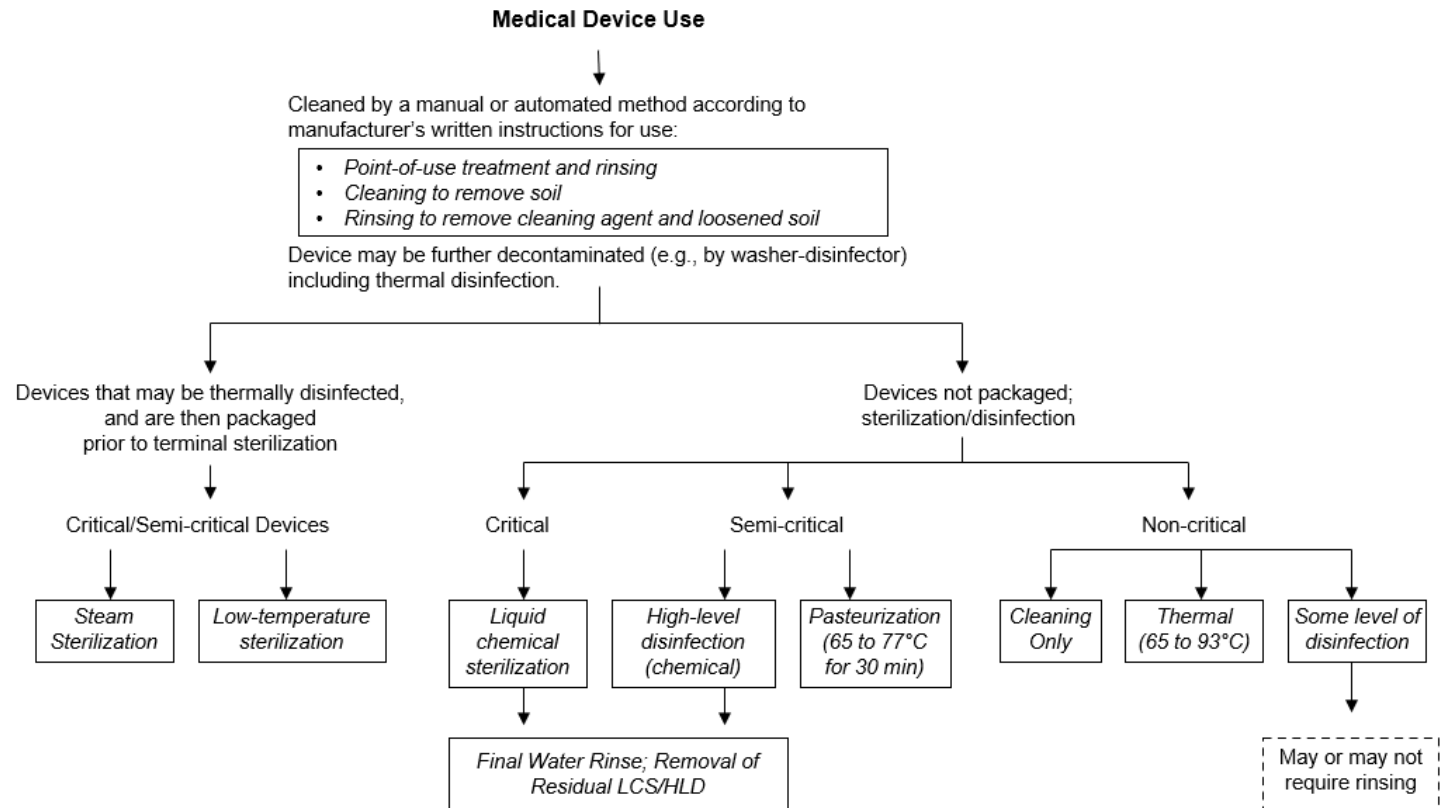
Water Quality Selection

Specify in Instruction for Use (IFU) Processing / Reprocessing Water Quality

- Utility Water
- Critical Water

Figure 1—Stages of medical device processing in which water quality is a consideration

Verify adequate water quality for each stage in the process indicated in boxed *italics*.



Is there a crack between the IFU and practice?



02

Risk-based
evaluation of water
control points across
the processing cycle:
Utility Water, Critical
Water, and steam.



Quality Risk Management



Microbiological Quality Level (MQL)

“A mechanism to measure the state of control of each independent step within a manufacturing process to determine the collective level of risk to the overall microbiological quality of the process and product.”

- Applies to the device processing cycle in a healthcare facility — point of use, cleaning, rinsing, disinfection, inspection, sterilization and storage
- Each step is an independent control point, with water quality as a shared input across them
- Device release based upon a demonstrated state of control and not end-of-process testing

The Four Principles of Microbiological Control Level (MQL)



Use Quality Risk Management (QRM) to minimize the probability of microbiological contamination

Ensure the product's Critical Quality Attributes (CQA) are achieved

Quantify the State of Control by measuring the microbiological risk associated with independent steps of the manufacturing process

Demonstrate reduced microbiological risk to the patient through process control

Slide courtesy of Stephen Langille, PhD
Senior Microbiology Consultant - ValSource

Water Quality – RISK ANALYSIS



ADVERSE EFFECT TO THE
MEDICAL DEVICE



ADVERSE EFFECTS TO
THE PROCESS



ADVERSE EFFECTS TO
THE PATIENT



ADVERSE EFFECT TO
PERSONNEL

Water Quality Risks – The CONTAMINANTS



Bacterial Endotoxin

Released from gram-negative cell walls and survives sterilization. Can cause fever, meningitis and a rapid drop in blood pressure if introduced to blood or sterile tissue.



Total Organic Carbon

Organic pollutants discolor devices, interfere with detergents, disinfectants and sterilants, and feed microbial growth and biofilm.



Hard Water / Salts

Calcium and magnesium deposit on instruments, reduce detergent effectiveness and degrade washer-disinfector performance.



Ionic Molecules

Chlorides, iron and copper pit, tarnish and corrode stainless steel, and discolor devices when exposed to heat.



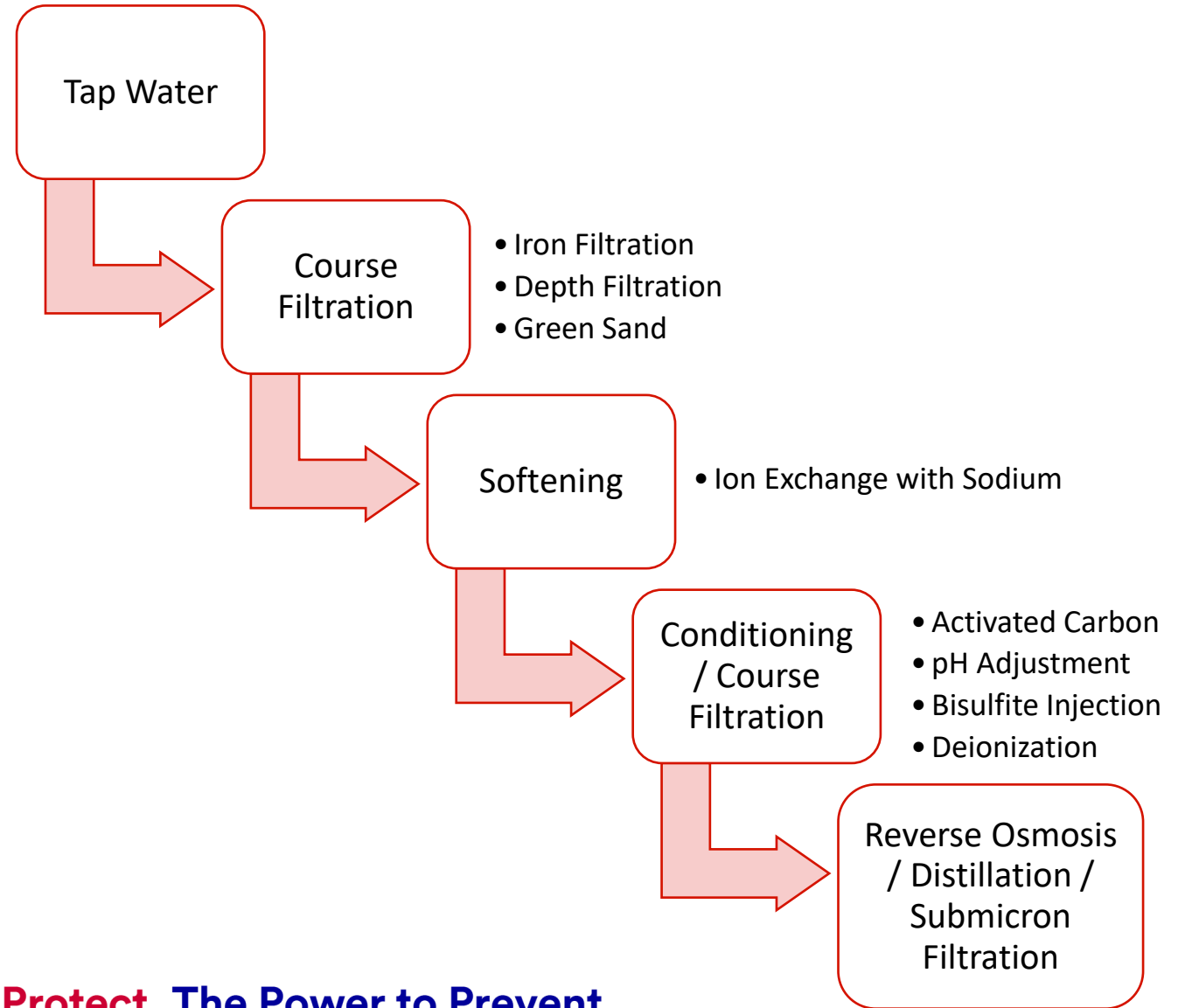
pH & Biofilm

Extreme pH impairs detergent action and causes pitting or corrosion; biofilm in distribution loops makes microbial load variable at the point of use.

Risk is contaminant- and step-specific: utility water carries hardness and organics into cleaning; critical water and steam drive ionic, endotoxin and residual risk at final rinse and sterilization. ST108 Annex B risk analysis is how you decide which water quality each step needs.

Water Quality– ENGINEERING CONTROLS

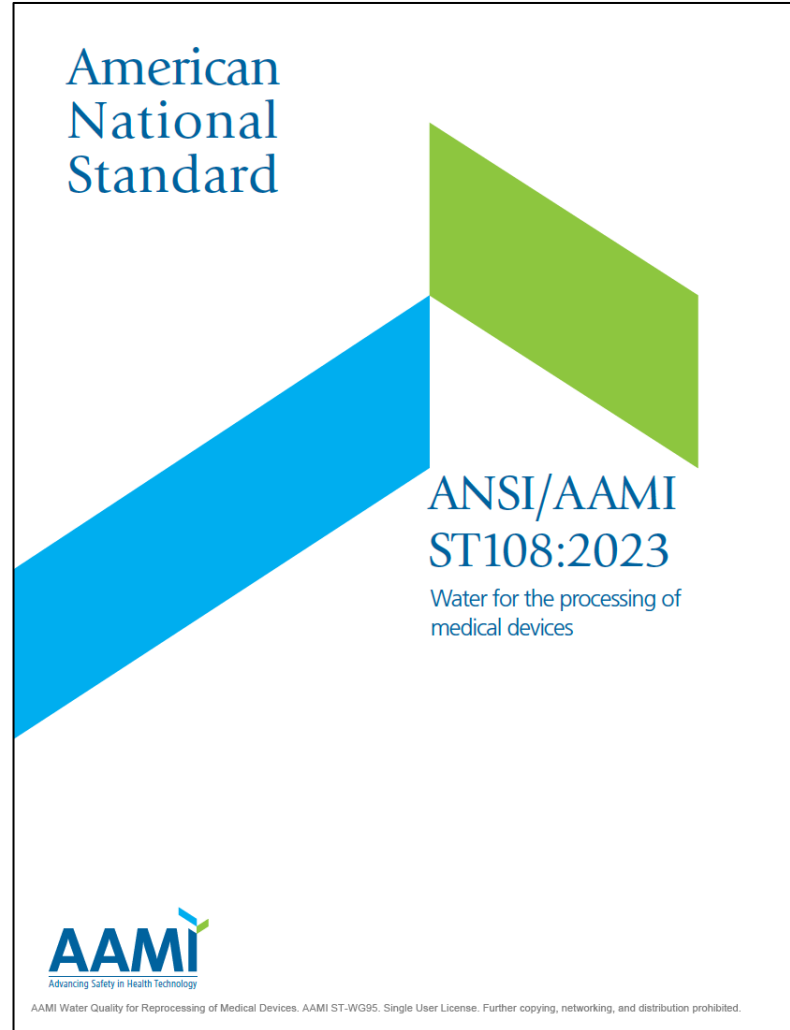
Processing Steps Are Water
Quality Dependent



ANSI/AAMI ST108: 2023

Normative: The What

- Roles & Responsibilities
- **Risk Analysis**
- Categories of Water Quality
- Water Quality Requirements
- Water System Installation / Operational / Performance Qualification
- Routine Monitoring
- Continuous Improvement
- Water System Maintenance



Informative: The How

- Application of Normative Requirements
- **Risk Analysis**
- Automated Endoscope Reprocessor
- Water in Cleaning and Heat Processes
- Water Treatment Technologies
- Water Treatment System Design
- Routine Monitoring
- Typical Water Quality Issues

Water Quality– CONTROL MONITORING

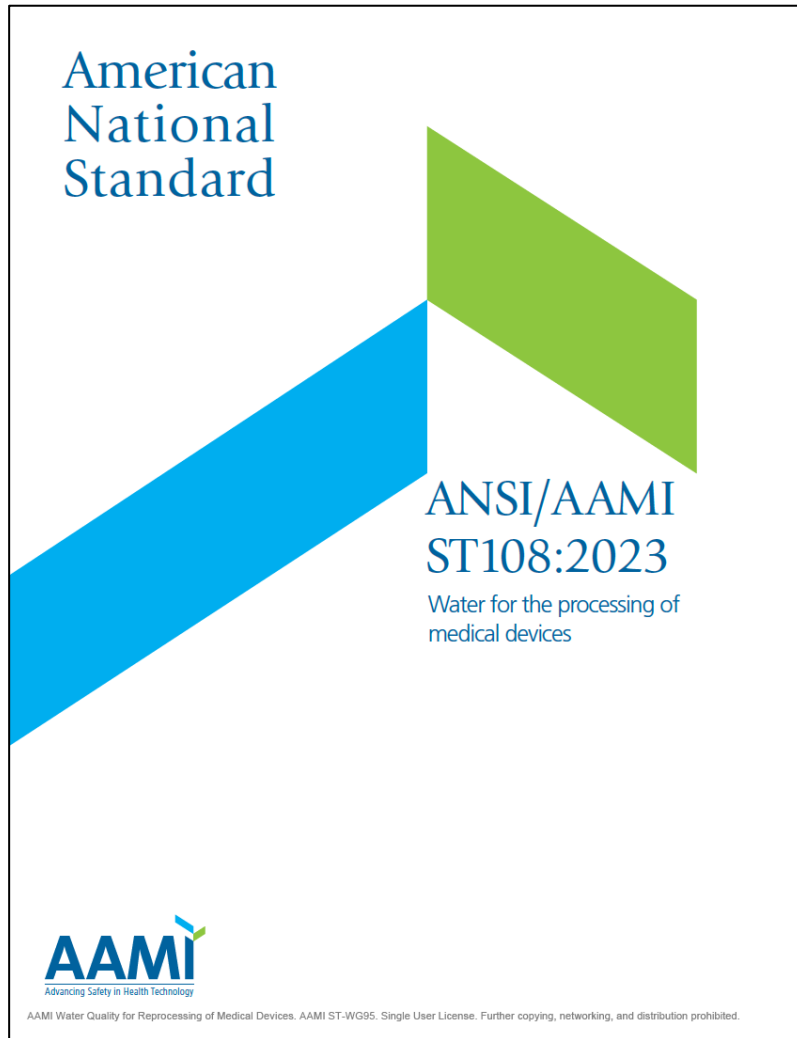


Table 2—Categories and performance qualification levels of water quality for medical device processing

Water Quality Measurement	Units	Utility Water	Critical Water	Steam*
pH @ 25 °C:	pH	6.5 – 9.5	5.0 – 7.5	5.0 – 9.2**
Total Alkalinity	mg CaCO ₃ /L	<400	<8	<8
Bacteria	CFU/mL	<500***	<10	N/A
Endotoxin	EU/mL	N/A***	<10	N/A
Total Organic Carbon (TOC)	mg/L (ppm)	N/A	<1.0	N/A
Color and Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment
Ionic Contaminants				
Aluminum	mg/L	<0.1	<0.1	<0.1
Chloride	mg/L	<250	<1	<1
Conductivity	µS/cm	<500	<10	<10
Copper	mg/L	<0.1	<0.1	<0.1
Iron	mg/L	<0.1	<0.1	<0.1
Manganese	mg/L	<0.1	<0.1	<0.1
Nitrate	mg/L	<10	<1	<1
Phosphate	mg/L	<5	<1	<1
Sulfate	mg/L	<150	<1	<1
Silicate	mg/L	<50	<1	<1
Total Hardness	mg CaCO ₃ /L	<150****	<1	<1
Zinc	mg/L	<0.1	<0.1	<0.1

Quality Risk Management



03

How chemical, microbial, and physical water parameters affect processing outcomes, equipment performance, and patient safety.



Tap Water Quality

DIFFERENT BASED ON GEOGRAPHICAL REGION



Common Tap Water Components:

Inorganic & Organic components

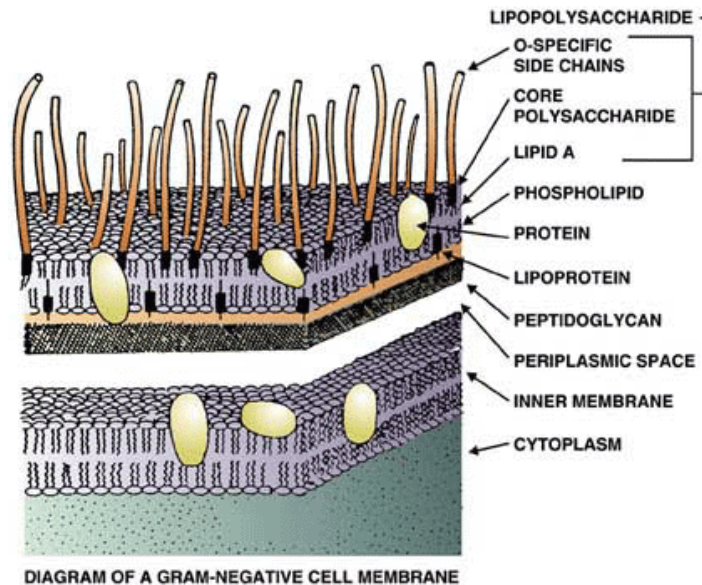
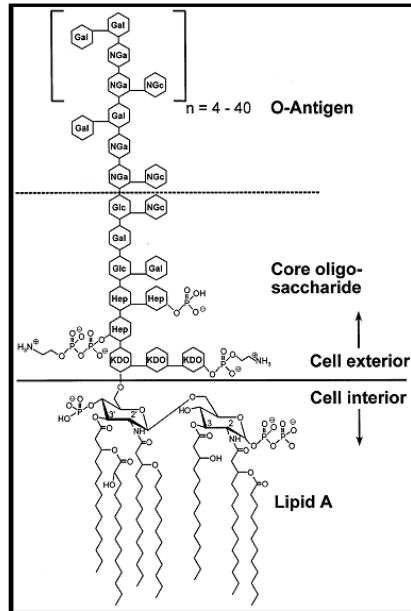
- Bacterial Endotoxins
- Organic Pollutants (e.g., microorganisms, plants, animals, pesticides)

Dissolved Salts (Hard Water)

Ionic Molecules (Chlorine, Iron, Copper, etc..) - Usually chlorinated to prevent microbial replication

What is Bacterial Endotoxin?

A high-molecular-weight complex that contains lipopolysaccharide (LPS), protein, and phospholipid originating from the outer membrane of Gram-negative bacteria.



Affinity and Inactivation of Bacterial Endotoxins for Medical Device Materials

Allan Kimble, James Hauschild, and Gerald McDonnell

Abstract

Endotoxins are high-molecular-weight complexes that contain lipopolysaccharide, protein, and phospholipid originating from the outer membrane of gram-negative bacteria. As gram-negative bacteria are naturally present in a variety of sources, endotoxins are commonly identified as contaminants in manufacturing environments. In industrial applications, endotoxin often is considered difficult to inactivate and to have a strong affinity with surfaces resulting from its hydrophobic chemical structure. This article describes the investigation of the true affinity of endotoxin, from various microbial sources in solution, for medical device material surfaces. In addition, endotoxin reduction was investigated with commonly used sterilization methods such as those based on ionizing radiation, dry and moist heat, and ethylene oxide sterilization. Endotoxin activity was found to be reduced following exposure to a range of sterilization modalities with the degree of activity reduction related to the source of endotoxin and the substrate material upon which it was present.

This research examined the affinity of bacterial endotoxins from various sources in water for the surfaces of representative medical device materials. The degree of affinity can be used to assess the risk of endotoxin remaining on a medical device after final cleaning and packaging. To further understand this risk, the effects of several common sterilization modalities were examined to determine the reduction in toxicity of bacterial endotoxin (if any) resulting from these processes.

Review of Literature

Bacterial endotoxins are the most prevalent microbial pyrogens.¹ Their source is from the gram-negative bacterial cell wall. When introduced directly into blood or tissue, endotoxin can cause fever,² meningitis, and decreased blood pressure at high doses

(estimated to be ≥ 350 endotoxin units [EU] in a typical human [at 70 kg or ~ 5 EU/kg], though lower levels often are conservatively defined for certain applications (e.g., intrathecal exposure).³ The immune reaction includes an initial alarm system for infection, recognition by toll-like receptors (e.g., TLR4) on innate immune cells,⁴ and cytokine secretion (e.g., interleukin [IL]-1 and IL-8) to stimulate the immune system, but it is self-regulated. Higher concentrations can lead to signs of fever and inflammation. Exposure to low concentrations is known to lead to immune tolerance within the host initial alarm response, mild inflammation reaction and resolution, and increased neutrophil activity (phagocytosis).⁵

Although traditionally considered to be the lipopolysaccharide (LPS) component of the outer membrane of the gram-negative bacteria cell wall, the structure of endotoxin actually is more complex and may be defined as a high-molecular-weight complex that contains LPS, protein, and phospholipid originating from the outer membrane of gram-negative bacteria.⁶ In addition, humans are naturally exposed to endotoxin from various sources, including direct surface and airborne contact, as well as through the gut microbiome.⁷

The purpose of this article is to consider bacterial endotoxins in more detail from a chemistry perspective. This allows for the examination of the composition and structure of the bacterial endotoxin molecule and its expected properties when in contact with medical device materials.

Bacterial endotoxin is associated with the outer cell wall of gram-negative bacteria, and a major component of endotoxin is the amphiphilic (or amphipathic) LPS molecule (Figure 1). The molecule consists of a hydrophobic lipid portion, as well as a hydrophilic polysaccharide chain and a hydrophilic O-antigenic oligosaccharide side chain. The molecular weight of LPS is in the

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Biomedical Instrumentation & Technology 2023

www.aami.org/bit 153

Kimble, Allan & Hauschild, James & McDonnell, Gerald. (2023). Affinity and Inactivation of Bacterial Endotoxins for Medical Device Materials. Biomedical Instrumentation & Technology. 57. 153-162. 10.2345/0899-8205-57.4.153.

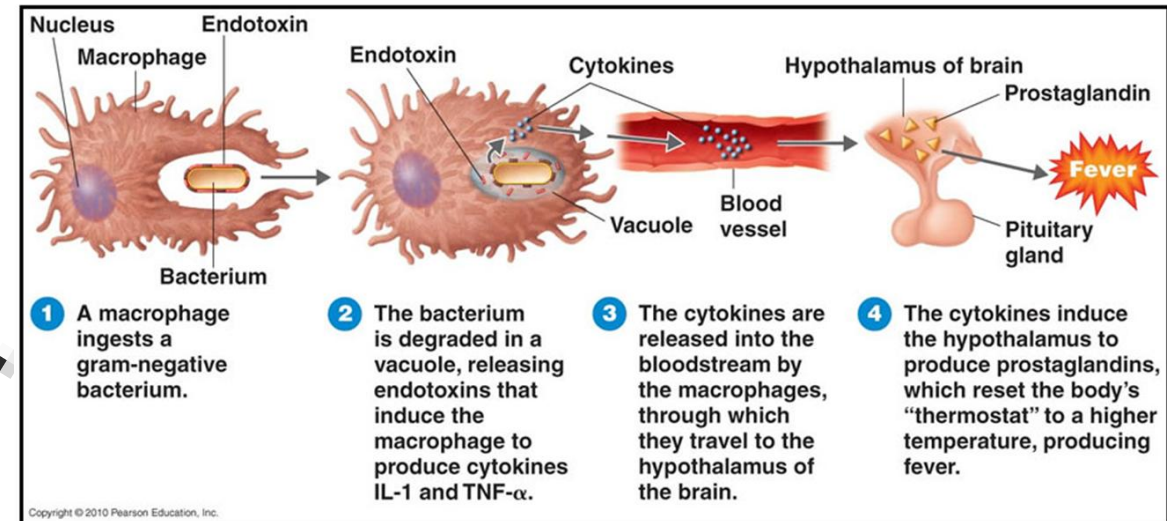
The Passion to Protect.
The Power to Prevent.

Why is Bacterial Endotoxin a Concern?

Endotoxin Risk

- The outer cell wall (LPS) is released into the environment when Gram-negative bacteria divide or lyse.
- Endotoxin can cause fever, meningitis, and a rapid fall in blood pressure if introduced into blood or tissues of the body
- Sterile Devices must have endotoxin levels within specified limits. - FDA Guidance 2016

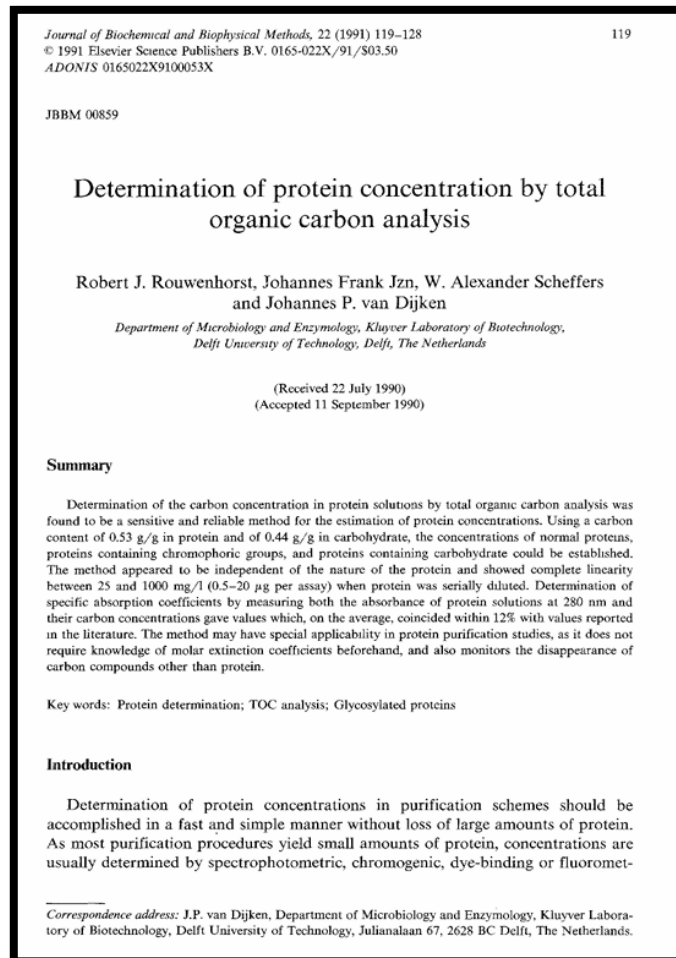
Endotoxins and the Pyrogenic Response



A detailed microscopic image showing a variety of aquatic organisms, including several large, colorful copepods (one with a prominent orange and purple body), numerous small, circular eggs or larvae, and various other smaller organisms. The background is filled with fine, wavy lines and small, dark, irregular particles, which are likely organic pollutants. The text "Organic Pollutants" is overlaid in red in the center of the image.

Organic Pollutants

Why is Total Organic Carbon (TOC) a Concern?



- A general indicator that the water is not in a state of control
- Signals that something is present in the water that can interfere with cleaning, disinfection or sterilization
- Residue left on devices after drying can provide nutrition for microorganisms and promote microbial growth

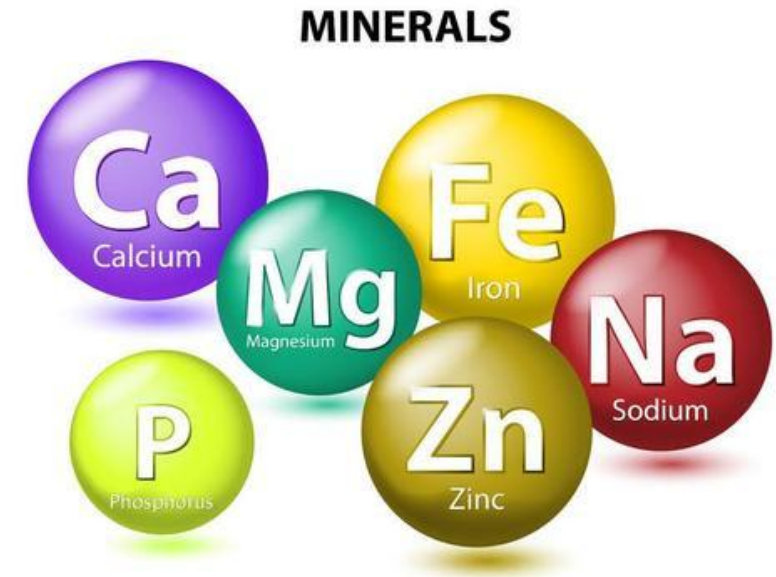
Robert J. Rouwenhorst, Johannes Frank Jzn, W. Alexander Scheffers, Johannes P. van Dijken, Determination of protein concentration by total organic carbon analysis, *Journal of Biochemical and Biophysical Methods*, Volume 22, Issue 2, 1991, Pages 119-128, ISSN 0165-022X, [https://doi.org/10.1016/0165-022X\(91\)90024-](https://doi.org/10.1016/0165-022X(91)90024-)

Why are Dissolved Salts a Concern?

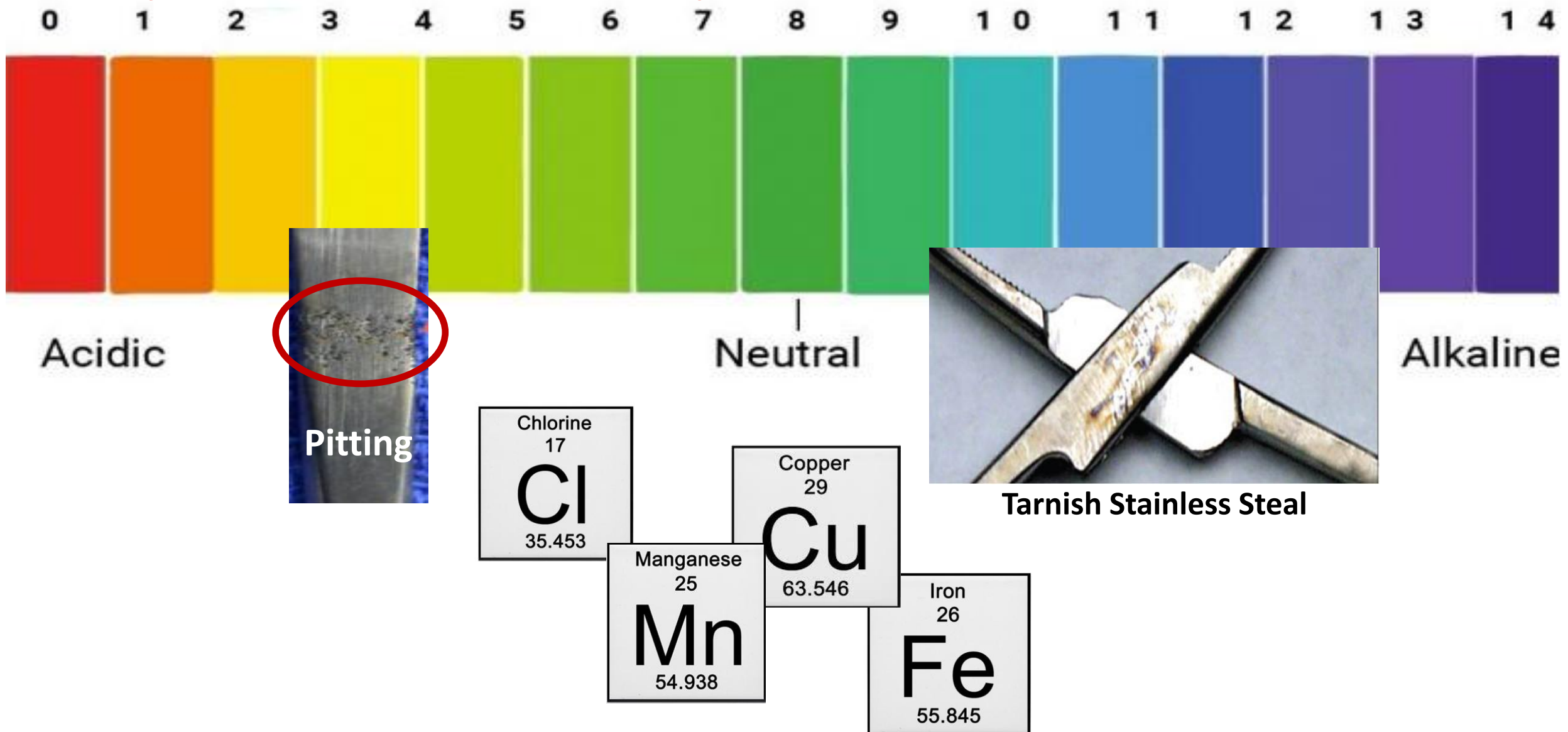
- Decreases the effectiveness of most detergents / disinfectants
- Decreases the performance of washer / disinfectors



Source: ANSI/AAMI ST108:2023



Why are Ionic Molecules / pH a Concern?



04

Key concepts of
ANSI/AAMI
ST108:2023 — water
categories,
monitoring
expectations, and
multidisciplinary
program
responsibilities.

American
National
Standard

ANSI/AAMI
ST108:2023

Water for the processing of
medical devices

Water Categories

Utility Water – cleaning
and rinsing

Critical Water – final steps
of processing

Steam - sterilization

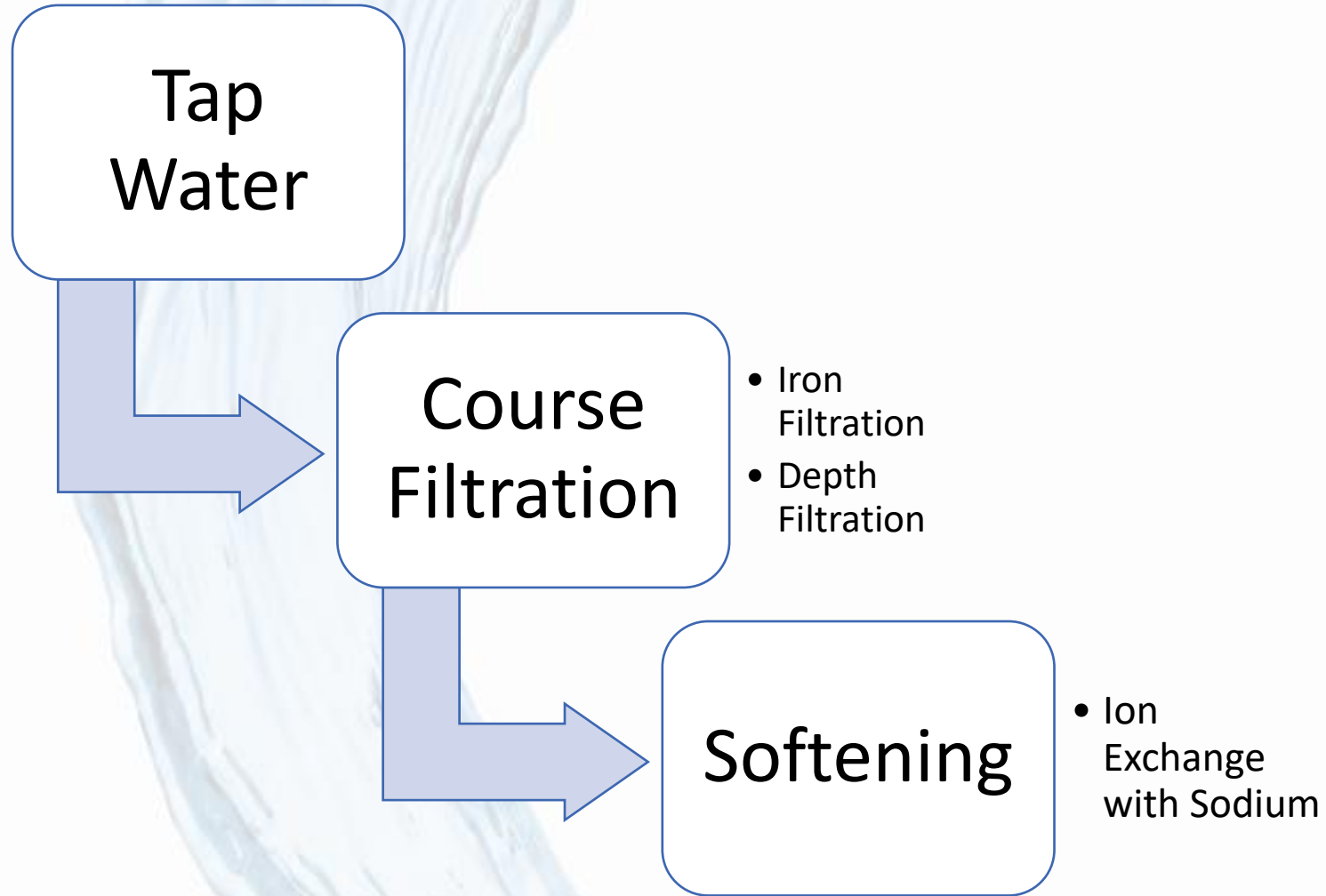
Water Quality Requirements

- Rationales for each value are included in section 6.3
- Updated quality requirements from TIR34
 - Alkalinity
 - TOC
 - Ionic Contaminates

Table 2—Categories and performance qualification levels of water quality for medical device processing

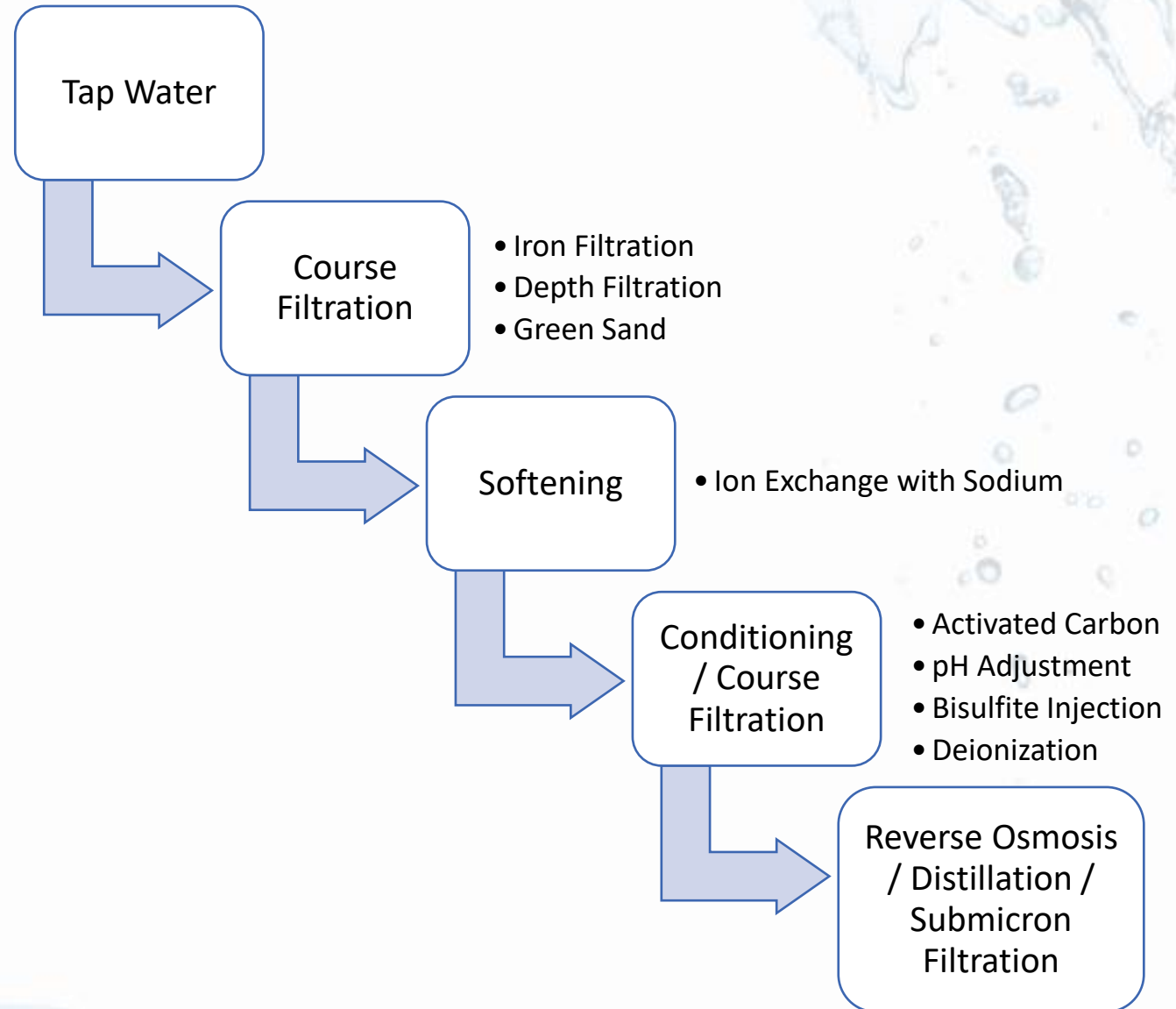
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Manganese	mg/L	<0.1	<0.1	<0.1
Nitrate	mg/L	<10	<1	<1
Phosphate	mg/L	<5	<1	<1
Sulfate	mg/L	<150	<1	<1
Silicate	mg/L	<50	<1	<1
Total Hardness	mg CaCO ₃ /L	<150****	<1	<1
Zinc	mg/L	<0.1	<0.1	<0.1

Utility Water- GENERATION



Critical Water- GENERATION

Processing Steps Are
Water Quality
Dependent



Routine Water Monitoring - REQUIREMENTS

Table 4—Water quality monitoring requirements

Water Quality Measurement	Units	Utility Water	Critical Water	Steam*
pH @ 25 °C:				
Conductivity				
Total Alkalinity				
Total Hardness				
Bacteria				
Endotoxin				
Color and Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment

pH – Measure of Hydrogen Ions

Ionic Compounds – Measured by Conductivity

Alkalinity – Dissolved Solids

Hard Water - Concentration of CaCO_3

Bacteria – Measured by a Bioburden Test

Bacterial Endotoxin – Measured by a BET Test

Monitoring - FREQUENCY

Table 5—Frequency for water quality monitoring at water generation system

Water quality measurement	Type of testing	Routine monitoring sampling site	Minimum frequency of testing*	
			Utility Water	Critical Water
pH	pH meter** or Colorimetric dipsticks (sample tested within 15 minutes)	After the last treatment step	Quarterly	Monthly
Conductivity	Conductivity meter (in line or by measurement of a collected sample)	After the last treatment step, Storage tanks (if used)	Quarterly	Daily
Total Alkalinity	Colorimetric dipsticks Alkalinity test kit**	After the last treatment step, storage tanks (if used)	Quarterly	Monthly
Total Hardness	Determination of ppm as CaCO ₃ by Colorimetric dipsticks, Titration kit**, or Handheld meter**	After the last treatment step	Quarterly	Monthly
Bacteria	Heterotrophic plate count (see Annex H)	Loop out and loop return points	N/A	Monthly
Endotoxin	LAL test (see Annex H)	Loop out and loop return points	N/A	Monthly

Table 6—Frequency for water quality monitoring at point-of-water-use

Water quality measurement	Type of testing	Routine monitoring sampling site	Minimum frequency of testing*		
			Utility Water	Critical Water	Steam
pH	pH meter** or Colorimetric dipsticks (sample tested within 15 minutes)	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Conductivity	Conductivity meter** or Colorimetric dipsticks	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Total Alkalinity	Colorimetric dipsticks or Alkalinity test kit**	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Total hardness	Determination of ppm as CaCO ₃ by Colorimetric dipsticks, Titration kit**, or Handheld meter**	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Bacteria	Heterotrophic plate count (see Annex H)	Each location of point-of-use in department	Quarterly	Monthly	N/A
Endotoxin	LAL test (see Annex H)	Each location of point-of-use in department	N/A	Monthly	N/A
Visual Inspection	Visual Inspection of inside of equipment - Look for residue, staining, scaling, and discoloration (Annex I)	Spray Arms/Inside Chamber Walls/Inside Interior of Machine	Daily	Daily	Daily

Water Management Program

ASHRAE 188:2018 –
Legionellosis: Risk Management
for Building Water Systems

Integrate water management
into existing programs

Multidisciplinary Team...the needed expertise

Local building code and infrastructure

Infection prevention principles

Operations unique to the facility, organization, health system

- Sterile processing functions and equipment
 - Decontamination
 - Sterilizers
- End-users of surgical instruments/medical devices
- Capital planning
- Risk management
- Quality

Water treatment

Executive authority

Multidisciplinary Team...WHO TO INCLUDE?

Senior organizational
leaders (Executive
sponsorship)

Facilities engineering

Infection preventionist

Sterile processing
technicians and
leaders

Clinical engineering

Perioperative team
members

Endoscopy team
members

Water treatment
specialist

Laboratory personnel

Risk managers

Quality improvement
specialists

Change management
specialists

Table 1—Multidisciplinary team responsibilities

Primary responsibility	Action
Facilities engineering personnel, multidisciplinary water management consultant or other external contracted personnel	General assessment of water quality. Per manufacturer guidelines routinely sample water and determine if values are within specified ranges per management plan
Facilities engineering personnel in conjunction with medical device processing personnel, multidisciplinary team, water management consultant or other external contracted personnel	Implementation of water treatment processes; determine appropriate method/equipment required for the facility's water supply
Medical device processing personnel in conjunction with clinical engineering personnel, external contracted personnel, or consultant	Assurance of proper water quality for the various stages in medical device processing using water quality monitoring
All members of the multidisciplinary team	Manages the water management program

Quality Risk Management



05

Practical tools and strategies to develop, assess, monitor, and continuously improve a water quality management program.



WATER - DECODED

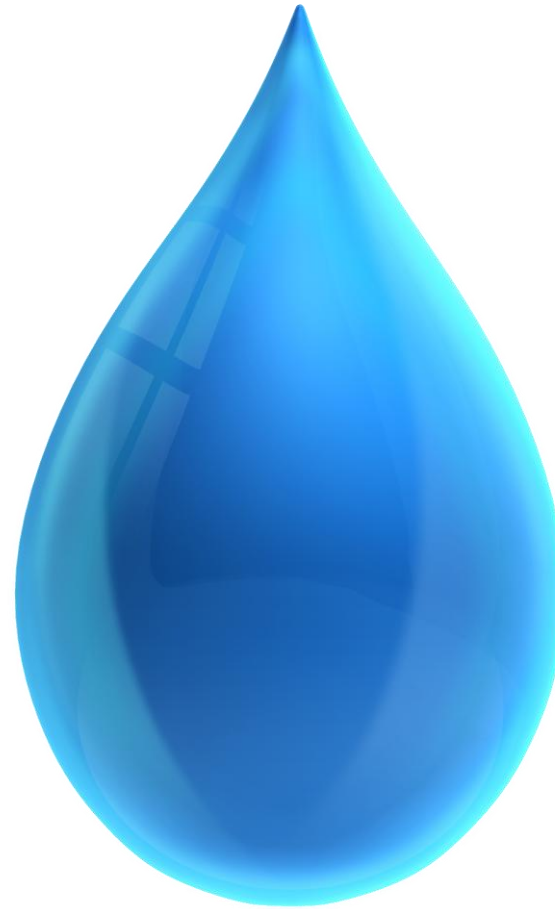
W is for Why

A is for Analysis

T is to Take Action

E is for Effects

R is Being Ready



If you see something...SAY SOMETHING!

Visual indicators are your early warning. Spotting, staining, corrosion, pitting and chalky deposits on devices, washers and sterilizers are documented signs of a water quality problem — the paper shows what to look for.

If it's in the water or steam, it ends up on the device. Visible damage can be remediated, but the underlying microscopic damage remains and can compromise cleaning, disinfection and patient safety.

You have the tools and the team. Simple routine tests (hardness, conductivity, pH, chlorides, TOC, bacteria, endotoxin) plus ST108's utility and critical water requirements give every member of the “village” a basis to raise a concern.

Kremer TA, McDonnell G. Sterilization Central: Water Quality in Medical Device Processing: The Power of Prevention. Biomed Instrum Technol. 2020 Jul 1;54(4):304-309. doi: 10.2345/0899-8205-54.4.304. PMID: 33171509..

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Water Quality in Medical Device Processing: The Power of Prevention

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Water plays an essential role in the processing of medical devices at healthcare facilities,¹ including use with critical, semicritical, and noncritical devices. Examples of water's role include:

- Point-of-use precleaning, where water often is used during or following use of the device to remove debris.
- Manual and/or automated cleaning, where water is utilized to dilute detergents, clean devices, and remove residual patient materials and detergents prior to further processing.
- Disinfection, both as the disinfectant itself (in thermal processes) and for the dilution of chemical disinfectants/sterilants and final rinsing to remove harmful residuals postdisinfection.
- Sterilization, where water (in the form of steam) is used directly as an antimicrobial or as a source of humidity during chemical sterilization (e.g., with ethylene oxide).

Despite its importance, the quality of the water used often is underestimated. Regardless of appearance, water can be a source of microorganisms and chemicals that can have a negative impact on device safety if used inappropriately during the processing cycle (Figure 1). This is well established in the peer-reviewed literature and highlighted in various processing standards and guidance documents,²⁻⁵ including particular emphasis in the AAMI technical information report (TIR) dedicated to water quality, AAMI TIR34:2014/(R)2017.¹

To further promote best practices, TIR34 is being revised to increase the level of importance for use and is intended to become an AAMI standard. This is further discussed in this article.

Water Quality: The Power to Prevent

Who is responsible for water quality within a healthcare facility? The adage, “it takes a village,” is an understatement when it comes to water quality in healthcare facilities. The combination of multiple individuals/departments, and their combined expertise,

can prevent a problem (seen or unseen) before it affects patient safety. It starts with an understanding of the water quality available from a public source, which varies over time. There are engineering considerations, maintenance requirements, infection prevention input, and manufacturers' specifications and instructions for use, as well as input from those managing or working within processing departments and those responsible for using the devices for their intended purpose. In fact, ensuring water quality requires a good understanding of the entire circle of processing, as an essential part of a quality management system.⁶

It is easy to take water quality for granted and to defer responsibility to others, but anyone in/or associated with that “village” can be a catalyst for best practices. They have the power to prevent adverse patient reactions and even protect the cost investment for medical devices and equipment at a facility. A useful mnemonic can be the subject itself, WATER, highlighting five important things

- to consider:
- **W: Why?** Be ready to understand and promote why water quality is important and how it can impact patient and device safety.
 - **A: Analysis.** Testing for water quality.
 - **T: Take action.** Take ownership in promoting and maintaining water quality requirements.



Figure 1. An example of a water sample, before and after heating/drying, showing chemical residuals



Situation 1: MANUAL PRE-CLEANING



- Utility Water – Hardness <150mg/L
- Salts in hard water may deposit on instruments
- Salts may impact detergent effectiveness

Situation 2: AUTOMATED CLEANING



- Critical Water (final rinse) – Conductivity < $10\mu\text{S}/\text{cm}$
- Excessive Ions can damage device surfaces
- Ions can discolor devices when exposed to heat

Situation 3: DEVICE INSPECTION



pH Residuals



High Chlorine



Hard Water



High Chlorine / Extreme
pH

Water Quality Concern

Questions?

