# WATER SAFETY & QUALITY DURING MEDICAL DEVICE REPROCESSING (MDR)

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# 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



Defensible documentation is essential and required

# INCORPORATING MEDICAL DEVICE REPROCESSING INTO A WMP















#### 1) Integrate MDR stakeholders into WMP Team

A. Collect water safety & quality guidance and requirements

Healthcare Water Management Teams should expand to include stakeholders responsible for MDR operations. The Team should have representation from the MDR equipment manufacturer, Infection Control, Biomed, Facility Management, MDR Chemistry provider and of course, the MDR staff. The collective efforts of this Team will drive safe and efficient operations.





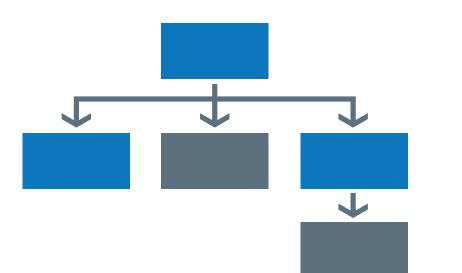




#### 2) Develop water safety & quality goals for MDR

A. Utility Water | B. Critical Water

Water source and water processing equipment design will dictate system capability. Equipment manufacturers and providers of MDR cleaning and sanitation chemistry will establish requirements for water quality. **AAMI TIR34** serves as a reference for water quality and safety for MDR operations.



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

A. Identify sources and processing steps

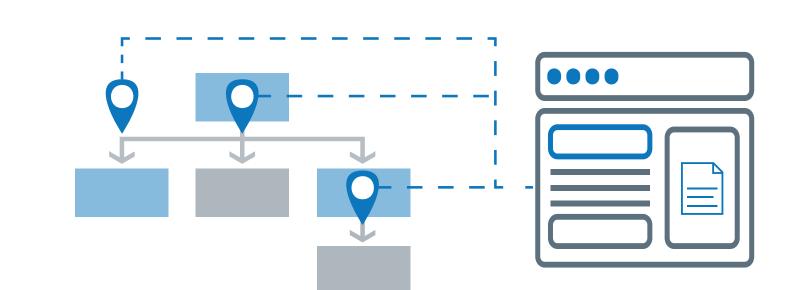
MDR water systems begin with unique water sources for supply, unique facility design for the distribution of water and finally, unique water processing systems within the MDR operation. This "uniqueness" must be understood by the Water Management Team (WMT) to effectively address the management of water to prevent safety issues and efficiency losses.



### 4) Analyze systems for safety, quality & efficiency

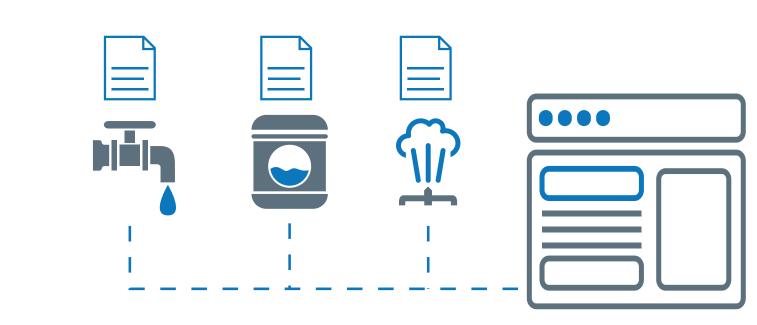
A. Evaluate water system design against water standards and design capacity

Each area of water processing within an MDR must be considered for its impact on safety and efficiency. The WMT must decide which water processing steps are significant contributors to safety and efficiency. The determination of "significant" requires that "controls" be established for the water processing step.



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

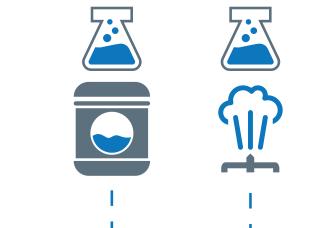
Control locations are points within the MDR water system defined by the WMT that could result in a significant change in water safety or efficiency. Appropriate measurements must be established with assigned control ranges or limits established. Most importantly, ownership and predetermined actions must be established if limits are being exceeded. Monitoring and corrective actions taken will be documented.



### 6) Develop Verification Strategy

The WMT will determine a schedule and frequency for reviewing that the Program Controls are being executed as planned. Documentation is reviewed to assure that corrective actions are being taken in alignment with Program documentation. Results of verification frequently offer improvements in Program controls. Often, verification is performed by an informed 3rd party to assure maximum defensibility of the Program.







## 7) Develop Validation Strategy

A. Monthly HPC | B. Quarterly AAMI Panel

The WMT will develop a measurement plan and frequency of assuring that Program safety and efficiency goals are being met. A validation response will be determined by the WMT and should be prioritized prior to testing. A failed validation test should always be first addressed by reviewing that Program controls have been implemented effectively. Persistent validation failure should result in changes to system design and/or Program controls.