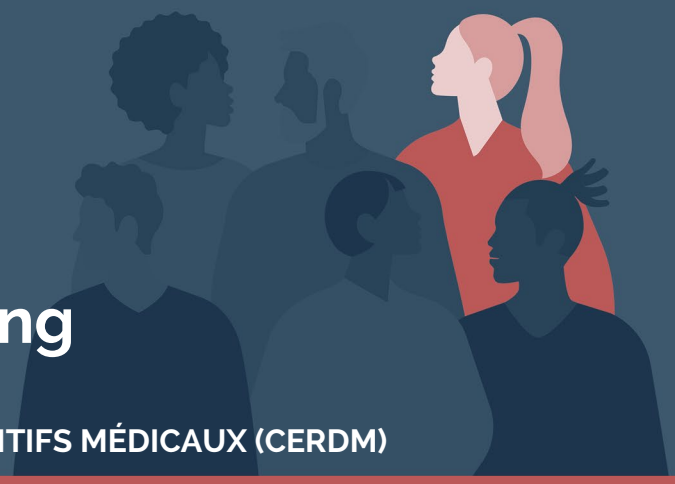
INSPQ INSTITUT NATIONAL DE SANTÉ PUBLIQUE DU QUÉBEC | 25 ANS



Quality of Water Used in Medical Device Reprocessing

CENTRE D'EXPERTISE EN RETRAITEMENT DES DISPOSITIFS MÉDICAUX (CERDM)

PROFESSIONAL PRACTICE GUIDE

MARCH 2019[1]

SUMMARY

This professional practice guide is a basic reference on the quality of water used for reusable medical devices reprocessing (MDR) and flexible endoscopic devices reprocessing (EDR). It aims to support activity management, to standardize practices and to improve the quality of MDR. It is intended for all persons working in health care institutions who are directly or indirectly responsible for quality assurance in MDR, including managers, MDR institution respondents, MDR staff, and persons responsible for the supply of drinking water and water treatment systems (Technical Services and Biomedical Engineering Department).

1 INTRODUCTION

This professional practice guide compiles normative, scientific and technical information on the quality of water used to reprocess reusable medical devices. It also discusses potential breakdowns (including issues related to water used in reprocessing: quality or interruption of service), quality assurance and the development of contingency plans. This document will help to harmonize and ensure the quality of MDR-related processes throughout Quebec's health care institutions. It supplements the information in practice guides previously published by the *Centre d'expertise en retraitement des dispositifs médicaux* (CERDM) of the *Institut national de santé publique du Québec* (INSPQ). CERDM publications are available at: https://www.inspq.qc.ca/cerdm.

[1] The current document is the 2023 English translation of the March 2019 French technical information sheet titled *Qualité de l'eau utilisée en retraitement des dispositifs médicaux*. The template was modified from the original document to reflect the new typology which includes the transfer of technical sheets into professional practice guides. In the event of any discrepancies, misstatement, omission or error appearing in the English translation, the original French version shall prevail.

Québec

To simplify the text, the term medical device (MD) will always refer to a reusable critical or semi-critical medical device. In addition, the term endoscopic device (ED) will always refer to a flexible endoscope for one of the following systems: digestive, gynecological, pulmonary, upper respiratory and urinary.

2 RESPONSABILITIES

Water quality is important at all stages of MDR. To ensure that it is adequate for reprocessing, there must be good collaboration between MDR staff and the managers of Technical Services or of the Biomedical Engineering Department.

2.1 MDRU manager

The medical device reprocessing unit (MDRU) manager is the most qualified person in a health care institution to monitor MDR quality.

As regards the recommended quality of water used in MDR, the MDRU manager must:

- ensure coordination with other services and authorities in the institution to foster better alignment of policies and procedures established locally and in connection with MDR;
- ensure that infection prevention and control (IPC) practices are followed within the MDRU;
- participate in the institution's quality assurance program (QAP) for water in order to define the appropriate quality for each stage in MDR;
- develop contingency plans to ensure continuity of services during maintenance or in the event of a breakdown of the water treatment system or problems with a building's drinking water supply;
- report any problems detected during MDR activities to the appropriate authorities at the health care institution, follow up on the problems and report any incidents or accidents related to MDR.

2.2 Technical Services manager and Biomedical Engineering Department manager

The managers of Technical Services and of the Biomedical Engineering Department are the people most qualified in a health care institution to oversee drinking water supplies and water treatment systems.

In partnership with the person responsible for the MDRU, those in charge of Technical Services and of the Biomedical Engineering Department must:

- ensure water quality control;
- ensure the availability and compliance of plumbing and water treatment systems, according to the water requirements of the MDRU;
- ensure the reception and commissioning as well as the preventive and corrective maintenance of the water treatment systems under their responsibility;
- keep inventory, maintenance records, warranty records and manufacturers' instructions for water treatment systems and reprocessing equipment that may be under their responsibility;
- implement a QAP to ensure a compliant water supply for MDR;
- collaborate on the development of contingency plans.

3 STANDARDS AND REFERENCE DOCUMENTS

Most sites of health care network institutions are supplied with drinking water from a municipal aqueduct. This means that MDRUs are usually supplied with water from that distribution system.

3.1 Drinking water

In Quebec, drinking water quality requirements are governed by the Regulation respecting the quality of drinking water (RQDW)[1]. Health Canada also issues drinking water guidelines through a federal-provincial-territorial committee[2].

3.2 Buildings

In regard to buildings, two chapters of the Québec Construction Code[3] deal specifically with plumbing installations: Chapter III, which covers plumbing, and Chapter I, buildings.

In addition to the Construction Code, the *Building Act*[4] provides for the adoption of a *Safety Code*[5]. The *Construction Code* is intended for designers and contractors, while the *Safety Code* is intended for owners.

Standard CSA Z317.1[6] concerns specifically plumbing installations in health care facilities. It supplements the codes in force.

Municipalities may also pass by-laws related to plumbing installations.

3.3 Reprocessing

CSA Standard Z314-18[7] addresses the entire reprocessing process, including the quality of water for cleaning, disinfection and sterilization. This standard, published in 2018, replaces several older standards, including CSA Z314.0[8] (general reprocessing requirements), CSA Z314.8[9] (decontamination of reusable MDs) and CSA Z314.3[10] (steam sterilization).

The CSA Group uses the TIR34 technical document published by the Association for the Advancement of Medical Instrumentation (AAMI) as the basis for developing criteria for reprocessing water. CSA Standard Z314-18 is based on the new version of the TIR34 technical document[11] published in 2014, while CSA Standard Z314.0, published in 2013, is based on an earlier version of TIR34[12]. The new version of the technical document contains important changes in the description of the types of water sought for reprocessing. The CERDM has used this latest version in this professional practice guide.

It should be noted that the practice guide on the reprocessing of critical MDs published by the INSPQ in 2014[13] was based on CSA Standard Z314.0 in order to describe the required water qualities. The present professional practice guide shall therefore be considered an update of the INSPQ's practice guide.

4 CHOICE OF WATER QUALITY

The quality of water used for MDR is very important. Inadequate water quality can lead to breakage of reprocessing equipment, have an impact on the effectiveness of detergents, lead to the buildup of deposits (stains) on MDs, damage their passive layer (e.g. corrosion pitting) and even promote microbial contamination of reprocessed MD[14]. Note that water quality higher than that required can also be detrimental to reprocessing equipment or to MDs that are not designed with materials compatible with high resistivity water.

4.1 Types of water sought according to medical device category and reprocessing step

The water used for reprocessing MDs must comply with the instructions of their manufacturers as well as with the reprocessing equipment and solutions used. The level of criticality of MDs, together with the reprocessing steps involved, have an impact on the quality of the water sought[13] [15] [16] [17].

Based on the most recent version of the AAMI TIR34 standard and CSA Standard Z314-18, the CERDM recommends that water used in MDR be divided into three categories: utility water, high quality utility water and critical water.

These three types of water (Table 1) are defined as follows:

- **utility water** is drinking water that may have undergone treatment in order to meet prescribed values;
- **high quality utility water** is utility water that may have undergone treatment in order to meet prescribed values for bacteria and endotoxin concentrations;
- **critical water** is usually obtained by using a water treatment system (e.g. a reverse osmosis system) to meet prescribed values.

Utility water may be used at any time for the cleaning and initial rinsing of MDs. However, for the final rinse, water quality must be consistent with the intended use of a MD.

Table 1 shows recommended water types according to the Spaulding Classification. This table is based on the AAMI TIR34 document and CSA Standard Z314-18. The characteristics presented are a basic reference for reprocessing. Water characteristics must also meet manufacturers' specifications for reprocessing equipment, MDs and the different solutions used (detergents and disinfectants).

Although a limit value for total organic carbon (TOC) is prescribed in the CSA standards and included in the INSPQ's guide on the reprocessing of critical MDs, some institutions seem to have difficulty complying with the limit value. The level of TOC found in drinking water can vary considerably from one municipality to another and according to the season. Aqueduct operators use this value simply as a guide. Therefore, the CERDM has decided not to include it in the desired characteristics for the different water types (Table 1). However, as far as possible and depending on available water treatment systems, institutions should attempt to achieve a maximum value of 1 mg/L for utility water and of 0.05 mg/L for critical water.

It is important to analyze the water used according to the parameters presented in Table 1. The water's characteristics will enable the MDRU and Biomedical Engineering or Technical Services staff, in consultation with manufacturers, to ensure that equipment and detergents are compatible with the available water. Adjustments may be required to optimize the performance of equipment and detergents.

Table 1. Types of water used in reprocessing

<table>
<tr><th colspan="3" rowspan="2">Spaulding Classification</th><th colspan="3">Types of water</th></tr>
<tr><th>Utility water (1)</th><th>High quality utility water (1)</th><th>Critical water (2)</th></tr>
<tr><td colspan="3">Critical</td><td>Pre-cleaning, cleaning and rinsing</td><td></td><td>Final rinsing</td></tr>
<tr><td rowspan="3">Semi-critical</td><td colspan="2">Flexible endoscopes, ultrasound probes</td><td>Pre-cleaning, cleaning and rinsing</td><td>Final rinsing</td><td></td></tr>
<tr><td rowspan="2">Respiratory and anaesthesia devices</td><td>Requiring pasteurization</td><td>Pre-cleaning, cleaning and final rinsing</td><td></td><td></td></tr>
<tr><td>Requiring thermal disinfection</td><td>Pre-cleaning, cleaning and rinsing</td><td></td><td>Final rinsing</td></tr>
<tr><td colspan="3">Non-critical</td><td>Pre-cleaning, cleaning and final rinsing</td><td></td><td></td></tr>
<tr><th colspan="3">Characteristics</th><th>Utility water (1)</th><th>High quality utility water (1)</th><th>Critical water (2)</th></tr>
<tr><td colspan="3">Hardness (CaCO3) (mg/L)</td><td colspan="2">< 150</td><td>< 1</td></tr>
<tr><td colspan="3">Resistivity (MΩ.cm)</td><td colspan="2">NA</td><td>> 0.1</td></tr>
<tr><td colspan="3">pH</td><td colspan="2">6-9</td><td>5-7</td></tr>
<tr><td colspan="3">Chlorides (mg/L)</td><td colspan="2">< 250</td><td>< 1</td></tr>
<tr><td colspan="3">Bacteria (CFU/ml)</td><td>NA</td><td>< 10</td><td>< 10</td></tr>
<tr><td colspan="3">Endotoxin (EU/ml)</td><td>NA</td><td>< 20</td><td>< 10</td></tr>
</table>

Table adapted from the AAMI TIR34 standard published in 2007 and 2014.

(1) Utility water is drinking water that may have undergone treatment in order to meet the values described in this table.

(2) Critical water is usually obtained by using a water treatment system (e.g. a reverse osmosis system). Such systems generally remove the majority of ionic contaminants and achieve values of < 0.2 mg/L for chlorides and iron and of < 0.1 mg/L for copper and manganese.

Water characteristics must meet the manufacturer's specifications.

5 WATER TREATMENT SYSTEMS THAT MAY BE USED IN MDR

Water treatment systems must be able to supply the various equipment with water of the desired quality: the quality must comply with the instructions of the manufacturers of the medical devices, reprocessing equipment and detergent solutions used. These systems should be used exclusively in MDR.

For reference, the AAMI TIR34 standard describes the various water treatment systems that may be required for MDR activities.

5.1 Why does water have to be treated?

Treated (or filtered) water may have to be used during reprocessing in order to reduce the water's organic and inorganic composition and/or its microbiological load.

Water treatment aimed at reducing the microbiological load is designed to:

- ensure that MDs do not acquire an excessive amount of microorganisms and endotoxins prior to being disinfected or sterilized, on account of the water used;
- ensure that MDs are not contaminated with viable microorganisms contained in the water when a final rinse is required following disinfection or sterilization.

In addition, water treatment systems reduce the content of organic molecules that can cause pyrogenic or other harmful immune reactions in the user.

Water treatment aimed at modifying the water's inorganic composition is designed to:

- prevent damage to MDs (e.g. deposits or corrosion);
- prevent inactivation of cleaning and disinfecting agents.

5.2 High quality utility water – filtration systems

Automated endoscope reprocessor (AERs) are usually equipped with filters. AER filters generally produce high quality utility water from utility water (Appendix 1).

Many institutions choose to install additional filters upstream from the equipment. These pre-filtration systems protect the AER filters and can thus reduce operating costs. However, it should be noted that the filter replacement frequency prescribed by an AER's manufacturer must always be complied with.

5.3 Critical water – Water treatment systems and their components

The design of a water treatment system must take into account the quality of the water that is to be produced, the quality of the feed water, the volume of water required, and the frequency of use. The treatment techniques used for a system's feed water (e.g. use of chlorine or chloramines in the distributed water) have an impact on water quality. Note that the future development of the MDRU's activities must be considered when planning the system.

Proper maintenance of a water treatment system and monitoring of water quality are essential to ensure that the reprocessing equipment receives water of the desired quality.

A water treatment system usually consists of three parts: a pre-treatment system, a principal system and a distribution system (Appendix 2).

5.3.1 Pre-treatment system

The configuration of a pre-treatment system depends mainly on the quality of the water supplied to it. Note that the system is usually supplied from the aqueduct. It may consist of several components, including softeners, activated carbon filters and pre-filters.

5.3.2 Principal system

The principal system usually consists of a reverse osmosis system and/or deionizing resins.

It should be noted that deionizing resins do not reduce bacterial load. On the contrary, they foster the proliferation of bacteria. Therefore, these resins must be used in combination with filters. This combination of resins and filters usually constitutes a back-up system used during maintenance or when the osmosis system breaks down.

5.3.3 Distribution system

The distribution system supplies various equipment or water points in the MDRU. This system must be designed to avoid bacterial proliferation. It can be looped to prevent water from stagnating in the piping. In addition, continuous water circulation at a speed of at least 1 m/s will minimize the formation of biofilm inside the pipes. Decontamination of the osmosis membranes and the distribution system is required to maintain the desired water quality. Two methods of decontamination are generally used: thermal and chemical. The network must be made of materials compatible with the desired water quality and the chosen decontamination method.

Sometimes the distribution system includes a tank for storing the water produced by the principal water treatment system. In that case, the tank must be designed to prevent bacterial growth. Deionizing resins may also be required in addition to the principal reverse osmosis system, in order to maintain the desired resistivity at all times.

5.4 Maintenance

In order to maintain the desired water quality, rigorous maintenance of the various water treatment systems must be carried out in accordance with the manufacturers' instructions. A complete analysis of the water's characteristics must be done at least once a year, while the analysis of certain other parameters can be carried out more frequently[11]. If test results are not compliant, an in-depth study of the water treatment system must be undertaken to remedy the situation and testing frequency should be increased to monitor the return to prescribed values.

The premises and other technical facilities must be designed so that they can be kept clean and all system components can be accessed safely and easily.

6 POTENTIAL BREAKAGES AND STEPS TO BE TAKEN

6.1 Aqueduct and plumbing systems in buildings

6.1.1 Potential breakages

The main breakages that can occur are as follows:

- significant drop in water pressure;
- interruption of the water supply;
- breakage of supply pipes;
- malfunctioning of the treatment plant (operator);
- spill (e.g. at a municipal water source);
- cross-connection (e.g. with a non-potable water pipe);
- intrusion (e.g. introduction of contaminants inside the pipes);
- maintenance work;
- construction work in a building.

6.1.2 Detection of a breakage

Institutions may learn of a breakage through a notice from the municipality (or the operator), a change in the water's appearance or odor, a drop in pressure or a non-compliant water test (performed by the institution).

6.1.3 Characteristics of water that do not meet the prescribed values for drinking water

Under certain circumstances, water may not be considered potable when chemical contaminants (e.g. hydrocarbons), high turbidity or biological contaminants (e.g. bacteria) are present.

Operators of aqueducts subjected to the *Regulation respecting the quality of drinking water* (RQDW) must regularly verify the quality of the drinking water they distribute in order to ensure that it meets the prescribed values. However, it is only when the fecal contamination indicator *Escherichia coli* is present in distributed water that a boil water advisory must be automatically issued to users. In other circumstances where prescribed values are exceeded, situations are evaluated on a case-by-case basis by the operator and the public health department of the region concerned. A notice of restriction of use is required only in the event of a threat to public health.

It should be noted that the RQDW does not set a maximum value for chlorine in the aqueduct network and that municipalities do not necessarily consider high chlorine levels (super-chlorination) to be abnormal. Therefore, institutions must be vigilant, especially when work is being done on the aqueduct

or when drinking water avoidance or boil water advisories have been issued. During such periods, water is often super-chlorinated to prevent bacterial contamination.

6.1.4 Steps to be taken

Institutions should take a number of steps to address and prevent breakdowns.

They should have a written contingency plan for situations where the supply of drinking water is interrupted. This plan should include a section that deals specifically with the capacity of the MDRU's water treatment system to be supplied with water that does not have all of the desired characteristics (non-potable water), or that identifies the steps that should be taken in the event of insufficient pressure or a complete shutdown of the water supply (see In-house contingency plan, including the return to normal, page 10).

This plan shall identify, by MD category, when reprocessing can be continued, what adjustments, if any, need to be made to the procedure, and when it shall be stopped. This plan shall also provide for the possibility of transferring reprocessing activities elsewhere, and for measures that shall be taken when the situation returns to normal (e.g. replacement of certain filters).

To prevent interruptions to the water supply, the institution may provide buildings with two separate water inlets, duplicate water inlet components (e.g. backflow preventers and booster pumps) and build water reserves.

6.2 Water treatment systems that may be used in MDRU

6.2.1 Potential breakages

Breakages in the operation of water treatment systems are related mainly to the following situations:

- breakage in the aqueduct or plumbing systems of buildings;
- clogged osmosis membranes;
- saturated or clogged filters;
- punctured osmosis membranes or filters;
- water that does not have the desired characteristics;
- component failure (e.g. pump breakdown);
- maintenance work.

6.2.2 Detection of a breakage

Breakages in water treatment systems can be detected by alarms built into the systems or by testing for non-compliant water. Low resistivity or a drop in pressure can also be indicators of a breakage.

6.2.3 Steps to be taken

Institutions should have a written contingency plan for dealing with potential breakdowns. This plan shall specify the extent to which each washer can be supplied with untreated (but potable) water and if manual reprocessing activities can be performed with untreated (but potable) water. The plan shall also identify when reprocessing can be continued and when it shall be stopped, whether reprocessing activities can be transferred, and what steps shall be taken when the situation returns to normal.

Making use of a water reserve could be seen as a means to prevent interruptions in the water supply. Such reserves would consist of, for example, systems with tanks and bottles of water whose characteristics correspond to those desired (Table 1). An emergency water treatment system could also be provided (e.g. by using deionizing resins). Duplication of certain components: e.g. double pump and double osmosis systems should be seen as a means to improve the safety of systems. A reserve of spare parts could also be set up.

6.3 Communications between the responsible authorities and the institution

Communication channels should be established between the institution, the aqueduct operator and responsible authorities at various levels of government.

When an aqueduct operator anticipates an interruption of service or a change in treatment technology, the operator should inform the institutions the aqueduct serves so that they can put an action plan in place.

Similarly, institutions should be informed of any unplanned service interruptions. Here is a list of some of the information that should be provided:

- start date;
- description of the problem and its impact on water quality;
- recommendations to protect users, if applicable;
- description of the actions taken with regard to the water by the operator (e.g. super-chlorination);
- measures planned to remedy the situation;
- anticipated end date (in some cases).

7 QUALITY ASSURANCE PROGRAM

The institution must implement a quality assurance program (QAP) approved by the authorities concerned in order to ensure a reliable supply of water to MDRUs and to limit the impact of potential breakages.

As regards water treatment systems and the water used in MDR, the institution must:

- use high quality components that meet manufacturers' specifications;
- use a qualified and trained workforce for preventive and corrective maintenance;
- implement a regular water quality monitoring program (aqueduct, utility water, high quality utility water, critical water);
- set up a register of test results;
- implement a preventive and corrective maintenance program for water treatment systems.

The quality of the water from an aqueduct may vary from one season to the next, depending on the water's source and treatment. The institution should be aware of the microbiological and chemical quality of the water supply and the water produced by water treatment systems.

To that end, it is possible to contact the municipality concerned in order to obtain its annual report on the monitoring of drinking water quality required by the RQDW. The institution must also ensure that this quality is maintained at all times within acceptable limits.

In general, different types of water (including water from the aqueduct) should be tested at least once a year to establish baseline data and comply with the anticipated water quality. For example, when an adverse event occurs, the institution must be able to compare the values obtained in connection to that event with baseline values. This allows for a more accurate assessment of the problem and the actions to be taken.

In the event of a breakage or non-compliant test results, managers of the affected units as well as IPC and risk management departments should be notified.

In addition to actions that must be taken in order to maintain operations, stakeholders must consider the possibility that potentially contaminated water may have been used for reprocessing. The impact of using that water must be assessed:

- risk to patients potentially exposed to devices reprocessed with non-compliant water;
- impact on reprocessing equipment and water treatment systems.

In addition, when necessary, the institution must report events to the appropriate authorities. For example, aqueduct operators must be notified if the water supply is non-compliant. The institution may call upon the expertise of the public health department in the region concerned and/or the CERDM if several users have been treated with improperly reprocessed MDs and in order to obtain support in analyzing and resolving the problem. Finally, it should be noted that other actors, such as civil protection authorities, can also support the institution regarding the actions to be taken.

8 IN-HOUSE CONTINGENCY PLAN, INCLUDING A RETURN TO NORMAL

8.1 Maintenance of reprocessing activities

Several solutions can be considered depending on the type of breakage.

If the breakage affects a component of the institution's water treatment system and the system's components are duplicated, service interruptions can be avoided by simply bypassing the failed component (which has a functional duplicate).

If the breakage affects a component of the water treatment system and it is not possible to bypass the failed element, then a back-up system can be used. This system usually includes a pre-treatment system (softener, carbon, filter) and a principal treatment system. The type of principal treatment used in the back-up system may vary depending on needs. Typically, it involves deionizing resins followed by a submicron filter. This type of system can be installed on a mobile cart.

All steps in the shutdown and commissioning of a treatment system or one of its components must be documented and known to the various stakeholders (Technical Services, Biomedical Engineering Department, MDRU, etc.).

In the event of a need for commercial water, the institution must assess the volume of water required and identify the appropriate formats. An agreement with a supplier should be drawn up beforehand.

8.2 Interruption of reprocessing activities

If the MDRU is unable to continue its operations during a breakage, the MDs could be transported to another site (back-up site). In some cases, inter-institutions agreements may be advantageous. All aspects must be clearly documented and transportation of the MDs must respect the standards in effect[18].

Contingency plans must take into account the aqueduct supplying each site. For example, in the event of a water main break, the back-up site must be supplied by a different water source.

8.3 Mandatory or preventive boil water advisories

Boil water advisories may be issued by the aqueduct operator in the event that fecal contamination (*E. coli*) is present in the water supply (mandatory boil water advisories) or when undesirable events lead to a risk of water non-compliance (preventive boil water advisories); for example, during a substantial drop in pressure or work on the aqueduct.

8.3.1 Regulation respecting the quality of drinking water in Québec

- Aqueduct operators must conduct monthly microbiological analyses. They must also test periodically for certain inorganic and organic substances. The frequency and parameters to be tested depend on the size of the population served.
- The indicators used to verify the microbiological compliance of distributed water are *E. coli* and total coliform bacteria.
- The drinking water distributed must not contain any *E. coli* bacteria. If their presence is detected, operators must immediately issue an automatic boil water advisory.
- In the event of water non-compliance and as required by the RQDW, operators will automatically notify the public health department of the region concerned and must notify the health care institutions in its territory.
- Health care institutions can also obtain help from the various stakeholders in the regional public health department, particularly the environmental health team and sometimes the infectious diseases team.

8.3.2 Steps to be taken for critical and semi-critical MDR

This document proposes a model tree for making decisions on critical and semi-critical medical device reprocessing in the event of a boil water advisory or visibly soiled water (Appendix 3).

Boil water advisories must be issued by the aqueduct operator when fecal contamination (e.g. *E. coli* bacteria) is present in distributed water (mandatory boil water advisory). Boil water advisories may also be issued when events occur that could result in microbiological contamination of the water, such as a disinfection treatment failure, a drop in water pressure, or work on the aqueduct. Such advisories are often called preventive boil water advisories.

Boil water advisories (including preventive advisories)

- No special precautions have to be taken for mechanical and manual washing if the final rinse is done with critical water.
- No special precautions have to be taken for pasteurization. Note that the pasteurization process consists of immersing respiratory and anesthesia devices in hot water at a minimum temperature of 71°C for a minimum contact time of 30 minutes [7] [9] [13].
- No special precautions have to be taken for sterilization.
- Sterilization and disinfection will eliminate any viable microorganisms that may remain on MDs providing the latter have been cleaned. MDs that have not been cleaned cannot be adequately sterilized or disinfected.

Visibly soiled water (high turbidity)

- In the case of manual washing, an MDRU should perform a five-minute purge of the tap before using the water and ensure that the water has cleared before cleaning. This method should be repeated between periods when the system is not in use. Otherwise, bottled water should be used.
- Choosing to use commercially available water (bottled water) should depend on the reprocessing step to be performed and the category of MD to be reprocessed. For example, in the case of critical devices, bottled water used for pre-cleaning, cleaning and initial rinsing should be drinking water, whereas that used for final rinsing should be sterile water (water for injectable preparations, irrigation water).
- In the case of mechanical washing, no special precautions have to be taken if the final rinsing is performed with critical water and it is reasonable to expect that the contaminants will not significantly alter the effectiveness of the detergents or damage the washers. In extreme situations (e.g. presence of sand or mud), mechanical washing should be stopped and replaced by manual washing using bottled water.
- Washer-pasteurizers should not be used for pasteurization. Pasteurization must be replaced by a thermal disinfection cycle in a washer-disinfector or by high-level disinfection (HLD) in manual mode, or sterilization.
- In the case of steam from a thermal power plant, MDRU staff should ask Technical Services if there is likely to be an interruption in service due to a problem with the feed water.
- For steam from a steam generator (integrated or not with the sterilizer) that is operated with treated water, the institution must validate the effectiveness of the water treatment system for purifying the soiled water before continuing with steam generation and sterilization.
- For steam from a steam generator (integrated or not with the sterilizer) that is operated with untreated water, sterilization must be stopped.

Monitoring of equipment

- In the case of reprocessing equipment, the person in charge of an MDRU must ensure that the daily maintenance to be performed by reprocessing staff is strictly adhered to (e.g. cleaning the equipment filter, ensuring that nozzles are not clogged, checking the detergent delivery system).
- In the case of steam sterilizers, MDRU staff and users must pay special attention to sterile packaging (e.g. stains and presence of water) and check the condition of filters.
- In the case of water treatment systems, the person in charge must pay special attention to the system by, among other things, monitoring water quality (e.g. resistivity) and the condition of the filters.

Return to normal

- In the case of water treatment systems, the institution must replace pre-filters (e.g., cartridge filters located at the beginning of the system) to avoid saturation or bacterial growth. Depending on the configuration of the system and the type of contamination, other components may need to be replaced and/or water testing may be required.

- It should be noted that in order to lift a boil water advisory, an operator must take several samples to demonstrate compliance with microbiological quality standards, including the complete absence of total coliform bacteria.

8.3.3 Steps to be taken for EDR

This document proposes a model decision tree for making decisions on EDR in the event of boil water advisories or visibly soiled water (Appendix 4).

Boiled water advisories (including preventive advisories)

- The institution may continue to use EDs in accordance with recognized good practices.
- After the final rinsing, it is necessary to carry out manual or mechanical drying followed by an injection of 70 % isopropyl alcohol.
- When EDs exit the AER, the drying process must be completed with compressed air of appropriate quality [19].
- Using 70 % isopropyl alcohol and drying before storage will better prevent the growth of residual microorganisms due to moisture that may remain in the channels during storage.
- If the AER has a drying cycle in its software program, there is no need to inject alcohol before final storage.

Visibly soiled water (high turbidity)

- For manual washing of MDs, MDRUs should perform a five-minute purge of the tap before use; if the water becomes clear, it can be used for cleaning. This method should be repeated between periods when the system is not in use. Otherwise, bottled water should be used.
- Choosing to use commercially available water (bottled water) should depend on the EDR step to be performed. In the case of semi-critical devices, bottled water used for pre-cleaning, cleaning and initial rinsing should be drinking water, whereas that used for final rinsing should be sterile water (water for injectable preparations, irrigation water).
- For HLD (manual or automated), the institution shall continue its usual reprocessing practices including drying and alcohol injection (unless the AER possesses a drying cycle).

Monitoring of devices

- The institution must pay special attention to the condition of water treatment system filters and AER filters.

Return to normal

- The institution must replace the pre-filters of the water treatment system and the filters of the AER to avoid saturation or bacterial growth.

Water avoidance advisories

Aqueduct operators issue a water avoidance advisory when chemical hazards threaten the quality of drinking water. Water covered by an advisory is unfit for use in MDR and EDR, even if the devices have been disinfected or sterilized.

8.3.4 Steps to be taken for MDR and EDR

This document proposes a model decision tree for making decisions on MDR and EDR in the event of a water avoidance advisory (Appendix 5).

Contaminated water (e.g. by hydrocarbons)

- A complete shutdown of MDR activities requires that a service corridor be put in place.
- In planning the service corridor, the institution must ensure that both sites are not served by the same aqueduct.
- The institution must follow the required MDR steps from end of use to return to storage once the devices have been reprocessed.

Return to normal

- If contamination has occurred or is suspected, the institution should change the pre-filters and filters in their water treatment systems and AERs (including carbon filters and deionizing resins) to avoid saturation and the potential release of contaminants. In the case of possible contamination of water distribution systems, osmosis membranes or equipment, purging and/or decontamination may be required.

9 CONCLUSION

The quality of water required for MDR depends on the type of medical device and disinfection or sterilization process used. Care must be taken, as water quality above or below that required may be harmful to reprocessing equipment or to medical devices.

Institutions administrators are responsible for ensuring that standards applicable to the quality of water used in reprocessing are met. In order to meet the prescribed values, water treatment systems must be optimally configured and well maintained.

Administrators must also ensure that contingency plans are well defined and known to the actors required to manage and apply such measures in MDR. Development of these plans must take into account potential breakage as well as the regional realities of the different sites.

RÉFÉRENCES

1 Gouvernement du Québec. *Regulation respecting the quality of drinking water (Environment Quality Act).* Chapter Q-2, r. 40.

2. Health Canada. Guidelines for Canadian Drinking Water Quality. Summary Table. Federal-Provincial-Territorial Committee on Drinking Water of the Federal-Provincial-Territorial Committee on Health and the Environment. 2017.

3. Gouvernement du Québec, *Construction Code (Building Act)*. Chapter B-1.1, r. 2.

4. Gouvernement du Québec. *Building Act*. Chapter B-1.1.

5. Gouvernement du Québec. *Safety Code* (Building Act). Chapter B-1.1, r. 3.

6. CSA Group. Special requirements for plumbing installations in health care facilities. Z317.1-16. October 2016.

7. CSA Group. Canadian medical device reprocessing. Z314-18. February 2018.

8. CSA Group. Medical device reprocessing – General requirements. Z314.0-13. March 2013.

9. CSA Group. Decontamination of reusable medical devices. Z314.8-14. February 2014.

10. CSA Group. Effective sterilization in health care settings by the steam process. Z314.3-14. January 2015.

11. Association for the Advancement of Medical Instrumentation (AAMI). Water for the processing of medical devices. TIR34: 2014.

12. Association for the Advancement of Medical Instrumentation (AAMI). Water for the processing of medical devices. TIR34: 2007

13. Institut national de santé publique du Québec (INSPQ). Guide de pratique. Retraitement des dispositifs médicaux critiques. May 2014.

14. Instrument Reprocessing Working Group (AKI). Reprocessing of Instruments to Retain Value. 11th edition 2017. www.a-k-i.org

15. Institut national de santé publique du Québec (INSPQ). Guide de pratique. Retraitement des dispositifs endoscopiques flexibles. October 2014.

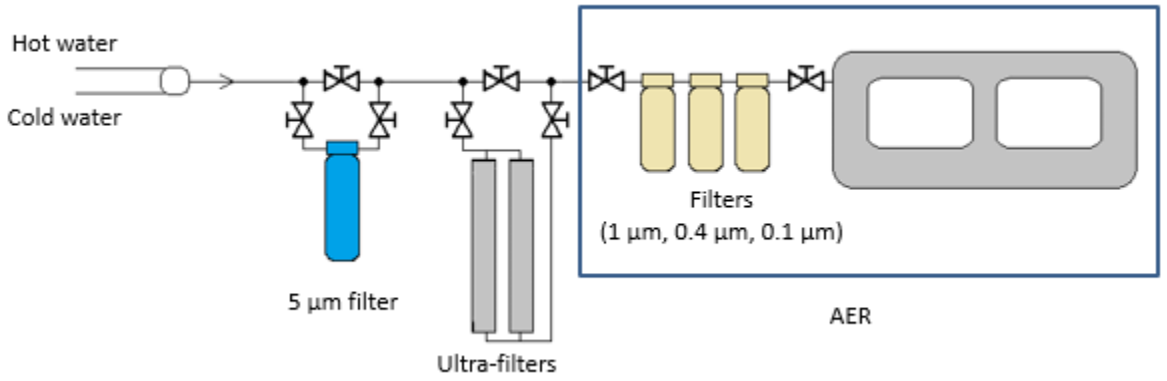
16. Institut national de santé publique du Québec (INSPQ). Fiche technique. Retraitement des sondes d'échographie et des sondes pour compteur gamma intraopératoire. July 2016.

17. Ministère de la Santé et des Services sociaux du Québec (MSSS). Unité de retraitement des dispositifs médicaux – Répertoire des guides de planification immobilière. 2011.

18. Institut national de santé publique du Québec (INSPQ). Guide de pratique. Transport des dispositifs médicaux en vue de leur retraitement par un organisme externe. May 2014.

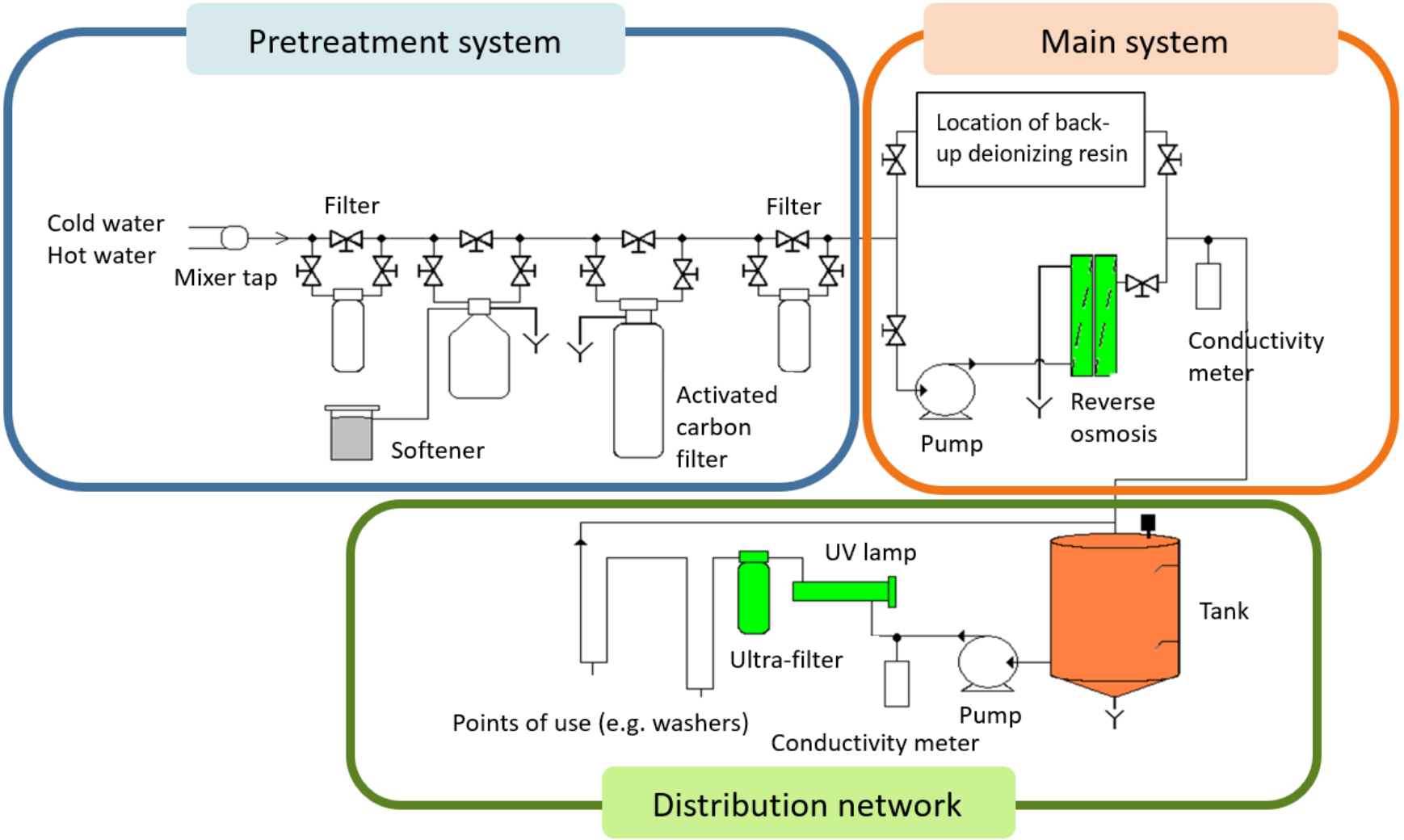
19. CSA Group. Medical gas pipeline systems — Part 1: Pipelines for medical gases, medical vacuum, medical support gases, and anaesthetic gas scavenging systems. Z7396.1-17. July 2017.

APPENDIX 1 UTILITY WATER – EXAMPLE OF A WATER TREATMENT SYSTEM FOR AN EDRU

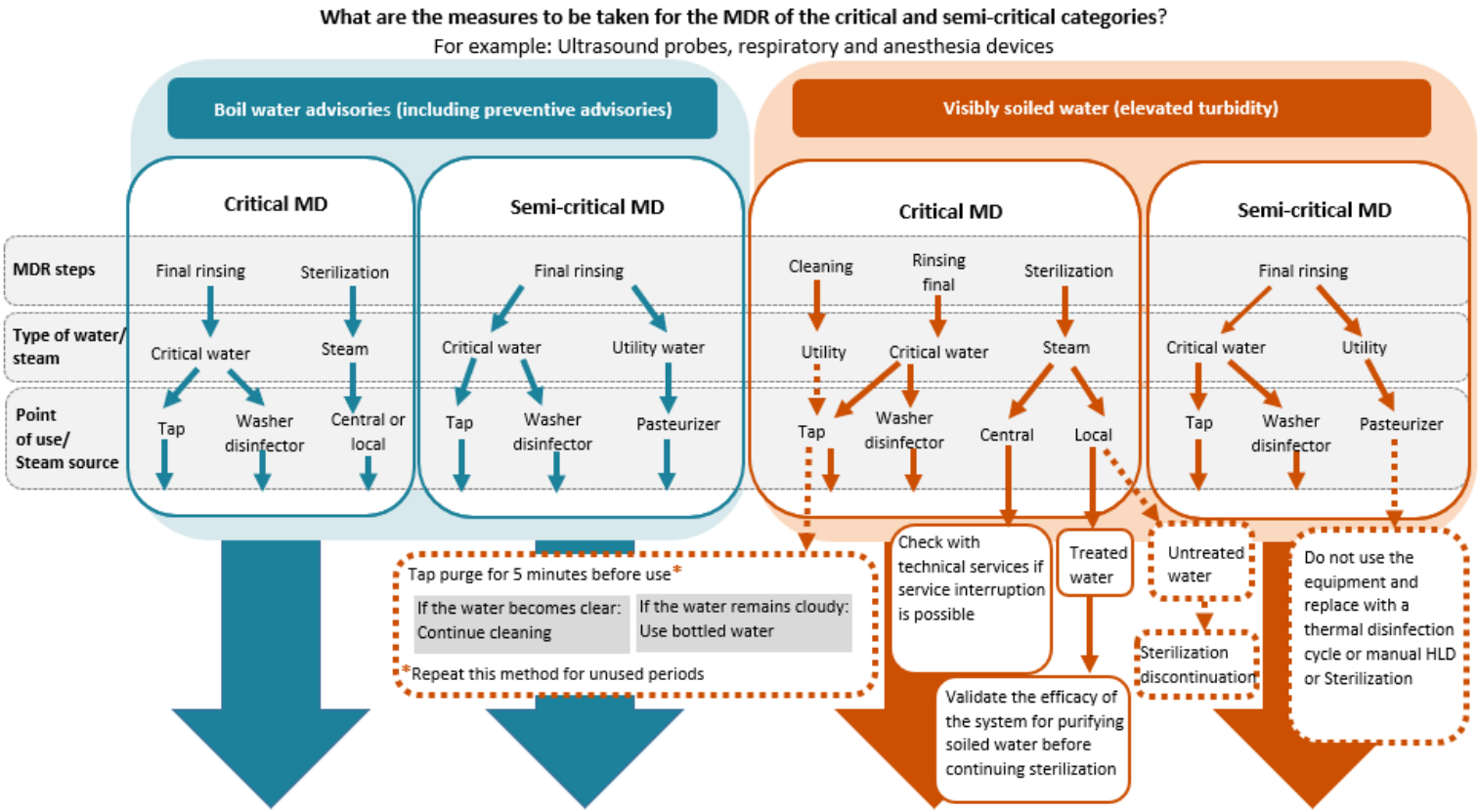


Equipment installed at the MUHC's Montreal General Hospital.

APPENDIX 2 CRITICAL WATER – EXAMPLE OF A WATER TREATMENT SYSTEM FOR AN MDRU

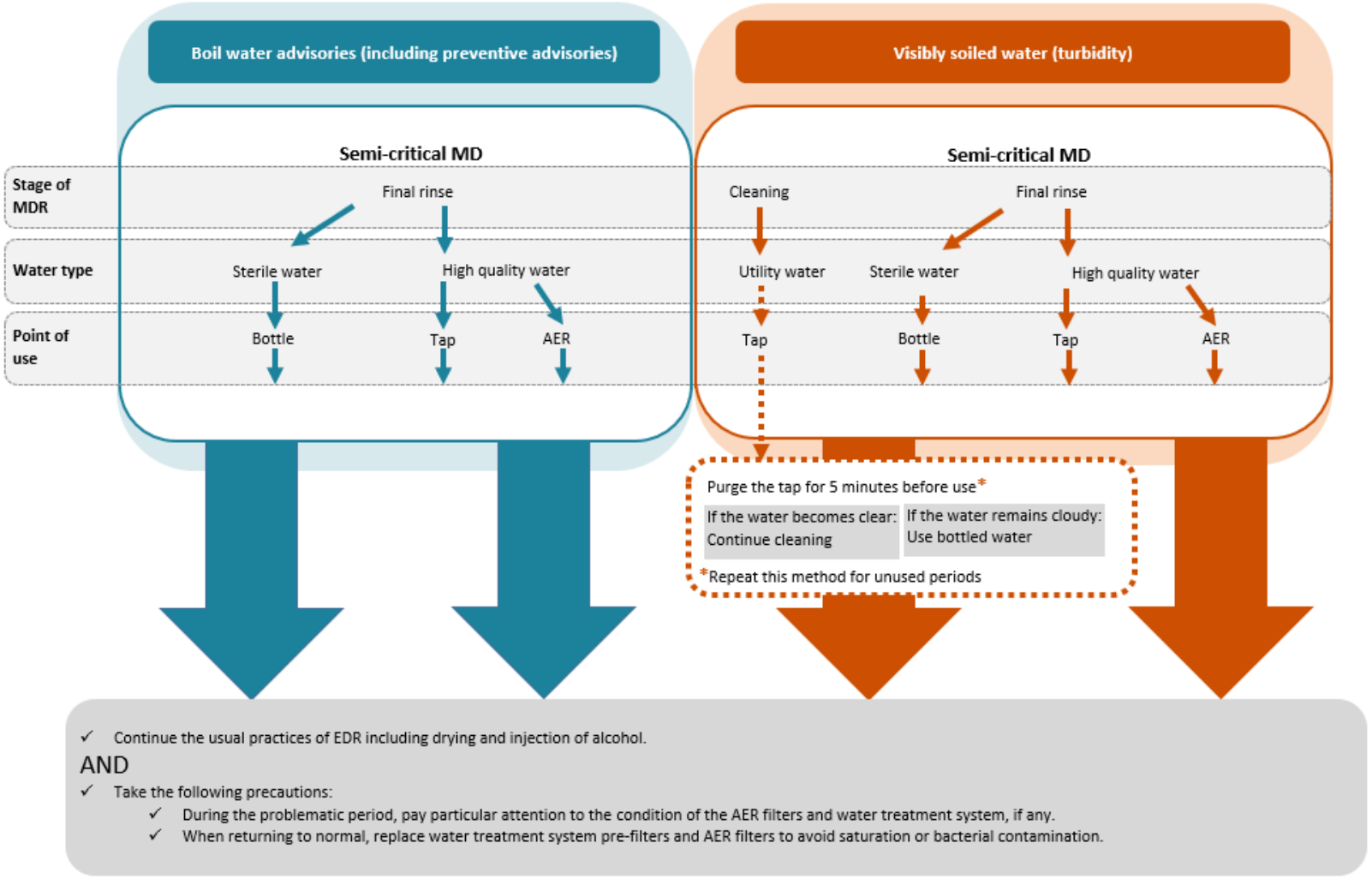


APPENDIX 3 DECISION TREE: BOIL WATER ADVISORIES OR VISIBLY SOILED WATER



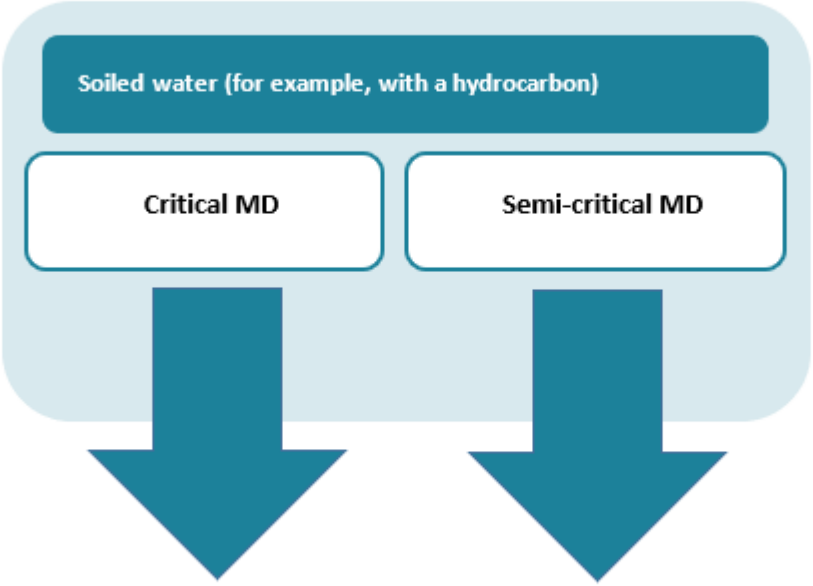
- ✓ Continue the MDR including daily maintenance related to reprocessing equipment (for example: cleaning of the washer filter, making sure the sprinklers are unobstructed, checking the detergent distribution system, etc.).
- ✓ Precautions to be taken for the water treatment system:
  - ✓ During the problematic period, pay particular attention to the system including monitoring of water quality (e.g. conductivity) and filter condition.
  - ✓ When returning to normal, replace the pre-filters (e.g. cartridge filters located at the beginning of the system) to avoid saturation or bacterial contamination. Depending on the configuration of the system and the type of contamination, additional components may need to be replaced and/or water testing may be performed.
- ✓ During the problematic period, pay particular attention to sterile packaging (stains and presence of water) and check sterilizer filters.

APPENDIX 4 DECISION TREE: BOIL WATER ADVISORIES OR VISIBLY SOILED WATER



APPENDIX 5 DECISION TREE: WATER AVOIDANCE ADVISORY

What are the measures to be taken for MDR and EDR?



- ✓ Establish a service corridor for reprocessing in another site or institution outside of the contaminated water distribution system.
- ✓ When returning to normal, replace the pre-filters and filters (including carbon filters and deionizing resins) to avoid saturation and a possible release of contaminants.

WATER AVOIDANCE ADVISORY – REPROCESSING STEPS[2]

User

Cleaning with available water

- Soak immersible MDs in an enzymatic solution
- Brush the channels, hinges, and joints of MDs
- Clean and rinse the MDs manually or clean them in a washer-disinfector
- Package the MDs according to the criteria required for MDs not classified in category 6.2 B

Transportation of contaminated MDs

- Transportation conditions:
  - Place in a closed cabinet
  - Place in an open cart under a cover
  - Place in a resealable container that can hold several MDs
- Characteristics of transport containers and outer packaging:
  - Is of good quality and sturdy enough to contain MDs and withstand any shocks that may occur during transport
  - Is constructed to remain tightly closed and thus prevent leakage under normal transportation conditions
  - Complies with the ergonomic weight limit of 25 pounds
  - Allows the MDs to be transported in a position that is parallel to the floor
  - Is made of material that is resistant to cleaning and disinfecting solutions
  - Is used exclusively for transporting contaminated MDs

Reprocessor

Carry out the reprocessing steps: cleaning, assembly, packaging and sterilization.

Transportation of sterile MDs

- Transportation conditions:
  - Place in a closed cabinet
  - Place in an open cart under an insulating dust-proof cover
  - Place in a resealable container
- Characteristics of transport containers and packaging:
  - Is made of material that is resistant to cleaning and disinfecting solutions
  - Is big enough
  - Is airtight
  - Is used exclusively for transporting contaminated MDs

[2] Reference: Guide de pratique *Transport des dispositifs médicaux en vue de leur retraitement par un organisme externe* published by the INSPQ (2014).

Quality of Water Used in Medical Device Reprocessing

AUTHORS

Centre d'expertise en retraitement des dispositifs médicaux
Andrée Pelletier, BScN, Scientific Advisor
Direction des risques biologiques
Institut national de santé publique du Québec

Martin Kirouac, PhD, Biomedical Technology Advisor
Groupe Biomédical Montérégie, CISSS de la Montérégie-Centre

Mélanie Fortier, PhD, Biomedical Technology Advisor
Groupe Biomédical Montérégie, CISSS de la Montérégie-Centre

IN COOPERATION WITH

Geneviève Germain, M Sc, Scientific Advisor
Gilbert Pichette, MD, FRCP, Microbiologist/Infectious Diseases Specialist, Medical Advisor
Richard Marchand, MD, Microbiologist/Infectious Diseases Specialist, Medical Advisor
Valérie Cortin, Eng., PhD, Scientific Advisor
Direction des risques biologiques

UNDER THE COORDINATION OF

Anne Kimpton, MSc, Scientific Team Leader
Direction des risques biologiques

READING COMMITTEE

André Matte, Eng
Direction des projets immobiliers, Ministère de la Santé et des Services sociaux

Caroline Poirot, Jr Eng, Association des physiciens et ingénieurs biomédicaux du Québec (APIBQ)

Denis Gauvin, MSc, Member of the Comité d'experts sur les risques microbiologiques de l'eau (CERMeau)
Direction de la santé environnementale, au travail et de la toxicologie
Institut national de santé publique du Québec

France Corbeil, BSc, Chemist
Laboratoire de santé publique du Québec
Institut national de santé publique du Québec

Mélissa Giroux, BsCN., Executive MBA, Chair, Association québécoise en retraitement des dispositifs médicaux (AQRDM)

Nathalie Brault, MSc, Member of the Comité d'experts sur les risques microbiologiques de l'eau (CERMeau)
Direction de santé publique de la Montérégie, CISSS de la Montérégie-Centre

Patrick Levallois, MD, Medical Specialist, CERMeau)
Direction de la santé environnementale, au travail et de la toxicologie
Institut national de santé publique du Québec

Philippe LeBlanc, Eng., M Eng, PMP, Coordinator – Opérations des bâtiments et CHU de Québec – Université Laval

Réjean Dion, M.D., Medical Advisor in Public Health (infectious diseases), Member of the Comité d'experts sur les risques microbiologiques de l'eau (CERMeau), Laboratoire de santé publique du Québec
Institut national de santé publique du Québec

Vicky Huppé, MSc, Scientific Advisor and Member of the Comité d'experts sur les risques microbiologiques de l'eau (CERMeau)
Direction de la santé environnementale, au travail et de la toxicologie
Institut national de santé publique du Québec

Wildrick Lafortune, Applied BSc, Certificate in Biomedical Engineering
Biomedical Equipment Control, McGill University Health Centre

ENGLISH TRANSLATION

Alison McGain, professional translator

Vanessa Molloy Simard, M.Sc., Mcb.A., RMCCM
Centre d'expertise en retraitement des dispositifs médicaux
Direction des risques biologiques
Institut national de santé publique du Québec

Mélanie Fortier, PhD, Biomedical Technology Advisor
Groupe Biomédical Montérégie, CISSS de la Montérégie-Centre

Martin Kirouac, PhD, Biomedical Technology Advisor
Groupe Biomédical Montérégie, CISSS de la Montérégie-Centre

Andrée Pelletier, BScN, Scientific Advisor
Centre d'expertise en retraitement des dispositifs médicaux
Direction des risques biologiques
Institut national de santé publique du Québec

LAYOUT

Linda Cléroux, Administrative Officer
Direction des risques biologiques

Legal deposit – 2nd quarter 2023
Bibliothèque et Archives nationales du Québec
ISBN: 978-2-550-83944-6 (Frenche PDF)
ISBN: 978-2-550-96285-4 (PDF)

Publication No: 2541 – English version

Institut national de santé publique Québec