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Quality of Steam Used in Medical Device Reprocessing

PROFESSIONAL PRACTICE GUIDE – CERDM

GUIDANCE AND RECOMMENDATIONS DECEMBER 2023

SOMMAIRE

FOREWORD

The Institut national de santé publique du Québec (INSPQ) is the public health expertise and reference centre for Québec. Its mission is to support Québec's Minister of Health and Social Services in carrying out the public health mission. As determined by the mandate entrusted by the Minister, the Institut also has the mission to support Santé Québec, the Nunavik Regional Board of Health and Social Services, the Cree Board of Health and Social Services of James Bay and the various institutions in carrying out their public health mission.

The *Guidance and Recommendations* collection brings together, under a single banner, a variety of scientific productions that assess the best available scientific knowledge and add a contextualized analysis involving a range of criteria and deliberations aimed at formulating recommendations.

This guide is a basic reference on the quality of steam used in reusable medical devices reprocessing (MDR). It was prepared at the request of the Ministère de la Santé et des Services sociaux as part of the mandate entrusted to the Centre d'expertise en retraitement des dispositifs médicaux (CERDM). It is intended for all persons working in health care institutions in the health and social services network (HSSN) who are directly or indirectly responsible for quality assurance in MDR, including managers, MDR institution respondents, MDR staff, and persons responsible for the production and distribution of steam (Technical Services and Biomedical Engineering Department). This guide is an update of the technical information sheet published by the CERDM in March 2021. Further details have been provided in this update, mainly with regard to condensate, contingency plans and Appendix 1.

Québec

1 INTRODUCTION

This publication was initially prepared in response to a number of complex steam support requests received by the CERDM. It is intended to provide a tool for consolidating and sharing expertise on the production and distribution of steam of acceptable quality and purity for MDR. The goal of sharing this knowledge is to reduce the recurrence of complex steam problems that generate significant costs, and to improve the quality of MDR.

This document supplements the information found in practice guides previously published by the INSPQ's CERDM. It first presents the standards and reference documents on the quality and purity of steam used for MDR. It then provides a definition of steam and specifies the type sought for MDR. Lastly, the guide describes practical means for producing and distributing steam for MDR in medical device reprocessing units (MDRUs). It also presents a quality assurance program (QAP) for ensuring that the recommended steam purity and quality standards are met.

The present guide will help to harmonize and ensure the quality of MDR-related processes throughout Quebec's HSSN institutions.

It reflects the knowledge of the INSPQ and the standards generally applicable to MDR at the time of publication. Given the development of knowledge in the field of MDR, stakeholders must continually update their knowledge through, for example, continuing education programs. They must also keep abreast of new applicable standards and guidelines.

To simplify the text, the term medical device (MD) always refers to a reusable critical medical device. Similarly, the term "water" refers to water in its liquid phase, and the term "steam", to water in its gas phase.

2 METHODOLOGY

This guide was developed with the collaboration of the CERDM's multidisciplinary expert committee.

A non-exhaustive literature review and regulation search were carried out on the production and required quality of steam for MDR. This professional practice guide produced in the process is based on CSA Standard Z314-23[1], which governs, among other things, the quality of steam used for sterilization purposes in Québec. It is also based on European Standard NF EN 285[2]. The principles and good practices presented in this guide are based as well on publications and memorandums from NSS Health Facilities Scotland[3] [4] [5] and the UK Department of Health[6], which offer more detailed reflection on how to solve steam-related issues in MDR. Guides put out by the INSPQ[7] and the *Ministère de la Santé et des Services sociaux* (MSSS)[8] were also consulted.

Concurrently, steam training sessions were taken with recognized industry specialists (Preston Phipps "Steam Specialities Seminar" and Maxi-Therm Inc. "Seminar on steam applications"). On-site visits of HSSN institutions built to the most up-to-date standards [McGill University Health Centre (MUHC) and Centre hospitalier de l'Université de Montréal (CHUM)] were also carried out to validate the guidelines adopted for the production and processing of steam for MD sterilization.

A reading committee, including experts from various sectors, was set up to assess the technical and scientific quality of this guide and the accuracy of its content. Lastly, three experts from this committee agreed to review the guide's pre-final version (version 1), based on the INSPQ's institutional review framework, in order to consolidate the quality of the guide.

3 RESPONSIBILITIES

In Québec, HSSN institutions are responsible for cleaning and sterilization procedures as well as for quality control, to ensure that MDR conditions comply with expected practices, including the quality of steam intended for MD sterilization, (manufacturer's instructions, standards and regulations in effect).

The quality of steam is essential to ensure that MD sterilization complies with current MDR standards. To ensure that it is appropriate for sterilization, there must be good collaboration between MDR staff and the manager of Technical Services or of the Biomedical Engineering Department.

In addition, it is important that the various stakeholders understand the physico-chemical principles applied to generate steam as described in this guide in order to comprehend how a sterilizer operates.

3.1 MDRU manager

The MDRU manager is the most qualified person in a health care institution to monitor MDR quality.

As regards the recommended quality of steam used in MDR, the MDRU manager must know the standards applicable to steam sterilization. As far as possible, they should also understand and keep up to date on the purpose of steam's desired characteristics, in other words, they should know:

- Their steam production and distribution network and its specifications, from the boiler to the sterilizer;
- The nature of the contaminants potentially present in the steam supply;
- Their sources;
- Their potentially harmful effects on steam purity and quality.

Under the institution's QAP, the MDRU manager must ensure that:

- The quality and purity of the steam supplied to the equipment meets its requirements in accordance with current standards and the manufacturer's instructions;
- Periodic maintenance of the steam generator and the distribution system that supplies the equipment is carried out in accordance with current standards and the manufacturer's instructions;

- The quality and purity of the steam are validated by specific tests (see the section Monitoring of feed water and steam);
- Contingency plans to ensure continuity of services during maintenance or in the event of a breakdown of the steam generation systems are in place and updated on a predefined basis by the institution.

3.2 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 the production and supply of steam.

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

- Ensure steam quality control;
- Monitor the composition of feed water that can affect the quality of steam;
- Ensure the availability and compliance of plumbing and steam production systems, according to the steam requirements of the MDRU
- Ensure the reception and commissioning as well as the preventive and corrective maintenance of the steam production and distribution systems under their responsibility;
- Keep inventory, maintenance records, warranty records and manufacturers' instructions for steam production systems and reprocessing equipment that may be under their responsibility;
- Implement a QAP to ensure a compliant steam supply for MDR;
- Collaborate on the development of contingency plans and updates;
- Know all the applicable standards and keep an eye on their development.

4 STEAM IN MDR

This guide focuses solely on the quality and purity of steam at the MDRU when it comes into direct contact with MDs, and acts as a sterilizing agent. The steam is used to power steam sterilizers (autoclaves).

The CERDM will not detail the specifications expected for steam when it is used as a heat source to heat water, as in washer disinfectors, for example. Nor will this guide detail sterilization problems related to poor practices[9] [10] (e.g. inadequate loading, incorrect packaging technique, or non-operational sterilizer).

The characteristics of the steam used in MDR for the purpose of sterilizing MDs are of great importance. In fact, steam of inadequate quality or purity can have repercussions that lead to incomplete sterilization due to insufficient energy transfer for destroying micro-organisms, the formation of wet packs, or the deposition of minerals leading to the appearance of corrosion on MDs, to name but a few[11] [12].

4.1 What is steam and its role in sterilization?

4.1.1 Steam

Before detailing the parameters that can be used to describe steam, here is a brief description of it [3].

Water vapor is a gas that forms when water changes from a liquid to a gas at the saturation point.

Steam is generated by the boiling of liquid water, which is then converted into gas. Boiling occurs at the saturation temperature, when the evaporated water vapor has sufficient pressure to displace the water immediately below the surface and form gas bubbles.

The formation of water vapor therefore depends on a unique temperature-pressure pair, called the saturation (boiling) point. Thus, at atmospheric pressure, steam is formed from pure water at 100°C, or at a higher pressure of 15.0 psig, for example, steam is formed at 121°C.

At the molecular level, this process occurs when water molecules (H_2O) are able to separate from the bonds that hold them together (i.e. hydrogen bonds).

Therefore, one might expect that the steam supplied to the sterilizer is composed solely of H_2O molecules, and think that the impurities in the water would be naturally separated from the gas created. However, it is important to understand that as water vaporizes and exits the boiler, the gases dissolved in the water are carried into the steam. In addition, the bursting of bubbles on the surface of boiling water is accompanied by the ejection of water droplets. These droplets contain the same dissolved and suspended compounds as those present in the boiler water. They are easily carried into the steam and thus transport contaminants to the sterilizer. As a result, these contaminants are often

able to reach the steam-consuming equipment, where they can come into contact with the product and possibly compromise user safety.

To obtain the right steam for sterilizing MDs, several factors come into play, including steam purity and quality.

4.1.2 Role of steam in sterilization

When steam enters the sterilizer chamber, it comes into contact with the cold outer layer of packaged items and rigid containers. The saturated steam condenses on the latter, leaving behind a small amount of water and transferring substantial heat to the various surfaces — the latent heat of condensation. The condensation of steam also reduces its volume by 99.9%, attracting more steam to replace that which has been converted into water. It is this phenomenon that enables steam to properly penetrate the load to be sterilized. As a result, the steam does not continue to condense on the outer layer, which is now at steam temperature; instead, it condenses on the next layer inwards. This process continues until the steam has heated all the items contained in the packs.

The heat transfer associated with condensation enables the temperature of the MDs to be raised much more rapidly with steam than with a source of dry heat, such as a Poupinel oven or a dry heat sterilizer.

Once the steam has penetrated the packs and heated their contents to the chosen sterilization temperature, the packs are held at this temperature for a pre-set time. The higher the temperature, the shorter the steam exposure time required.

Typical sterilization temperatures are 121°C (250°F) for a gravity cycle and 132°C (270°F) to 135°C (275°F) for a dynamic air removal (vacuum) cycle. The corresponding saturation pressures are 15.0 psig at 121°C and 26.9 psig to 30.7 psig from 132°C to 135°C[1].

Once the sterilization cycle is complete, the steam is evacuated using a partial vacuum, and the sterilized items are dried using the chamber's radiant heat and the evaporative effect of vacuum methods.

4.1.3 Types of steam

There is no standard definition for describing steam produced from water treated to meet defined characteristics, or steam produced with water whose physico-chemical qualities are not or only slightly controlled.

That being said, the terms *clean steam* or *pure steam* and *plant steam* or *utility steam* are commonly used. The most common terms are:

- **Clean steam**, which refers to water with controlled physico-chemical parameters that meet or exceed critical water specifications (see Section entitled water on page 9. No additives are used in its production.

[1] Calculations done using https://www.tlv.com/global/US/calculator/steam-table-temperature.html

- **Plant steam**, which refers to steam made from water treated for the needs of the boiler (often softened). Chemical additives are used during production to better control the steam production process.

4.2 Steam quality

CSA Standard Z314-23[1] describes steam quality according to four parameters: dryness, non-condensability ratio, superheat and dynamic pressure (see figure 1 and table 1):

- **Dryness (Saturation) of steam**: steam dryness is a measure of how much liquid water is present in the flowing steam. It is expressed as a "dryness fraction," which is a percentage by mass.
- **Non-condensable gases**: gases of this type cannot be liquefied by compression under the conditions of temperature and pressure used during the sterilization process and they will remain in gaseous form.
- **Superheat**: superheated steam is saturated steam (100% steam, 0% liquid water, see figure 1) that has been heated beyond its saturation point. Superheat is the difference between the steam's measured temperature and its saturation temperature at a given pressure (e.g. the saturation temperature of steam at atmospheric pressure is 100°C, which means that a measured temperature of 110°C at the same pressure corresponds to a superheat of 10°C) [2].
- **Dynamic steam pressure**: dynamic pressure represents the flow velocity of a liquid. To ensure that a sterilizer is working properly, the dynamic steam variation range specified by the sterilizer manufacturer or shown in the following table must respected.

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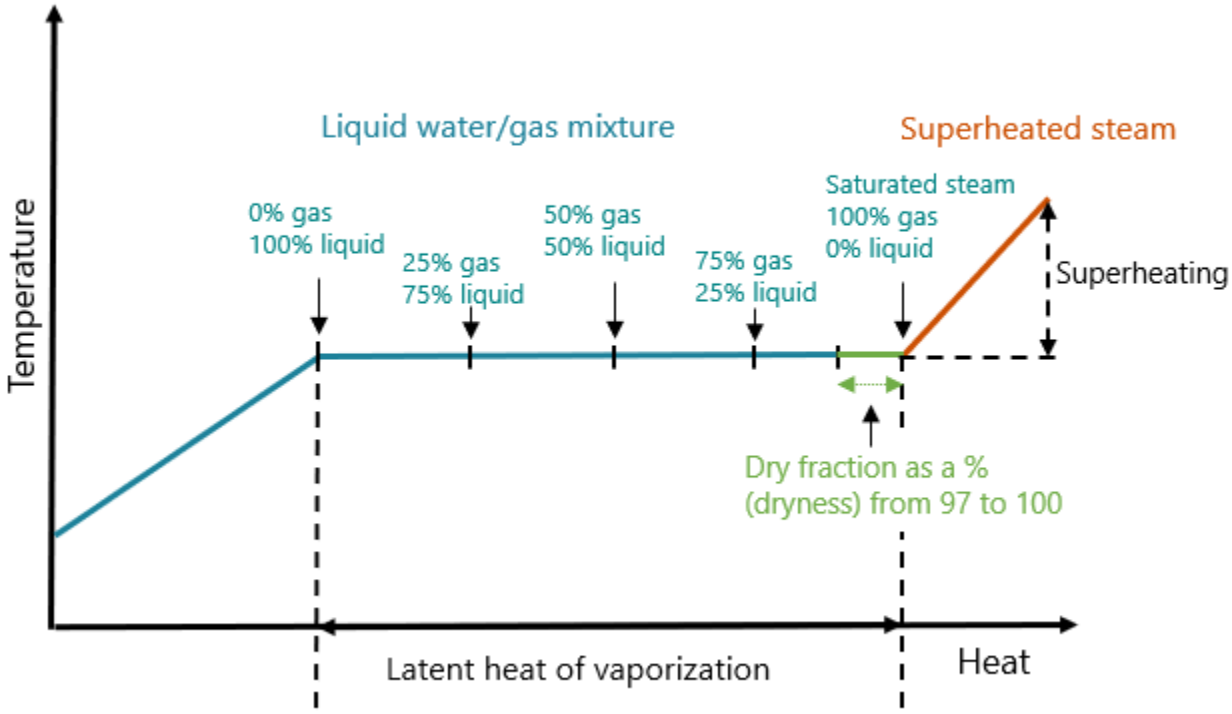
Figure 1 Diagram: constant pressure vaporization of water



Source : adapted from *Changements d'états : Vaporisation et condensation*. (2019, 23 July). Wikiversity (fr.wikiversity.org) https://fr.wikiversity.org/wiki/Changements_d%27%C3%A9tats/Vaporisation_et_condensation

Table 1 Recommended parameters for steam at the inlet of the sterilizer

Steam variable	Recommended parameters
Dryness fraction (%)	97 to 100*
Non-condensable gases (volume/volume)	≤ 3.5%**
Superheat	≤ 25°C**
Dynamic pressure (for steam supply line)	50 to 80 psig*** (i.e. 345 to 552 kPa)

Source : CSA Standard Z314-23, Table 18.1.

* See ANSI/AAMI ST79 [13].

** See EN 285.

*** Relative pressure.

The European standard specifies that the superheat temperature must not exceed 25°C when the steam expands to atmospheric pressure during the superheat test[2].

4.3 Steam purity

To ensure the purity of steam, it is essential to understand that steam contaminants can come from several sources:

- Water from which steam is generated;
- The boiler feed water treatment process;
- Materials used for the steam distributing system up to the sterilizer.

4.3.1 Feed water

The composition of the water used to generate steam has a direct influence on MDs, reprocessing equipment and the distribution system (see table 2).

Table 2 Potential effects of the water used to generate steam

Composition and characteristics of water used to generate steam	Effects on users	Effects on MDs and the distribution system
Metals (lead, cadmium, mercury, aluminium, iron, potassium)	Toxic in cumulative doses	• Stains on MDs • Discoloration of the chamber
Hardness (presence of calcium and magnesium)	Risk of infection	• Calcium desposits • Sterilization may be compromised
pH (presence of carbonates, hydroxydes and bicarbonates)	Unknown	• Pitting on MDs • Stains and corrosion
Organic components (endotoxins and amines)	Toxic effects and possible carcinogens	• Endotoxin and amine deposits on MDs
Halogens (chloride, fluoride, bromide)	Unknown	• Corrosion of MDs and of distribution system and sterilizer materials

To contribute to steam purity, Annex G of CSA Standard Z314-23[1] stipulates that feed water for steam generators used to reprocess MDs should preferably be softened or deionized water, or critical water if available and compatible with the distribution system and sterilizer materials.

Table 3a below presents the different types of water used in MDR; it has been adapted from the technical information sheet on the *Quality of Water Used in Medical Device Reprocessing*[7].

HSSN institutions may refer to it for details on the physico-chemical characteristics of water recommended for generating steam.

Table 3a Types of water used in MDR

	Types of water		
	Utility water (1)	**High quality utility water (1)**	**Critical water (2)**
Critical MD (Spaulding Classification)	Pre-cleaning, cleaning and rinsing		Final rinsing / steam
Characteristics	**Utility water (1)**	**High quality utility water (1)**	**Critical water (2)**
Hardness ($CaCO_3$) (mg/L)	< 150		< 1
Resistivity (MΩ·cm)	NA		> 0.1
pH	6-9		5-7
Chlorides (mg/L)	< 250		< 1
Bacteria (CFU/ml)	NA	< 10	< 10
Endotoxins (EU/ml)	NA	< 20	< 10

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.

Source: "Table 1. Types of water used in reprocessing" presented in the technical information sheet on water[7], table adapted from the AAMI TIR34 standard published in 2007 and 2014[14].

4.3.2 Condensate composition

Steam condensate is the liquid phase of steam (water in the gaseous phase) that is formed when steam is cooled below the saturation temperature.

Since the resulting steam or condensed water comes into direct contact with the MD, the composition of the condensate should meet at least the same criteria required as those for the final rinse water of MD surfaces during the reprocessing process for critical MDs (i.e. critical water).

The composition of steam condensate depends on the quality of feed water, its sampling point and the presence of any chemicals (additives).

Note that the composition of steam condensate sampled at the inlet of the sterilizer differs from the composition of the boiler feed water due to the vaporization and condensation of the water.

It also differs from the composition of the condensate at the outlet of the sterilizer. Condensate contains additional contaminants from the sterilized load and is therefore not representative of steam purity [2].

Table 3b shows the characteristics[2] of the condensate from steam sampled at the sterilizer inlet. These values are expected when critical water supplies the steam generator.

The switch to critical feed water has impacts (detailed below) on all installations.

Table 3b Suggested characteristics of condensate taken from the sterilizer inlet (generator supplied with critical water)

Characteristics	Suggested values (European standard for [2] condensate*
Hardness ($CaCO_3$) (mg/L)	<1
Resistivity (MΩ·cm)	>0.24
pH	5-7
Chlorides (mg/L)	≤ 0.1
Bacteria (CFU/ml)	NA
Endotoxins (EU/ml)	< 0.25**

* Section 13 "Service and working environment: NF EN 285: 2015"[2].

** " Table 6: maximum values of contaminants in steam condensate collected according to the methods described in EN 285: 2015" Scottish Health Technical Memorandum 01-01, Decontamination of medical devices in a Central Decontamination Unit, Part C: Sterilization by steam [5].

4.3.3 Quality of the distribution system and sterilizer materials by type of steam

As a rule, materials that come into contact with steam:

- Must be resistant to steam and condensate;
- Must not lead to a deterioration of steam quality;
- Must not release any substance known to be toxic in quantities likely to create a health or environmental hazard.

However, steam produced from critical or equivalent water has very low conductivity, and this results in a very aggressive and corrosive medium (because it is ion-hungry). Given that clean steam has no corrosion inhibitor, contrary to factory-generated steam, it is strongly recommended that the metal components of systems (such as generators, steam distribution networks and sterilizers) be made of stainless steel, with 316L stainless steel[8] being the most highly recommended. It is also essential to ensure the uniformity of materials throughout the system to avoid galvanic corrosion.

4.3.4 Treatment of boiler feed water

To combat scaling and corrosion problems in the steam production and distribution system, additives are commonly added to the water feeding the boiler for steam production or to the condensate return line, particularly in building heating systems.

Under CSA Standard Z314-23 Clause 18.6.2.2 [1], the addition of chemicals used as additives in the boiler must be done in accordance with Guideline No. 4 of Health Canada's Guidelines for Incidental Additive Submissions[15]. To that end, the present document specifies that the total amine concentration in steam must not exceed 25 ppm. For example, additives containing cyclohexylamine, morpholine, octadecylamine, diethylaminoethanol, trisodium nitrilotriacetate or hydrazine must be checked for compliance with the total amine concentration and their individual permitted concentrations.

Despite these maximum permissible concentrations, all chemicals added to boiler water can be transported in the steam as contaminants, either by water droplets carried into the steam during the evaporation process, or as volatile components present as gases. Steam that comes into contact with MDs can therefore be potentially contaminated by these additives. For this reason, the United Kingdom[6] specifies that it is essential to ensure the purity of the steam that comes into contact with MDs, i.e. to sterilize them with steam produced from additive-free water.

4.4 Summary of international recommendations to ensure steam quality and purity

Based on the requirements and recommendations for steam quality and purity detailed in the previous chapter, the recommended requirements for generating steam for sterilization can be summarized as follows:

- Boiler feed water must be as free as possible of contaminants, and meet the water quality characteristics of the last rinse, i.e. critical water;
- Feed water and steam systems must not be treated with chemical additives;
- The steam distribution system must be made of corrosion-resistant material, with 316L stainless steel being the most highly recommended;
- Steam must meet standard specifications for dryness (saturation), non-condensable gas content, superheat and dynamic pressure (table 1).

5 STEAM IN PRACTICE IN THE MDRU

5.1 Steam production

During MDRU construction and renovation activities, and in the event of problem situations requiring immediate intervention, institutions should ensure that steam production meets the recommendations set out above.

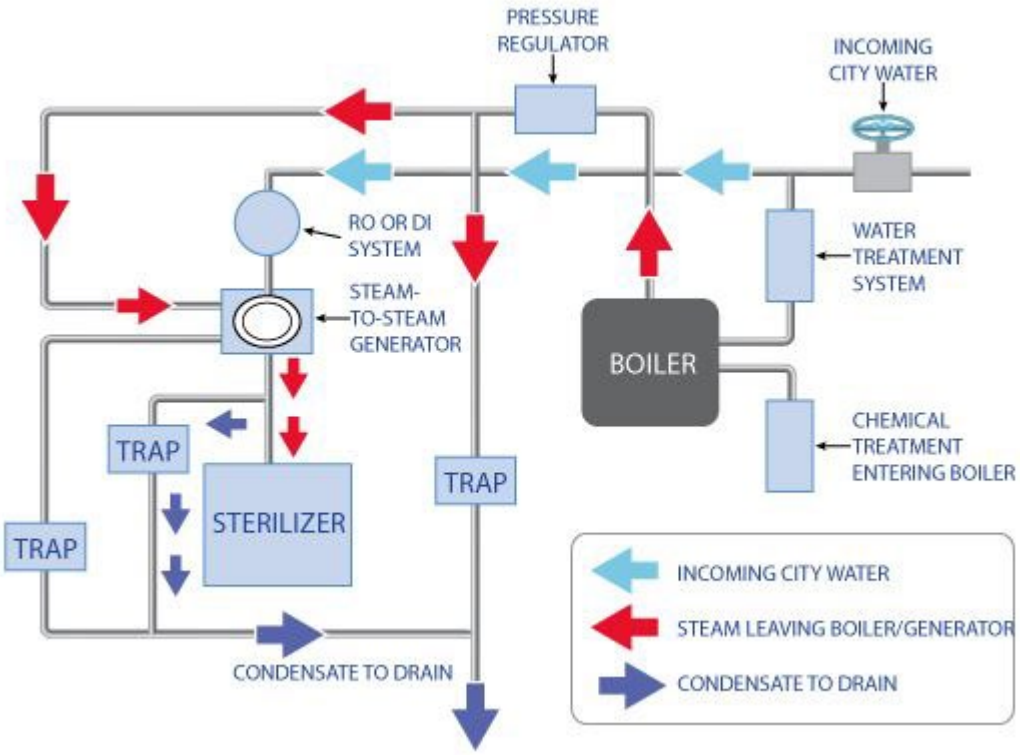
When refurbishing a MDRU or building a new one, the quality and purity of the steam produced by the main boiler should be checked first. If the steam produced by the institution's main boiler meets the criteria specified in the previous chapter, it is essential to draw up a QAP detailing the preventive maintenance required and the regular tests needed to maintain steam quality and purity long term.

However, an institution's main boiler is primarily designed to meet requirements other than those of the MDRU, in particular those of the heating systems. As a result, the steam produced is very often unsuitable to use in the sterilization of MDs.

If the steam produced by the institution's main boiler does not meet the desired specifications in MD sterilization, the first step is to validate whether changes in operating practices and technical modifications can sufficiently improve the quality and purity of the steam to make it suitable for MD sterilization.

If the modifications to be made are too extensive, the installation of a clean steam generator supplied with critical water serving only the sterilizers of the MDRU should be considered. These clean steam generators are usually steam-to-steam heat exchangers coupled with the main steam network, or small electric steam generators. Figure 2 below shows an example of a steam generator installation for an HSSN institution.

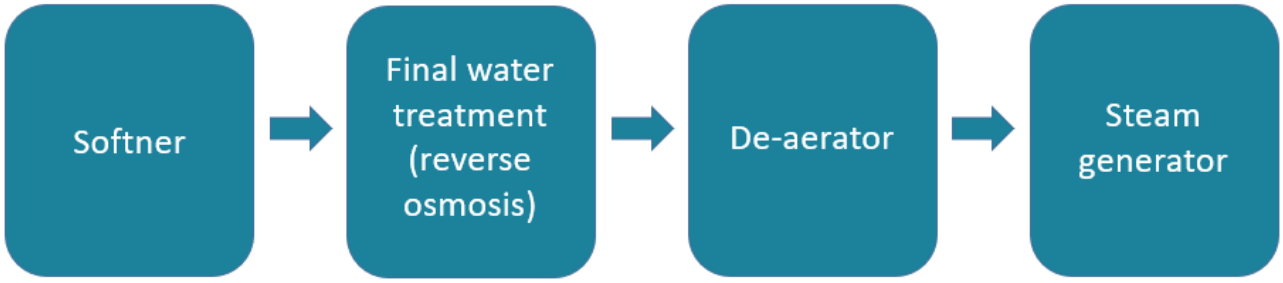
Figure 2 Proposal: producing steam with a steam-to-steam generator



Source : from Steris University (2015, December 30). *Guide to Optimal Steam Generation*. https://www.steris.com/healthcare/knowledge-center/sterile-processing/guide-to-optimal-steam-generation

As shown in figure 3, the production of steam of the quality and purity expected for sterilization can be broken down into the following main steps, with an appropriate preventive maintenance schedule:

Figure 3 Steps: from water to steam for the sterilizer



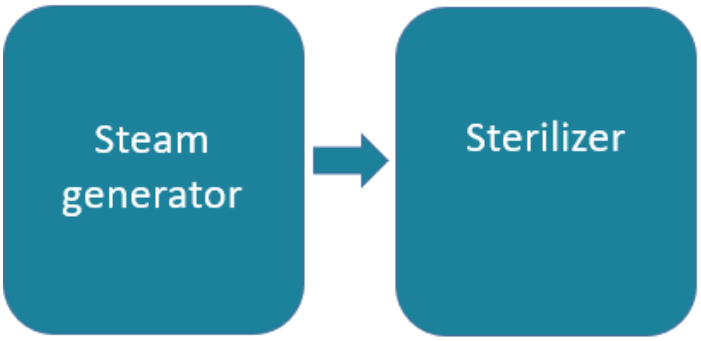
- **Critical water production**: the water supplied to the dedicated clean steam generator consists of drinking water treated to meet critical water characteristics. The steps required to produce critical water can be found in the technical information sheet *Quality of Water Used in Medical Device Reprocessing*, published by the INSPQ[7].
- **De-aerator**: the treated water is then passed through a de-aerator before being sent to the generator. This stage corresponds to de-aeration, which is designed to eliminate corrosive and non-condensable gases.
- **Steam production**: the dedicated clean steam generator must produce steam that meets MDR requirements. Since this generator will operate without a condensate return system, it is important to set up a maintenance program based on the manufacturer's instructions, including purging at regular intervals, either automatically (the most highly recommended option) or manually. A poor purge schedule can lead to deposit and corrosion build-ups in the generator, fouling of steam traps, and staining of the chamber, carts and MDs.

If the condensate return was designed to feed the steam generator for MD sterilization, it would have to be retreated beforehand so that its composition meets the characteristics of critical water.

5.2 Steam distribution

Once steam has been generated, particular attention must be paid to how it is distributed to the sterilizer (see figure 4).

Figure 4 Steps: Steam production up to the sterilizer



The distribution network must be made of stainless steel to prevent corrosion. This constraint applies to every part of the system that comes into contact with steam, from the inside of the steam-to-steam generator to the steam distribution network, the sterilizer, and the piping and chamber of the sterilizer itself. In fact, due to its aggressive nature, steam can attack the surface of pipes. If the residues of this corrosion become detached from the surfaces and are carried into the steam, this can cause black or reddish-brown discoloration on the sterilization packs.

Pipe insulation, steam traps and riser vents help to eliminate condensate and non-condensable gases from the steam network.

The function of a steam trap is as follows. When steam condenses in the distribution network, it produces condensate. To prevent condensate build-up in the system, and thus ensure that steam remains dry, condensate must be removed from the system. A steam trap is very similar to a valve. It is installed to remove liquid condensate and other non-condensable gases from the supply network and thus enable the latter to remain filled with "dry" steam.

CSA Standard Z314-23[1] (18.6.4.3) specifies that "*Condensate traps shall be:*

a) Installed at i) the end of every horizontal pipe run; ii) the entry point to each piece of equipment; and iii) each vertical rise; and

b) made of material that is compatible with all connected parts of the steam supply system."

It is also essential to ensure uniformity of materials throughout the network to avoid galvanic corrosion.

The network's design, with no dead ends, and a pipe size adapted to steam flow and demand, also contributes to better steam quality and purity at the point of use.

Lastly, to ensure the absence of particles in the steam, filters can be installed on the steam line and will require regular maintenance and replacement.

As specified in CSA Standard Z314-23[1] (Clause 18.6.4.4):

Equipment connection points feeding each steam sterilizer shall:

a) be taken off the top of the main steam line; and

b) have: i) a sampling location for testing the quality of the steam condensate (portable condenser connection); ii) a pressure gauge; and iii) pressure regulation devices, as appropriate.

5.3 Potential breakdowns and problems

5.3.1 Water carryover

The most frequently encountered problem is the presence of water in a sterilization load. If all the sterilizer's operating conditions are met (adequate loading, correct packaging technique and proper functioning), the possibility of water carryover should be checked.

When operating the boiler or generator, the main precaution to take against water being carried into the steam is to prevent priming and foaming as much as possible.

Priming[3] is a phenomenon associated with steam production, in which large quantities of boiler water may sporadically be transferred to the steam. This is often due to a sudden increase in steam demand, which reduces the pressure above the water and lowers the boiling point, thus increasing the intensity of bubbling/boiling. An overly high water level in the boiler can also lead to priming. Priming can be reduced by standard good operating practices, such as operating the boiler at maximum pressure, using pressure reduction valves when demand causes a reduction in pressure in the distribution

system, and maintaining adequate water levels. Additionally, the boiler must be sized to meet peak demand.

Foaming[3] occurs when boiler water contains high concentrations of impurities. These impurities reduce the water's surface tension and thus increase agitation at the surface. This agitation can lead to the formation of stable foam above the water surface, known as foaming, which in turn causes substantial droplet entrainment. The level of total dissolved solids (TDS) in the boiler water is another important factor in preventing foaming. It is recommended not to exceed a TDS level of 2 000 ppm[2] in water used for steam production. The use of critical water helps to limit this phenomenon.

5.3.2 Steam specification deviations at the sterilizer inlet

If steam quality parameters at the sterilizer inlet deviate from expected characteristics, see table 1: Recommended parameters for steam at the inlet to the sterilizer (from CSA Standard Z314-23, Table 18.1): steam produced by the generator or boiler may no longer be suitable for sterilizing.

STEAM SATURATION AND SUPER HEATING

If the steam produced does not comply with the steam saturation percentage specified in the standard, this could have an impact on sterilization.

- For example, if steam saturation is below 97%, excess moisture carried in suspension may cause condensate to accumulate on the loads during the transfer of the steam's latent heat in the sterilizer. This excess moisture cannot be evacuated in the normal drying cycle during sterilization, with the result that wet loads may be observed.
- Conversely, dry steam (dry fraction close to 100%) may not compensate for superheated steam. In fact, superheated steam is often generated following a drop in pressure when steam passes through pressure reduction valves. Since the total energy contained in the steam remains the same, the energy resulting from the drop in the steam's pressure will cause the existing moisture to be transformed into steam. If the steam is already 100% dry, or if excess energy is still present after the moisture has been converted into steam, this energy will cause the temperature of the steam to rise, resulting in superheated steam (Figure 1). The standard tolerates up to 25°C of superheat measured when steam expands at atmospheric pressure[1].

The efficiency of superheated steam sterilization can be compared with that of dry heat sterilization, since condensation and latent heat transfer do not occur until the superheated steam gives up its superheating energy and its temperature reaches the saturated steam temperature. The duration of the sterilization plateau may then be insufficient to achieve a reduction in the infectious load equivalent to that of sterilization.

The following example comes from the book *Sterilization Technology for the Health Care Facility*[16] which compares saturated steam and dry heat sterilization. During saturated steam sterilization, *B. stearothermophilus* spores are killed within 15 minutes at 121°C. If dry heat is used, more than six hours will be needed to kill these same spores at a temperature of 121°C.

If there is significant overheating during a cycle, the indicators and identification cards will show burn marks, and the sterilization cycle must be considered to have failed.

Steps to be taken[3]:

- To avoid steam saturation below 97%, check that the generator is working properly (no water carryover or priming), that the feed water is of good quality to avoid foaming, that the steam traps are working correctly properly, and that the network is correctly insulated;
- To avoid superheating, monitor the dryness and pressure of the steam before it passes through the various pressure reduction valves in the network, and be sure not to exert excessive pressure reduction of the steam too close to the sterilizer.

NON-CONDENSABLE GAS LEVELS

In practice, non-condensable gases are composed of air, particularly carbon dioxide (CO_2) and oxygen (O_2). They do not mix with steam and pose a problem, as they lower the temperature of the steam and isolate the instruments to be heated and sterilized. Thus, during sterilization, the steam-air mixture surrounds the outside of the packets in the load. The steam condenses, leaving non-condensable air on the surface of the packs. As the heating process continues, more steam condenses, concentrating more air, which then enters the packs. Steam penetration capacity is therefore reduced, and this can lead to sterilization problems in the middle of the packaging. If indicators are strategically distributed in the load to be sterilized, the presence of air and other non-condensable gases will be noted, with one or more indicators failing. CSA Standard Z314.7-03[17] considers an average leak rate of 1 mm Hg/min or less over the measured period to be acceptable. Non-condensable gases can also cause corrosion in the distribution system.

Steps to be taken:

- Make sure there is a de-aerator in front of the steam generator, and check the sterilizer for leaks using the leak test;
- Make sure to purge the pipes when steam production is stopped;
- Check that your system has passed the Bowie-Dick Test.

STEAM PRESSURE

If the steam pressure at the sterilizer inlet does not meet the manufacturer's specifications or those of the standard, the sterilizer will not be able to reach the temperature and pressure values necessary for the sterilization conditions of the MDs as established during the validation of the sterilizer cycles.

Steps to be taken:

- Check the condition and sizing of the steam generator and steam distribution system components;
- If other steam-consuming equipment is to be connected to the steam distribution network, it must be ensured that variations in steam flow according to requirements do not disturb the pressure at the sterilizer inlet to such an extent that it no longer meets the required specification.

6 QUALITY ASSURANCE PROGRAM

The institution must implement a quality assurance program (QAP) approved by the concerned authorities in order to ensure reliable production of steam of adequate quality and purity. This QAP is based on close collaboration between the managers of the MDRU, Technical Services and the Biomedical Engineering department.

The institution must:

- Implement a preventive and corrective maintenance program for the steam production and distribution system;
- Use skilled labour for preventive and corrective maintenance of the steam production and distribution system;
- Implement a regular steam quality and purity monitoring program;
- Set up a test results log.

6.1 Monitoring of feed water and steam

6.1.1 Sampling

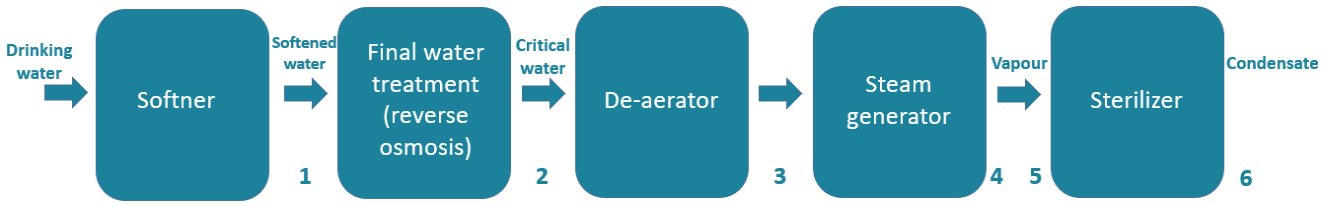
To ensure that steam production is running smoothly, samples must be taken on a regular basis at the various stages of the process.

Without limiting sampling to the points suggested below, it is important to have sampling points that ensure each stage of steam production can be controlled with regard to:

- the production of high-quality feedwater for the steam generator (points 1, 2 and 3 in figure 5);
- the steam generator, for both the water in the generator and the steam leaving the generator (point 4);
- the steam sterilizer inlet. Once the sample cools to room temperature, it corresponds to the condensate (point 5).

It is important that samples be taken using a method that does not contaminate them. If necessary, refer to the good sampling practices clearly detailed in Section 21 of Standard NF EN 285, entitled « Steam quality test"[2].

Figure 5 Suggested sampling points



6.1.2 Sampling frequency

CSA Standard Z314-23[1] (Clause18.6.1.3 Steam evaluation) requires that samples be taken and analyzed:

"a) upon commissioning of new equipment in MDRA[2] and annually or as per manufacturer's MIFUs;[3]

b) following a change from one sterilizer to another;

c) following an issue where staining of equipment/medical devices has occurred; and

d) followingwet loads after stem sterilization."

Point a) of the standard includes steam generator and sterilizer start-up.

The following situations also require samples to be taken and analyzed:

- When modifications are made to components of the steam production and distribution system;
- Following a change in the quality of boiler or steam generator feed water (fluctuation in the composition of drinking water or in the manner in which boiler water composition is regulated);
- In the event of maintenance or major work on the system requiring the interruption of production;
- After an event or a breakdown.

6.1.3 Sample analysis

Samples in liquid format (feed water or steam condensate) are sent for analysis to an accredited laboratory, while steam quality tests should be carried out using the method described in Section 21 of Standard NF EN 285[2], entitled "Steam quality test". Many companies can also help with steam quality testing.

The test results must be recorded in a log to allow comparison of the values obtained over time or after an event[7].

Institutions must ensure that the quality and purity of steam supplied to the sterilizer are maintained within recommended acceptable limits at all times.

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2 MDRA is the equivalent of MDRU in this document.

3 MIFU manufacturer's instructions in this document.

6.2 Monitoring of the steam distribution system

The steam distribution system must also be included in the monitoring program in order to ensure the quality and purity of the steam entering the sterilizer.

A steam trap monitoring program must be put in place and include regular inspection and maintenance, if necessary.

It is important to know which services, other than the MDRU, use the same steam distribution system in an HSSN institution, and when the use of these services peaks (e.g. during cooking, heating, etc.).

It is also a good idea to check that the distribution network does not have any steam or condensate leaks, and that the steam supply network is always optimally insulated.

Lastly, steam pressure at the sterilizer inlet must also be monitored.

6.3 Maintaining MDR activities

Steam production shutdowns during servicing and maintenance programs must be carried out in collaboration with the managers of the MDRU, Technical Services, the Biomedical Engineering Department and clinical services that use MDs. Similarly, any changes to the distribution system or boiler water quality control methods should be communicated to the MDRU manager in order to monitor their possible impact on steam sterilization.

In the event of breakage, problems or non-compliant test results, the managers of the MDRU, Technical Services, the Biomedical Engineering Department, infection prevention and control and risk management must be notified.

The design of the steam production system for the MDRU must include a contingency plan allowing for steam generation redundancy to minimally cover emergency needs in the event of a failure of the steam generation system.

The preferred solution would be to ensure partial or total redundancy of the dedicated steam generation system by providing more than one steam generator. If no additional generators were available, a bypass route allowing the sterilizers to be supplied with steam from the facility's main boiler could be used, for example. If that alternative were chosen, it would have to be documented and the MDRU manager would need to be informed. This alternative would have to be used on a temporary and exceptional basis, as it entails the aforementioned risk of using steam that does not meet the specifications expected for sterilization. Therefore, this option would have to be evaluated by a multi-disciplinary team before being implemented and consider the context of steam production in the main boiler.

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

7 RECOMMENDATIONS OF THE CERDM

The CERDM recommends that HSSN institutions:

- Follow the sterilizer manufacturer's instructions on use and maintenance;
- Ensure the quality of steam so that it will meet the specifications for dryness (saturation), non-condensable gas content, superheat and dynamic pressure (table 1);
- Maintain steam purity according to the manufacturer's recommendations. Purity can be measured via the composition of steam condensate taken from the sterilizer inlet;
- Ensure that the sterilizer, steam generator and steam distribution system are of adequate size to meet both regular and peak steam requirements, and thereby guarantee continuous steam quality and purity. The sizing of the various components must take into account any other steam-consuming equipment in the institution that might be connected to the steam distribution network that supplies the MDRU. The sizing of steam-related equipment and systems for the MDRU must also be verified whenever any changes are made to them;
- Choose corrosion-resistant materials when selecting a sterilizer and for the entire steam distribution network;
- Adhere to maintenance schedules for the steam distribution system (e.g. regular maintenance of steam traps, also known as "condensate traps");
- **Prioritize clean steam instead of factory steam for MDR**.

If clean steam is used (preferred choice):

- Ensure that feed water complies with specific characteristics, i.e. those of critical water;
- Do not treat feed water and the steam system with chemical additives;
- Choose corrosion-resistant materials, with 316L stainless steel being the most highly recommended choice for sterilizers and steam distribution systems;
- Check condensate composition for clean steam (manufacturer's values or values suggested in table 3b).

If plant steam is used (not the preferred choice), the CERDM recommends that the HSSN institution implement risk mitigation measures, i.e.:

- Ensure that feed water complies with specific characteristics, i.e. those required by manufacturers;
- Ensure compliance with maximum concentrations of chemicals, particularly amines (see section Treatment of boiler feed water);
- Check condensate composition for factory steam (according to manufacturer's values).

8 CONCLUSION

It is important to understand that steam is evaluated on the basis of its quality and purity.

The quality and purity of steam required for optimal sterilization of MDs depends on a number of factors. Optimal facilities and an adequate level of supervision, including regular monitoring, are required for these devices to be sterilized with an adequate supply of steam.

Any deviation from the expected quality or purity could affect the service life, reliability and efficiency of a steam production system, its distribution network, the sterilizer, MD safety, and therefore the health and safety of users.

By complying with applicable standards and implementing regular monitoring and maintenance of systems, within the framework of a QAP with qualified personnel, institutions ensure that the risks of deviations and breakdowns are kept to a minimum.

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Appendix 1 - Summary table of steam-related issues

Issue	Effects on MDs and the distribution network	Effects on users and on achieving sterility	Possible measures to be taken
Contaminants likely to be present in feed water for steam production (see table 2)	• Stains and corrosion on MDs • Discoloration of the sterilizer chamber • Calcareous deposits • Pitting on MDs • Corrosion in the distribution network • Organic matter and toxins	Cumulative toxicity	• Use water of critical quality as feed water • Install filters on the steam line • Eliminate the addition of additives to steam feed water. If impossible, ensure compliance with a maximum value of 25 ppm amines
Priming (large quantity of boiler water transferred to steam) Foaming (formation of stable foam above the surface of the feed water)	• Presence of water in a sterilization load (despite proper sterilizer operating conditions) • Stains on MDs	Possible failure of sterilization	• Priming: check boiler size to ensure that it meets demand • Foaming: do not exceed 2000 ppm total dissolved solids in feed water (use water of critical quality as feed water)
Superheat	• Burn marks visible on chemical indicators and identification cards	Possible failure of sterilization	• Check dryness and steam pressure at sterilizer inlet
High non-condensable gas content	• Failure of quality control indicators in the sterilization cycle		• Install a deaerator in front of the steam generator or check its condition • Check for the presence of vents on steam distribution network risers • Check sterilizer for leaks using the leak test • Check the Bowie-Dick Test every day of use

Appendix 1 - Summary Table Of Steam-Related Issues (Cont.)

Issue	Effects on MDs and the distribution network	Effects on users and on achieving sterility	Possible measures to be taken
Low steam pressure	• Sub-optimal sterilizer operation	Possible failure of sterilization	• Check the condition and sizing of the steam generator and steam distribution system components • If other steam-consuming equipment is connected to the steam distribution network, make sure that requirement-based variations in steam flow do not disturb pressure at the sterilizer inlet to such an extent that it no longer meets the required specifications
Inadequate dryness	• Impairment of the physical integrity of MDs, the sterilization load and the steam production system (e.g. possibility of wet loads, corrosion, etc.)		• Implement a preventive and corrective maintenance program for the steam production and distribution system and check the: – Operation of the generator (no water carryover) – Operating conditions in the distribution system (steam pressure and flow) – Quality of feed water – Thermal insulation of the steam distribution network and the sterilizer – Operation of the steam traps • Ensure that preventive and corrective maintenance is carried out by qualified personnel • Set up a regular steam quality monitoring program and record the results obtained.

Appendix 2 - Sterilization problem checklist

This appendix is based on a document provided by Steris: *Wet Pack Troubleshooting Workbook*[18]

Many factors can come into play when a sterilization problem occurs. A thorough investigation can help identify the causes and resolve the situation.

The first step to be taken when a problem occurs is to keep a log of its occurrence containing a detailed description of the problem and the conditions under which it occurred.

First of all, check the practices of the MDRU by:

- Doing basic sterilizer checks (e.g. Bowie-Dick Test, leak test and preventive maintenance recommended by the sterilizer's manufacturer);
- Checking sterilizer loading practices.

If the MDRU's sterilization practices are compliant, close collaboration between the managers of the MDRU, Technical Services and the Biomedical Engineering Department will make it easier to identify the problem's causes and to eliminate it. Collaboration among these managers should make it possible to verify:

- Steam quality and purity at the sterilizer inlet;
- The distribution network and steam traps;
- Boiler water quality;
- Any change occurring at the same time in the operation of the boiler or in controlling the quality of its water, any modification or alteration of the steam distribution system, or any change in the institution's steam demand on that distribution line.

Appendix 3 covers the verification of load configuration/distribution and content in the sterilizer, as well as good packaging practices. Staff should be trained in how to load sterilizers so as to prevent overloading, as well as in pack size, weight and density. They should also check the positioning of items in the sterilizer, and the packaging technique used.

Sterilizer

In particular, check the following:

- Adherence to preventive maintenance and sterilizer calibration frequency. Carry out maintenance and calibration as required.
- Cleanliness of the steam inlets and outlets in the sterilizer chamber, with cleaning as required. It is good practice to clean lint and other debris from the sterilizer drain daily.
- Compliance of the steam pressure at the sterilizer inlet with the manufacturer's set value, and adjust if necessary.

- Results of a Bowie-Dick Test to check the efficiency of air and non-condensable gas removal and the ability of steam to penetrate a standardized load.
- Performance on a leak test to ensure that there are no leaks (an average leak rate of 1 mm Hg/min or less over the measured period is acceptable). Check the steam to chamber valve: a leaky valve will flow steam into the chamber during the dry phase and create wet loads; however, an air elimination test (Bowie-Dick) will pass.
- Sterilizer alignment to ensure proper drainage. Adjust levels if necessary.
- The presence of water spots inside the sterilizer chamber, which is a sign of condensate build-up. Check the steam line for water carryover.
- Proper operation and maintenance of the chamber and jacket steam traps with different load sizes.
- The pressure reduction valve.
- The stability of the sterilizer's pressure regulating valve (PRV) to prevent excessive pressure fluctuations in the sterilizer. Is the PRV gap properly adjusted? If the gap is too small, superheat can occur; if the gap is too big, the large amount of steam can heat the load too quickly and create too much condensate. Replace the reduction valve/adjust the gap, if necessary.

Steam production

In particular, check the following:

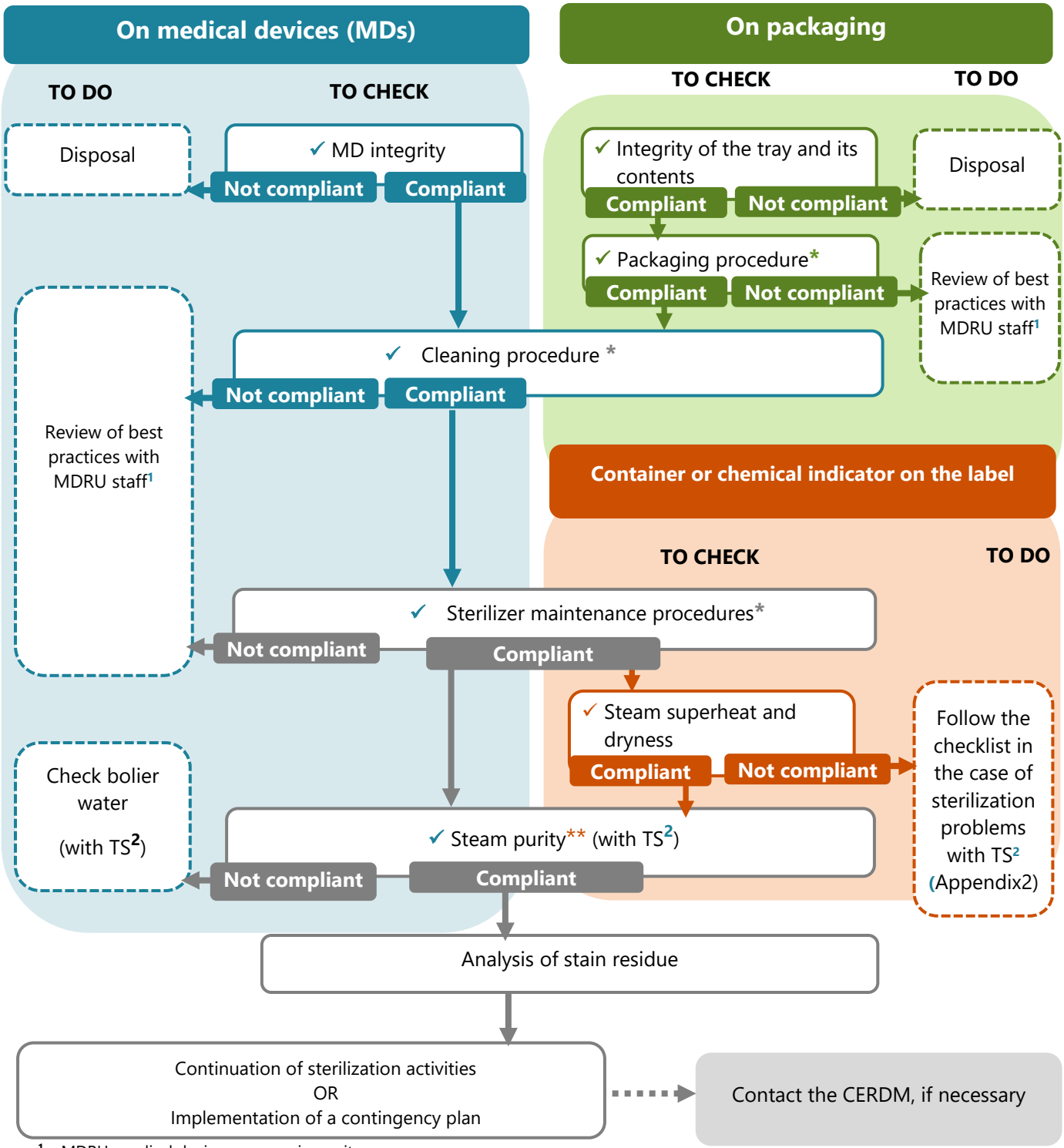
- Frequency of boiler/generator maintenance.
- The composition of feed water and condensate at the sterilizer inlet.
- The sizing of the steam generator and of the distribution pipes. The use of a pressure reduction valve can attenuate fluctuations. Adjust if necessary.
- The water level in the boiler/generator: high water levels can lead to carryover. Take the necessary steps to ensure that the boiler operates optimally. If the water level fluctuates regularly or if evidence of particles is found, check and correct the water treatment and purge regularly, if necessary.
- Correct execution of boiler/generator start up/shut down procedures. Steam trap priming may be compromised during an incorrect restart sequence and result in the subsequent introduction of liquid into the pipes.
- Correspondence between the volume of steam produced and the network's requirements, including during peak consumption periods. In cases where the institution's boiler serves the sterilization needs, of the MDRU, seasonal changes may be responsible, for example, for the introduction of liquid into the steam distribution network, and steam traps exposed to excess condensate may lose prime. Resetting steam traps may be overly time-consuming. It is a good practice to physically check the steam traps after each change of season, as well as after each maintenance and restart of the boiler/steam generator.
- Steam pressure at the generator outlet and the sterilizer inlet.
- Does the boiler undergo regular purging?
- Has the steam generator been descaled?

Steam distribution network

In particular, check the following:

- The location, selection and operation of steam traps. Failing or faulty steam traps can cause intermittent wet pack issues. Steam traps should be serviced regularly, in accordance with manufacturer's instructions. Adjust, if necessary.
- Compliance of the network design with best practices. If necessary, bring the design up to standard by ensuring, for example, that:
  - Piping support is sloped properly for condensate drainage;
  - The pipe diameter is adequate for steam flow and expected fluctuations. A diameter that is too small to meet steam demand will create an overly high flow rate. High steam velocities can cause steam traps to malfunction and allow condensate to accumulate.
- The sizing of condensate collectors. Adjust if necessary.
- Incoming steam lines, which are equipped with a pressure gauge, calibrated at regular intervals. Check static pressures (without sterilizers running) and dynamic pressures (with sterilizers running). Ensure that the dynamic pressure at the sterilizer inlet remains within the set values during the operation of all sterilizers.
- Filters: A filter is designed to remove particulates in the steam, but it is not a miracle solution but is not a remedy for bad upstream piping configuration or malfunctioning traps. Filters cannot completely remove large amounts of condensate.
- Piping insulation: Damaged or missing insulation can create additional condensate that may exceed designed trap capacity. To prevent steam supply pipes from being cooled by air from the air-conditioning system, check that they are not placed directly under the diffusers. But if that is the case, adjust the directional vents to protect the piping.
- Environmental conditions in order to identify significant temperature differences in the work space; for example:
  - Ensure that there is no significant temperature difference in the work space by regulating the heating and cooling system properly;
  - Ensure there is air differential discrepancy between load/unload work spaces;
  - Adjust the heating/cooling system seasonally to maintain proper temperature and humidity levels in prep/load/unload areas;
  - Verify proper amount of air exchanges per hour and negative air pressure between load/unload areas.

Appendix 3 – Decision tree - Stains



[1] MDRU: medical device reprocessing unit.

[2] TS: Technical Services.

* See detailed verification steps on the next page and in Appendix 2.

** See the definition in section 4.2 of this document.

Detailed verification steps

Verification of packaging procedure

- ✓ Good packaging material (envelope and absorbent fabric)
- ✓ Good packaging method
- ✓ Appropriate tray (also called an organizer) in good condition
- ✓ Compliance with the instructions of the packaging and tray manufacturer
- ✓ Major change in packaging (envelope and absorbent fabric)

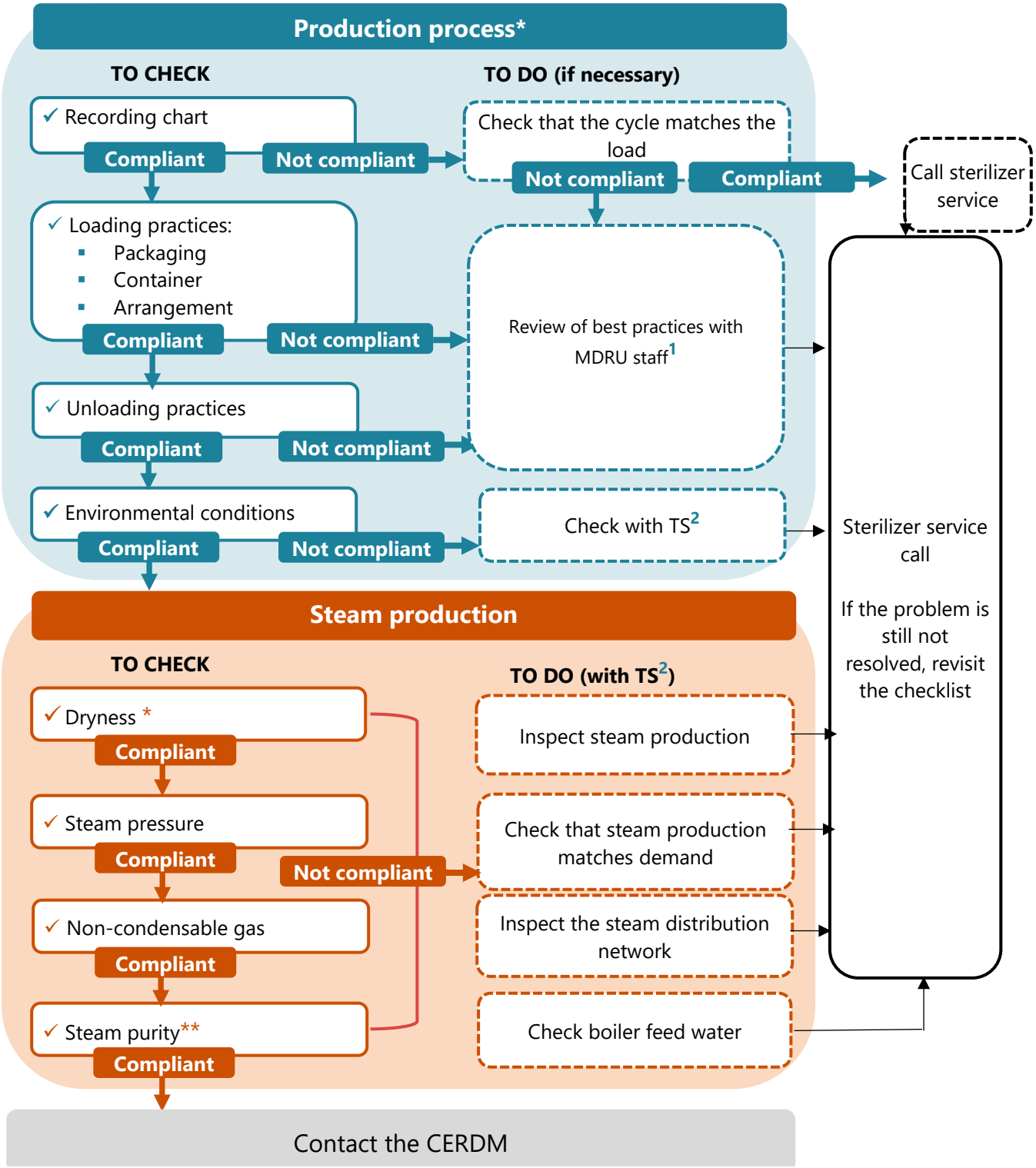
Verification of cleaning procedure

- ✓ Validated reprocessing product recommended for the reprocessing step concerned
- ✓ Compatibility of the detergent solution used and the hardness of the water
- ✓ Right dosage
- ✓ Sufficient soaking time
- ✓ Adequate brushing
- ✓ Adequate rinsing (water quality/quantity)
- ✓ New instruments treated separately
- ✓ Compliance with manufacturer's instructions
- ✓ Adequate loading in mechanical washers
- ✓ Appropriate wash cycle
- ✓ Good maintenance of mechanical washers (e.g. clean the washer filter, ensure that nozzles are not blocked, check the detergent dispensing system etc.)
- ✓ Compliant cleaning tests

Verification of sterilizer maintenance procedures

- ✓ Sterilizer maintenance carried out by user (e.g. clean the filter, ensure the inner chamber is clean, etc.)
- ✓ Preventive sterilizer maintenance carried out by the assigned department in accordance with the contract

Appendix 4 – Decision tree – Presence of water



[1] MDRU: medical device reprocessing unit.

[2] TS: Technical Services.

* See detailed verification steps on the next page and in Appendix 2.

** See the definition in section 4.2 of this document.

Detailed verification steps

Verification of the loading procedure

- ✓ Packaging system (material or container) designed for sterilization
- ✓ Good configuration and content of device sets and loads
- ✓ Appropriate drying time according to the following criteria:
  - ✓ Size and type of packages
  - ✓ Size and type of sterilizer load
  - ✓ Sterilizer characteristics
- ✓ Compliance with manufacturer's instructions on packaging (envelope and absorbent cloth) and the sterilizer
- ✓ Significant change in packaging or load configuration

Verification of unloading procedure

- ✓ Suitable sterilization process
- ✓ Appropriate load cooling period depending on pack size and type

Verification of environmental conditions

- ✓ Proper air temperature for cooling sterilization loads
- ✓ Appropriate location of loads to be cooled (not above a ventilation grid)

Quality of Steam Used in Medical Device Reprocessing

AUTHORS

Centre d'expertise en retraitement des dispositifs médicaux
Direction des risques biologiques
Institut national de santé publique du Québec

Caroline Poirot, Biomedical Engineer
Groupe Biomédical Montérégie, Centre intégré de santé et de services sociaux de la Montérégie-Centre

(Version 2.0)
Valérie Cortin, Senior Scientific Advisor
Andrée Pelletier, Nursing Advisor
Vanessa Molloy Simard, Scientific Advisor
Direction des risques biologiques
Institut national de santé publique du Québec

IN COOPERATION WITH

Valérie Lapierre, Nursing Advisor (Version 2.0)
Caroline Bernier, Scientific Advisor (Version 1.0)
Direction des risques biologiques
Institut national de santé publique du Québec

Martin Kirouac, Biomedical Technology Consultant (Version 1.0)
Groupe Biomédical Montérégie, Centre intégré de santé et de services sociaux de la Montérégie-Centre

Richard Marchand, Microbiologist Infectious Disease Specialist
Institut de cardiologie de Montréal

Caroline Huot, Medical Officer
Direction de la santé environnementale, au travail et de la toxicologie
Institut national de santé publique du Québec

REVIEWERS

March 2021 (1.0) Version:

The reviewers were asked for their input on the pre-final version of this advisory and therefore did not review or endorse its final content.

Gnahoua Zoabli, Member of the Association des physiciens et ingénieurs biomédicaux du Québec (APIBQ)

Mélissa Giroux, Chair
Association québécoise en retraitement des dispositifs médicaux (AQRDM)

Philippe Laporte, Coordinator
Groupe Biomédical Montérégie, CISSS de la Montérégie-Centre

READING COMMITTEE

March 2021 (1.0) Version:

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

Mélanie Fortier, Biomedical Technologies Advisor
Groupe Biomédical Montérégie, Centre intégré de santé et de services sociaux de la Montérégie-Centre

Raymond Lach, President and Founder
Maxi-Therm Inc.

Steve Picard, Coordinator
Opérations des bâtiments par Direction des services techniques
Centre hospitalier universitaire de Québec – Université Laval

Marcello Manocchio (Version 2.0), Chemist, Scientific Advisor
Laboratoire de santé publique du Québec
Institut national de santé publique du Québec

UNDER THE SUPERVISION OF

Valérie Cortin, Professional Coordination

Anne Kimpton, Scientific Unit Head
Direction des risques biologiques

DECLARATIONS OF CONFLICT OF INTEREST

The authors together with the collaborators and the reviewers have duly completed their declarations of conflict of interest and no situations at risk of real, apparent, or potential conflicts of interest were found.

LAYOUT

Judith Degla, Administrative Assistant
Direction des risques biologiques

ENGLISH TRANSLATION

Alison McGain, Professional Translator

Vanessa Molloy Simard, Scientific Advisor
Direction des risques biologiques
Institut national de santé publique du Québec

Caroline Poirot, Biomedical Engineer
Marjorie Riopel-Methot, Mechanical Engineer
Groupe Biomédical Montérégie, Centre intégré de santé et de services sociaux de la Montérégie-Centre

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