

Thermo Diagnostics Company LLC www.thermo-diagnostics.com

Steam Quality Testing - Frequency

AAMI/ANSI ST79 (2017) "Comprehensive guide to steam sterilization and sterility assurance in health care facilities"

How often are facilities supposed to test steam quality? Here is what the Standard says:

- upon installation or relocation of the sterilizer
- after any change to the steam distribution lines or boiler supply water
- when investigating sterilization process failures
- when periodically assessing sterilization loads for wet packs

Here are the relevant sections:

3.3.3.2 Steam quality

Facility engineering personnel should ensure steam quality by

- a) monitoring, controlling, and documenting the process of generating steam;
- b) testing steam against the following critical variables:
- steam dryness between 97% and 100%,

• noncondensable gases (e.g., air) at a level (less than 3.5% v/v condensate) that will not impairsteam penetration into sterilization loads,

• superheat of steam (expressed as a temperature in degrees above saturation point) of less than 25°C (77°F);

c) maintaining steam traps and boilers/generators; and

d) assessing and documenting the steam quality upon installation or relocation of the sterilizer and after any change to the steam distribution lines or boiler supply water.

Table 4—Potential causes to be investigated for steam sterilization process failures

Sterilizer or utility malfunctions

Poor steam quality or quantity

Wet steam

- Improper insulation of steam lines
- Malfunction of trap in steam line or no trap in steam line
- Malfunction of drain check valve or no drain check valve
- Steam contact with a cold load
- Too much water in steam produced at boiler
- Superheated steam
- Improper come-up of chamber
- Desiccated packaging materials (e.g., towels)
- Steam pressure too low for the temperature
- Excessive reduction of steam pressure too close to sterilizer
- Faulty steam control valve or pressure reducer control valve
- Other steam problems
- Variations in steam pressure because of clogged filter, poorly engineered piping, or excessive demands
- Out-of-calibration pressure gauges and controllers
- Clogged steam lines
- Clogged steam supply strainer
- Clogged chamber drain line, strainer, or chamber drain screen
- Malfunction of valves

Annex L

(informative)

Steam quality

L.1 Introduction

This Annex provides guidelines on how to achieve and maintain adequate steam quality for steam sterilization processes.

L.2 General considerations

As recommended in 3.3.3 of the main text, steam systems should be designed to ensure that a continuous and adequate supply of saturated steam is available to the sterilizer. The critical variables are the dryness of the steam, expressed as a dryness fraction, and the level of noncondensable gas (such as air), expressed as a fraction by volume. Steam dryness should be at a value between 97% and 100%, and the level of noncondensable gas should be at a level at which it will not impair steam penetration into sterilization loads.

Steam pipework should be insulated, and it should be designed so that any condensate flows by gravity in the same direction as the steam, except for vertical rises between floors. This general principle applies equally to steam mains, branch connections, and pipework on the sterilizer itself, especially in situations where the steam is generated in a location remotely located from the sterilizer. Air vents and steam traps should be fitted at each vertical rise. Care should be taken to trap, drain, and return any condensate that could be collected in pockets in the pipework. Dead legs should be avoided. (A "dead leg" is a section of pipe that leads nowhere and does not form part of a constant circulation system; in a steam line, condensate can form in a dead leg and become stagnant.) Branch steam lines should exist from the top of the main lines to reduce condensate carryover. The accumulation of condensate during the periods when the sterilizer is not in operation should be avoided, particularly in any part of the pipework and fittings between the take-off from the manifold and the sterilizer chamber. This can be achieved by the correct declination of each portion of pipework and by adequate trapping throughout the steam distribution system. At installation, an assessment of the steam quality should be made and documented. Steam quality should be maintained by monitoring and controlling the process of generating steam; maintaining steam traps, boilers, and generators in good working order; and periodically assessing sterilization loads for wet packs. In some circumstances, a steam separator may be used to remove entrained water and increase the degree of steam saturation.