

Update Decontamination Standards & Guidelines 2011

Key Elements AAMI ST 79¹

AAMI realized that the efficacy of any sterilization process, including saturated steam, depends on a consistent system for *lowering and limiting bio-burden before sterilization*. AAMI supports the verification of the cleaning process.

Section 7.5.2.2

“...Many types of soil could be present on reusable medical devices, but **dried blood is especially difficult to remove**. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a significant challenge to cleaning. It must be rehydrated and then washed away. Blood adheres to surfaces through mechanical and chemical means. Fibrin filaments in coagulated blood pack themselves into microscopic irregularities in the surface of instruments and have to be mechanically scrubbed away or chemically treated....”

Section 7.5.3.3

“...Mechanical cleaning equipment should be **tested upon installation, weekly (preferably daily) during routine use**, and after major repairs. A major repair is a repair that is outside the scope of routine preventive maintenance and that significantly affects the performance of the equipment. Examples include replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, or computer control or an upgrade to software..”

Section 7.5.5

“...Sterile processing personnel are increasingly aware of the need to control and standardize the steps taken to ensure the sterility of devices for patient use. ***Because disinfection and sterilization cannot be assured unless the cleaning process is successful, professionals in the field ought to seek out whatever means are available and practical to verify this function.*** A quality system would call for monitoring and documenting decontamination processing parameters, whether the process is accomplished by hand or mechanically....”

Section D.1

“...Organic soil such as blood, serum, lipids, tissue fragments, and inorganic salts can impede the disinfection or sterilization process if it is not removed during cleaning...”

Section 10.2 and ANNEX D

“...Health care personnel may perform verification tests as part of the overall quality assurance program. This verification may include the use of test devices that monitor the functionality of the cleaning equipment in cleaning surfaces and that ensure adequate fluid flow in equipment that has adaptors for lumened devices...”

ANNEX D

“...***Organic soil such as blood***, serum, lipids, tissue fragments, and inorganic salts ***can impede the disinfection or sterilization process*** if it ***is not removed during cleaning***. Most of these soil components are substrates for the sterilants used for disinfection or sterilization; that is, they are competitors for sterilant action. If these soil components are insufficiently removed, they can also protect microorganisms from inactivation by limiting the diffusion of the sterilant to the microorganisms' location on the medical device....***Coagulated blood test. Metal coupon with strip of coagulated blood soil. After cleaning, visually inspect with comparison to chart to confirm removal of soil. A lumen version is available for testing.*** Blood and protein; detected as visible red (blood) or visible “film” (fibrin,protein) ... Valuable as a quality assurance indicator for functionality of washer-disinfector”

AORN²

The 2008 AORN RP for Cleaning and Care of Surgical Instruments and Powered Equipment Recommendation XXII – Quality section is now supporting the testing of mechanical instrument washers before initial use, weekly during service, and after major maintenance.

TJC³

In standard E.C.6.20 it states that medical equipment is maintained, tested and inspected

FDA⁴

The FDA, AAMI and other regulatory bodies recommend that **any simulated-use testing be done with a surrogate device that closely approximates the actual types of soils the instrument is to be exposed to in clinical use**. Further, the surrogate device should be made of the same type of material as the instrument it represents.

Healthmark⁵

Healthmark is the only company with comprehensive tests for this purpose - tests to measure water temperature, water quality, cleaning efficiency, and directly test residual soil on instruments- the TOSI: dried blood soil on a stainless coupon is directly analogous to dried blood on a stainless instrument.

This document summarizes AAMI, AORN, JCAHO standards and guidelines. Please note that AAMI, AORN, TJC are copyright material, to read the complete text of these standards go to their web site and purchase the actual standards and guidelines.

¹ AAMI ST 79:2009A;www.aami.org

² Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment 2008; www.aorn.org

³ www.jcaho.org

⁴ <http://www.artificialtestsoil.com/FDAreferencePage.htm>

⁵ <http://www.healthmark.info/proformance.html>