Steam Sterilization Validation for Healthcare Institutions

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Introduction

- This presentation will give an overview of the development of on-site validation and verification for Central Sterile Processing Departments in the US as defined by the US National Standard, ANSI/AAMI ST79, “Comprehensive guide to steam sterilization and sterility assurance in health care facilities”
- Areas to be discussed are:
  - Cleaning,
  - Sterilization, and
  - Environmental Monitoring

Overview

- Global Regulatory Perspective
- Short History of ST79
- Basic Premise of Verification/Validation in ST79
- Specific Areas
  - Cleaning
  - Sterilization
  - Environmental Monitoring

Global Viewpoint: Cleaning

- Standards that apply to cleaning:

Country/ Continent	Standard	Applicability
World	ISO 15883 series	Requirements for washing/disinfection machinery; methods to test cleaning performance
World	ISO 17664:2004	Instructions for reprocessing
Japan	JIS T7329:2008	Washer sterilizers for medical use
Japan	JIS Z 2801	How to test for antimicrobial efficacy (applicable to washer disinfectors)
USA	AAMI ST81	Instructions for reprocessing
USA	FDA Guidance 2002	Guidance Document: Medical Washers and Medical Washer-Disinfectors
USA	AAMI ST79	How to clean instruments in a healthcare institution

Global Viewpoint: Sterilization

- The standards that apply to steam sterilization vary from country to country or continent to continent

Country/ Continent	Standard	Applicability
World	ISO 17665-1:2006	Development, validation, and routine control of a steam sterilization process
World	ISO 17664:2004	Instruction for reprocessing
Japan	JIS T 0816-1:2010	Development, validation, and routine control of a steam sterilization process
Japan	JIS Z 2801	How to test for antimicrobial efficacy
Europe	EN285	How to build and validate a steam sterilizer
USA	AAMI ST8	How to build and validate a steam sterilizer
USA	AAMI ST79	How to steam sterilize in a healthcare institution

History of ST79

- First published in 2006
- Updated on a continuing basis
- Major revision in 2010
- Another major revision is in the works now

Scope of ST79

- **Section 1.1, General**
  - This recommended practice provides guidelines for decontamination and steam sterilization processing in hospitals and other health care facilities. These guidelines are intended to promote sterility assurance and to assist health care personnel in the proper use of processing equipment

Scope of ST79, Continued

- **Section 1.2 Inclusions**
  - a) functional and physical design criteria for sterilization processing areas;
  - b) staff qualifications, education, and other personnel considerations;
  - c) processing recommendations;
  - d) installation, care, and maintenance of steam sterilizers;
  - e) quality control; and
  - f) quality process improvement

Basic Premise of Verification and Validation in ST79

- **Definitions from AAMI/ISO TS11139**
  - **Validation**
    - documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.
  - **Verification**
    - confirmation through the provision of objective evidence, that specified requirements have been fulfilled.
  - In either case, document, document, document!

Cleaning Verification

- Section 7.5.5 of ST79 discusses the need to verify cleaning
  - Visual inspection, including the use of a magnifier if available
  - Measurement of residual soil/protein as possible
- Water quality is a critical parameter in cleaning, and defined in the related standard, TIR 34

Verification of Function of Mechanical Cleaning Equipment

- In section 10.2, there is a requirement to monitor the proper function of automated washers, specifically:
  - Residual soil testing
  - Test against standardized test methods to ensure expected outcomes
  - Measure key parameters to ensure function
  - Flow through lumen connections

Verification Techniques

- Annex D discusses a number of ways to verify cleaning
  - This includes providing documented procedures for the CSSD staff
  - Providing process controls to allow measurement of the effectiveness of cleaning
    - These process controls generally consist of purchased items, such as TOSI, Verify All Clean, Wash-Checks, SonoCheck, LumCheck, etc.
    - Residual ATP testing is also a popular approach

Sterilization Verification

- Section 10.4 requires:
  - monitoring of every package and sterilization load
  - routine monitoring of sterilizer efficacy
  - qualification testing of the sterilizer after installation, relocation, sterilizer malfunction, major repairs, and sterilization process failures, and
  - periodic product quality assurance testing

These are discussed in the next few slides, but first, a few notes on chemical indicators

Chemical Indicators Used in Monitoring Healthcare Steam Sterilization

- There are four types of chemical indicators used
  - Type 1-process indicator, used in labels or tape on the outside of the load
  - Type 4 or 5-process integrator, used internal to the load; these are supposed to mimic the response of a biological indicator
  - Type 6-process emulator, used internal to the load instead of an integrator; these are designed not to change unless the entire cycle up to the end of steam exposure has run correctly
  - Bowie-Dick-air removal/steam penetration test. Not a sterilization indicator, but a sterilizer function test

Monitoring of Every Package and Sterilization Load: No Implants

- Physical monitoring of cycle
- External and internal chemical indicator monitoring of packages
- Optional monitoring of the load with a Process Challenge Device (PCD) containing:
  - a Biological Indicator (BI)
  - a BI and a Type 5 integrating indicator
  - a Type 5 integrating indicator
  - a Type 6 emulating indicator

Monitoring of Every Package and Sterilization Load: Implants

- Physical monitoring of cycle
- External and internal chemical indicator monitoring of packages
- Required monitoring of the load with a Process Challenge Device containing:
  - a Biological Indicator and a Type 5 integrating indicator

Routine Sterilizer Efficacy Monitoring

- Physical monitoring of cycle
- External and internal chemical indicator monitoring of packages
- Weekly, preferably daily monitoring with a PCD containing a BI (The PCD may also contain a CI)
- Monitoring is done in a fully loaded chamber.
- In IUSS cycles, monitoring is done in an empty chamber.
- For dynamic-air-removal sterilizers, daily Bowie-Dick testing in an empty chamber

Sterilizer (Re)qualification Testing

- After installation, relocation, malfunctions, major repairs, sterilization process failures
  - Physical monitoring of cycle
  - External and internal chemical indicator monitoring of packages
  - Monitoring of three consecutive cycles in an empty chamber with a PCD containing a BI. (The PCD may also contain a CI.)
  - For dynamic-air-removal sterilizers, monitoring of three consecutive cycles in an empty chamber with a Bowie-Dick test pack

Periodic Product Quality Assurance Testing

- Physical monitoring of cycle
- Placement of BIs and CIs within product test samples

Steam Quality

- Steam quality has been called “The last unknown in steam sterilization”
- It isn’t unknown if you conform to EN 285
- It is become a real issue for consideration in the US through Annex M of ST79
- Three aspects:
  - Steam dryness
  - Non-condensable gases
  - Superheat

Environmental Monitoring

- There are three major aspects of environmental monitoring discussed in ST79
  - Lighting levels
  - Differential pressure
  - Temperature and Humidity

Lighting

Work Area/Function	Minimum/Average/ Maximum (Lux)
General inspection	500/750/1000
Detailed inspection	1000/1500/2000
Sink areas	500/750/1000
General work areas	200/300/500
Processed goods storage	200/300/500

Differential Pressure/Airflow

- Airflow is used to minimize recontamination of items that have been cleaned or sterilized.

Area	Airflow	Air changes/ hour	Air exhausted to outdoors?
Soiled/ Decontamination	Negative (in)	10	Yes
Sterilizer Equipment Access	Negative (in)	10	Yes
Sterilizer load/unload	Positive (out)	10	Yes
Restrooms/ housekeeping	Negative (in)	10	Yes
Preparation and packaging	Positive (out)	10, down draft	No
Textile pack room	Positive (out)	10, down draft	No
Clean/sterile storage	Positive (out)	4, down draft	No

Temperature and Humidity

- Workplace temperature and humidity are important parameters in maintaining sterility and keeping staff comfortable.
- Recommended ranges are:
  - Temperature: 20-23°C, except in decontamination, where it should be 16-18°C
  - Humidity: 30-60% RH, up to 70% in sterile storage
- Levels should be recorded at least once a day.

Summary

- Validation is not done in US healthcare institutions
- Verification is, and there are a large number of areas defined in ST79 that bring together the technical aspects of how cleaning, sterilization and environmental controls work with the knowledge of the best sterile processing minds in the US to provide guidance that will help create good patient outcomes

Thank you for your interest!

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