The Significance of Validation to US CSSD Managers

Jonathan A. Wilder, Ph.D.

President, H & W Technology, LLC/Stericert Co.

Managing Director, Quality Processing Resource Group, LLC

Introduction

- This presentation contrasts on-site verification based upon:
  - ANSI/AAMI ST79, “Comprehensive guide to steam sterilization and sterility assurance in health care facilities”
- Complete validation per:
  - ISO 17665-1, “Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices”

  and
  - ISO 15883-1, “Washer-disinfectors — Part 1: General requirements, terms and definitions and tests
- And the current state of acceptance of these in the US CSSD.

Overview

- US Regulatory Perspective
- Basic Premises of Verification/Validation
  - in ST79
  - in ISO 17665-1
  - in ISO 15883-1
- Validation of Critical Process Parameters (IQ, OQ, PQ)

US Standards: Cleaning

- Standards that apply to cleaning:

Standard	Applicability
AAMI ST81	Instructions for reprocessing
FDA Guidance 2002	Guidance Document: Medical Washers and Medical Washer-Disinfectors
AAMI ST79	How to clean instruments in a healthcare institution
ANSI/AAMI ST15883-1: 2009/(R)2014	Washer-disinfectors — Part 1: General requirements, terms and definitions, and tests

US Standards: Sterilization

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

Standard	Applicability
ISO 17665-1:2006	Development, validation, and routine control of a steam sterilization process
AAMI ST8	How to build and validate a steam sterilizer
AAMI ST79	How to steam sterilize in a healthcare institution

Premise of ST79

- Basic premise: To provide guidance to healthcare institutions on how to ensure that FDA-cleared equipment maintains its function at the required levels
- It is a document for users, not manufacturers
  - Qualification testing is limited to surrogate load items, and is not a complete qualification test

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 ISO 17665-1

- **1 Scope**
- **1.1 Inclusions**
- **1.1.1** This part of ISO 17665 specifies requirements for the development, validation, and routine control of a moist heat sterilization process for medical devices.

Scope of ISO 15883-1

- 1 Scope
- This part of ISO 15883 specifies general performance requirements for washer-disinfectors (WD) and their accessories that are intended to be used for cleaning and disinfection of re-usable medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice. It specifies performance requirements for cleaning and disinfection as well as for the accessories which can be required to achieve the necessary performance. The methods and instrumentation required for validation and re-validation, after essential repairs, are also specified.

Differences Between ST79 and the ISO documents

- ST79 requires verification of machine performance after installation, major repair or process failure
- ISO documents require validation of performance before the machine is released to the market, after installation or repair, and when new loads with different challenges are introduced

In short…

- ST79 is about verification of a machine that is generally trusted, and
- The ISO documents are about validation of a machine assuming nothing about its capabilities

- Note also that the American version of ISO 15883-1 removes the requirement for routine control and monitoring and periodic revalidation of the washer.
- ST79 adds it back in (section 10.2, annex D)

Validation and Verification

- **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!

Comparison of Verification and Validation

- Validation assumes nothing and checks everything to ensure that the sterilizer is capable of doing what is needed and does it.
- Verification assumes that things are being done correctly and is only a check for failure due to installation, repair, process failure…

Do US CSSD Managers Validate?

- No.
- This is a task they farm out to the manufacturers, installers, consultants
- Reporting of installation/operational/ performance qualification is varied and not always done
  - And the managers do not know that they should have this information or have the right to it

Do US CSSD Managers Understand the Value of Validation?

- Some do. Some do not.
- The ISO standards are seen as manufacturer's standards, not user standards
- As ST79 has evolved, it has begun to define proper measurement of baseline performance when the machine is newly installed
  - Without knowledge of the baseline, it is impossible to know if a machine is unreliable, or just "unhappy" where it is due to marginal utilities

ISO Machine Validation

- Due to the FDA clearance process, under ST79, one can assume that the machine is capable of doing what it is claimed to do, and only verification testing is required.
- Under the ISO documents, no assumptions are made, and a complete validation must be carried out.

Validation: What is Tested?

- IQ, OQ, PQ,…
- Requalification
- Load Qualification

Installation Qualification

- IQ: Installation Qualification
  - Tests to prove that the machine is what was ordered, has appropriate components, meets safety requirements, meets requirements of standards for measurement and control.
    - Utilities
    - Manufacture
    - Components
    - Wiring
    - Pump rotation…

Operational Qualification

- OQ: Operational Qualification
  - Tests to demonstrate that the machine can carry out cycles needed for its application, has temperature distribution that meets the requirements of the standards.
    - Process alarm tests
    - Empty-chamber, possibly loaded temperature mapping
    - Vacuum leak test-if prevacuum cycles used (sterilizer)
    - Bowie-Dick test-if prevacuum cycles used (sterilizers)
    - Transducer calibration
    - Self disinfection cycle testing (washer/disinfectors)

Performance Qualification: Sterilizer

- PQ: Performance Qualification
  - Tests to prove that either specific or worst-case loads are rendered sterile in a sterilization half cycle.
    - Use of at least 10 biological indicators in the load
  - Requires temperature mapping of the load at the locations of the biological indicators and in the sterilizer control position.
    - Biological testing
    - Thermal profiling

Performance Qualification: Washer/Disinfector

- Tests to show that all surfaces and instruments in a washer are cleaned to a predetermined level
- Tests of disinfection for thermal or liquid chemical disinfectants, at least ten locations
- Self disinfection tests

Load Qualification and Requalification

- Load Qualification: Testing with specific worst-case loads for proper cycle execution and cleaning or sterilization outcomes
- Requalification: Periodic requalification of the machines involving a repeat of IQ, OQ, PQ

Current Situation

- ST79 is beginning to advocate for limited validation of machinery after installation beyond the minimal testing that is currently required
- CSSD managers are beginning to see the value of proper baseline measurements of the performance of their machinery
- The AAMI Benchmarking program is a force that provides some feedback that points to a greater reliance on validation

Which Validation Activities are Being Done?

- These are not really full validations, but…
  - Washer testing with commercial indicators and, sometimes, inoculated Crile Clamps per the German standards
  - Sterilizer temperature profile testing
  - Opinion leaders are doing these as they discover that the testing is available

Data Analysis Methodology

- Qualitative, visual measures of cleaning must be ranked to compare them to a quantitative method.

Ranking	Clamp Visual	TOSI	WashChecks	Verify All Clean
0	Clean	Clean	Clean	Clean
1	One fleck of blood remaining in box lock	Small residual clear protein	Light tint	Trace
2	Flecks of blood remaining in box lock	Large residual clear protein, <10% of surface red	Noticeable tint	Small residual, one side of indicator
3	Spot of blood remaining in box lock	10-30% of surface red	Splotch of original color	Small residual, both sides of indicator
4	Large spot of blood remaining in box lock	30-80% of surface red	Mostly untouched	Large residual, both sides of indicator
5	Untouched	Mostly untouched	Untouched	Untouched

Results: Machine A, high and low temperature cycles

	High-Temperature (69-74°C) Cycles					Low-Temperature (45°C) Cycles				
Parameter	Clamp Residual µg protein	Clamp Visual	Indicator A	Indicator B	Indicator C	Clamp Residual µg protein	Clamp Visual	Indicator A	Indicator B	Indicator C
Average	171.9	1.5	1.8	0.0	1.6	42.7	0.4	0.5	0.0	1.9
Standard Deviation	140.9	1.2	1.2	0.0	1.7	39.9	0.6	0.8	0.0	1.4
Correlation to Clamp Data		0.5	0.1	N/A	-0.3		-0.1	0.3	N/A	0.2

Why are Validations Not Done?

- Ignorance of what can be done and the benefit of doing it
- Dependence on the FDA to ensure proper function of a machine through the 510(k) program
- Lack of technical acumen and training on the part of sterile processing managers
  - They are managers, not engineers or scientists. They don't know what they don't know.

Summary

- Validation is the creation of a baseline of performance of the sterilizer or washer.
- Verification is making sure that it still works.
- Without both being done on a regular basis, the outcomes of sterilization will not be what you need and expect.
- The US CSSD is not a center of validation activity. Yet.
- But it appears to be on the rise.

Thank you for your interest!

- Contact info:

- Jonathan A. Wilder
- +1-585-329-9939
- info@stericert.com or jwilder@qprgllc.com