CHL Self-Study Lesson Plan
Lesson No. CHL 357 (Supervisory Continuing Education - SCE)

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Periodic Device Testing: A Vital Part of Equipment Performance Qualifications

LEARNING OBJECTIVE

1. Identify industry standards and resources that support periodic device testing for steam sterilization, and learn factors that contribute to moisture events
2. Explain the methods and attributes used to identify product families
3. Demonstrate how documentation supports equipment performance qualifications as a part of good quality management systems
4. Learn how the use of checklists can prevent process missteps and support a periodic device testing program

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HEALTHCARE FACILITIES ACROSS THE COUNTRY ARE PROCESSING millions of surgical instruments and medical devices daily. As a result, Central Service (CS)/Sterile Processing leaders are responsible for a number of processes or steps that go into processing these devices.

CS leaders must ask whether their department's processes support next steps, or whether their processes are fragmented and do not meet next step specifications. They must also ask whether processing of reusable medical devices is a function that is taken for granted. In most cases, this is probably not the case; however, if the team does not make use of quality management systems, they are more than likely missing a much greater opportunity. CS leaders must also ask how well their department manages risk in support of patient safety.

OBJECTIVE 1: IDENTIFY INDUSTRY STANDARDS AND RESOURCES THAT SUPPORT PERIODIC DEVICE TESTING FOR STEAM STERILIZATION, AND LEARN FACTORS THAT CONTRIBUTE TO MOISTURE EVENTS

The International Association of Healthcare Central Service Materiel Management's (IAHCSMM's) Central Service Leadership Manual speaks to technical essentials in steam sterilization and is in harmony with current Association of periOperative Registered Nurses (AORN) guidelines and Association for the Advancement of Medical Instrumentation (AAMI) standards.[1] Industry standards and professional guidelines should be required reading for all essential personnel who perform device processing and speak to and support safe device processing. ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, supports periodic device testing for steam sterilization. The standard defines installation qualification (IQ) as a process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification; operational qualification (OQ) as a process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures; and performance qualification (PQ) as a process of obtaining and documenting evidence that the equipment, as installed and operated according to operational procedures, consistently performs in accordance with predetermined criteria and, thereby, yields a product meeting its specification.

ANSI/AAMI ST79 further recommends that facilities have a quality system model in place for reprocessing medical devices in healthcare facilities – a validated system in which the sterilizer manufacturer and appropriate representatives of the healthcare facility

conduct installation and operational qualification. In addition, the individual medical device manufacturer, the manufacturer of the packaging (wrap, container or pouch) and the sterilizer manufacturer recommend validated means of sterilizing the specific devices to be reprocessed, in lieu of a formal performance qualification.[2]

MANAGING MOISTURE EVENTS

Wet packs can occur in all sizes and models of steam sterilizers. When the boiler, steam delivery system, sterilizer performance, sterilization process, load content and tray configuration, and clinical practice all work in harmony and support the overall process, one can expect that will contribute to quality patient care. When wet packs do occur, it is often assumed to be a clinical practice issue associated with improper load content and tray configuration; however, it is hypothesized that a lack of sufficient documentation supporting periodic device testing (again, as recommended in ANSI/AAMI ST79) correlates to increased moisture events. In other words, CS departments rarely verify that their particular clinical practices, tray configuration and load content are effective in producing sterile, dry sets.

Recent history shows there is a need to be vigilant and consistently committed toward working with and educating healthcare professionals, clinicians and technicians. Recommendations should support an unbiased eye that occasionally checks on technical processes leading up to steam sterilization. CS leaders and their teams should also be reminded of ever-changing industry standards and the importance of updating current policies and procedures to reflect those changes. Ensuring all requirements are met, consistently providing products that meet requirements, and confirming that staff understand and are in control of processes are all critical steps.

OBJECTIVE 2: EXPLAIN THE METHODS AND ATTRIBUTES USED TO IDENTIFY PRODUCT FAMILIES

ANSI/AAMI ST79, specifically, Section 10 Quality Control, Part 10.9, speaks to periodic product quality assurance testing of routinely processed items. Unfortunately, this section does not provide great detail on how to perform that testing. A little-known document that supports periodic testing is ANSI/AAMI/ISO TIR 17665-3, *Sterilization of health care products - Moist heat - Part 3: Guidance on the designation of a medical device to a product family and processing category*. The general scope of the document provides guidance for the attributes (characteristics) of a medical device that should be considered by the user when assigning a medical device to a product family (for the purpose of identifying and aligning it to a processing category for a specific moist heat sterilization process). There are 28 device families described in this document. General attributes include: Material, weight, design, sterile barrier system and/or packaging system.[3]

Table 1 - Attribute	Code
Design	(a)
Weight	(b)
Material	(c)
Sterile barrier system	(d)

Figure 1 – General Attributes

DESIGN

ANSI/AAMI/ISO TIR 17665-3 speaks to the complex and nature of materials that are used to construct medical devices. Materials used in the manufacturing of sterile barrier systems and/or packaging systems, and the combinations of different medical devices in procedure sets, for example, can adversely affect conductivity, air removal and moist heat penetration. This can result in a failure in obtaining the required sterility assurance level. The classification of a medical device into a product family can assist with the development of moist heat sterilization process conditions for the medical device. Assigning a medical device to a particular product family is the first stage of performance qualification at the point of use, as specified in ISO 17665-1 and ISO 17665-2. The efficacy of sterilization for a medical device (using the sterilization process for that product family) should be assessed and documented together with any pretreatments, such as cleaning and disinfection to reduce bioburden, and lubrication and humidification of some materials (e.g., Those containing cellulose).[3]

In ANSI/AAMI/ISO TIR17665-3, the attributes that relate to efficient sterilization are used to identify a product family has been selected from operational experience, engineering considerations and experimental data. This information relates to efficacy of the different types of moist heat sterilizers and their sterilization processes, and the types and design of differing medical devices and sterile barrier systems and/or packaging systems. Medical devices labeled by the manufacturer as capable of being sterilized via moist heat may be categorized into product families by users.[4]

Not all medical devices, however, will fit into one of the product families described in ISO 17665. In these cases, new product families will need to be identified based on the consideration of the products attributes; they will also require additional performance qualification.

Medical devices that have been classified into different product families are often processed in the same sterilization load when assembled in randomly-selected load configurations.

MD	Attribute																Steam penetration resistance (estimated)							
PF	Design (a)								Material (b)		Weight (c)				Sterile barrier system and/or packaging system (d)				(e)							
	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7	+
1	X								X		X	X	X		X				X							
2	X								X					X	X					X						
3	X									X	X	X	X		X					X						
4	X									X				X	X						X					
5	X								X				X			X				X						
6	X									X	X	X					X	X			X					
7	X									X			X	X		X	X	X				X				
8			X						X		X	X			X	X	X	X			X					
9			X						X				X	X	X	X	X	X				X				
10			X							X	X	X			X						X					
11			X							X	X	X				X	X	X				X				
12			X							X			X	X		X	X	X					X			
13				X						X	X				X	X					X					
14				X						X	X						X	X				X				
15				X						X		X	X	X			X						X			
16		X							X		X				X					X						
17		X							X		X						X	X			X					
18		X								X	X				X					X						
19		X								X	X					X	X	X			X					
20					X				X		X				X							X				
21					X				X		X	X				X	X	X					X			
22					X					X	X	X			X								X			
23					X				X				X	X		X	X	X					X			
24					X					X	X	X				X	X	X					X			
25					X					X			X	X		X	X	X					X			
26						X			X	X			X	X		X	X	X						X		
27						X			X			X	X		X	X	X	X					X			
28						X				X		X			X	X	X	X						X		
29[a]							X		X	X															X	
+																										

[a] Special – sterilization process should be developed and qualified.
+ New product families that may be identified by the user.

Figure 1 Medical Device Product Family Table

This approach is common in healthcare facilities where it is generally not feasible to qualify each sterilization load. This is an acceptable practice, as long as the sterilization process and sterilizer are capable of sterilizing the range of product families in the sterilization load.

Note: Care should be taken to ensure that the combination of product families does not create a greater challenge than that set by individual product families.

MASTER PRODUCT – Medical device or procedure set used to represent the most difficult-to-sterilize item in a product family or processing category.

PROCESSING CATEGORY – Collection of different products or product families that can be sterilized together.

Each medical device, whether new or modified, should be classified using the general attributes listed. Some combinations of physical characteristics may cause an unpredictable, adverse change to the steam penetration resistance; this can lead to an underestimation of the difficult-to-sterilize item. In such situations, performance qualification should always be performed.

Some attributes will be specialized by the manufacturer of the medical device, and others by the user. The manufacturer of a medical device will usually specify the attributes needed by the user to assess its steam penetration resistance and to select a processing category for a specific sterilizer and sterilization process. Both the resistance and the category should be reassessed when the medical device is to be combined with others in a sterile barrier system and/or packaging system.

The sterilization process should be qualified to verify that the required lethality will be delivered to all medical devices processed together.

WEIGHT

The weight of a medical device (or part of a medical device, if processed separately), or for a collection of medical devices grouped into a single sterile barrier system and/or packaging system, should be assigned to one of the codes indicated. This information may be required when judging heat-up time; cooling time/drying time; exposure time in a mixed-weight sterilizer load; stability of a single or composite construction material; and amount of condensate and its effect on steam penetration.

MATERIAL

The materials used to manufacture a medical device will be metallic, nonmetallic or a combination of both. Typically, metallic materials will have a high thermal conductivity, and non-metals will have low thermal conductivity. Materials with low thermal conductivity exhibit higher temperature differences throughout the material when compared to materials with high thermal conductivity. Both types of materials present challenges to the sterilization process. The moisture content of the material may also influence the heat transfer into the product. This should be taken into account during performance qualification, with the material in its most

challenging state.

When compared to materials with low thermal conductivity, materials with high thermal conductivity and equal heat capacity will initially generate more condensate in a given time period. It will also absorb and release energy faster, and more quickly attain a state of equilibrium.

STERILE BARRIER SYSTEM

Except when a medical device is to be presented aseptically immediately after being reprocessed, the device will be contained in a sterile barrier system and/or packaging system prior to being sterilized. When establishing steam penetration resistance and moisture retention for a medical device or a collection of medical devices, the influence on the combined steam penetration resistance caused by the system and materials used in its construction should be known. Information on the intended use of sterile barrier systems will be available from the manufacturer.

OBJECTIVE 3: DEMONSTRATE HOW DOCUMENTATION SUPPORTS EQUIPMENT PERFORMANCE QUALIFICATIONS AS PARTOF A GOOD QUALITY MANAGEMENT SYSTEM

Documentation is essential; without legible documentation, one cannot verify that processes are successfully completed. Training and education should include equipment inservicing, checklists, and operator competency, as well as documentation to identify team members' knowledge at each level. A similar level of training and competency verification, as well as product compatibility, should also apply to sterility assurance products used to support sterilization equipment.

Devices to be processed should have their manufacturer's Instructions for Use (IFU) reviewed for identity of special cycles and medical device compatibility, as well as documentation that verifies specific product and device testing was performed.

Performance qualification is a critical part of the total equipment installation process; however, it is often overlooked or misunderstood by healthcare professionals. Installation and operation qualifications should be performed and signed off by the installation team and/or field service representative completing the installation. Only upon completion and receipt of documentation of these first two steps should the healthcare professional begin performance qualification testing of identified product and device families frequently processed in the CS department and/or location of their new equipment.

Documentation that supports the collection of all relevant facts about the device(s) being processed is essential and should not be taken lightly. CS leaders

Reusable Medical Device Profile

Device Name:	Date Purchased: Month/year	Useful Life Expectancy: Years

Manufacturer #1:		Product #	UDI#
Manufacturer #2:		Product #	UDI#

When completing this worksheet, provide as much information as possible to build a successful profile; a profile that will support your department's quality management system and help to reduce, if not prevent, non-conforming product from reaching the clinical Customer and ultimately the patient.
Identifying two sources for your devices (raw materials) establishes redundancy and a back-up supply in case of delivery delays. It also allows the user to establish those manufacturers with quality systems built into their manufacturing and supporting your department's quality management system.

Part 1: Material Composition

Material Code (a):	1 ☐ Metal	2 ☐ Non-metal
	☐ Stainless Steel	☐ Polymer/plastic
	☐ Brass	☐ Adhesives
	☐ Copper	☐ Glass
	☐ Other	☐ Electronics
Multiple parts:	☐ Yes	☐ No
Comments:		

When completing Part 1: Material Composition of this worksheet, reference the medical device's instruction for use (IFU). If this information cannot be obtained from the IFU you may have to reach out to the manufacturer to help identify the device's material composition. Identifying multiple parts of the device also helps to understand if there are multiple metals or non-metals whereby further appreciating how this effects steam resistance.

Part 2: Device Weight

Weight Code (b):	1 ☐ < 50g. (<1.76 oz.)	2 ☐ 50 - 499g. (1.76-17.60 oz.)	3 ☐ 500 - 1999g. (17.60 - 70.51oz.)	4 ☐ >2000g. (>70.51oz.)
Comments:				

When completing Part 2: Device Weight of this worksheet, reference the medical device's instruction for use (IFU). If this information cannot be obtained from the IFU you may simply purchase a scale that allows measurement in ounces rather than pounds. You will actually need both for establishing weight for your department assembled trays per Customer specifications. It is also suggested keeping a conversion chart on hand as a reference document.

Part 3: Design & Structure

Design/Structure Code (c):	1 ☐ Solid, hallow	4 ☐ Porous	7 ☐ Other
	2 ☐ Pin and box joints	5 ☐ Tubing, moving parts, tortuous path	
	3 ☐ Lumen	6 ☐ Lumen surrounded by a large mass	
Size:	Lumen Length:	Lumen Diameter:	
Comments:			

Work Sheet – Reusable Medical Device Profile – WI Periodic Device Testing Page 1

Figure 2 Reusable Medical Profile Sample Form

Figure 3: Product Device Testing - Load Documentation (Sample)

Date: Saturday, May 2, 2015	**Test Load Configuration:** Sterilizer #02 Load #01
Instrument Load Weight: Approximately 236.8 lbs.	**Class 6 Challenge Pack:** Passed
Exterior Inspection: No visible droplets	**Interior Inspection:** Visible droplets/dampness
Note: Cold load – warm-up 15 minutes in chamber (1:48-2:07)	

Tray A* – 17.7 lbs. Core Case #2 Hip Instr.	Tray B* – 8.4 lbs. Micro Drill (internal moisture droplets noted)	Tray C* – 19.5 lbs. AcetabluarCup (internal moisture droplets noted)	Tray D – 13.1 lbs. Acetabular Grater System	Tray E – 21.2 lbs. Tapered Hip #1
Tray F – 13.5 lbs. Master Retractor Set & Lumbar Retractor	Tray G - ? lbs. Cervical Instr.	Tray A – 17.7 lbs. Core Case #2 Hip Instr.	Tray H* – 18.4 lbs. Tray #3 Instr & Broaches (wrapped) (internal moisture droplets noted)	Tray I – 8.9 lbs. Cordless Driver
Tray J – 27.7 lbs. Abdominal Hysterectomy	Tray K – 9.4 lbs. Micro Laryngoscopy	Tray L* – 21.5 lbs. Tray #3 Instr & Broaches (Vendor Tray) (internal moisture droplets noted)	Tray M – 24.3 lbs. Dental Set	Tray N – 15.5 lbs. Minor Set

Specific Load Comments

Tray B* Micro Drill – droplets found bottom level under silicone mat

Tray C* Acetabular Cup – droplets found on 2nd level in (2) cup areas

Tray H* Tray #3 (wrapped) – bottom level between poly and case small droplets found

Tray L* Tray #3 (Vendor Tray) – droplets found bottom level

**Tray names replaced with letters so not to place focus on a specific vendor. The Sterile Processing Department will use actual nomenclature when documenting their testing results.*

and their staff should plan, review and adjust their documentation according to an established periodic audit schedule.

The sample document in Figure 2, "Reusable Medical Device Profile," promotes a systematic and organized method of recording pertinent information and specifications needed to support device processing steps, in accordance with ANSI/AAMI/ISO TIR17665-3 and ANSI/AAMI ST79.

OBJECTIVE 4: LEARN HOW THE USE OF CHECKLISTS CAN PREVENT PROCESS MISSTEPS AND SUPPORT A PERIODIC DEVICE TESTING PROGRAM

Checklists help prevent healthcare professionals from missing steps in a process. What follows are a few bulleted steps CS leaders should consider when organizing and collecting information to support the department's periodic device testing program:

- Obtain/purchase a copy of ANSI/AAMI ST79 and ANSI/AAMI/ISO TIR17665-3 for the department's reference library.
- Identify and develop a written work instruction (WI) outlining the department's periodic device testing process.
- Identify, obtain/collect and store all original equipment manufacturer IFU for every device processed in the CS department.
- Establish and complete a reusable medical device profile for all devices processed in the CS department.
- Identify and place all reusable medical devices processed in the CS department into product families.
- Identify three master products to be tested from each product family.
- Per ANSI/AAMI ST79, Section 10, place biological and chemical indicators throughout the master product, and test according to established cycles.
- Perform three concurrent successful cycles, and record and document all findings.
- Maintain documentation for future reference (to support surveillance and/or credentialing audits, as well as risk analysis from future moisture events).
- Establish a periodic review and audit of the department's processes to ensure they meet established specifications and requirements.

QUALITY SYSTEMS ASSIST QUALITY PROCESSING

External resources and references used to support department systems, policies and procedures should be identified, and periodic device testing should be performed. CS leaders should research and develop the CS department's periodic device testing procedure and work instructions; identify and place the medical device tray(s) in one of the product families; document efficacy; document to achieve sustainable and reproducible results; and establish and implement performance qualification testing. It is also important to ask CS

Healthcare professionals should strive to complete each step of device reprocessing with the highest degree of care and quality, in the name of patient safety. It is a duty of all CS leadership and a responsibility of those who proudly display the CHL credential to advance their knowledge and continually improve processes within the CS department.

team members how well they believe the department supports patient safety.

CONCLUSION

Healthcare professionals should strive to complete each step of device reprocessing with the highest degree of care and quality, in the name of patient safety. It is a duty of all CS leadership and a responsibility of those who proudly display the CHL credential to advance their knowledge and continually improve processes within the CS department. Periodic device testing, process evaluation, ongoing training, and comprehensive documentation all play an important part in equipment performance qualifications, and the delivery of safe, sterile and well-functioning instruments that promote patient safety and positive outcomes.

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