EDUCATION

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Quality Management Systems and the Challenge of Moisture Events

Richard Schule,
Director Clinical Education

One Integrated Approach to Healthcare.

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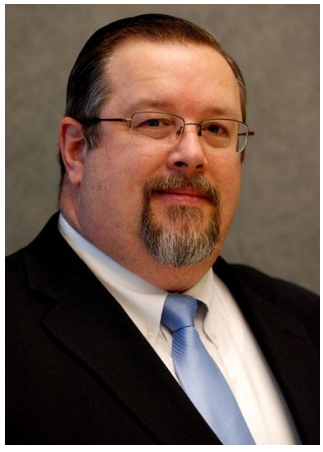

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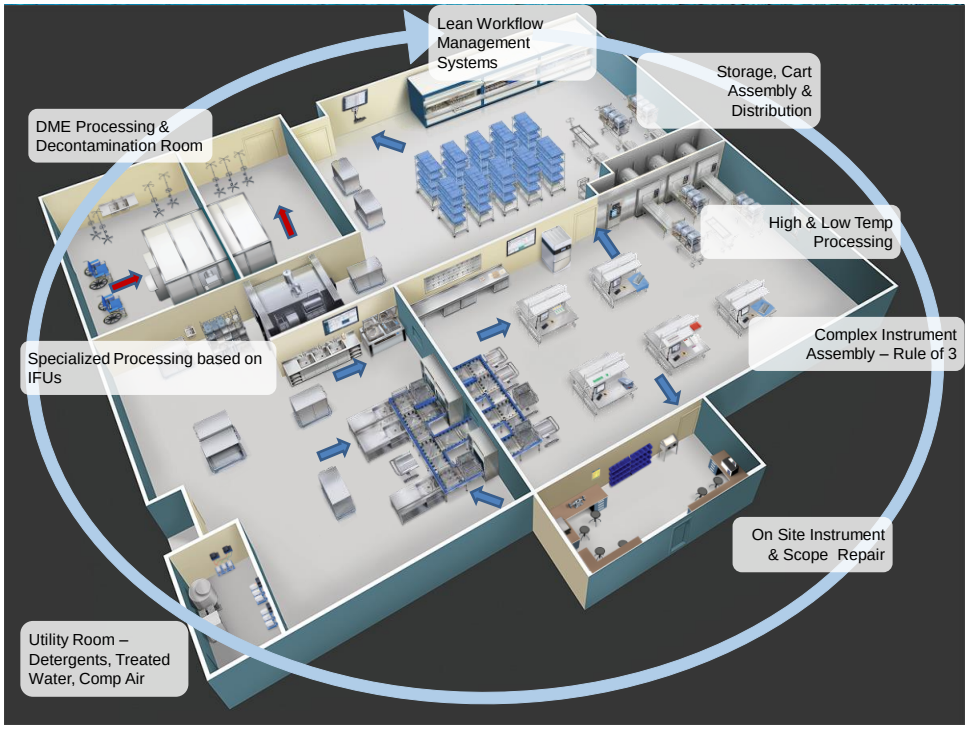
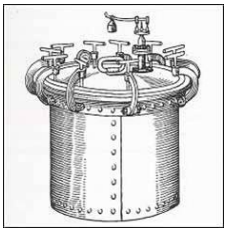
Director Clinical Education



How Well Does Your Department Support Patient Safety..?

Evolution of Steam Sterilization



Steam Sterilization

Objectives

- Discuss the importance of periodic device testing as it applies to quality systems and patient safety.
- Identify standards and documents in the industry supporting periodic device testing.
- Explain the methods and attributes used to identify product families.
- Demonstrate documentation supporting good quality management systems.

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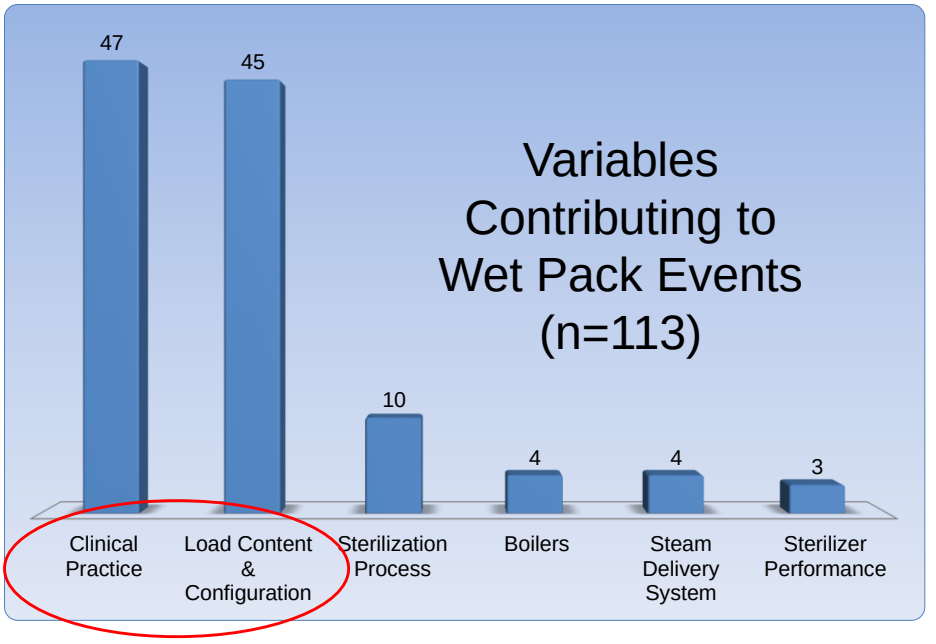
Terms and Definitions

- **Installation Qualification (IQ)**
- **Operational Qualification (OQ)**
- **Performance Qualification (PQ)**



Why Do It..?

- To ensure that the combination of product families *does not create a greater sterilization challenge* than set by the individual product families.
- To *ensure all requirements are met*.
- To *consistently* provide products that *meet requirements*.
- *Understanding and controlling the processes* is key to managing them effectively.

WE MAKE PATIENTS SAFER™

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Quality Program

- ANSI/AAMI ST79, Section10.9 speaks to periodic product quality assurance testing of routinely processed items
- Major changes made in
  - Packaging
  - Wraps
  - Load configuration
    - Dimensional
    - Weight
    - Type of material of packaging or wrap

Quality Management Systems

- Introducing systematic structure to achieve better control of processes and help focus on meeting objectives.
- Review requirements pertaining to CSSD.

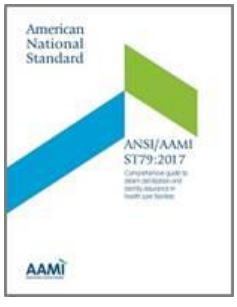
ISO 9001

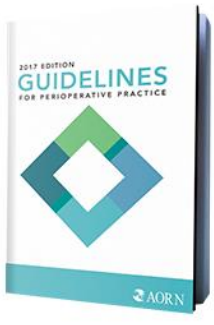
ISO 17665

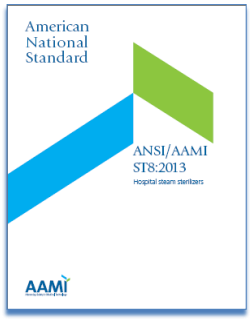
ISO 13485

ASQ

Standards





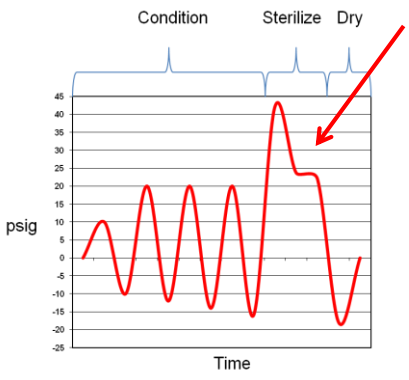


AAMI Standards Then and Now

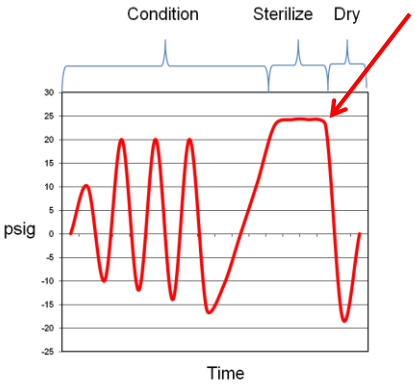
- ***Before*** **AAMI ST8: 2001 – less process control**
  - Jacket 4-6 °above chamber temperature
  - Chamber temp 285°F or greater during conditioning
  - Chamber temp range during sterilize -2→+2° F (268-272°F)
- ***After*** **AAMI ST8: 2001 – strict control**
  - Jacket temperature controlled at no greater than sterilize temperature 270 °F
  - Chamber temperature range during sterilize - 0→+3° F (270-273°F)

Cycle Differences

Typical Pre-vacuum Cycle Graphs



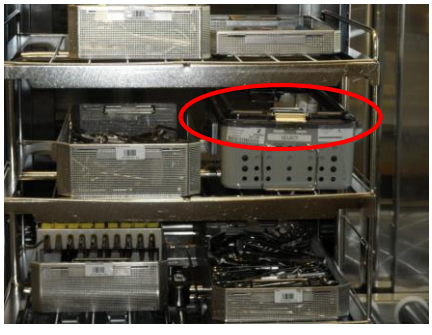
Before AAMI ST8: 2001

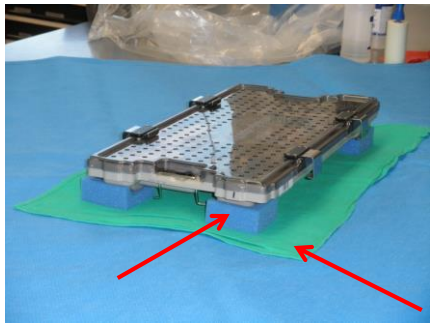


After AAMI ST8: 2001

Increasing Complexity

Pretreatment(s) Equally Important





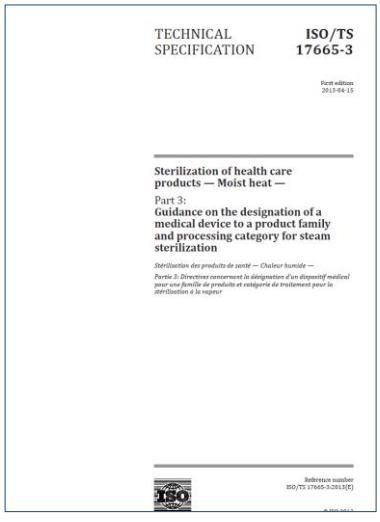
ISO/TS 17665-3

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


TECHNICAL SPECIFICATION
ISO/TS 17665-3
First edition
2013-04-15
Sterilization of health care products — Moist heat —
Part 3:
Guidance on the designation of a medical device to a product family and processing category for steam sterilization
Stérilisation des produits de santé — Chaleur humide —
Partie 3: Directives concernant la désignation d'un dispositif médical pour une famille de produits et catégorie de traitement pour la stérilisation à la vapeur
Reference number
ISO/TS 17665-3:2013(E)

Scope of Docoument

- Provides guidance about the attributes of a medical device to be considered by the user when assigning a medical device to a product family.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Terms and Definitions

- **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.

Terms and Definitions

- **Steam Penetration Resistance** – challenge to a sterilization process from a medical device, including any sterile barrier/packaging system that may delay attainment of the process parameters for moist heat sterilization on all parts of the medical device.

Objectives

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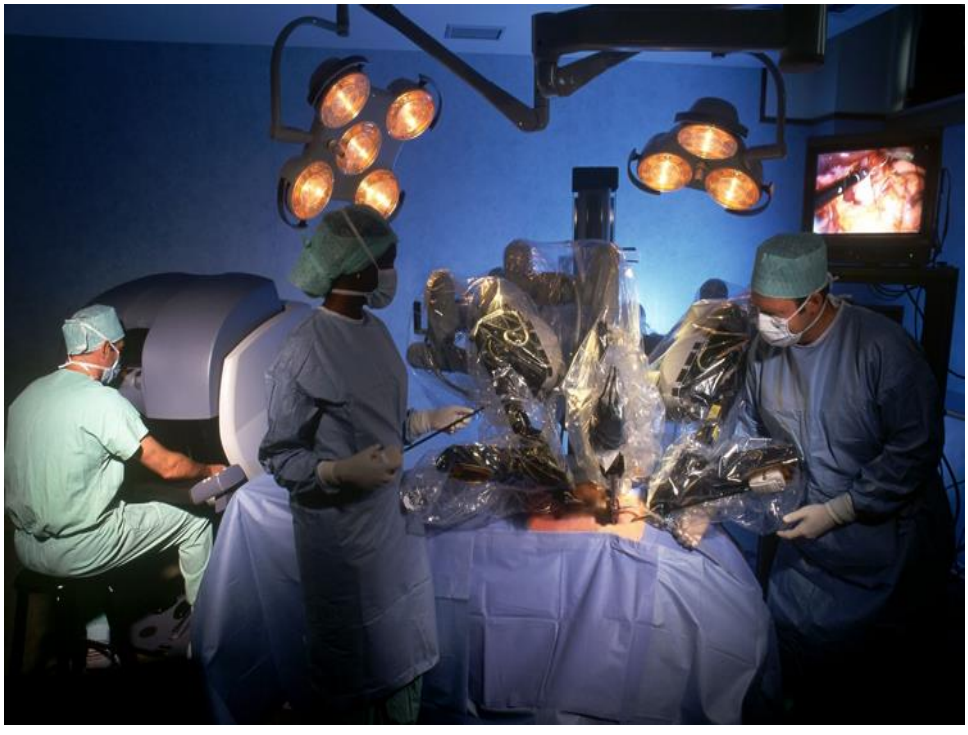


General Attributes

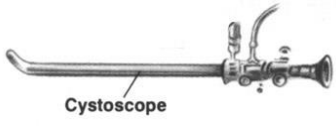
Table 1 — General attributes

Attribute	Code
Design	a
Weight	b
Material	c
Sterile barrier system	d

Device Design (a)

Table 2 — Design

Structure	Code (a)	Example
Solid, hollow	1	Bowl, jug, dish, bottle, chisel, single piece skin retractor, single component empty instrument tray
Pin and box joints	2	Scissor, forceps, needle holder
Lumen	3	Laparoscopic sheath, sucker, cannulated reamer, rigid endoscope, cannulated screws
Porous	4	Linen, filters, gauze
Tubing, moving parts, tortuous paths	5	Power tool hose, silicone tubing, dental hand piece, ear nose throat drill,
Lumen surrounded by a large mass	6	Drill, cannulated screw driver, obturator, ratchet handle, bored handle
Other	7	Pre-filled syringe

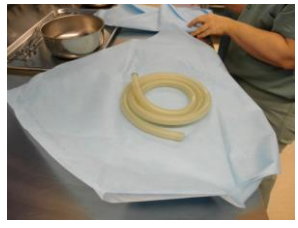


Device Composition (b)

Table 3 — Materials

Material	Example material	Code (b)
Metal	Stainless steel, carbon steel copper and copper-based alloys. Other metals or combinations of metal.	1
Non-metal	Glass, cellulose, polycarbonate, PVC, PTFE, silicon. Other non metals.	2





Device/Tray Weight (c)

Table 4 — Weight

Weight g	Code (c)
Less than 50	1
50 to 499	2
500 to 1999	3
2000 and greater	4

Sterile Barrier / Packaging

Table 5 — Sterile barrier system and/or packaging system

Sterile barrier system	Code (d)
None	1
Single wrapped/pouch	2
Double wrapped in wrapping material or pouches, double wrapped container or tray, reusable sterilization container according to manufacturers instructions	3
Combination of two or more systems, for example, a reusable sterilization container with an inner sterile barrier system	4

Product Family (pf)

Table 6 — Product families

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			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			

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

Device Design (a)

MD								
PF	Design (a)							
	1	2	3	4	5	6	7	+
1	x							
2	x							
3	x							
4	x							
5	x							
6	x							
7	x							
8			x					
9			x					
10			x					
11			x					
12			x					
13				x				
14				x				
15				x				
16		x						
17		x						

Table 2 — Design

Structure	Code (a)	Example
Solid, hollow	1	Bowl, jug, dish, bottle, chisel, single piece skin retractor, single component empty instrument tray
Pin and box joints	2	Scissor, forceps, needle holder
Lumen	3	Laparoscopic sheath, sucker, cannulated reamer, rigid endoscope, cannulated screws
Porous	4	Linen, filters, gauze
Tubing, moving parts, tortuous paths	5	Power tool hose, silicone tubing, dental hand piece, ear nose throat drill,
Lumen surrounded by a large mass	6	Drill, cannulated screw driver, obturator, ratchet handle, bored handle
Other	7	Pre-filled syringe



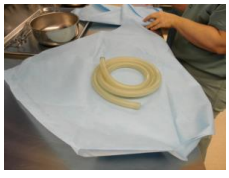
Material (b)

Attribute

Material (b)	
1	2
x	
x	
	x
	x
x	
	x
	x
x	
x	
	x
	x
	x
	x
	x
	x
x	

Table 3 — Materials

Material	Example material	Code (b)
Metal	Stainless steel, carbon steel copper and copper-based alloys. Other metals or combinations of metal.	1
Non-metal	Glass, cellulose, polycarbonate, PVC, PTFE, silicon. Other non metals.	2

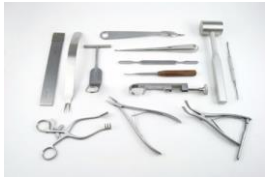




Weight (c)

Weight (c)			
1	2	3	4
x	x	x	
			x
x	x	x	
			x
x	x	x	
x	x		
		x	x
x	x		
		x	x
x	x		
x	x		
		x	x
x			
x			
	x	x	x
x			

Table 4 — Weight

Weight g	Code (c)
Less than 50 < 1.76 oz.	1
50 to 499 1.76 – 17.60 oz. (1.1)	2
500 to 1999 17.64 – 70.51 oz. (4.4)	3
2000 and greater > 70.55 oz.	4



Sterile Barrier System (d)

Sterile barrier system and/or packaging system (d)			
1	2	3	4
x			
x			
x			
x			
	x		
		x	x
	x	x	x
x	x	x	x
x	x	x	x
x			
	x	x	x
	x	x	x
x	x		
		x	x
		x	
x			

Table 5 — Sterile barrier system and/or packaging system

Sterile barrier system	Code (d)
None	1
Single wrapped/pouch	2
Double wrapped in wrapping material or pouches, double wrapped container or tray, reusable sterilization container according to manufacturers instructions	3
Combination of two or more systems, for example, a reusable sterilization container with an inner sterile barrier system	4

Product Family (pf) (cont')

Table 6 *(continued)*

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	+
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.

Example One

Design: **a1**

Material: **b1**

Weight: **c1**

Sterile barrier system and/or packaging system: **d1**

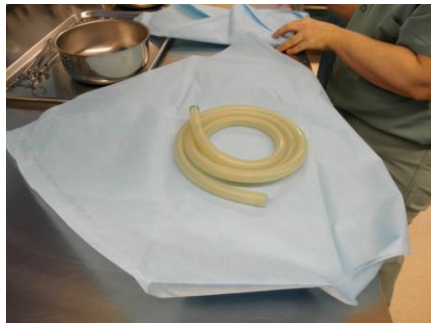
Product Family (pf) 1

Example Two

Design: **a5**

Material: **b2**

Weight: **c1**



Sterile barrier system and/or packaging system: **d3**

Product Family (pf) 24

Example Three

Design: **a6**

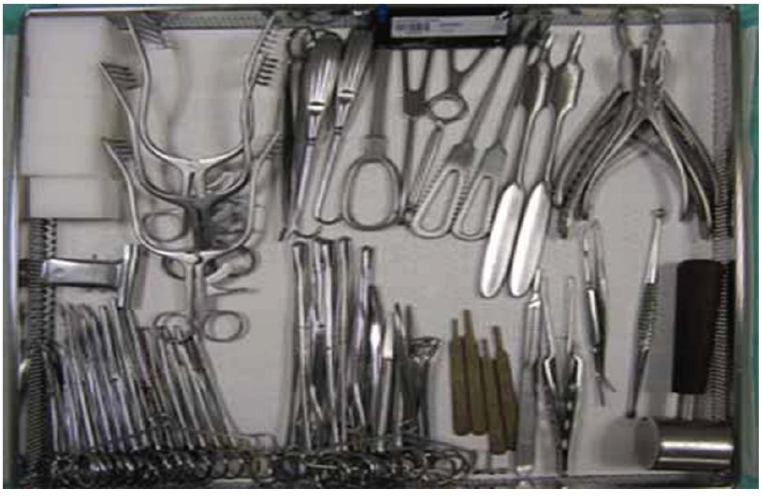
Material: **b2**

Weight: **c2**

Sterile barrier system and/or packaging system: **d3**

Product Family (pf) 28

General Orthopaedic Tray



Analysis General Orthopaedic Tray

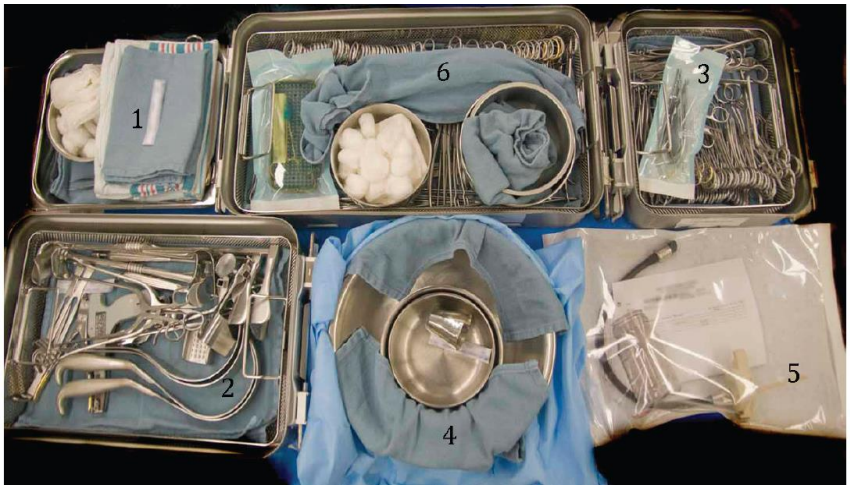
Attribute	Description	Code	Steam penetration resistance (estimated)
General description	Large number of different types and weights of instruments assembled onto a tray liner in a metal tray. Double wrapped with nonwoven wrapper x2 Total weight approximately 8 000 g		e5
Design	Solid	a1	e1
	Perforated aluminium tray	a1	e1
	Pin/box joint	a2	e2
Material	Stainless steel	b1	e1
Weight	50 g to 800 g	c1	e1
		c2	e1
		c3	e1
Sterile barrier system and/or packaging system	Single use 2 ply wrapper	d3	e3

Product family – Classification Based on Estimates: General Orthopaedic Tray

Table B.13 — Product family — Classification based on estimates: General orthopaedic set

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	+
17	x	x							x				x						x	x	x		x			

Surgical Back Table Set-up



Master Product/Family Member

- Assessment for complex orthopaedic sets.

Objectives

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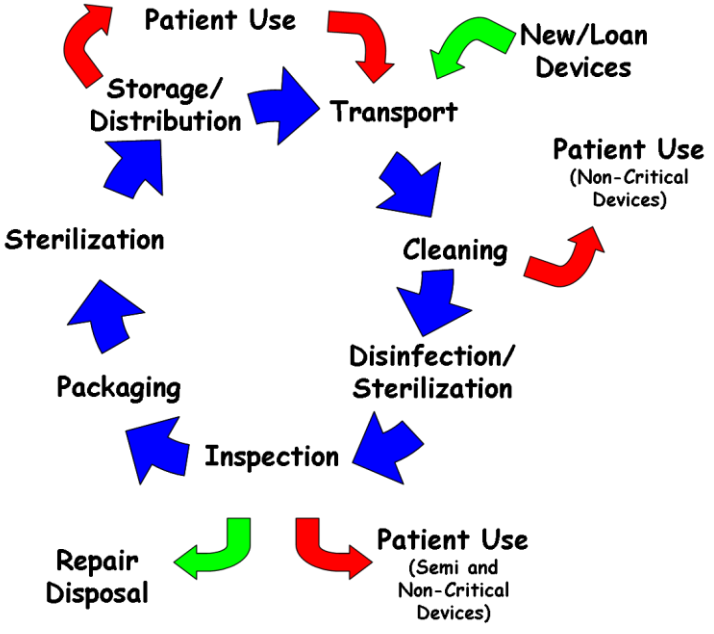
Risk assessment

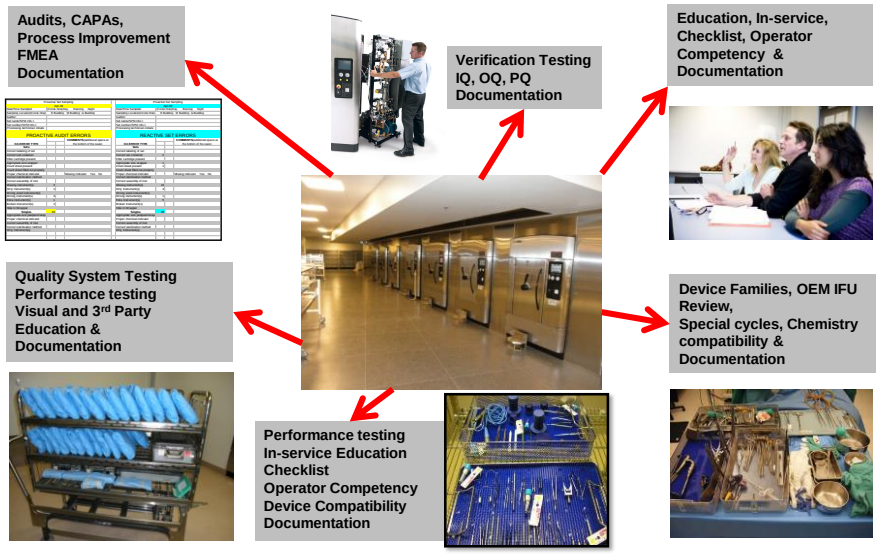
Hazard Scale

Likelihood Scale			5 Death or total systems loss Catastrophic	4 Major Injury or illness Critical	3 Lost Time, Injury or illness Serious	2 First Aid Incident Marginal	1 Very Minor, Little Consequence Negligible
5	Likely to Occur frequently	Frequent	25 = Re-think	20 = Re-think	15 = Re-think	10 = Reduce	5 = Inform
4	Likely to occur several times	Probable	20 = Re-think	16 = Re-think	12 = Reduce	8 = Reduce	4 = Inform
3	Sometimes	Occasional	15 = Re-think	12 = Reduce	9 = Reduce	6 = Inform	3 = Inform
2	Unlikely but Possible	Remote	10 = Reduce	8 = Reduce	6 = Inform	4 = Inform	2 = No Action
1	Very Unlikely Assumption that it will never occur	Improbable	5 = Inform	4 = Inform	3 = Inform	2 = No Action	1 = No Action

Risk Score = Likelihood v. Severity

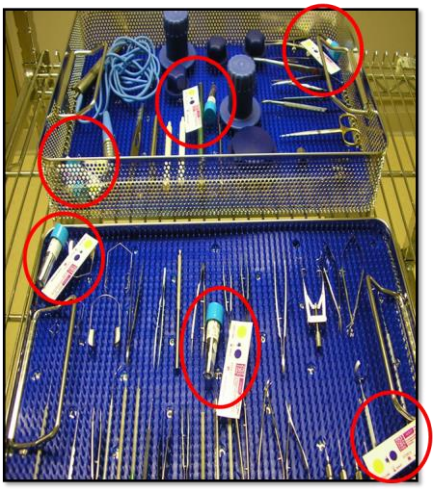


System & Work Instructions



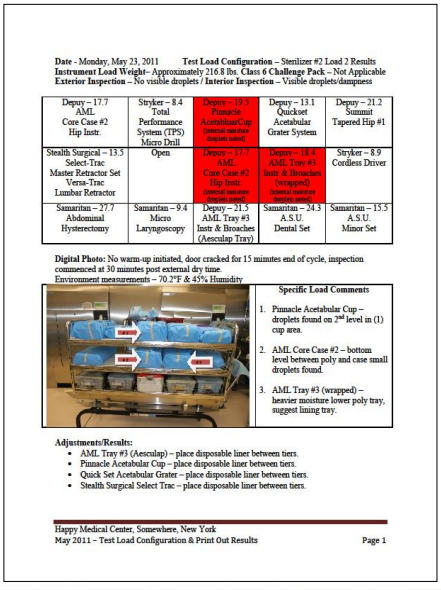
Performance Qualification

- Installation of sterilizer
  - Installation checklist
- Operation of sterilizer
  - Bowie Dick testing
  - BI/Challenge pack
- Performance of sterilizer
  - Instrument set testing



Document for Effectiveness

Device Testing Documentation



Date - Monday, May 23, 2011 **Test Load Configuration** – Sterilizer #2 Load 2 Results
Instrument Load Weight– Approximately 216.8 lbs. **Class 6 Challenge Pack** – Not Applicable
Exterior Inspection – No visible droplets / **Interior Inspection** – Visible droplets/dampness

Depuy – 17.7 AML Core Case #2 Hip Instr.	Stryker – 8.4 Total Performance System (TPS) Micro Drill	Depuy – 19.5 Pinnacle AcetabluarCup (internal moisture droplets noted)	Depuy – 13.1 Quickset Acetabular Grater System	Depuy – 21.2 Summit Tapered Hip #1
Stealth Surgical – 13.5 Select-Trac Master Retractor Set Versa-Trac Lumbar Retractor	Open	Depuy – 17.7 AML Core Case #2 Hip Instr. (internal moisture droplets noted)	Depuy – 18.4 AML Tray #3 Instr. & Broaches (wrapped) (internal moisture droplets noted)	Stryker – 8.9 Cordless Driver
Samaritan – 27.7 Abdominal Hysterectomy	Samaritan – 9.4 Micro Laryngoscopy	Depuy – 21.5 AML Tray #3 Instr & Broaches (Aesculap Tray)	Samaritan – 24.3 A.S.U. Dental Set	Samaritan – 15.5 A.S.U. Minor Set

Digital Photo: No warm-up initiated, door cracked for 15 minutes end of cycle, inspection commenced at 30 minutes post external dry time.
Environment measurements – 70.2°F & 45% Humidity

Specific Load Comments

1. Pinnacle Acetabular Cup – droplets found on 2nd level in (1) cup area.
2. AML Core Case #2 – bottom level between poly and case small droplets found.
3. AML Tray #3 (wrapped) – heavier moisture lower poly tray, suggest lining tray.

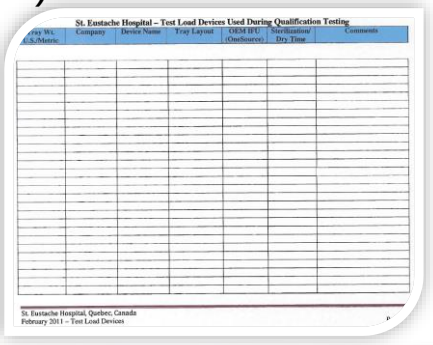
Adjustments/Results:
- AML Tray #3 (Aesculap) – place disposable liner between tiers.
- Pinnacle Acetabular Cup – place disposable liner between tiers.
- Quick Set Acetabular Grater – place disposable liner between tiers.
- Stealth Surgical Select Trac – place disposable liner between tiers.

Happy Medical Center, Somewhere, New York
May 2011 – Test Load Configuration & Print Out Results Page 1

- Clearly written/typed
- Visual
- Electronically sent
- Eliminates guess work
- One page with a wealth of information

Quality Systems

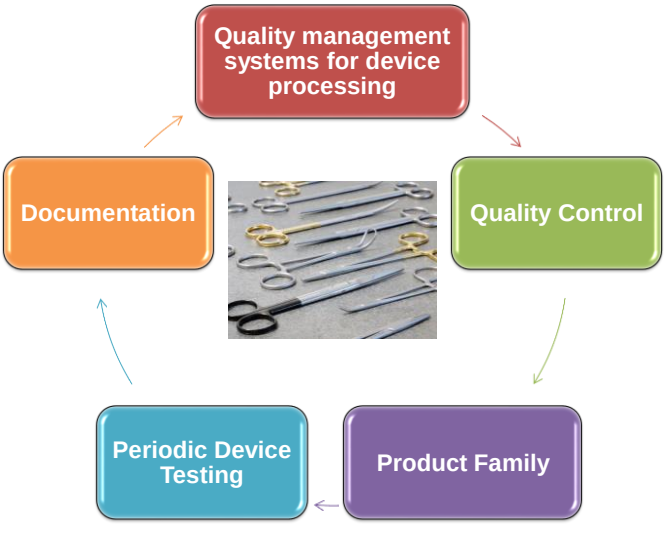
- Documenting is critical when assessing moisture related issues
- Standardizing on the worst case scenario
- CAs/PAs (improvement)
- Trending (analysis)


St. Eustache Hospital – Test Load Devices Used During Qualification Testing

Tray Wt. (Lb./Metric	Company	Device Name	Tray Layout	OEM IFU (OneSource)	Sterilization/ Dry Time	Comments

St. Eustache Hospital, Quebec, Canada
February 2011 – Test Load Devices

Performance Qualification



8.2 Monitoring and Measurement

- Customer satisfaction
- Internal audits
- Monitoring and measurement of processes
- Monitoring and measurement of product

What are You Doing To Improve?

10 Things Your Organization Can Do Now to Improve Reprocessing

This top 10 list emerged from the presentations, audience discussions, and follow-up input to AAMI. It is intended to be inspiring, and serve as a refresher on some of the basics. It does not take the place of standards, regulations, or internal policies, nor is it intended to suggest a standard of care. While some priority items from the summit will take time to address, we want everyone to know that there are at least 10 things that an organization can begin to do immediately, without waiting for other actions, such as long-term standards and research.

1. ***The basics:*** Cleaning and disinfection/sterilization of reusable devices are separate, equally important processes and must be performed before each patient use according to the device manufacturers' written instructions for use (IFU). For more information go to www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm.
2. ***The right tools:*** Have the IFU as well as all cleaning implements and equipment required by the IFU readily available in all the reprocessing areas.
3. ***Create a multidisciplinary committee:*** To review the priority issues and set a plan for solving them throughout the organization. The following areas should be represented: OR, infection prevention and control, healthcare technology management (biomed), endoscopy, risk management, quality, safety, education, and materials management.
4. ***Share lessons learned:*** Remind senior management and safety officers that it costs a lot less to "do it right the first time." Share lessons learned from other healthcare organizations that have had to inform patients of exposure to inadequately reprocessed reusable devices.
5. ***Written procedures:*** Establish a formal program for reprocessing, including written standardized policies and procedures that include a chain of accountability. Expert guidance can be obtained from industry experts in order to resolve conflicts between the IFU and facility policies. Written procedures should also be developed and implemented for central sterile processing reporting of inadequate instructions, equipment problems, and in-service issues to the manufacturer and, when applicable, to the FDA's MedWatch program.

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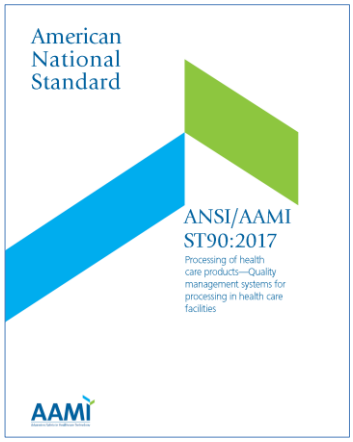
6. ***Standards matter:*** Know the current standards, recommended practices, and IFU.
7. ***Purchasing:*** Central sterile processing should be included in purchasing decisions for medical devices, to provide input on whether the device can be reprocessed appropriately and with the facility's existing resources.
8. ***Separate and standardize functions and locations:*** Separate central service (warehouse, stocking, etc.) from reprocessing; create standardized job descriptions and functions.
9. ***Training:*** Train, train, and retrain. Ideas include: assess staff competencies; negotiate for training budget with cost/benefit analysis to prove value; partner with vendors for education; create a list of available continuing education units (CEUs) for easy access by staff; work with human resources to create career ladders for certification and promotion; promote the importance of certification. Note: In-service for loaner or new instruments should include reprocessing in-service areas that are separate from (or in) central sterile processing.
10. ***Assessment:*** Conduct an audit of compliance with standards and regulations, using any number of available tools and resources. See References and go to: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm252941.htm.

ANSI/AAMI ST90

New ANSI/AAMI document specifies minimum requirements for quality management systems (QMS) where an organization needs to demonstrate its ability to effectively, efficiently, and consistently reprocess (clean, decontaminate, disinfect, sterilize) reusable medical devices in order to prevent infections, pyrogenic reactions, or other adverse patient events.

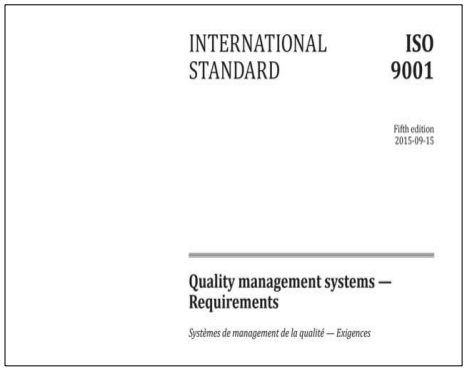


AAMI News, September 2017
Page 22

The Tale of Two Documents

ISO 13485 – 65 pages

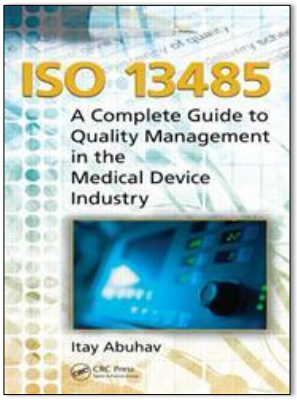
ISO 9001 – 35 pages



Improve Processing with ISO 13485

10 Things To Improve Reprocessing	ISO 13485 Supporting Requirement(s)
1. The basics	5.4.1 Quality objectives 6.3 Infrastructure 7.2.2 Review of requirements related to the product
2. The right tools	4.2.3 Control of documents 7.2.2 Review of requirements related to the product
3. Create a multidisciplinary committee	5.1 Management commitment 5.2 Customer focus ← 5.6.2 Management review input 6.3 Infrastructure
4. Share lessons learned	5.5.3 Internal communication 7.2.3 Customer communication ← 8.5.2 Corrective action 8.5.3 Preventive action
5. Written procedures	3.0 Terms and definitions 4.2 Documentation requirements 4.2.3 Control of documents 4.2.4 Control of records
6. Standards matter	4.2 Documentation requirements ← 4.2.3 Control of documents
7. Purchasing	7.4.1 Purchasing process 7.4.2 Purchasing information 7.4.3 Verification of purchased product
8. Separate and standardize functions and locations	1.0 Scope 6.4 Work environment
9. Training	6.2.2 Competencies, awareness and training ← 6.4 Work environment
10. Assessments	6.4 Work environment 8.2 Monitoring and measurement ←

ISO 13485



- Greater emphasis on the use of procedures to regulate and control how activities and processes should be performed.
- More prescriptive whereby insisting on the use of formal procedures.

AAMI Publications

- Corrective and Preventive Action (CAPA)
  - Implementation
  - Controlling non-conforming products
- Management Responsibility
- Quality Audits

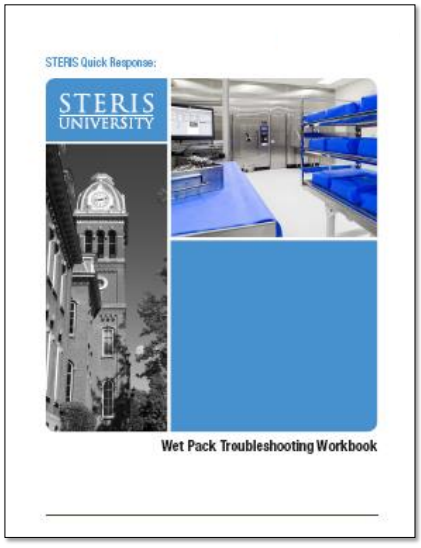
Action Plan

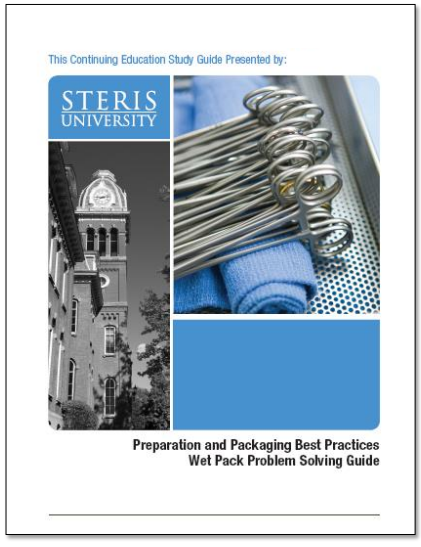
- Identify external resources and references used to support department systems, policy and procedures, specifically periodic device testing.
- Research and develop your department's periodic device testing procedure and work instructions.
- Identify and place your medical device tray(s) in one of the product families.

Action Plan

- Document for effect.
- Document to achieve sustainable reproducible results.
- Establish and implement performance qualification testing.
- AAMI/FDA 2011 Summit “to do” list, how does your department measure up?
- Make patients safer by delivering quality products and services.

Identify Wet Pack Resources

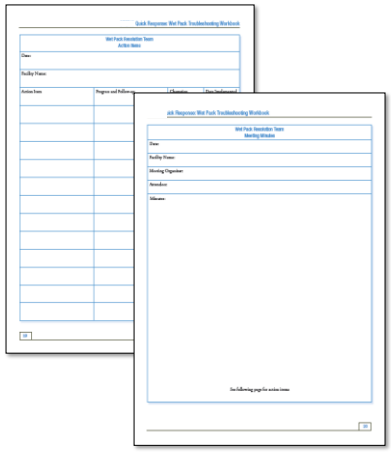




Quick Response Wet Pack Resolution Workbook

The key to a quick wet pack resolution:

- Thorough documentation by all stakeholders to include:
  - Meeting minutes
  - Assigned actions items
  - Follow-up & conclusion
- Forms located at end of the Workbook



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- http://www.aami.org/publications/summits/2011_Reprocessing_Summit_publication.pdf
- International Organization for Standardization ISO/TS 17665-3:2013 (E) Sterilization of health care products – Moist heat – Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization, 51 pages. Purchase from http://webstore.ansi.org.

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Questions