EDUCATION

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Sterilization Failures: How They Fit Into Your QMS Program

One Integrated Approach to Healthcare.

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Partnerships

CCI® The Leader in Perioperative Certification

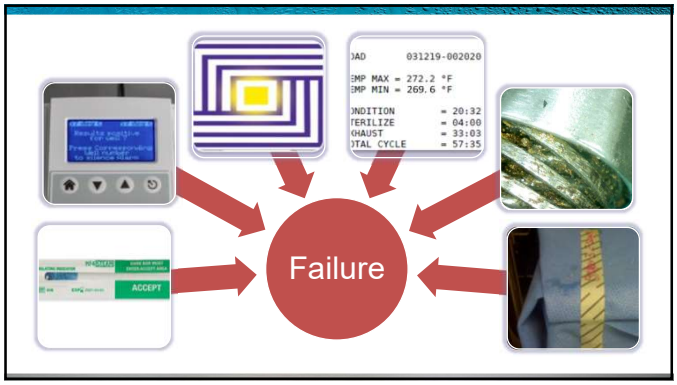
Through a partnership with CCI®, it also meets CNOR® and CSSM® recertification requirements for perioperative nurses.

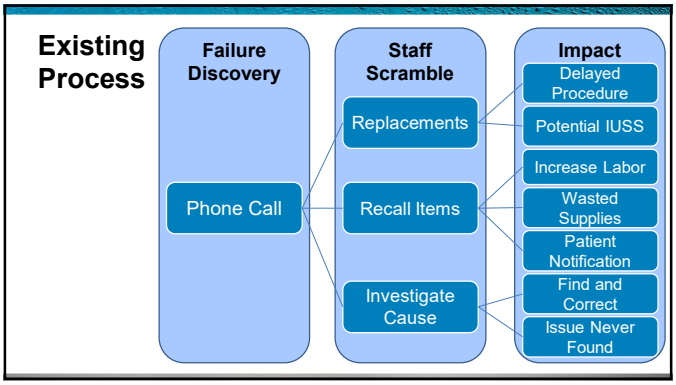
Learning Objectives

- Identify sterilization failures
- Identify preventive actions to prevent sterilization failures
- Identify how sterilization failures fit into the departmental Quality Management System (QMS) program

Sterilization Modalities

- High temperature
  - Steam
- Low temperature
  - Vaporized hydrogen peroxide
  - Vaporized hydrogen peroxide with gas plasma
  - Vaporized hydrogen peroxide with ozone
  - Ethylene oxide
  - Ozone





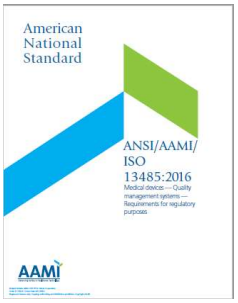
What happened?

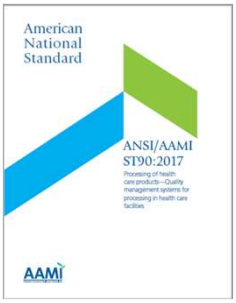
- Investigation initiated
- Equipment checked – all good here
- Assembly checked – nothing out of the ordinary
- Hmm, can't figure it out
- I hope it doesn't happen again

Reactive Outcomes

- Rushed actions
- Time consuming
- Root cause not identified & fixed
- Customer dissatisfaction
- Negative work environment
- Staff dissatisfaction
- Potential negative patient outcomes

QMS Superhero





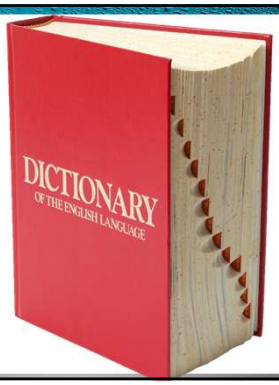
QMS in a Healthcare Organization

ANSI/AAMI ST90:2017

"*Minimum Requirements to effectively, efficiently, and consistently process medical devices to prevent adverse patient events and non-manufacturer-related device failure.*"

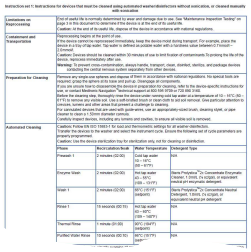
QMS Language

- Instructions for use
- Non-conformity
- Corrective action
- Preventive action
- Risk assessment



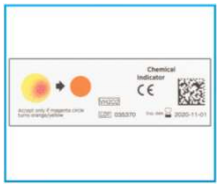
Instructions for Use (IFU)

- Written recommendations provided by the manufacturer of a device that provide instructions for operation & safe & effective processing



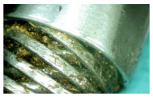
Nonconformity

- The result of nonfulfillment of a specified requirement



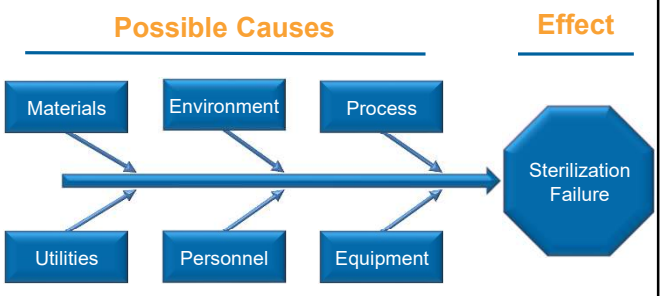
Corrective Action

- Action taken to eliminate the cause of a detected nonconformity or other undesirable situation


Dirty device


Correction


Corrective action



Preventive Action

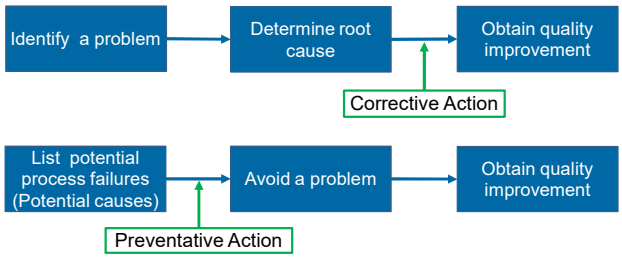
- Action to eliminate the cause of a potential nonconformity or other undesirable potential situation

Clogged spray arm | May give dirty devices | PM of spray arms

Preventive Action Outcomes

- Standardized actions
- Scheduled actions
- Preventive measures

Corrective Vs. Preventative Actions



Prevention = Positive Outcomes

Satisfied customers | Positive work environment | Positive staff | Positive patient outcomes

Where Do We Begin?

Risk

The possibility of a non-conformity occurring that may lead to harm

Risk Management

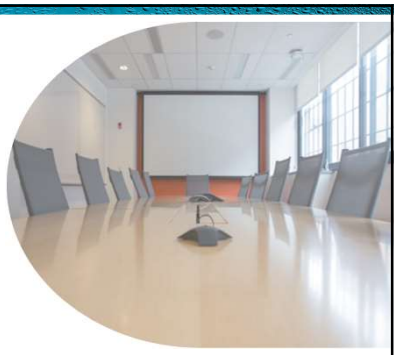
Identification and mitigation of events that may lead to harm

Develop the Team

- Sterile processing staff
- Peri-operative staff
- Infection prevention staff
- Risk management/quality management
- Facilities/biomed
- Vendor/manufacturer (ad hoc)

The Meeting

- Start-up meeting
- Team goal
- Meeting schedule
- Expectations for;
  - Attendance
  - Participation
  - Reporting

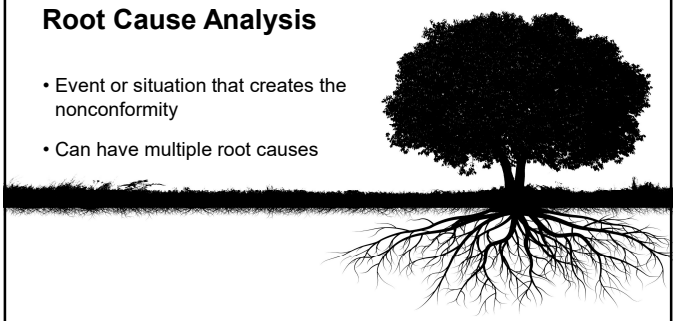


Identify Non-Conformity/ Harm

- Process and procedures
- Staff activities
- Department feedback, reports and inspections
- Customer complaints
- Recalls and incident reports
- Quality/infection prevention

Root Cause Analysis

- Event or situation that creates the nonconformity
- Can have multiple root causes

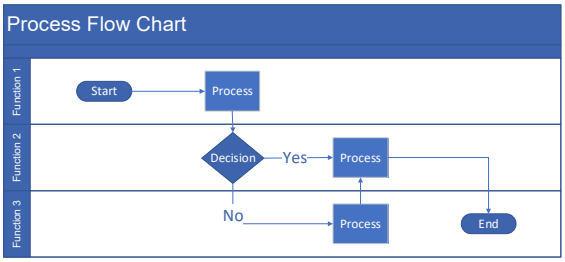


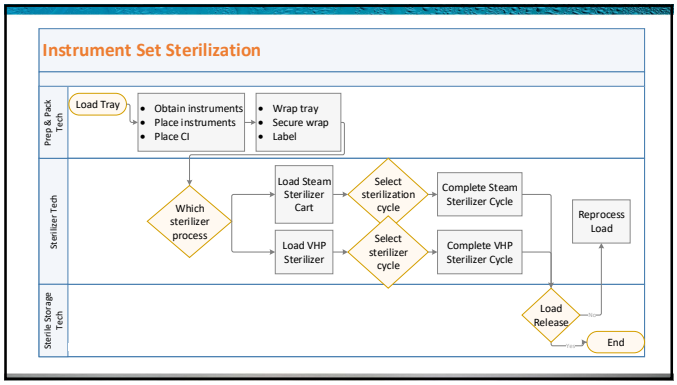
Root Cause Analysis Methods

- 5 Whys
- Cause & Affect Diagram/Ishikawa Diagram (Fishbone)
- Failure Modes & Effects Analysis (FMEA)
- *Hazard Analysis & Critical Control Point (HACCP)*
- *Fault Tree Analysis*

- Additional information: http://asq.org

Process Mapping



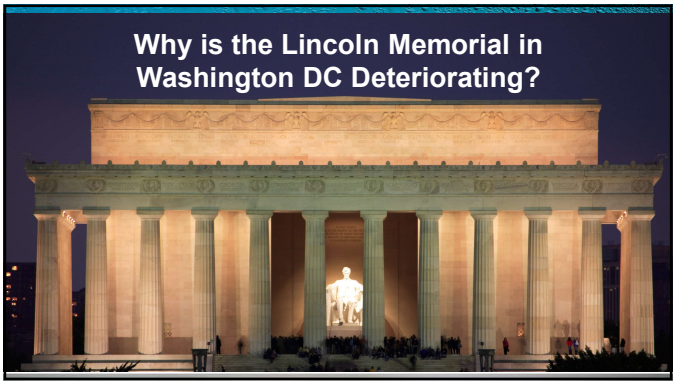


Two Ways of Thinking

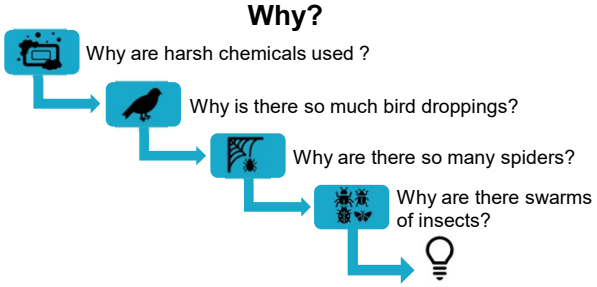
Start with nonconformity	Start with event/situation
• Trouble shoot / failure investigations • Specific nonconformity	• Process focused • Process changes

5 Whys

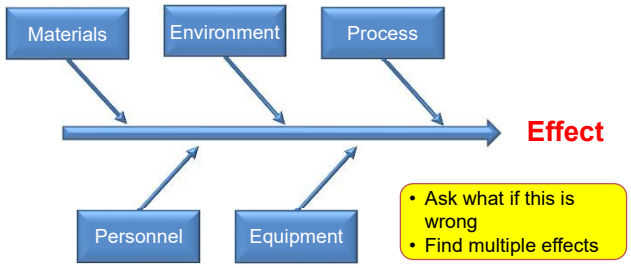
- Cause and effect question sequence
- Ask until the root cause of a defect or problem is identified



Problem: The Memorial is Deteriorating Why?

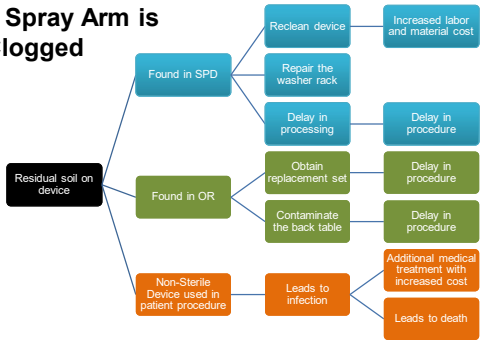


Ishikawa (Fishbone) Diagram



- Ask what if this is wrong
- Find multiple effects

Washer Spray Arm is Clogged



Failure Mode Effects Analysis

Failure Mode

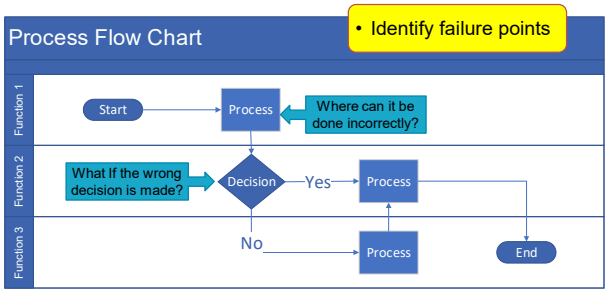
- Uses the process map
- Looks to the 5 failure sources in the fishbone

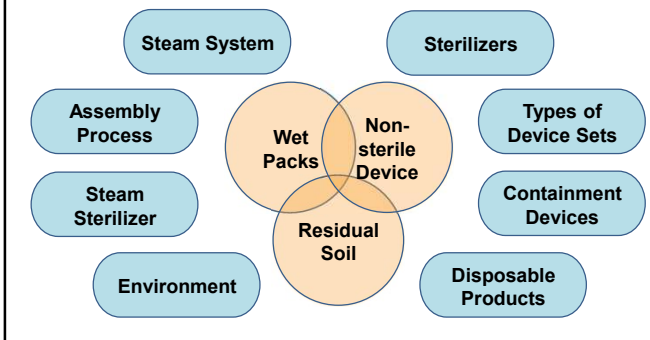
Potential Cause	Failure Effect	Current Controls	Risk Level	Mitigation	New Risk Level
• Multiple	• Local • End	• Multiple	• Probability • Severity	• Remove the cause • Reduce probability	• Probability • Severity

Failure Mode	Failure Cause	Failure Effect	
		Local Effect	End Effect
Residual soil on device following cleaning	Improper loading of washer - disinfector prevents soil removal	Device must be recleaned	Added labor and cost
			Delayed procedure
		Residual soil prevents sterilization of the device	Cross contamination resulting in infection
			Cross contamination resulting in infection & death
	Sprayer arm blocked	Device must be recleaned	Added labor and cost
			Delayed procedure
		Residual soil prevents sterilization of the device.	Cross contamination resulting in infection
			Cross contamination resulting in death

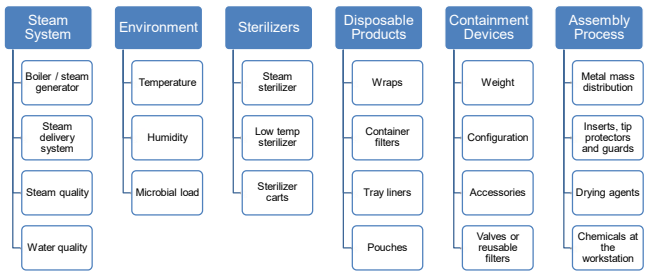
Process Mapping

- Identify failure points





Break it Down



Assess Risk

- Probability of occurrence
- Severity of harm or hazard

Measurement

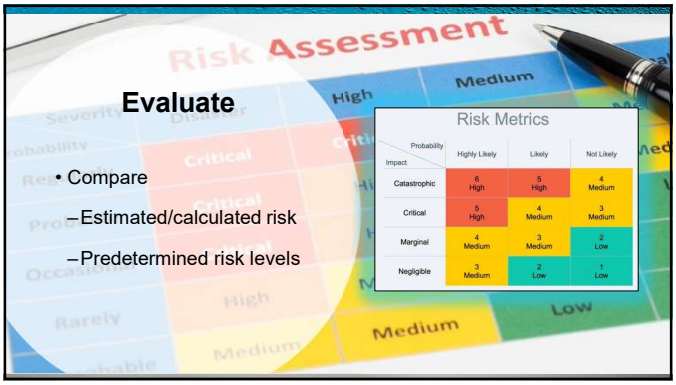
Probability

- Estimated frequency of events
- Reported occurrences at facility
- Industry baselines

Severity

- Impact of harm to patient, facility and environment
- Potential financial cost
- Public sensitivity

Evaluate



- Compare
  - Estimated/calculated risk
  - Predetermined risk levels

Failure Mode	Failure Cause	Failure Effect: Local Effect	Failure Effect: End Effect	Current Risk Control	Current Risk Level: S	P	Risk
Residual soil on device following cleaning	Improper loading of washer - disinfector prevents soil removal	Device must be reclaened	Added labor and cost		N	HL	1
			Delayed procedure		M	L	2
		Residual soil prevents sterilization of the device.	Cross contamination resulting in infection	• Magnified inspection	CR	NL	3
			Cross contamination resulting in infection & death	• Prophylactic antibiotics given	CA	NL	4
	Sprayer arm blocked	Device must be reclaened	Added labor and cost		N	L	1
			Delayed procedure		M	NL	2
		Residual soil prevents sterilization of the device.	Cross contamination resulting in infection	• Magnified inspection	CR	NL	3
		Residual soil prevents sterilization of the device.	Cross contamination resulting in infection & death	• Prophylactic antibiotics given	CA	NL	4
	Did not follow all steps in endoscope IFU	Device must be reclaened	Added labor and cost		N	NL	1
			Delayed procedure		M	NL	2
		Residual soil prevents sterilization of the device.	Cross contamination resulting in infection	• Visual inspection	CR	HL	5
		Residual soil prevents sterilization of the device.	Cross contamination resulting in infection & death	• Visual inspection	CA	NL	4

Severity	
N	Negligible
M	Marginal
CR	Critical
CA	Catastrophic

Probability	
HL	Highly likely
L	Likely
NL	Not likely
I	Improbable

Mitigate

- Prevention!!!!!

Order of Mitigation

1. Remove the risk
- Reusable to disposable
- Ethylene oxide to vaporized hydrogen peroxide

2. Minimize the probability of occurrence
- Preventative maintenance
- QC tests and inspections

3. Warn of residual risk
- Procedures
- Placards

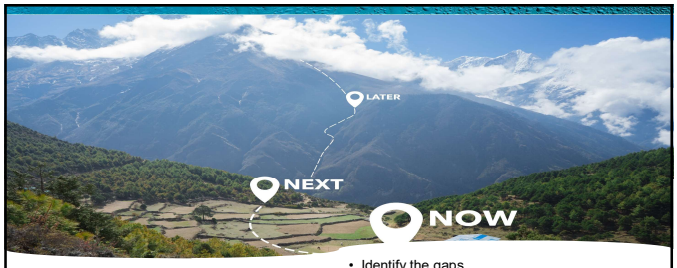
Examples of Risk Mitigation

Risk	Remove	Reduce	Warn
Wet packs from poor steam quality	Wrap pipes to eliminate condensate	Preventative maintenance on steam traps	Placard to remind staff to perform empty cycle after boiler shut down
Incorrect loading on sterilizer cart	Purchase sterile instrumentation	Staff competency verification	Loading guide wall chart

Examples of Risk Mitigation

Risk	Remove	Reduce	Warn
Expired chemical indicator does not detect sterilization failure	Use parametric release	Practice FIFO	Expiration date printed on strip
Inappropriate assembly creates wet tray	Divide tray into two new tray configurations	Staff competency verification	Label tray with loading diagram

Failure Mode	Failure Cause	Failure Effect: Local Effect	Failure Effect: End Effect	Current Risk Control	Current Risk Level: S	Current Risk Level: P	Current Risk Level: Risk	Proposed Mitigation	New Risk Level: S	New Risk Level: P	New Risk Level: Risk
Residual soil on device following cleaning	Improper loading of washer - disinfector prevents soil removal	Device must be recleaned	Added labor and cost	• Magnified inspection	N	HL	3	• Magnified inspection	N	HL	3
			Delayed procedure		M	L	2	• Protein detection test	M	L	2
		Residual soil prevents sterilization of the device.	Cross contamination resulting in infection	• Magnified inspection	CR	NL	3	• Borescope inspection	CR	I	2
			Cross contamination resulting in infection & death	• Prophylactic antibiotics given	CA	NL	4	• Prophylactic antibiotics given	CA	I	3
	Sprayer arm blocked	Device must be recleaned	Added labor and cost	• Magnified inspection	N	L	3		N	L	3
			Delayed procedure		M	NL	2	• Magnified inspection	M	NL	2
		Residual soil prevents sterilization of the device.	Cross contamination resulting in infection	• Magnified inspection	CR	NL	3	• Protein detection test • Borescope inspection	CR	I	3
		Residual soil prevents sterilization of the device.	Cross contamination resulting in infection & death	• Prophylactic antibiotics given	CA	NL	4	• Prophylactic antibiotics given	CA	I	4
	Did not follow all steps in endoscope IFU	Device must be recleaned	Added labor and cost	• Visual inspection	N	NL	1		N	HL	3
			Delayed procedure		M	NL	2		M	L	3
		Residual soil prevents sterilization of the device.	Cross contamination resulting in infection	• Visual inspection	CR	HL	5	• Visual inspection • Protein detection test • Borescope inspection	CR	NL	3
		Residual soil prevents sterilization of the device.	Cross contamination resulting in infection & death	• Visual Inspection	CA	NL	4		CA	NL	4



Closing the Gap

- Identify the gaps
- Prioritize
- Plan for implementation

Monitor

- Effective mitigation
- Effective corrective action
- Confirms risk assessment assumptions
- Observe for new risks or changes in non-conformity frequencies

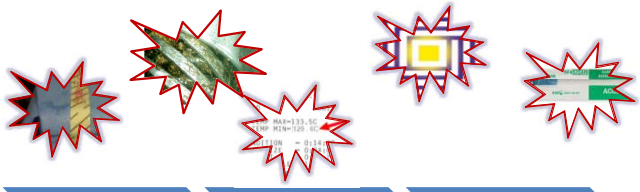
The purpose of risk management is to control risk

The purpose of monitoring is to measure the effectiveness of controls

Monitor

- Schedule dependent on risk assessment team's recommendations
- Scheduled reviews of
  - The risk management program
  - Risk assessments
  - Individual risks
  - Corrective actions
- Update risk documents, as needed
- Report to designated departments

Chaos Becomes Order with QMS



Process Specifications → Control Checks → Non-Conformities

Preventative actions | Corrective actions

Stop Reactivism. Move to Preventionism

- Read your facility's risk management policies and procedures
- Identify your team
- Kick-off your sterilization failure risk assessment

Other Resources

References

- Association for the Advancement of Medical Instrumentation (AAMI), Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, ANSI/AAMI ST79:2017.
- Association for the Advancement of Medical Instrumentation (AAMI), Processing of Healthcare Products – Quality Management Systems for Processing in Health Care Facilities, ANSI/AAMI ST90:2017.
- Occupational Safety and Health Administration (OSHA). Medical & First Aid Standard. Code of Federal Regulations, Title 29, Part 1910.133
- Occupational Safety and Health Administration (OSHA). Eye and Face Protection Standard. Code of Federal Regulation,. Title 29, Part 1910.151
- AORN 2018 Guideline for Sterilization
- http://www.haccpalliance.org/sub/haccpmodels/guidebook.pdf

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