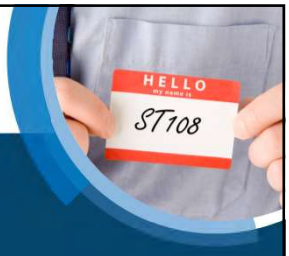
STERIS UNIVERSITY



Introduction to ANSI/AAMI ST108

university.STERIS.com

Disclosures

1. **Successful completion:** Participants must complete the entire program and submit required documentation. No partial credit will be given.
2. **Conflict of interest:** Employee of STERIS.
3. **Commercial company support:** Fees are underwritten by education funding provided by STERIS.
4. **Non-commercial company support:** None.
5. **Alternative/Complementary therapy:** None.

Continuing Education

- STERIS Corporation is an approved provider of continuing nursing education by **CBRN** – provider # CEP 11681 and an approved Administrator Education Unit (AEU) and Infection Prevention Control (IPCH) provider by **BASC** – provider # 1417.
- This program is approved for:
  - **0** hour(s) of GI Specific content credit by **ABCGN** (American Board of Certification for Gastroenterology Nurses),
  - **1** AEU(s) & **1** IPCH(s) by **BASC** (Board of Ambulatory Surgery Certification), and
  - **1** contact hour(s) of continuing education credit
    - **CBRN** (California Board of Registered Nursing);
    - **CBSPD** (Certified Board for Sterile Processing and Distribution); and
    - **HSPA** (Healthcare Sterile Processing Association).

Continuing Education

CCI® The Leader in Perioperative Certification

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

Learning Objectives

- Describe the scope of the ANSI/AAMI ST108 standard, Water for the processing of medical devices
- Describe the focus of each section within the standard

Insufficient Water Quality = Poor Outcomes


Medical Device Damage

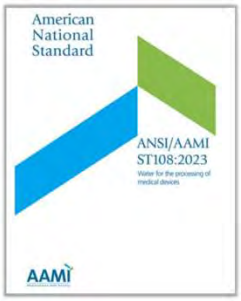

Processing Equipment Damage


Processing inefficiencies


Negative Patient Outcomes

Scope:

- Healthcare
- Water quality requirements for processing medical devices
- Maintenance and quality assurance



5 Subject Areas

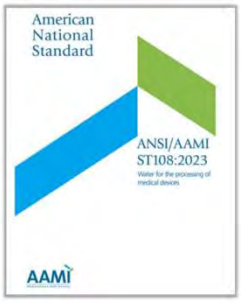
- Roles and Responsibilities
- Water Quality and Use
- Water Treatment Systems
- Quality Control
- Special Considerations

AAMI
aami.org/store

ANSI WEBSTORE
webstore.ansi.store

Exclusions:

- Hemodialysis
- Laboratory water
- Steam quality specifications
- Water within medical equipment
- Municipal water quality
- Post use water testing



Key Definitions - POU

Point-of-use treatment (POU)

Device treatment immediately following use that may include rinsing, flushing, and preparation for transport.

Point-of-water use (POU)

Closest point in the distribution loop where water is exposed to a medical device during processing.

Point-of-water use system (POU system)

A water treatment system in which purification takes place just before a single water supply outlet.

(ANSI/AAMI ST108, 2023)

Key Definitions – Water Management Program

A multistep process to identify hazardous conditions and take steps to minimize the growth and transmission of waterborne pathogens in building water systems; the program requires continuous review and documentation of the plan's implementation, operation, and mitigation strategies as appropriate.

(ANSI/AAMI ST108, 2023)

Key Definitions – Water Treatment System

Collection of water purification devices and associated piping, pumps, valves and gauges that together produce treated water of a specified quality and deliver it to the point-of-water-use.

(ANSI/AAMI ST108, 2023)

1

Roles and Responsibilities

Roles and Responsibility

Multidisciplinary Team

Risk Analysis

Roles And Responsibilities

Section 4 and 5

- Multidisciplinary team identification
- Roles and responsibilities
- Water risk analysis

Annex B: Risk analysis

Annex I: Typical presentation of water quality issues during processing of medical devices

Multidisciplinary Team Responsibilities

- Water Management Program
- Establishes training and competencies
- Obtains necessary resources
- Reporting

Multidisciplinary Team

Team Member	Responsibilities
Executive Sponsorship	Resource allocation and support
Facility engineering	Installation, validation, and qualification
Clinical engineering	Risk management, equipment selection, construction, etc.
Water treatment specialist	Water treatment
Surgical suite / procedure room	Visual device inspection
Device processing	Alert leaders of potential water quality issues
Infection prevention	Surveillance monitoring, risk assessment, escalation

Risk Analysis

When

- Prior to water treatment Implementation
- Periodically

What

- Medical Devices
- Processes
- Patient (indirect)

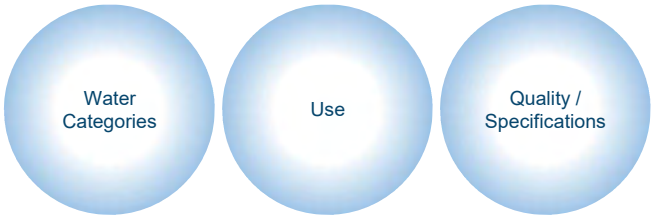
Help

- Annex B
- Annex I

2

Water Quality And Use

Water Quality And Use



Water Quality and Use

Section 6 and 7

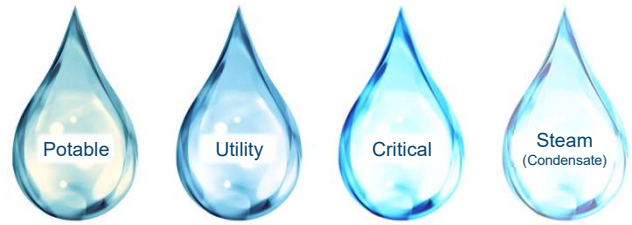
- Categories of water
- Water selection and requirements

Annex A: Guidance on the application of the normative requirements

Annex C: Automated Endoscope Reprocessor (AER)

Annex D: Water used in cleaning and moist heat processes

Types Of Water



Environmental Protective Agency (EPA) | ANSI/AAMI ST108 | ANSI/AAMI ST108 | ANSI/AAMI ST108

Water Quality

Properties

- pH
- Total Alkalinity
- Color & Turbidity
- Conductivity

Impurities

- Bacteria and Endotoxin
- Total organic carbon (TOC)
- Silicate
- Aluminum, copper, iron, manganese, zinc
- Chloride, nitrate, phosphate, sulfate

Purity Progression

See Table 2

Bacteria (Heterotrophic Plate)	n/a	<500 CFU/ml	<10 CFU/ml	n/a
Copper	≤1.3 mg/L	<0.1 mg/L	<0.1 mg/L	<0.1 mg/L
Total Hardness	No limit	<150 mg $CaCO_3$/L	<1 mg $CaCO_3$/L	<1 mg $CaCO_3$/L

Use

Manual Cleaning

- Utility Water

Point-of-Use Treatment

- Cold water rinse
- Cleaning solutions
- Intermediate rinse

Utility Water

- Final rinse

Critical Water

Washers And Washer Disinfectors

- Initial rinse
- Wash stage
- Post-wash rinse stage
- Chemical disinfection stage

Utility Water

- Final rinse
- Thermal disinfection

Critical Water

Cleaning Chemistry Exception

- Tap water exception
- Formula specific
- Must test water
- Cleaning and intermediate rinse

Ultrasonic Cleaner

- Cold water rinse
- Cleaning solutions

Utility Water

- Unless different in the instructions for use
- No rinse water recommendations

Manual High-Level Disinfection

- Cleaning
- Post-wash rinse
- Disinfectant Solution

Utility Water

- Post disinfection rinses

Critical Water

Mechanical High-Level Disinfection

- Cleaning Solutions
- Intermediate post wash rinses
- HLD Solution (from concentrate)
- Post HLD rinses including final rinse*

*Unless different in the instructions for use

Utility Water

Sterilization

Liquid Chemical Sterilization

- Follow instructions for use liquid chemical sterilant

Steam Sterilization

- Steam condensate and ANSI/AAMI ST79 steam quality

3 Water Treatment Systems

Water Treatment Systems

Design

Qualification Testing

Maintenance

Water Treatment Systems

Section 8, 9, and 12

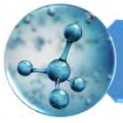
- Water system design
- Qualification
- Maintenance

Annex E: Water treatment technologies

Annex F: Water treatment system design

Types Of Water Treatments

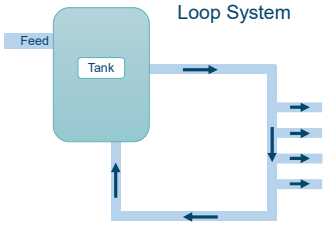
Physical Treatment



Chemical Treatment

Design Considerations

- Order of treatment equipment
- Delivery system design
- Loop system
- Water sampling access



Qualification

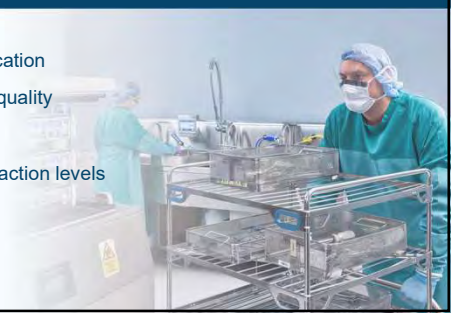
Installation an Operational Qualifications (IQ/OQ)

- Proper Installation
- Test each treatment step
- Test point-of-water use
- Establish alert and action levels

Qualification

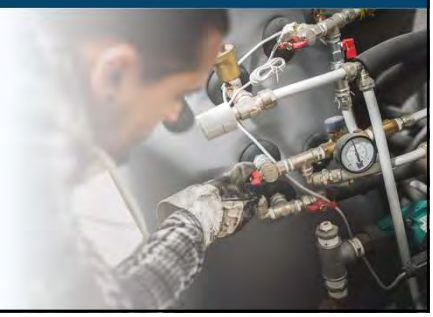
Performance Qualification

- Water volume and quality
- Seasonal variation
- Confirms alert and action levels



Maintenance

- Daily checks
- Monthly disinfection
  - Tanks
  - Loop system
- Instructions For Use



4 Quality Control

Quality Control

Routine Testing

Continuous Improvement

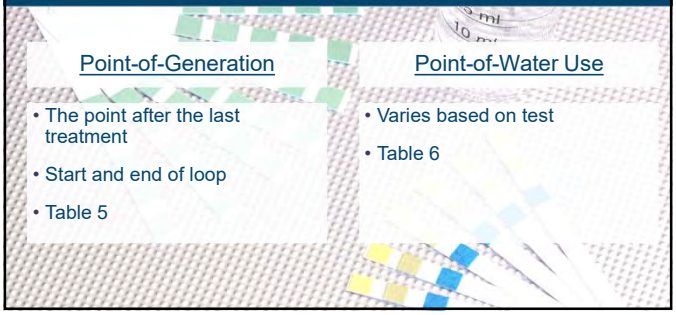
Quality Control

- Section 10 and 11
  - Routine Monitoring
  - Continuous improvement

Annex G: Routine monitoring of water treatment equipment & produced water

Annex H: Maintaining microbiological quality

Sampling Locations



Point-of-Generation	Point-of-Water Use
• The point after the last treatment	• Varies based on test
• Start and end of loop	• Table 6
• Table 5	

Utility Water

	Point of Generation	Point of Water Use
Daily	• None	• Visual Inspection
Quarterly	• pH • Conduc • Total Al • Total Hardness	ductivity l Alkalinity • Total Hardness

Additional Testing: type of impurities and treatment equipment

Critical Water

	Point of Generation	Point of Water Use
Daily	• Conductivity	• None
Monthly	• pH • Condu • Total A • Total H • Bacterial • Endotoxin	• pH nductivity al Alkalinity al Hardness • Bacterial • Endotoxin

Additional Testing: type impurities and treatment equipment

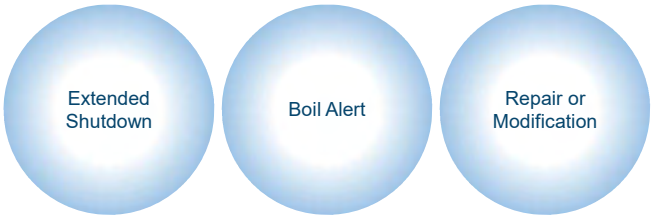
Steam Condensate

	Point of Generation	Point of Water Use
Daily	• None	• None
Monthly	• None	• None
Quarterly	• None	nductivity al Alkalinity • Total Hardness

Additional Steam Quality Requirement in ANSI/AAMI ST79 Section 3.3.3.2

5 Special Considerations

Special Considerations



Special Considerations

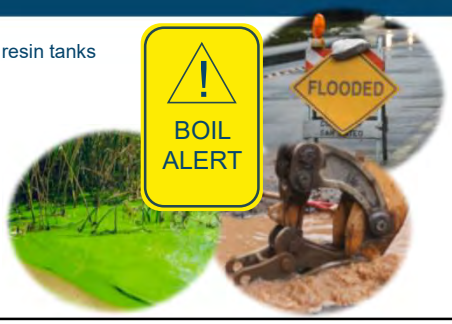
- Section 13
  - Post construction and extended shutdowns
  - Extended boil water alerts
  - Interruptions in service
  - System repair or modification

Extended Shutdown

- Remove stagnant water
- Reduce bacterial counts
- Remove aerators and flush sink lines
- Qualification

Boil Alerts

- Change filters and resin tanks
- Disinfect and flush



System Wide Disinfection Required When:

- Installation of new or replacement equipment
- Major repair
- Expansion
- Non-compliant bacteria levels

Action Items

- Perform a baseline water quality risk assessment.
- Acquire ANSI/AAMI ST108.
- Plan the next steps.

References

- Association for the Advancement of Medical Instrumentation (AAMI) (2021) *ANSI/AAMI ST79:2017 with Amendments A1:2020, A2:2020, A3:2020, A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. AAMI
- Association for the Advancement of Medical Instrumentation (AAMI) (2023) *ASNI/AAMI ST108:2023 Water for the processing for medical devices*. AAMI

Questions?

Thank you!

Visit us at **university.steris.com**

Supporting a Strong Department
Developing **Future Leaders**

STERIS
UNIVERSITY

3M℠ Health Care Academy

Sterilization Quality Control for the ASC

Location: **Date**

Disclosure

Name
Title
email
3M Medical Solutions Division

Disclaimer

Important Information:

The content of this webinar is based on current United States information including regulations, standards, guidelines, and practices as of [date].

Requirements in other countries may be different and US guidance may change in the future.

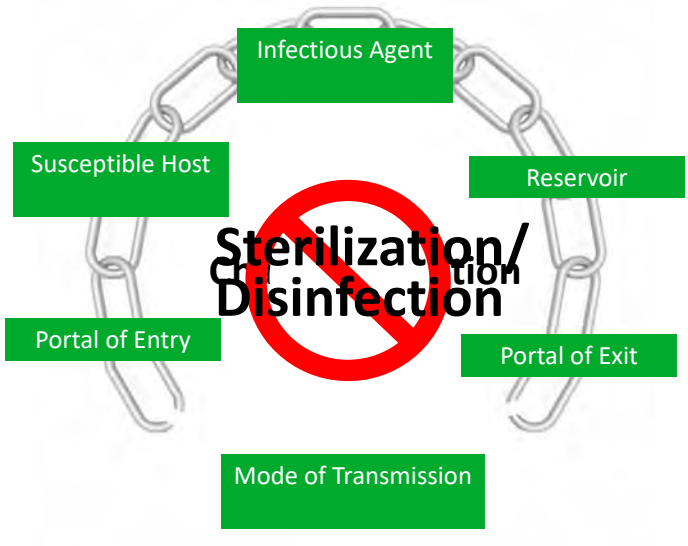
Always consult product *Instructions For Use* and follow local laws and regulations.

This presentation contains an overview of general information and should not be relied upon, in isolation, to make specific decisions.

3M

3

Disease Transmission Cycle



3M

4

Accreditation - The Joint Commission

Most Challenging Ambulatory Health Care Standard for 2019

- **IC.02.02.01 – The organization reduces the risk of infections associated with medical equipment, devices, and supplies.**

Compliance Tips

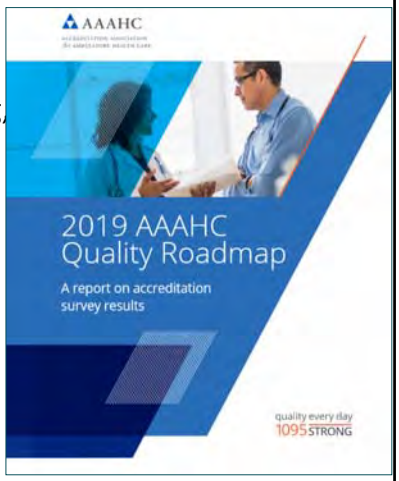
- Review MIFU for disinfectants, ultrasonic cleaners and sterilizers
- Staff education/competency assessment
- Periodic review of quality logs
- Adherence to MIFU, evidence-based guidelines, and facility policy

Joyce Webb, RN, BSN, MBA Project Director, Division of Standards and Survey Methods, The Joint Commission
https://www.jointcommission.org/resources/news-and-multimedia/blogs/ambulatory-buzz/2020/09/02/top-10-most-challenging-ambulatory-care-standards-in-2019/

AAAHC – 2019 Quality Roadmap

QC-related Instrument/Equipment Reprocessing Findings

- Insufficient (or no) monitoring and documentation of cleaning, HLD and sterilization; failure to follow manufacturer's instructions for use
- Sterile packages missing both internal and external indicators
- Missing processing date of sterilized packs
- Biological indicator testing done monthly, instead of weekly, per CDC guidelines



AAAHC REPORT IDENTIFIES AREAS OF COMPLIANCE AND OPPORTUNITIES FOR IMPROVEMENT
https://www.aaahc.org/aaahc-report-identifies-areas-of-compliance-and-opportunities-for-improvement/
Accessed 7/27/2020

Learning Objectives

- Review sterilization modalities typically used in the ASC setting
- Describe available sterilization monitoring tools
- Discuss current guidelines and recommended practices for quality control monitoring of steam and vaporized hydrogen peroxide sterilization processes

 7

Sterilization – Guidelines/Recommended Practices

2020 Edition AORN *Guidelines for Perioperative Practice.* AORN Inc.

ANSI/AAMI ST79:2017 – *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

ANSI/AAMI ST58:2013 (R2018) *Chemical sterilization and high level disinfection in health care facilities*

 8

Basic Definitions

Cleaning	High-Level Disinfection (HLD)	Sterilization
• **Removal** of organic soil • Microbes and soil can still be present • Device can still be infectious	• Microbial **kill** under defined conditions • Not all spores are killed • Effectiveness dependent on meticulous cleaning	• **Kills** all living organisms including spores • Effectiveness dependent on meticulous cleaning

Critical Devices Require Sterilization

"Prepare a sterile field for patients undergoing operative or other invasive procedures"

"Only sterile items should come into contact with the sterile field."

AORN 2020, *Guideline for Sterile Technique*, Recommendations 3.1 and 3.7.

Review sterilization modalities typically used in the ASC setting

Sterilization processes used in ASCs

High Temperature

Steam

"Saturated steam under pressure should be used to sterilize heat- and moisture-stable items unless otherwise indicated by the device manufacturer."

AORN 2020, *Guideline for Sterilization*, Recommendation 5.1

Sterilization processes used in ASCs

High Temperature

Steam

Low Temperature (chemical processes)

Ethylene oxide

Vaporized hydrogen peroxide

with plasma (e.g. Sterrad™)

 13

Sterilization processes used in ASCs

High Temperature

Steam

Low Temperature (chemical processes)

Ethylene oxide

Vaporized hydrogen peroxide

with plasma (e.g. Sterrad™)

without plasma (e.g. V-PRO® Systems)

 14

Steam Sterilization

- Fast
- Effective
- Inexpensive
- Technologically well understood
- Relatively easy to use
- Items can be packaged and maintained sterile
- No hazardous residues after sterilization

3M

 15

Steam Sterilization

Three critical variables for steam sterilization to be effective:

Time

Temperature

Steam

3M

 16

Steam Quality - NCGs

Non-condensable gases (NCGs) in the steam or chamber will prevent uniform and effective condensation, resulting in inadequate sterilization conditions.

What is the most common non-condensable gas?

AIR!!

 17

Steam Sterilization Cycle Types
Goal: Air removal

Gravity displacement

- Steam into the top of the chamber drives air out the bottom

Dynamic air removal

- Pre-Vacuum
  - Series of vacuum pulls/pressure pulses to drive air out
- Steam Flush Pressure Pulse (SFPP)
  - Positive pressure steam pulses with gravity flush

 18

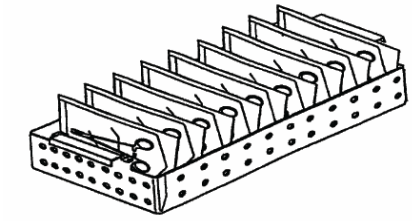
Loading the Steam Sterilizer - Instrument Sets

Place instrument sets and rigid containers horizontally

- To maintain distribution of metal mass
- Allow air removal
- Sterilant penetration
- Condensate drainage
- Drying
- Prevents shifting of set contents

ANSI/AAMI ST79:2017, Section 10.1.3

Loading the Steam Sterilizer - Paper-Plastic Pouches



- Used for small, lightweight, low-profile items
- Closed so that seals are smooth
- Double pouch only if validated by manufacturer

ANSI/AAMI ST79:2017, Sections 9.5.4 and 10.1.2
Sketch reprinted from ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 &A3:2012 with permission of Association for the Advancement of Medical Instrumentation, Inc. © 2012 AAMI

Loading the Steam Sterilizer - Solid-bottom pans and Basins

Place items tilted on edge and oriented in the same direction for:

- Condensate drainage
- Displacement of air
- Rapid, even distribution of steam throughout the load

ANSI/AAMI ST79:2017, Section 10.1.5

Loading the Steam Sterilizer - Rigid Sterilization Container Systems

Inspect before each use

- Latching mechanism, valves, gasket, etc.

Place flat on shelf below absorbent items

Stack only if indicated by manufacturer

Do not stack containers from different MDMs

ANSI/AAMI ST79:2017, Sections 9.8 and 10.1.6

Unloading the Steam Sterilizer

Verify sterilization parameters

Remove cart and place in a low traffic area, no air-conditioning cold-air-vents

Allow items to cool to room temp before handling

- May use infrared thermometer

Do not touch items during the cooling process

- Could wick bacteria from hands into packaging

Do not transfer warm items to a cool metal rack or shelving (could cause condensate to form → contamination

ANSI/AAMI ST79:2017, Section 10.3; AORN Guideline for Sterilization, RP 5.4

VH2O2 Sterilization

Vaporized hydrogen peroxide sterilization

Advantages	Limitations
High efficacy	Materials compatibility
Rapid activity	Penetrability
Cost effectiveness	Organic material resistance
Monitoring capability	Toxic
	Technique Sensitive

Vaporized hydrogen peroxide sterilizer options

Advanced Sterilization Products (ASP)® - "*the plasma sterilizers*"

STERRAD® 100S

STERRAD® NX

STERRAD® 100NX

Vaporized hydrogen peroxide sterilizer options

STERIS® - *"the V-PRO® family"*

V-PRO® maX 2 | V-PRO® maX | V-PRO® 1 plus | V-PRO® 1 | V-PRO® 60

VH2O2 Sterilization Critical Parameters

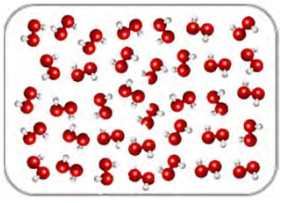
Variable identified as being essential to the attainment of sterilization

ISO 11140-1:2014

Sterilization of health care products — Chemical indicators — Part 1: General Requirements

Time

Temperature



Hydrogen peroxide concentration

VH2O2 sterilant delivery methods

Different technologies: different H_2O_2 delivery containers

Fixed Volume Injection

- Single-dose capsules
- Multiple-use cup

3M

 29

Safe and effective use of VH2O2 in healthcare

- Adhere to the sterilizer chamber loading weight limits
  - Limits on weight and device types per models and cycles is complex!
  - Always refer to the sterilizer manufacturer's instructions for use
- Adhere to loading weight limits for rigid containers
- Assure packaging and devices are adequately dry
- Double check the packaging is labelled for VH2O2 sterilization
- Double check device is labeled for VH2O2 sterilization
- Reduce or stop the use of extraneous materials in VH2O2

3M

 30

VH2O2 Sterilizer chamber loading practices

Follow sterilizer IFU

Example – Sterrad® 100S

- *Allow 1 inch from top of load and the electrode*
- *Allow 1 inch between packages in the load*
- *Place packages flat on shelves in a single layer*
- *Do not stack trays*

*STERRAD® 100S Instrument Processing Guidelines AD-51825-01 US_C

VH2O2 Sterilizer Chamber loading practices

STERRAD® 100NX® Express cycle

EXPRESS
Load Preparation: Bottom shelf only
(10.7 lbs or 4.85 kg)

Empty

EXPRESS
Load Preparation: Bottom shelf only
(10.7 lbs or 4.85 kg)

*STERRAD® 100NX System Cycle Selection AD-090152-0-CT_C

How does an ASC determine which sterilization processes to run?

- Sterilization Modality?
  - Steam
    - Method of air removal
    - Temperature
    - Exposure time
    - Dry time

By consulting the device manufacturers' Instructions for Use (IFU)
Online resource: oneSOURCEdocs.com

ANSI/AAMI ST79:2017, Section 10.2.2

Healthcare Facility Responsibility

Obtain and adhere to manufacturer's written instructions

- ***Cleaning***
- ***Packaging***
- ***Sterilization modality***
- ***Cycle type***
- ***Exposure time***
- ***Exposure Temperature***
- ***Drying time (if recommended)***

IFUs should be accessible to staff performing sterilization

Steam: Reconcile cycle parameter differences between the Sterilizer Manufacturer, Device Manufacturer, and Packaging Manufacturer

VH2O2: Device manufacturer and packaging manufacturer should both reference the same sterilizer model and cycle type

AORN 2020 Guideline for Sterilization, RP I.4

Describe available sterilization monitoring tools

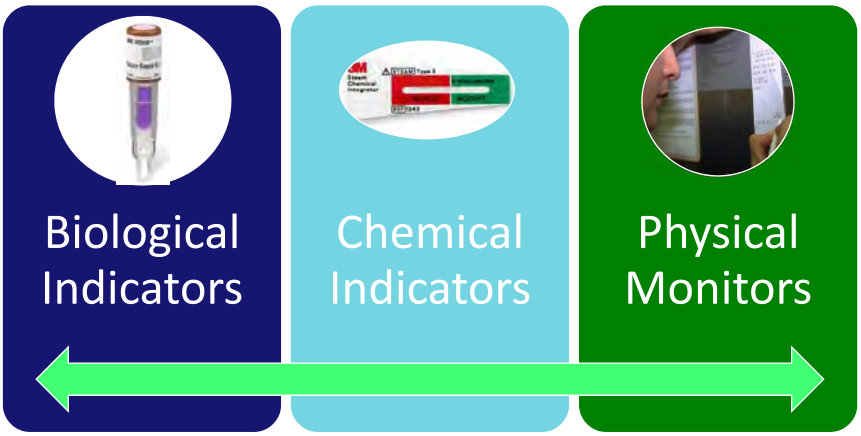
Sterilization Process Monitoring

Goal of the sterilization process?

- To kill microorganisms!
  - *You can't see sterility!*
  - *You can't test sterility of processed devices in your ASC in any practical way!*

We use several monitoring tools to gather information about the process to demonstrate the process was effective

Sterilization Process Monitoring Tools

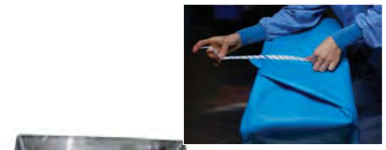


Biological Indicators for Sterilization Monitoring

Test systems containing viable microorganisms providing a defined resistance to a specified sterilization process

Chemical Indicators for Sterilization Monitoring

- *Devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or used in specific tests of sterilization equipment*



Primary Applications

1. Exposure Indicators (outside every pack)
2. Internal Chemical Indicators (inside every pack)
3. Sterilizer Test Indicators

ANSI/AAMI/ISO 11140-1:2014, ANSI/AAMI ST79:2017 Section 13.5.2, ANSI/AAMI ST58:2013 (R2018) Section 9.5.3

Types of Chemical Indicators

Type 1 Process Indicators (external)

Type 2 Indicators for use in specific tests

(e.g. Bowie-Dick test)

Internal

Type 3Single variable Indicators (internal)

Type 4 Multi-variable Indicators (internal)

Type 5 Integrating Indicators (internal)

Type 6 Emulating Indicators (internal)

There is no hierarchical significance to the types

ANSI/AAMI/ISO 11140-1: 2014, ANSI/AAMI ST79:2017 section 13.5.2

Discuss current guidelines and recommended practices for quality control monitoring of steam and vaporized hydrogen peroxide sterilization processes

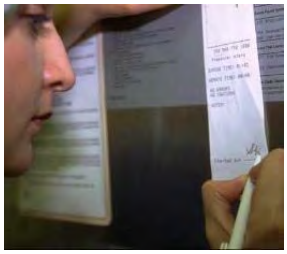
ANSI/AAMI ST79 Section 13
Steam Sterilization Process Monitoring

Four levels of testing . . .

1 Routine load release	Testing of each non-implant and implant load
2 Routine sterilizer efficacy monitoring	Establishing a regular pattern of testing the efficacy of the sterilization process
3 Sterilizer qualification testing	Testing of the sterilizer after events occur which could affect the ability of the sterilizer to perform
4 Periodic product testing	Testing of routinely processed items to ensure the effectiveness of the sterilization process and to avoid wet packs

ANSI/AAMI ST79:2017, Section 13

Routine Load Release Nonimplants

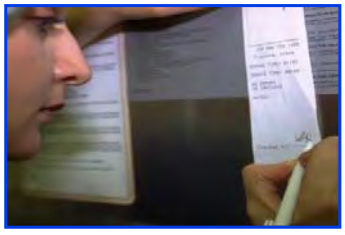


- Physical monitors
- External process indicator (Type 1) on every package
- Internal CI (preferably Type 5 or 6) inside every package
- Optional monitoring of load with a PCD containing a
  - BI
  - BI and a Type 5 CI
  - Type 5 integrating indicator
  - Type 6 emulating indicator
- Evaluation of all data by an experienced, knowledgeable person
- Do not distribute load if any data suggests a sterilization process failure

 43

Physical Monitors

Physical monitor checked for every cycle to verify correct cycle was selected and cycle parameters were met



"Sterilizers that do not have recording devices should not be used, with the exception of sterilizers used together with accessory recording devices or printouts."

ANSI/AAMI ST79:2017, Section 13.5.1

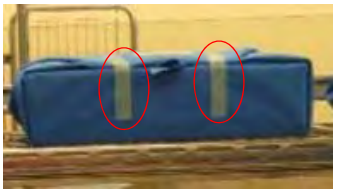
 44

Exposure indicators (External CIs)

For visual confirmation that the pack or package was exposed to the process

Every packaged item should have an external process indicator (Type 1)

Do not provide information on the quality of the sterilization process

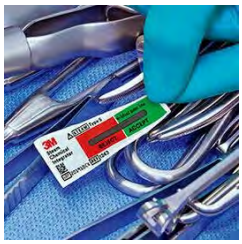


ANSI/AAMI ST79:2017, Section 13.5.2.2.1

Internal Chemical Indicators (CI)

Place a chemical indicator inside every package

- ✓ Can be Type 3, 4, 5, or 6 but **preferably** a Type 5 or Type 6 CI



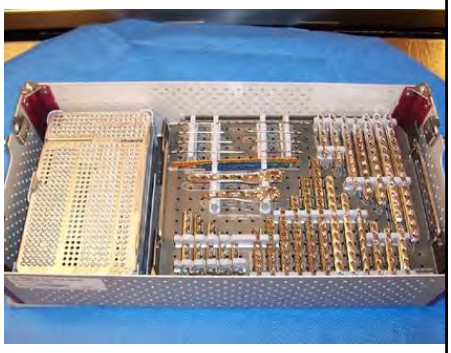
ANSI/AAMI ST79:2017, Section 13.5.2.2.2

Steam Sterilization Quality Control

Implants vs Non-Implants

AAMI & AORN place the highest level of quality control test requirements on loads that contain an implant

Rationale is that implants present the highest level of risk



 47

Routine Load Release Implants

- Physical monitors
- External process indicator (Type 1) on every package
- Internal CI (preferably Type 5 or 6) inside every package
- A PCD containing a BI and a Type 5 integrating indicator
- Evaluation of all data by an experienced, knowledgeable person
- Do not distribute load if any data suggests a sterilization process failure

- The load should be quarantined until the results of the BI testing are available
- Type 5 integrating indicator used to release implant in emergency situations

ANSI/AAMI ST79:2017, Sections 13.6.3, Table 2

 48

Early Release of Implants

If documented medical exceptions dictate release of implant before BI result:

- Exception Form for Premature Release of Implantable:
  - Name of implant
  - Name of patient
  - Name of surgeon
  - Reason for premature release
  - **What could have prevented the premature release**

ANSI/AAMI ST79:2017 13.6.3 and Annex K

Annex K

Exception Form for Premature Release of Implantable Device/Tray

NOTE—In a documented emergency situation, implantable devices will be released from quarantine in Central Service without the biological monitor result. This form should accompany the implant to the Operating Room. Operating Room personnel should complete this form and return it to Central Service within 24 hours.

PLEASE COMPLETE ALL INFORMATION:

DATE: _____ SHIFT: _____ TIME: _____ AM PM

PERSON COMPLETING THIS REPORT IN CENTRAL SERVICE: _____

The following implantable devices/trays were prematurely released to the Operating Room:

_____

_____

_____

NAME OF OR PERSON REQUESTING PREMATURE RELEASE OF DEVICES:

_____

OPERATING ROOM REPORT:

PATIENT NAME: _____

SURGEON NAME: _____

TIME OF PROCEDURE: _____ AM PM DATE: _____

REASON PREMATURE RELEASE WAS NEEDED: _____

_____

_____

_____

WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS DEVICE? TRAY? _____

_____

_____

_____

NAME OF OR PERSON COMPLETING THIS REPORT: _____

DATE REPORT COMPLETED: _____ FORM RETURNED TO CENTRAL SERVICE ON: _____

_____

Figure L.2—Exception form for premature release of implantable device/tray

Routine Sterilizer Efficacy Monitoring

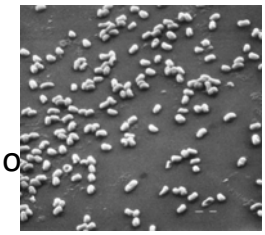
- **Divided into sections**
  - Sterilizers larger than 2 cubic feet
  - Table-top sterilizers
  - Gravity-displacement cycles

Photo courtesy of Rose Seavey,
The Children's Hospital – Denver

ANSI/AAMI ST79:2017, Section 13.7

Routine Steam Sterilizer Efficacy Monitoring

- Biological indicators containing *Geobacillus stearothermophilus* spores
- Select a BI that is suitable for use in the specific sterilizatio cycle
- Frequency: BI PCD should be used for routine sterilizer efficacy monitoring at least weekly, but preferably every day that the sterilizer is in use



Geobacillus stearothermophilus spores (ATCC 7953)

ANSI/AAMI ST79:2017, Section 13.5

 51

BI Process Challenge Device (PCD)

"Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process."

- User assembled PCD
  - Challenge test pack or tray (e.g., AAMI 16-towel pack, gravity IUSS containment device, representative table-top PCD)
- Pre-assembled, commercially available PCD
  - FDA Cleared
  - Note: not available for table-top sterilizers

ANSI/AAMI ST79:2017, Sections 2.9 and 13.5.4

 52

Routine Efficacy Monitoring with a BI PCD

Frequency of Monitoring with a BI PCD: Weekly, preferably daily

Sterilizers larger than 2 cubic feet

- AAMI 16 towel pack or commercially available disposable, FDA cleared BI PCD
- Commercially available PCDs recommended
- Full load on bottom shelf over drain
- Each cycle type should be tested

ANSI/AAMI ST79:2017, Sections 13.7,1, 13.7.2

 53

Routine Efficacy Monitoring Dynamic-air-removal IUSS

- Use a pre-assembled, commercially available BI PCD
- Monitoring of IUSS cycles may be done in an empty chamber (Table 1)

AAMI ST79:2017 Table 1 and Sections 13.7.2.1 and 13.8.4

 54

Routine Efficacy Monitoring with a BI PCD

Frequency of Monitoring with a BI PCD: Weekly, preferably daily

Gravity Displacement Sterilizers

- Representative BI PCD
- Test each type of tray configuration used
- Placed on bottom shelf over the drain
- Otherwise empty chamber

ANSI/AAMI ST79:2017, Sections 13.7.1, 13.7.4

 55

Routine Efficacy Monitoring with a BI PCD

Frequency of Monitoring with a BI PCD: Weekly, preferably daily

Table top sterilizers

- BI PCD should be representative of the package or tray routinely processed, and most difficult to sterilize
- Contains items normally present during routine sterilization
- BI PCD placed in full load in cold point (check with sterilizer manufacturer)

ANSI/AAMI ST79:2017, Sections 13.7.1, 13.7.3

 56

Biological Indicators - Positive Control

Incubate a positive control BI each day that a test BI is incubated in each incubator or auto-reader

- From same lot number as test BI

Purpose is to verify the test system is working and to ensure:

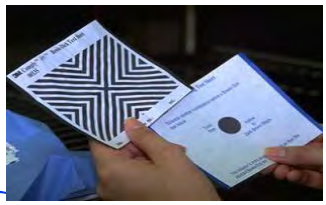
- Correct incubation conditions
- Viability of spores
- Capability of medium to promote growth
- Proper functioning of auto-reader and incubator

ANSI/AAMI ST79:2017, Section 13.7.2.4

 57

Routine Sterilizer Efficacy Monitoring

- Bowie-Dick Testing
  - **270-275ºF dynamic-air removal sterilizers (i.e., Pre-vacuum or vacuum-assisted sterilizers)**
  - **Run Bowie-Dick test pack:**
    - Empty chamber
    - Performed each day the sterilizer is used, before the first processed load



BD test sheet with uniform color change

ANSI/AAMI ST79:2017, Section 13.7.6

 58

Routine Steam Sterilizer Efficacy Monitoring
Pre-vac IUSS Sterilizer larger than 2 cubic feet

1. Warm-up Cycle
2. Bowie-Dick Test
3. BI PCD
4. Non-implant loads
5. BI + Type 5 CI PCD with any IMPLANT loads

 59

Routine Steam Sterilizer Efficacy Monitoring
Sterilizer larger than 2 cubic feet

1. Warm-up Cycle
2. Bowie-Dick Test
3. BI PCD
4. Non-implant loads
5. BI + Type 5 CI PCD with any IMPLANT loads

 60

ANSI/AAMI ST79:2017 Recall

"13.7.5 Actions to take when BIs, CIs, or physical monitors indicate a sterilization process failure"

"c) If the cause of the failure is not immediately identified, the load should be quarantined, and all loads back to the last negative BI should be recalled. Items in these loads should be retrieved, if possible, and reprocessed (see 13.7.5.2). The sterilizer in question should be taken out of service until the cause of the failure is identified and corrected."

ANSI/AAMI ST79:2017, Section 13.7.5

 61

ANSI/AAMI ST79:2017 Recall

"13.7.5 Actions to take when BIs, CIs, or physical monitors indicate a sterilization process failure"

"c) If the cause of the failure is not immediately identified, the load should be quarantined, and all loads back to the last negative BI should be recalled. Items in these loads should be retrieved, if possible, and reprocessed (see 13.7.5.2). The sterilizer in question should be taken out of service until the cause of the failure is identified and corrected."

ANSI/AAMI ST79:2017, Section 13.7.5

 62

Considerations for monitoring every steam sterilization load with a BI PCD:

Uniform standard of care

Highest level of quality control

Reduce risk of monitoring mistakes

Simplifies staff training

Minimize impact of a recall

Fast readout BIs facilitate frequent monitoring

 63

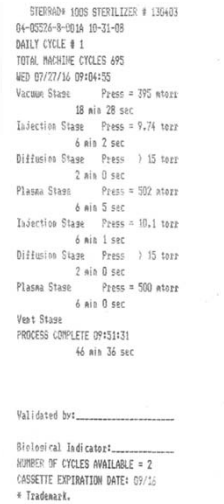
Sterilization Monitoring for Hydrogen Peroxide Systems

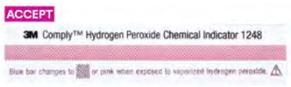
 64

AAMI ST58:2013 (R2018) Section 9 Quality Control

9.5 monitoring gaseous chemical sterilization processes

- Physical Monitors
- Chemical Indicators
- Biological Indicators





AAMI ST58:2013 Section 9 Quality Control

9.5 monitoring gaseous chemical sterilization processes

Physical Monitors

… physical monitoring and other indicators of sterilizer performance should never be considered a substitute *for careful adherence to prescribed packaging and loading procedures … (AAMI ST58)*

- cycle identification number
- end of the cycle examine and interpret
- verify cycle parameters met and initial

AAMI ST58:2013 Section 9 Quality Control

Recommended Chemical Indicator (CI) Usage

- Exposure Control:
  external CI on every package

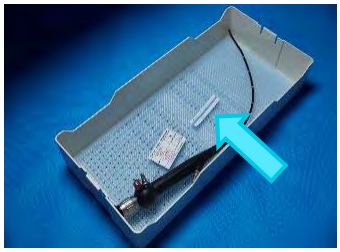
"Using chemical indicators
…..*A CI should be used on the outside of each package unless the internal indicator is visible…"*

AAMI ST58:2013, Section 9.5.3.2

AAMI ST58:2013 Section 9 Quality Control

Recommended Chemical Indicator (CI) Usage

- Internal CI inside every package, tray, containment device, cassette, instrument tray



"Using chemical indicators
…. The CI should be placed in that area of the package, tray, or containment device that creates the greatest challenge to sterilant penetration..."

- AAMI ST58:2013, Section 9.5.3.2

AAMI ST58:2013 Section 9 Quality Control

Biological Indicators

9.5.4.1 General considerations

"…Biological indicators are intended to demonstrate whether the conditions were adequate to achieve sterilization."

9.5.4.3 Frequency of use…

"A PCD with the appropriate BI should also be used at ***least daily, but preferably in every sterilization cycle*** *(see 9.5.4.5)"*

Each load containing implantable.."

AAMI ST58:2013, Section 9.5.4.3

AAMI ST58:2013 Section 9 Quality Control

- Daily Control BI

Acceptance criteria:

- Negative result from test BI
- Positive result from control BI
- Appropriate readings from physical monitors
- CI with acceptable end-points

AAMI ST58:2013 (R2018), Section 9.5.4.5.3

Key Learnings

- Accreditation surveyors continue to focus on device reprocessing
- Consult device manufacturers' Instructions for Use (IFU) for validated sterilization parameters
- Quality control monitoring, according to current standards and evidence-based guidelines, is an important element of all sterilization processes

Questions?

THANK YOU!

References

Association for the Advancement of Medical Instrumentation.

- *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* ANSI/AAMI ST79:2017. Arlington, VA. 2017.
- *Chemical sterilization and high level disinfection in health care facilities.* ANSI/AAMI ST58:2013 (R2018). Arlington, VA. 2018.

Association of periOperative Registered Nurses. *Guidelines for Perioperative Practice* 2020 Edition. Denver, CO. 2020.

- *Guideline for Sterile Technique*
- *Guideline for Sterilization*

Thank you

This Concludes the CE Portion of Our Program

- Please use your phone to access the QR code on the right by opening your camera app and pointing it at the square.
- A link may also be provided if you wish to fill it out on your computer.
- Fill in the subsequent evaluation, and you will be issued a CE certificate for 1 contact hour for your records.
- Your Nursing License number is required to issue a continuing education contact hour.
- If you are unable to fill out the evaluation, you may request a paper evaluation.

Elizabeth Even, MSN, RN, CEN, Standards Interpretation Group

Most Common EC/IC Challenges

February 22, 2024

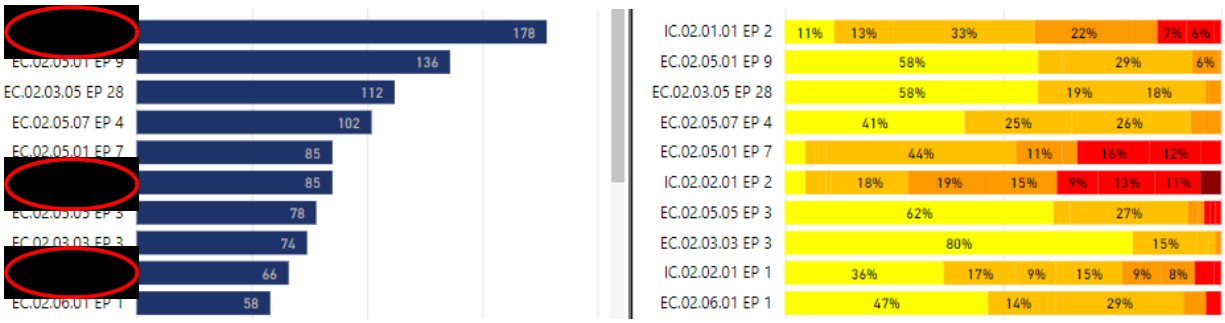
Faculty Introduction

- Elizabeth Even, RN, MSN, CEN
- Senior Associate Director, SIG
- Clinical and PES
- Standards +
- Entire Accreditation process

Objectives

- Identify the top-cited standards in the Infection Control and Environment of Care Chapters in 2023
- Tools and Tips for Compliance
- How Leaders can affect change

Top 10 EC/IC Findings 2023



ASC 1/1/23-12/1/23

What is the Root Cause?

Resources

Accountability

Process Development

Process Oversight

Education/Training/Competency

Understanding the Root Cause Can Help Guide Activities and Resource Allocation

Short term fix

Long term solution

IC.02.01.01 EP2

The organization uses standard precautions, * including the use of personal protective equipment (PPE), to reduce the risk of infection

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

From CDC.gov

Standard Precautions

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Use Standard Precautions to care for all patients in all settings.
Standard Precautions include:

- 5a. Hand hygiene
- 5b. Environmental cleaning and disinfection
- 5c. Injection and medication safety
- 5d. Risk assessment with use of appropriate personal protective equipment (e.g., gloves, gowns, face masks) based on activities being performed
- 5e. Minimizing Potential Exposures (e.g. respiratory hygiene and cough etiquette)
- 5f. Reprocessing of reusable medical equipment between each patient and when soiled

https://www.cdc.gov/infectioncontrol/guidelines/core-practices/index.html

Observations: Standard Precautions

Standard Precautions Not Performed

- Hand hygiene not performed after glove removal
- Gloves not worn when obtaining blood for blood glucose monitoring

Supplies not available

Process, procedure or policy unclear

Lack of accountability

Key Elements: Personal Protective Equipment

Exposure Control Plan

Written document guides PPE Program

Risk assessed and updated annually

PPE Available

Types appropriate for exposure

Sized to fit healthcare workers

Available in locations of use

Trained Employees

Employees know why specific type of PPE should be used

Employees are competent to choose

Employees trained to don, doff, and discard or disinfect

Use Enforced

Monitoring and feedback provided

Employees use PPE

Action Taken When Issues are Identified

If identified as an issue, improve use

Observations: Personal Protective Equipment

Personal Protective Equipment (PPE) not worn

- OSHA hazard assessment not performed
- Process, procedure or policy unclear
- Supplies were not available
- Staff were untrained
- Lack of accountability

Staff did not correctly don and doff PPE

- Staff member did not don PPE per MIFU
- Employees were removing PPE in a manner that could contaminate themselves or the environment.

Re-usable PPE not reprocessed as required by manufacturer's instructions for use

- Staff were not trained to clean and disinfect reusable PPE

IC.02.01.01 EP2 Observations

"It was observed that CRNA did not perform cleaning of three newly opened medication vials."

"It was noted that five single use/dose medication vials were being used on multiple patients without adherence to CDC guidelines."

"Provider failed to complete hand hygiene immediately after removing his surgical gloves and surgical attire upon completion of cardiac catheterization procedures which was contrary to the organization policy"

Observations - Standard Precautions – Injection and Medication Safety

Injection Safety

- Failure to swab the top of vials before access
- Multidose vials taken into patient treatment area
- Utilization of single patient IV fluids to make flush syringes

5c. Injection and Medication Safety References and resources: 11, 17-20	1. Use aseptic technique when preparing and administering medications 2. Disinfect the access diaphragms of medication vials before inserting a device into the vial 3. Use needles and syringes for one patient only (this includes manufactured prefilled syringes and cartridge devices such as insulin pens). 4. Enter medication containers with a new needle and a new syringe, even when obtaining additional doses for the same patient. 5. Ensure single-dose or single-use vials, ampules, and bags or bottles of parenteral solution are used for one patient only. 6. Use fluid infusion or administration sets (e.g., intravenous tubing) for one patient only 7. Dedicate multidose vials to a single patient whenever possible. If multidose vials are used for more than one patient, restrict the medication vials to a centralized medication area and do not bring them into the immediate patient treatment area (e.g., operating room, patient room/cubicle) 8. Wear a facemask when placing a catheter or injecting material into the epidural or subdural space (e.g., during myelogram, epidural or spinal anesthesia)

Key Elements: CDC Standard Precautions - Medication and Injection Safety

Activities Align with Requirements
- Laws, Codes and Regulation
- Manufacturer's Instructions for Use
- Required EBG

Supplies Available

Observed Activities Align with Organizational Processes, procedures or policies

Interventions/Activities Implemented
- Included relevant organizational components and functions
- Training, education and/or competency

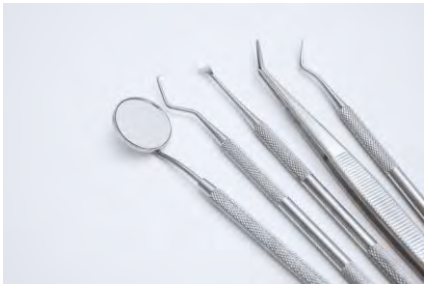
IC.02.02.01 EP2

High-level disinfection (HLD) and sterilization

- #1 on the Most Frequently Cited Higher-Risk Accreditation Requirements
- In the Top 10 Infection Control Findings

Highest Percentage of High-Risk Findings and findings evaluated for Immediate Threat to Health and Safety

Wide Variety of Supplies, Instruments and Devices Used in Ambulatory Settings



- Single use vs. reusable
- Varying levels of disinfection/sterilization required
- Wide variation in sterilization cycle parameters

What Type of Instruments/Devices do you have in Your Inventory?

Single use

May be supplied non-sterile and require sterilization prior to use

May be supplied sterile and ready to use

Reusable

May be supplied non-sterile and require sterilization prior to first use and after each use

May be supplied sterile and requires sterilization after each use

Manufacturer's Instructions for Use (IFU)

- Most items utilized throughout all steps of reprocessing will have instructions for use
  - Equipment
  - Biologic indicators, Chemical indicators
  - Accessories used for reprocessing
  - Instruments/Devices
  - Cleaning accessories
- Provides instructions for use, maintenance, cleaning, disinfection and/or sterilization, when the item is not longer suitable for use
- Compatible disinfection/sterilization processes
  - May have instructions for reprocessing that surpass intended use (e.g., used for semi-critical procedure, IFU only provides instructions for sterilization

Know your Instruments, Devices and Equipment

This is Critical

- Validate the type of sterilization cycle that your sterilizer uses
  - Gravity Displacement
  - Dynamic Air Removal (Prevac, Steam Flush Pressure Pulse)
- Follow the MIFU of the instruments/devices being sterilized based on the type of sterilizer in use

One standard sterilization cycle/parameters is often not sufficient for reprocessing the different types of instruments and dental handpieces used in a dental office

IC.02.02.01 EP2

Staff members performing quality control testing of the sterilizer are not currently incubating positive controls with the processed BI when performing biological indicator testing, as required per the manufacturer's recommendations.

Vaginal probes were disinfected after patient use using a disinfectant wipe and did not undergo high level disinfection as required by the MIFU.

Review of sterile processing noted failure to perform sterilization of surgical instruments in accordance with manufacturer's instructions for use (IFU)

Key Elements – High Level Disinfection

Available Supplies	• MIFU available • Supplies necessary to decontaminate and perform high level disinfection available
Manufacturer Instructions for Use Followed	• For all steps of the process • From point of use through storage
Competent Employees	• Staff who perform HLD are trained and competent • Staff who oversee process are competent to evaluate the process
Infection Prevention and Control Involvement	• Process to evaluate adherence to procedures
Staff Accountability	• Leadership hold staff accountable

Observations: MIFU Conflicts and Clarifications

- **Unclear MIFU not clarified**
- **Conflicts within MIFU not clarified**
  - MIFU does not contain instructions for level of reprocessing based on intended use of the item
- **MIFU between instruments /sterilization accessories used not clarified**
  - Cycle parameters

IC.02.02.01 EP1:
Low and Intermediate Level Disinfection

Product selection

Contact time

Key Elements: Implementation

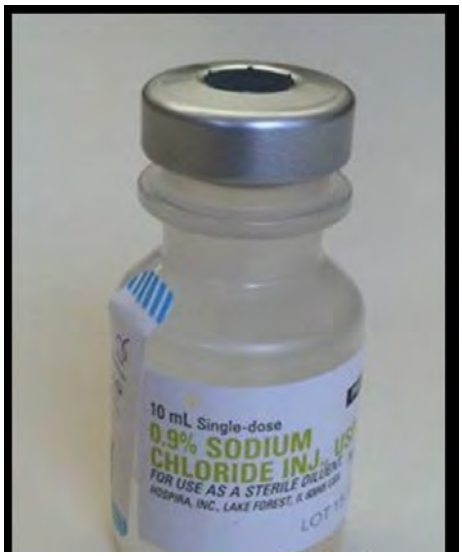
- Compliant Process
- Resources
- Competent Employees
- Infection Prevention and Control Involvement
- Accountable Staff
- Oversight

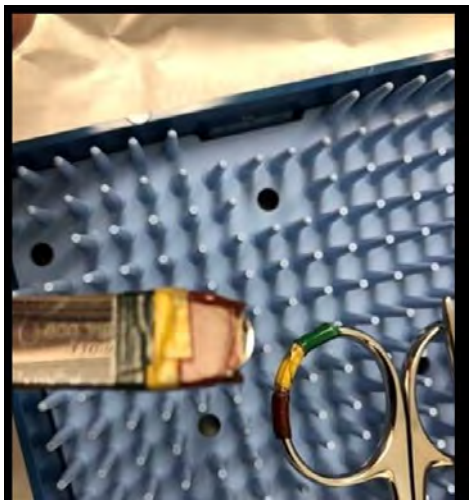
Compliance Tactics

- Ensure adequate qualified infection control (IC) leadership
- Periodic review of IC program
- Ensure necessary resources to support IC program are available
- Appropriate staff training and competencies
- Routine process checks implemented by leadership

What's the problem?!

What's the problem?!

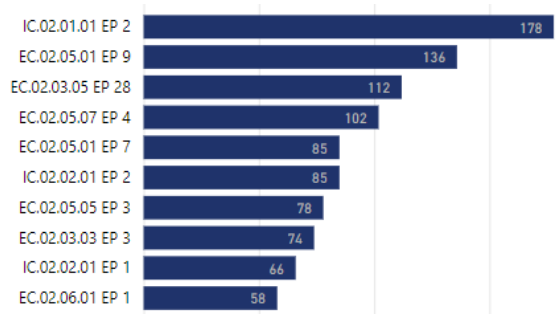


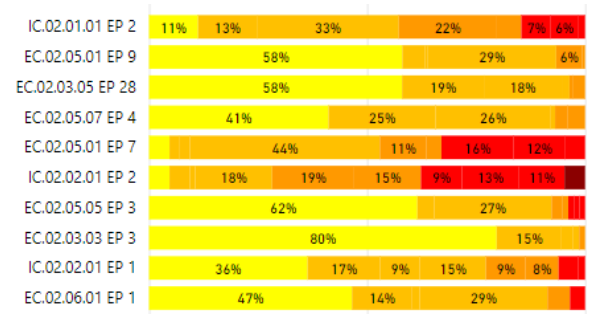


What's the problem?!

Environment of Care

Top 10 EC/IC Findings 2023



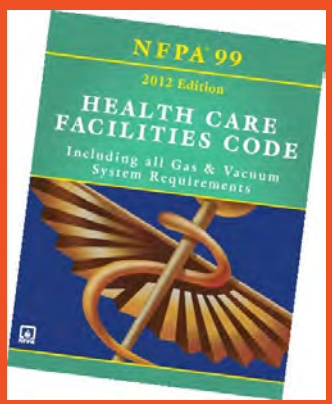


Application of NFPA 99

Health Care Facilities Code

2012 Edition

Adopted by CMS on May 4, 2016
Federal Register (Vol.81, No.86)



Referenced in TJC Environment of Care Standards

NFPA 99 includes code requirements for:

Chapter 5	Gas and Vacuum Systems
Chapter 6	Electrical Systems
Chapter 9	Heating, Ventilation, and Air Conditioning
Chapter 10	Electrical Equipment
Chapter 11	Gas Equipment
Chapter 14	Hyperbaric Facilities
Chapter 15	Features of Fire Protection

Is the facility NEW or EXISTING?

Buildings are considered existing occupancies if final plans for construction, additions, renovations, or changes in occupancy were approved by the local authority having jurisdiction before July 5th, 2016

Commonly Used Acronyms

AHC	Ambulatory Health Care	NFPA	National Fire Protection Association
ASC	Ambulatory Surgical Center	PCRA	Pre-construction Risk Assessment
CoP	Condition of Participation	PDA	Preliminary Denial of Accreditation
EP	Element of Performance	PFI	Plan for Improvement
ESC	Evidence of Standards Compliance	PFP	Priority Focus Process
FMEA	Failure Mode Effects Analysis	PFT	Priority Focus Tool
FSA	Focus Standards Assessment	PPE	Personal Protective Equipment
ICM	Intracycle Monitoring	RFI	Requirement for Improvement
ICRA	Infection Control Risk Assessment	SDS	Safety Data Sheet
ILSM	Interim Life Safety Measures	SOC	Statement of Conditions
ITL	Immediate Threat to Life	SPFI	Survey Plan for Improvement
MOS	Measure of Success	TLW	Time Limited Waiver

FACILITY GUIDELINES INSTITUTE

The keystone to health care planning, design, and construction

- For further information, refer to Guidelines for Design and Construction of Health Care Facilities, 2022 edition, administered by the Facility Guidelines Institute and published by the American Society for Healthcare Engineering (ASHE).

Utility System Control Labels

- The organization labels utility system controls to facilitate partial or complete emergency shutdowns. (EC.02.05.01 EP9)
- Examples of utility system controls that should be labeled:
  - Utility source valves
  - Utility system main switches and valves
  - Individual circuits in an electrical distribution panel
  - Fire alarm circuit

Utility System Control Labels

- Utility source valves

Utility System Control Labels

- Utility system main switches and valves

Utility System Control Labels

- Individual circuits in an electrical distribution panel
- "The electrical panel had 7 circuits in the on position that were labeled as spares. This was confirmed by the facility staff."

Utility System Control Labels

- The fire alarm system's circuit is clearly labeled as Fire Alarm Circuit; the disconnect method (that is, the circuit breaker) is marked in red; and access is restricted to authorized personnel.
- Information regarding the dedicated branch circuit for the fire alarm panel is located in the control unit.

EC.02.05.07 EP4

Every week, the organization inspects the emergency power supply system (EPSS), including all associated components and batteries. The results and completion dates of the inspections are documented.

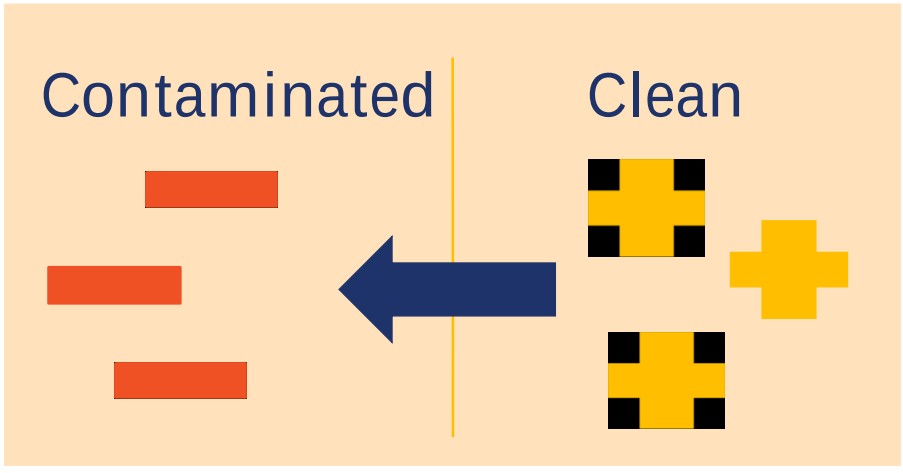
Solution:

Educate maintenance staff and implement appropriate documentation process.

Control of Airborne Contaminants

The ventilation system provides appropriate pressure relationships, air-exchange rates, filtration efficiencies, relative humidity, and temperature (EC.02.05.01 EP7)

- Operating rooms
- Special procedure rooms that require a sterile field
- Rooms for patients diagnosed with or suspected of having airborne communicable diseases
- Patients in "protective environment" rooms
- Laboratories
- Pharmacies
- Sterile supply/processing rooms
- Other sterile spaces.



Air-Pressure Relationships

Observation:

Observed in Building Tour. The air pressure in the clean side of sterile processing was negative to the corridor. The air pressure in the clean and sterile storage room (approximately 3/4 sterile items) was negative to the corridor.

Solution:

Implement monitoring process (automated)

Compliance Tactics

Interior Spaces are Safe and Suitable

- Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, or services provided. (EC.02.06.01 EP1)

Hazardous Chemical Risks

- The organization minimizes risks associated with selecting, handling, storing, transporting, using, and disposing of hazardous chemicals. (EC.02.02.01 EP5)

Fire Safety Equipment & Building Features

- Testing requirements from EC.02.03.05:
  - Supervisory signal devices on the inventory
  - Vane-type and pressure-type water flow devices and valve tamper switches
  - Duct detectors, heat detectors, manual fire alarm boxes, and smoke detectors
  - Visual and audible fire alarms, including speakers and door-releasing devices
  - Fire alarm equipment on the inventory for notifying off-site fire responders
  - Electric motor–driven fire pumps monthly and diesel engine–driven fire pumps every week under no-flow conditions
  - Water-storage tank high- and low-water level alarms

Fire Safety Equipment & Building Features (continued)

- Main drains at system low point or at all system risers
- Fire department water supply connections
- Fire pumps under flow
- Hydrostatic and water-flow tests for standpipe systems
- Carbon dioxide and other gaseous automatic fire-extinguishing systems
- Inspects portable fire extinguishers
- Maintenance on portable fire extinguishers, including recharging
- Hydrostatic tests on standpipe occupant hoses

Fire Safety Equipment & Building Features (continued)

- Operates fire and smoke dampers one year after installation and then at least every four years to verify that they fully close
- Automatic smoke-detection shutdown devices for air-handling equipment
- Sliding and rolling fire doors, smoke barrier sliding or rolling doors, and sliding and rolling fire doors in corridor walls and partitions for proper operation and full closure
- Inspection and testing of fire door assemblies
- Elevators with firefighters' emergency operations

ITM Time Frames for Inspections Defined

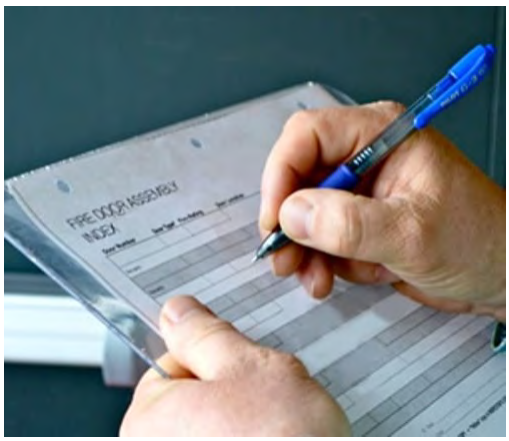
- The Joint Commission EC chapter defines time as:
  - Every 36 months/every 3 years = 36 months from the last event, plus or minus 45 days
  - Annually/every 12 months/once a year/every year = 1 year from the last event, plus or minus 30 days
  - Every 6 months = 6 months from the last event, plus or minus 20 days
  - Quarterly/every quarter = every three months, plus or minus 10 days
  - Monthly/30-day intervals/every month = 12 times a year, once per calendar month
  - Every week = once per calendar week

EC.02.03.05 Document List & Review Tool

STANDARD - EPs	See Legend C	NC	NA	IOU	Document / Requirement	Frequency	Q 1/ Semi	Q 2	Q 3/ Semi	Q 4/ Annual
EC.02.03.05					Fire Protection and Suppression Testing and Inspection					
EP 1					Supervisory Signals-including: Control valves; pressure supervisory; pressure tank, pressure supervisory for a dry pipe (both high and low conditions), steam pressure; water level supervisory signal initiating device; water temperature supervisory; and room temperature supervisory.	Quarterly				
EP 2					Water flow devices	Semiannually				
					Tamper switches	Semiannually				
EP 3					Duct, heat, smoke detectors, and manual fire alarm boxes	Annually				
EP 4					Notification devices (audible & visual), and door-releasing devices	Annually				
EP 5					Emergency services notification transmission equipment	Annually				
EP 6					Electric motor-driven fire pumps tested under no-flow conditions	Monthly				
					Diesel-engine-driven fire pumps tested under no-flow conditions	Weekly				
EP 7					Water storage tank high and low-level alarms	Semiannually				
EP 8					Water storage tank low water temp alarms (cold weather only)	Monthly				
EP 9					Sprinkler systems main drain tests on all risers	Annually				
EP 10					Fire department connections inspected (Fire hose connections N/A)	Quarterly				
EP 11					Fire pump(s) tested – under flow	Annually				
EP 12					Standpipe flow test every 5 years	5 years				
EP 13					Kitchen suppression semi-annual testing	Semiannually				
EP 14					Gaseous extinguishing systems inspected (no discharge req.)	Annually				
EP 15					Portable fire extinguishers inspected monthly	Monthly				
EP 16					Portable fire extinguishers maintained annually	Annually				
EP 17					Fire hoses hydro tested 5 years after install; every 3 years thereafter	5 years / 3 years				
EP 18					Smoke and fire dampers tested to verify full closure	1 year after install At least every 6 years thereafter				
EP 19					Smoke detection shutdown devices for HVAC tested	Annually				
EP 20					All horizontal and vertical roller and slider doors tested	Annually				
EP 25					Inspection and testing of door assemblies by qualified person	Annually				
EP 27					Documentation of maintenance testing and inspection activities for EPs 1-20 and 25 includes: activity name; date; inventory of devices, equipment or other items; frequency; contact info for person performing activity; NFPA standard; activity results					

Fire Door Inspections

- Annual inspection
- Knowledgeable person
- Operating components
- Both sides of the opening
- Documented



Portable Fire Extinguishers

- Monthly visual inspection
  - Accessible
  - Fully charged
  - Any parts broken
  - Correct type
- Annual maintenance by a licensed fire protection service company
- Extinguishers less than 40 lbs. cannot be installed above 60" (measured from top)

EC.02.03.05 EP28

Documentation of maintenance, testing, and inspection activities for Standard EC.02.03.05, EPs 1–20, 25 (including fire alarm and fire protection systems) includes the following:

- Name of the activity
- Date of the activity
- Inventory of devices, equipment, or other items
- Required frequency of the activity
- Name and contact information, including affiliation, of the person who performed the activity
- NFPA standard(s) referenced for the activity
- Results of the activity

Sterilizer Testing and Maintenance

- The organization conducts performance testing of and maintains all sterilizers.
- These activities are documented EC.02.04.03 EP4 (IC.02.02.01 EP2)

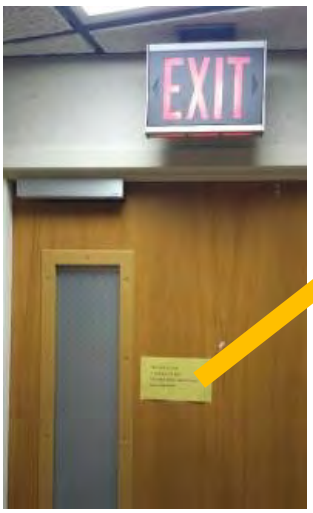
EC.02.05.05 EP3

The organization inspects, tests, and maintains the following: Utility systems.

The completion dates and test results are documented.

What's the problem?!

What's the problem?!

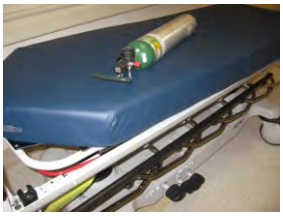


This is not an exit!
PLEASE DO NOT
OPEN

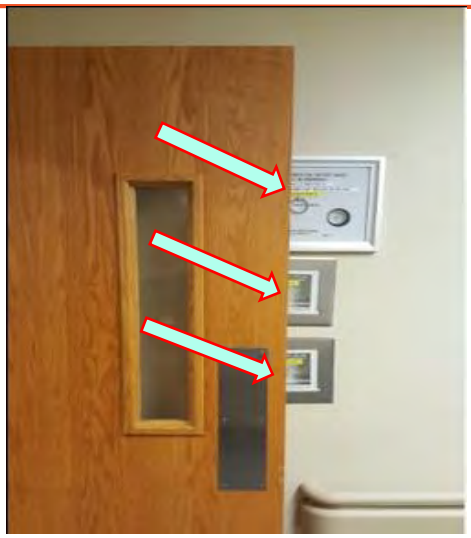
What's the problem?!

What's the problem?!

What's the problem?!



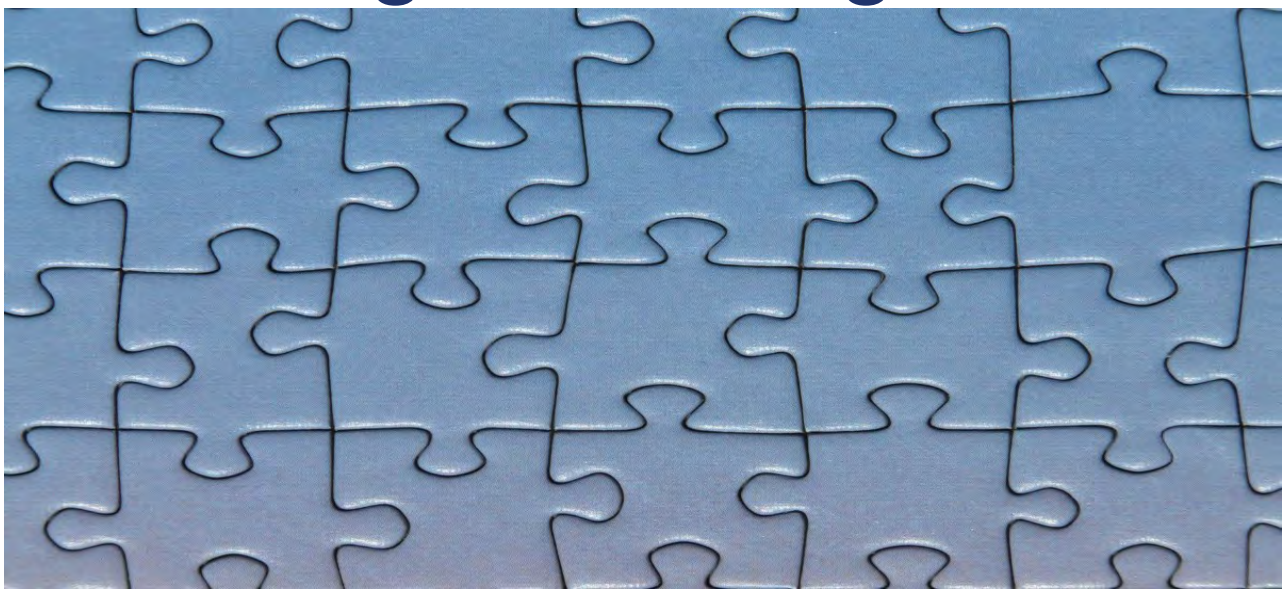
What's the problem?!



What's the problem?!

Points for creativity?!?

Putting it all together



Leadership Oversight

- Who do you need and where do you need them?
  - High risk areas/procedures
  - High-level disinfection/sterilization
  - Surgery/procedures
  - Dental

Safety Culture

- Leaders can build safety cultures by readily and willingly participating with care team members in initiatives designed to develop and emulate safety culture characteristics.

- Effective leaders who deliberately engage in strategies and tactics to strengthen their organization's safety culture see safety issues as problems with organizational systems, not their employees, and see adverse events and close calls ("near misses") as providing "information-rich" data for learning and systems improvement.

Sentinel Event Alert

A complimentary publication of The Joint Commission
Issue 57, March 1, 2017
Revised: June 16, 2021 (to end)

The essential role of leadership in developing a safety culture

In any health care organization, leadership's first priority is to be accountable for effective care while protecting the safety of patients, employees, and visitors. Competent and thoughtful leaders[1] contribute to improvements in safety and organizational culture.[2,3] They understand that systemic flaws exist and each step in a care process has the potential for failure simply because humans make mistakes.[4,5] James Reason compared these flaws – latent hazards and weaknesses – to holes in Swiss cheese. These latent hazards and weaknesses must be identified and solutions found to prevent errors from reaching the patient and causing harm.[6,7] Examples of latent hazards and weaknesses include poor design, lack of supervision, and manufacturing or maintenance defects.

The Joint Commission's Sentinel Event Database reveals that leadership's failure to create an effective safety culture is a contributing factor to many types of adverse events – from wrong site surgery to delays in treatment.[7]

In addition, through the results of its safety initiatives, The Joint Commission Center for Transforming Healthcare has found inadequate safety culture to be a significant contributing factor to adverse outcomes. Inadequate leadership can contribute to adverse events in various ways, including but not limited to these examples:

- Insufficient support of patient safety event reporting[8]
- Lack of feedback or response to staff and others who report safety vulnerabilities[9]
- Allowing intimidation of staff who report events[9]
- Refusing to consistently prioritize and implement safety recommendations
- Not addressing staff burnout[10,11]

In essence, a leader who is committed to prioritizing and making patient safety visible through every day actions is a critical part of creating a true culture of safety.[12] Leaders must commit to creating and maintaining a culture of safety; this commitment is just as critical as the time and resources devoted to revenue and financial stability, system integration, and productivity. Maintaining a safety culture requires leaders to consistently and visibly support and promote everyday safety measures.[13] Culture is a product of what is done on a consistent daily basis. Hospital team members measure an organization's commitment to culture by what leaders do, rather than what they say should be done.

The Joint Commission

www.jointcommission.org

https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf

What is the Root Cause?

Resources

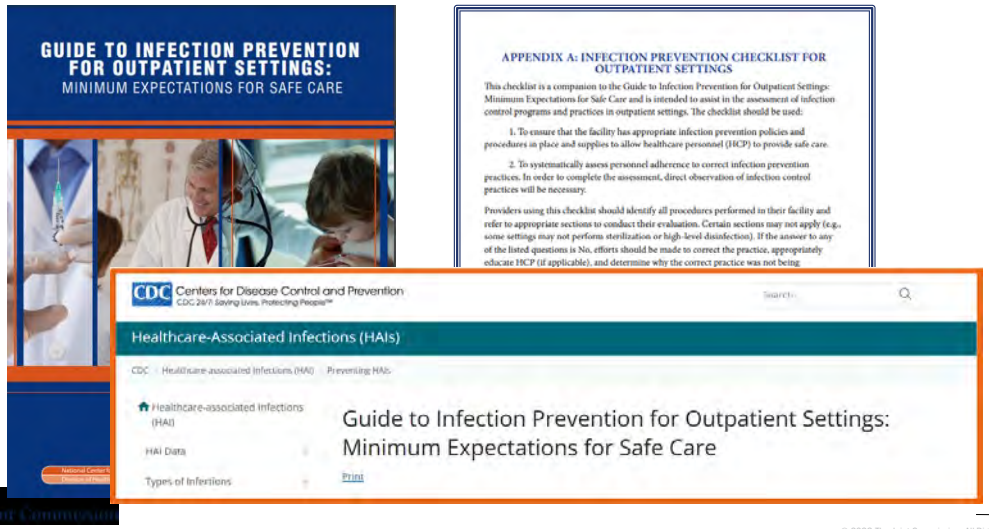
Accountability

Process Development

Process Oversight

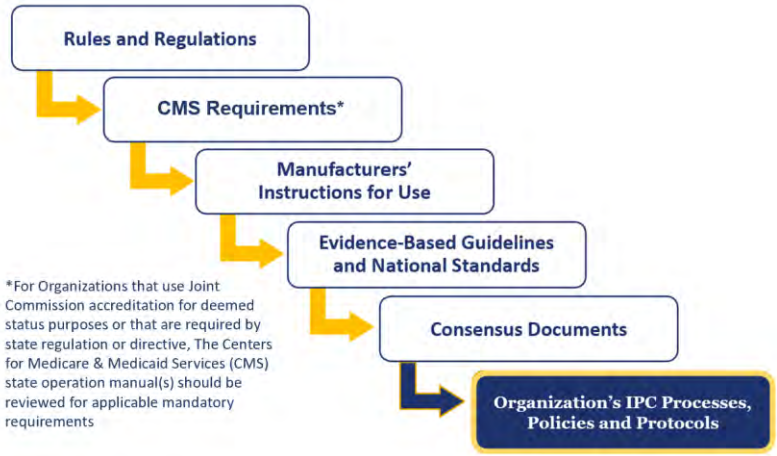
Education/Training/Competency

Ambulatory Infection Prevention Resources



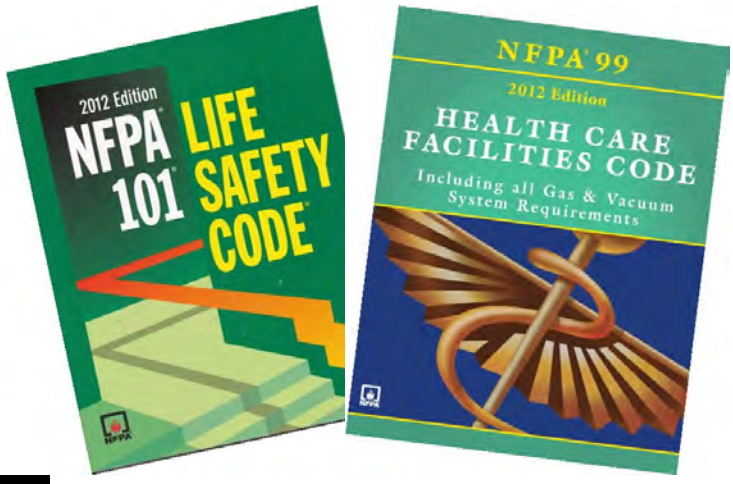
https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html

Approach to Assessing Compliance



Modified from April 2019 Perspectives (available at https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/infection-prevention-and-hai/ic-hierarchical-approach-to-scoring-standards-april-2019-perspectives.pdf © The Joint Commission. Used with permission.

The Basis for Physical Environment Standards



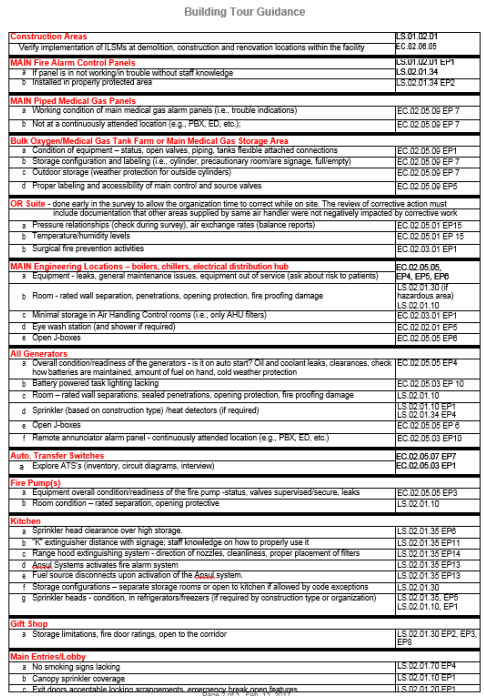
Survey Resources

- To prepare for document review, the Survey Activity Guide includes a "*Life Safety and Environment of Care—Document List and Review Tool*"
- This resource is located on The Joint Commission website at https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/physical-enviroment/lsc_ec_doclist_revtool.pdf

Building Tour Guidance

- Reflects what a tour should include
- Lists related standards / EPs
- Only guidance
- Does not reflect touring order

Available online: https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/physical-enviroment/life-safety-code/building_tour_guidance1.pdf



Building Tour Guidance

Construction Areas	LS.01.02.01
a Verify implementation of ILSMs at demolition, construction and renovation locations within the facility	EC.02.06.05
MAIN Fire Alarm Control Panels	LS.01.02.01 EP1
a If panel is in not working/in trouble without staff knowledge	LS.02.01.34
b Installed in properly protected area	LS.02.01.34 EP2
MAIN Piped Medical Gas Panels	
a Working condition of main medical gas alarm panels (i.e., trouble indications)	EC.02.05.09 EP 7
b Not at a continuously attended location (e.g., PBX, ED, etc.);	EC.02.05.09 EP 7
Bulk Oxygen/Medical Gas Tank Farm or Main Medical Gas Storage Area	
a Condition of equipment – status, open valves, piping, tanks flexible attached connections	EC.02.05.09 EP1
b Storage configuration and labeling (i.e., cylinder, precautionary room/are signage, full/empty)	EC.02.05.09 EP 7
c Outdoor storage (weather protection for outside cylinders)	EC.02.05.09 EP 7
d Proper labeling and accessibility of main control and source valves	EC.02.05.09 EP5
OR Suite - done early in the survey to allow the organization time to correct while on site. The review of corrective action must include documentation that other areas supplied by same air handler were not negatively impacted by corrective work	
a Pressure relationships (check during survey), air exchange rates (balance reports)	EC.02.05.01 EP15
b Temperature/humidity levels	EC.02.05.01 EP 15
b Surgical fire prevention activities	EC.02.03.01 EP1
MAIN Engineering Locations – boilers, chillers, electrical distribution hub	EC.02.05.05,
a Equipment - leaks, general maintenance issues, equipment out of service (ask about risk to patients)	EP4, EP5, EP6
b Room - rated wall separation, penetrations, opening protection, fire proofing damage	LS.02.01.30 (if hazardous area) LS.02.01.10
c Minimal storage in Air Handling Control rooms (i.e., only AHU filters)	EC.02.03.01 EP1
d Eye wash station (and shower if required)	EC.02.02.01 EP5
e Open J-boxes	EC.02.05.05 EP6
All Generators	
a Overall condition/readiness of the generators - is it on auto start? Oil and coolant leaks, clearances, check how batteries are maintained, amount of fuel on hand, cold weather protection	EC.02.05.05 EP4
b Battery powered task lighting lacking	EC.02.05.03 EP 10
c Room – rated wall separations, sealed penetrations, opening protection, fire proofing damage	LS.02.01.10
d Sprinkler (based on construction type) /heat detectors (if required)	LS.02.01.10 EP1 LS.02.01.34 EP4
e Open J-boxes	EC.02.05.05 EP 6
f Remote annunciator alarm panel - continuously attended location (e.g., PBX, ED, etc.)	EC.02.05.03 EP10
Auto. Transfer Switches	EC.02.05.07 EP7
a Explore ATS's (inventory, circuit diagrams, interview)	EC.02.05.03 EP1
Fire Pump(s)	
a Equipment overall condition/readiness of the fire pump -status, valves supervised/secure, leaks	EC.02.05.05 EP3
b Room condition – rated separation, opening protective	LS.02.01.10
Kitchen	
a Sprinkler head clearance over high storage.	LS.02.01.35 EP6
b "K" extinguisher distance with signage; staff knowledge on how to properly use it	LS.02.01.35 EP11
c Range hood extinguishing system - direction of nozzles, cleanliness, proper placement of filters	LS.02.01.35 EP14
d Ansul Systems activates fire alarm system	LS.02.01.35 EP13
e Fuel source disconnects upon activation of the Ansul system.	LS.02.01.35 EP13
f Storage configurations – separate storage rooms or open to kitchen if allowed by code exceptions	LS.02.01.30
g Sprinkler heads - condition, in refrigerators/freezers (if required by construction type or organization)	LS.02.01.35, EP5 LS.02.01.10, EP1
Gift Shop	
a Storage limitations, fire door ratings, open to the corridor	LS.02.01.30 EP2, EP3, EP8
Main Entries/Lobby	
a No smoking signs lacking	LS.02.01.70 EP4
b Canopy sprinkler coverage	LS.02.01.10 EP1
c Exit doors acceptable locking arrangements, emergency break open features	LS.02.01.20 EP1

Connect With Us

Joint Commission Connect

Ask a Standards Question

Report a Safety Concern

Request a Speaker

Subscribe to E-Alerts

Contact Us

Questions?