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The Joint Commission Infection Prevention & Control Standards: Challenges & Strategies for Success

March 25, 2024

The Joint Commission

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Objectives

Review	• Updates to the Infection Control Standards
Discuss	• The top Infection Control non-compliant standards
Clarify	• The expectations of the Infection Control standards
Provide	• Examples for how to identify the root cause of non-compliance with the Infection Control Standards

New Infection Control Standards and Elements of Performance:

HAP/CAH Programs

IC Chapter Rewrite Milestones

CMS has approved the new Infection Control requirements and survey processes for HAP/CAH

HAP/CAH IC standards were published in January 2024 and go into effect in July 2024

IC Chapter Rewrite for non-hospital programs: Implementation January 2025 (ALC, NCC, OME) and July 2025 (AHC, BHC, LAB)

Overview

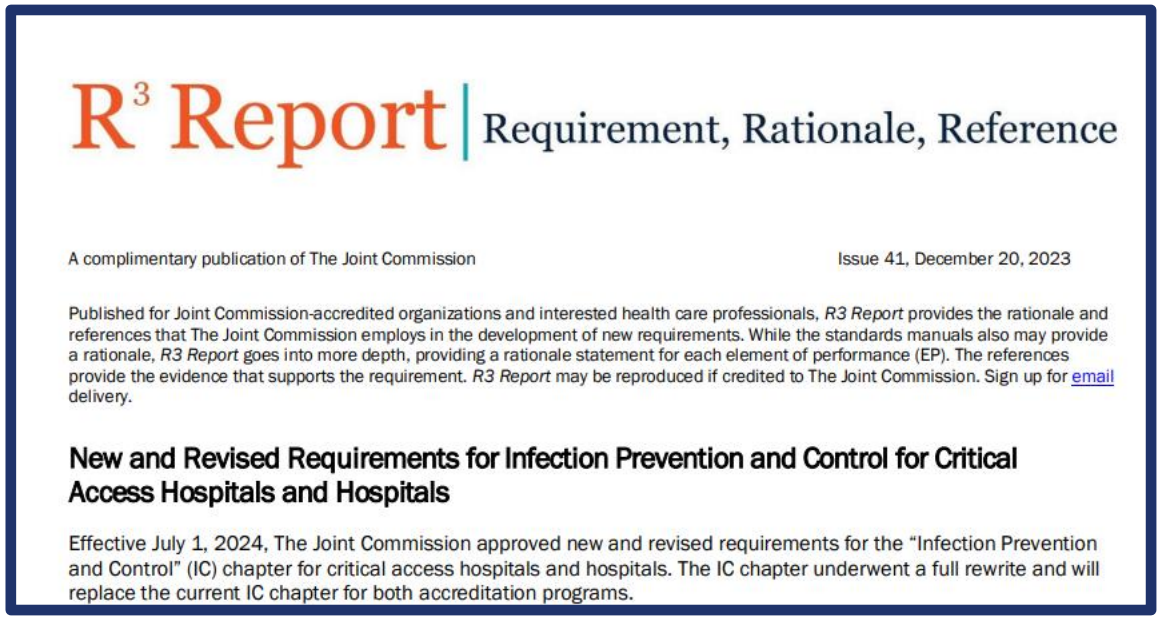
The IC chapter underwent a full rewrite and will replace the current IC chapter for both HAP and CAH accreditation programs

Consistent with the ongoing initiative to simplify requirements and provide more meaningful evaluations of hospitals

Eliminated requirements that do not add value to accreditation surveys

Focus on the structures that are essential to support quality and safety and identify a framework for a strong infection prevention and control program

Align more closely to law and regulation, the Centers for Medicare & Medicaid Services' (CMS) Conditions of Participation (CoPs), and the Centers for Disease Control and Prevention (CDC) Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings



R³ Report | Requirement, Rationale, Reference

A complimentary publication of The Joint Commission — Issue 41, December 20, 2023

Published for Joint Commission-accredited organizations and interested health care professionals, *R3 Report* provides the rationale and references that The Joint Commission employs in the development of new requirements. While the standards manuals also may provide a rationale, *R3 Report* goes into more depth, providing a rationale statement for each element of performance (EP). The references provide the evidence that supports the requirement. *R3 Report* may be reproduced if credited to The Joint Commission. Sign up for email delivery.

New and Revised Requirements for Infection Prevention and Control for Critical Access Hospitals and Hospitals

Effective July 1, 2024, The Joint Commission approved new and revised requirements for the "Infection Prevention and Control" (IC) chapter for critical access hospitals and hospitals. The IC chapter underwent a full rewrite and will replace the current IC chapter for both accreditation programs.

https://www.jointcommission.org/standards/r3-report/r3-report-issue-41-new-and-revised-requirements-for-infection-prevention-and-control-for/

What Will the New Infection Control Chapter Look Like?

Condensed and Reorganized Standards/Elements of Performance

12 Standards

51 Elements of Performance

4 Standards

14 Elements of Performance

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Reference Guide: Infection Control Standards

Effective July 1, 2024, for Hospitals (HAP) & Critical Access Hospitals (CAH) Only

Infection Control Topic	Old IC Standard/EP	New IC Standard/EP
Infection prevention and control program leader and responsibilities	IC.01.01.01, EPs 1,2,3, 4,6	IC.04.01.01, EPs 1,2
Responsibilities of the governing body and hospital leaders	N/A	IC.04.01.01, EP 1 IC.05.01.01, EPs 1,2
Resources for the infection prevention and control program	IC.01.02.01, EPs 1,2,3	IC.05.01.01, EP 1
Infection risk identification and annual review	IC.01.03.01, EPs 1,2,3	IC.06.01.01, EPs 1,2
Setting goals for/prioritizing infection prevention and control activities based on risk	IC.01.04.01, EP 1	IC.06.01.01, EP 1
Infection prevention and control plan	IC.01.05.01, EP 2	N/A
Requirements for infection control policies and procedures	N/A	IC.04.01.01, EPs 3,4
Use of evidence-based national guidelines when developing infection prevention and control activities	IC.01.05.01, EP 1	IC.04.01.01, EP 3
Requirements for policies and procedures addressing the reprocessing reusable devices, including the use of manufacturers' instructions	N/A	IC.04.01.01, EP 4
Access to and use of public health and safety data	N/A	IC.05.01.01 EP 1 IC.06.01.01 EP 1
Surveillance of infections or infection control processes	IC.01.05.01, EP 2 IC.02.01.01, EP 1	IC.06.01.01, EP 3
Outbreak management	IC.01.05.01, EP 5 IC.02.01.01, EP 5	IC.06.01.01, EP 4
The infection prevention and control program is hospitalwide	IC.01.05.01, EP 6	IC.04.01.01 EP 5
Influx of potentially infectious patients	IC.01.06.01, EPs 2,3,4	See EM requirements
Implementation of infection prevention and control activities, including cleaning, disinfection, and sterilization	IC.02.01.01, EPs 1,2,3, 10, 11 IC.02.02.01, EPs 1,2,4,5	IC.06.01.01, EP 3
Storage and disposal of infectious waste	IC.02.01.01, EP 6 IC.02.02.01, EP 3	See EC.02.02.01
Communication of information to staff, visitors, patients, families on responsibilities in infection prevention and control, e.g., posters or pamphlets	IC.02.01.01, EP 7	IC.06.01.01, EP 4
Communication of infection surveillance, prevention, and control information to the appropriate staff within the hospital	IC.02.01.01, EP 8	IC.05.01.01, EP 2 IC.06.01.01, EP 4 IC.07.01.01, EP 1
Reporting to local, state, and federal public health authorities	IC.02.01.01, EP 9	IC.04.01.01, EP 3 IC.07.01.01, EP 1
Patient notification and follow-up after exposure to infection or incorrectly reprocessed medical/surgical device	IC.02.03.01, EP 4	IC.04.01.01, EP 4
Occupational health	IC.02.03.01, EPs 1, 2	IC.06.01.01, EP 5
Protocols to support preparedness for high-consequence infectious diseases or special pathogens	N/A	IC.07.01.01, EPs 1,2
Staff vaccination against influenza	IC.02.04.01 EPs 1-9	IC.04.01.01, EP 3 IC.06.01.01, EP 5
Practices to prevent HAIs (MDRO, CLABSI, CAUTI, SSI)	IC.02.05.01, EPs 1, 2, 3	IC.04.01.01 EP 3 IC.06.01.01 EP 3

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Reference Guide: Infection Control Standards

Effective July 1, 2024, for Hospitals (HAP) & Critical Access Hospitals (CAH) Only

Infection Control Topic	Old IC Standard/EP	New IC Standard/EP
Evaluation of the infection prevention and control plan	IC.03.01.01, EPs 1,7	N/A
Communication of evaluation results with the quality and safety leaders.	IC.03.01.01, EP 6	IC.05.01.01, EP 2
Total Number of EPs	**51**	**14**

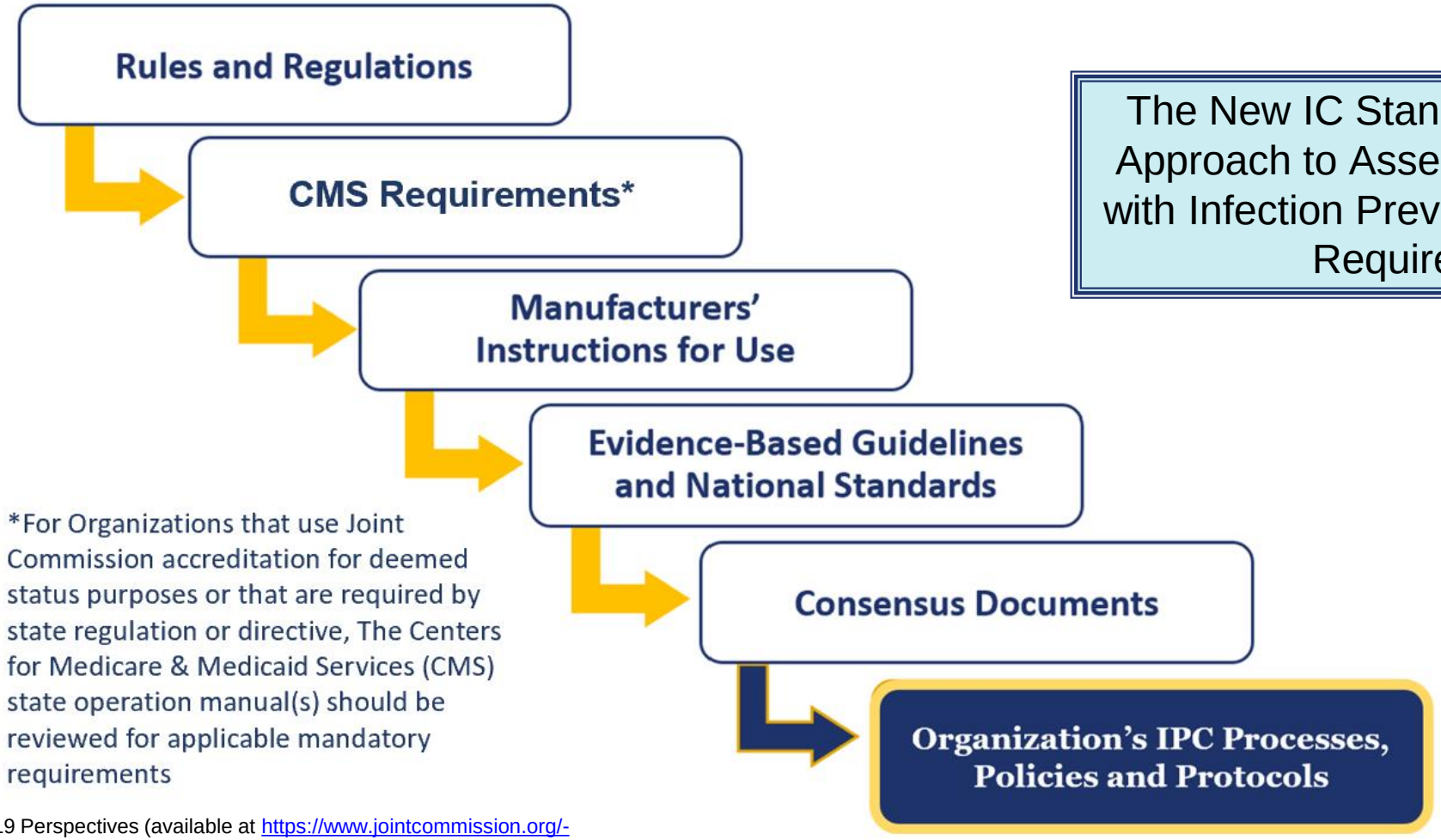
Infection Prevention and Control's Responsibilities

Directly Responsible for:

Developing and implementing	Hospitalwide infection surveillance, prevention, and control policies and procedures
Documenting	The infection prevention and control program surveillance, prevention, and control activities
Competency-based training/education	Competency-based training and education of hospital staff on infection prevention and control policies and procedures and their application
Preventing and controlling	Health care–associated infections, including auditing of adherence to infection prevention and control policies and procedures
Communicating and collaborating	With all components of the hospital involved in infection prevention and control activities
Communicating and collaborating	With the QAPI on infection prevention and control issues

IC.05.01.01 EP1 Hospital policies address the roles and responsibilities for infection prevention and control program within the hospital and how the various hospital committees and departments interface with the infection prevention and control program (for example, how to report infectious/communicable disease issues to the infection prevention and control program).

Approach to Assessing Compliance with Infection Prevention and Control Requirements



*For Organizations that use Joint Commission accreditation for deemed status purposes or that are required by state regulation or directive, The Centers for Medicare & Medicaid Services (CMS) state operation manual(s) should be reviewed for applicable mandatory requirements

The New IC Standards Uphold the Approach to Assessing Compliance with Infection Prevention and Control Requirements

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 hospital's policies and procedures for cleaning, disinfection, and sterilization of reusable medical and surgical devices and equipment address the following:

- Cleaning, disinfection, and sterilization of reusable medical and surgical devices in accordance with the Spaulding classification system and manufacturers' instructions
- The use of EPA-registered disinfectants for noncritical devices and equipment according to the directions on the product labeling
- The use of FDA-approved liquid sterilants for the processing of critical devices and high-level disinfectants for the processing of semicritical devices in accordance with the FDA-cleared label and device manufacturers' instructions
- Required documentation for device reprocessing cycles (e.g., sterilizer cycle logs, the frequency of chemical and biological testing, and the results of testing for appropriate concentration for chemicals used in high-level disinfection, etc.)
- Resolution of conflicts or discrepancies between a medical device manufacturer's instructions and manufacturers' instructions for automated high-level disinfection or sterilization equipment
- Criteria and the process for the use of immediate-use steam sterilization
- Actions to take in the event of a reprocessing error or failure identified either prior to the release of the reprocessed item(s) or after the reprocessed item(s) was used or stored for later use

Infection Prevention and Control Program

- Reflects the scope and complexity of the hospital's services

Apply to all staff providing patient care, treatment or services

Apply to all inpatient and outpatient care locations

Apply to all care, treatment and services provided

Scope of surveillance is consistent with scope and complexity of the hospital's services

Policies and procedures address the special populations served by the hospital

Evidence that new locations, services and areas are incorporated

Many Requirements Have Been Clarified

In a new Infection Prevention and Control Assessment Tool

Infection Prevention and Control Program Assessment Tool

Required Documents and Data

- Assessment of infection risks
  Note: Performed at least annually, the format is determined by the hospital.
- Results of infection control surveillance
  Note: Infection control surveillance includes surveillance of healthcare–associated infections (HAIs), such as data submitted to the National Healthcare Safety Network (NHSN) for Centers for Medicare & Medicaid (CMS) or State requirements, and data on any epidemiologically important organisms or infectious diseases that have impacted the hospital during the preceding 12 months.
- Infection prevention and control policies and procedures that guide program activities and methods (in electronic or paper form)
- Documentation of completed job-specific staff education, training, and competencies on infection control and prevention
- Program documents demonstrating that the problems identified by the infection prevention and control program have been reviewed and addressed in collaboration with the hospital's quality assessment and performance improvement leaders and other leaders (for example, the medical director, nurse executive, and administrative leaders).
  Note: The format of this documentation is determined by the hospital. Examples may include relevant committee meeting agendas and minutes, presentations, reports, planning documents.
- Documentation demonstrating the governing body's oversight of the program implementation and performance (for example, governing body minutes)

Table: Elements of Compliance and Scoring Guidance

Elements of Compliance	Standard(s)/EP(s)
Infection Prevention and Control Program & Leader(s)	
1. An infection preventionist(s) or infection control professional(s) has been appointed by the hospital governing body, based on the recommendation of the medical staff and nursing leaders, and is qualified through education, training, experience, or certification.	IC.04.01.01 EP 1
2. The hospital defines the qualifications for the infection preventionist(s) or infection control professional(s), which may be met through ongoing education, training, experience, and/or certification (such as that offered by the Certification Board for Infection Control).	HR.01.01.01 EP 1
3. The infection preventionist(s)/infection control professional(s) perform the following activities in collaboration with all departments, programs, and areas involved in infection prevention and control activities: a. Development and implementation of hospitalwide infection surveillance, prevention, and control policies and procedures that adhere to law and regulation and nationally recognized guidelines b. Documentation of the infection prevention and control program and its surveillance, prevention, and control activities c. Competency-based training and education of hospital staff on infection prevention and control policies and procedures and their application Note: The outcome of competency-based training is the staff's ability to demonstrate the skills and tasks specific to their roles and responsibilities. Examples of competencies may include donning/doffing of personal protective equipment and the ability to correctly perform the processes for high-level disinfection (HLD). (For more information on competency requirements, refer to HR.01.06.01 EPs 1, 3, 5, 6)	IC.04.01.01 EP 2

Reprocessing Reusable Medical Equipment

Standard Precautions: Reprocessing of Reusable Medical Equipment Note: Reprocessing of reusable medical equipment is performed in accordance with the Spaulding classification system, manufacturers' instructions, and hospital policies and procedures.	
1. Only devices labeled as reusable are reprocessed directly by the hospital onsite or offsite via a reprocessing vendor. If the hospital elects to reuse any devices labeled for single use by the manufacturer, these devices are reprocessed by an entity that is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question. The hospital has documentation from the third-party reprocessor confirming this is the case.	IC.06.01.01 EP 3
2. Manufacturers' instructions for medical devices and equipment are available to the staff performing reprocessing. The hospital may use posters or other condensed methods to provide critical information to staff performing reprocessing to ensure reprocessing consistent with the instructions for use.	IC.05.01.01 EP 1
3. Reusable non-critical medical equipment (for example, blood glucose meters and other point-of-care devices, blood pressure cuffs, oximeter probes) are cleaned and disinfected according to manufacturers' instructions after each use or when visibly soiled.	IC.06.01.01 EP 3
4. Hydrotherapy equipment (for example, Hubbard tanks, tubs, whirlpools, spas, birthing tanks) are drained, cleaned, and disinfected using an EPA-registered disinfectant according to manufacturers' instructions after each patient use.	IC.06.01.01 EP 3
5. Responsibility for cleaning and disinfection of reusable noncritical patient-care equipment and devices is clearly designated.	IC.06.01.01 EP 3

High-level Disinfection

High-level disinfection:	
6. All reusable semi-critical items receive at least high-level disinfection prior to reuse, in accordance with manufacturers' instructions.	IC.06.01.01 EP 3
7. Flexible endoscopes are inspected for damage and leak tested as part of each reprocessing cycle, in accordance with manufacturers' instructions.	IC.06.01.01 EP 3
8. Items are thoroughly pre-cleaned according to manufacturers' instructions and visually inspected for residual soil prior to high-level disinfection. For instruments with lumens (for example, endoscopes), pre-cleaning of devices must include all channels using cleaning brushes of appropriate size.	IC.06.01.01 EP 3
9. Manufacturers' instructions are followed for the following: a. Enzymatic cleaners or detergents b. Reusable cleaning brushes c. Chemicals used in high-level disinfection, including instructions for preparation, testing for appropriate concentration, and replacement (for example, prior to expiration) Note: The results of testing for appropriate concentration are documented to ensure minimal effective concentration of the active ingredient. d. Disinfection temperatures and length of time e. Device rinsing following high-level disinfection	IC.06.01.01 EP 3
f. If automated reprocessing equipment is used, manufacturers' recommended connectors are used to assure that all endoscope channels are appropriately disinfected.	
10. Devices are dried thoroughly prior to storage/reuse in accordance with manufacturers' instructions.	IC.06.01.01 EP 3
11. After high-level disinfection, devices are stored in a manner that protects them from damage or contamination.	IC.06.01.01 EP 3
12. The hospital has a system in place to identify which endoscope was used on a patient for each procedure.	IC.06.01.01 EP 3

Sterilization

Sterilization:	
13. All reusable critical items are sterilized prior to reuse, in accordance with manufacturers' instructions.	IC.06.01.01 EP 3
14. Items are thoroughly pre-cleaned according to manufacturers' instructions and visually inspected for residual soil prior to sterilization. Note: For instruments with lumens, pre-cleaning of devices must include all channels using cleaning brushes of appropriate size.	IC.06.01.01 EP 3
15. Enzymatic cleaner or detergent is used and discarded according to manufacturers' instructions.	IC.06.01.01 EP 3
16. Cleaning brushes are single-use, disposable items or, if reusable, cleaned and either high-level disinfected or sterilized (per manufacturers' instructions) at least daily.	IC.06.01.01 EP 3
17. After pre-cleaning, items are appropriately wrapped-packaged for sterilization (for example, the package system selected is compatible with the sterilization process being performed, hinged instruments are open, and instruments are disassembled if indicated by the manufacturer).	IC.06.01.01 EP 3
18. The sterilization process is monitored by using a combination of mechanical, chemical, and biological indicators to ensure the effectiveness of the sterilization process. Indicators are used in accordance with the sterilizer or sterilizer accessory (pouch, casket, tray, etc.) manufacturers' instructions.	IC.06.01.01 EP 3
19. For dynamic air removal–type sterilizers (for example, prevacuum steam sterilizers), an air removal test (Bowie-Dick test) is performed each day the sterilizer is used to verify efficacy of air removal in accordance with manufacturers' instructions.	IC.06.01.01 EP 3
20. Sterile packs are labeled with the sterilizer used, the cycle or load number, the date of sterilization, and, if applicable, the expiration date.	IC.06.01.01 EP 3
21. Logs for each sterilizer cycle are current and include results from each load, in accordance with the hospital policies and procedures. Note: For the absence of policies and procedures, score IC.04.01.01 EP 4	IC.06.01.01 EP 3
22. After sterilization, medical devices and instruments are stored so that sterility is not compromised.	IC.06.01.01 EP 3
23. Sterile packages are inspected for integrity and compromised packages are repackaged and reprocessed prior to use.	IC.06.01.01 EP 3
24. If immediate-use* steam sterilization (IUSS) is performed, all of the following criteria are met: a. Work practices ensure proper cleaning and decontamination, inspection, and arrangement of the instruments into the recommended sterilizing trays or other containment devices before sterilization. b. Once clean, the item is placed within a container intended for immediate use. c. The sterilizer cycle and parameters used are selected according to the manufacturers' instructions for use for the device, container, and sterilizer. d. The sterilizer function is monitored with mechanical monitors and chemical and biologic indicators that are validated for use with the sterilization cycle and in accordance with the device and sterilizer manufacturers' instructions. e. The processed item must be transferred immediately*, using aseptic technique, from the sterilizer to the actual point of use, the sterile field in an ongoing surgical procedure. *"Immediate use" is defined as the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another.	IC.06.01.01 EP 3
25. Immediate-use steam sterilization is not performed on the following devices: a. Implants (except in documented emergency situations when no other option is available) Note: If IUSS must be used for an implantable device, the name of the patient/patient's unique identifier and any other information needed to accurately link the instrument processed using IUSS back to the patient must be recorded. b. Post-procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease or similar disorders c. Devices that have not been validated with the specific cycle employed d. Single-use devices that are sold sterile	IC.06.01.01 EP 3
26. Staff follow hospital policies and procedures in the event of a reprocessing error or failure identified either prior to the release of the reprocessed item(s) or after the reprocessed item(s) was used or stored for later use. Note: Depending on the nature of the incident, examples of actions may include quarantine of the sterilizer, recall of item(s), stakeholder notification, patient notification, surveillance, and follow-up. Note: For the absence of policies and procedures, score IC.04.01.01 EP 4.	IC.06.01.01 EP 3

Customer Resources

Available on the Extranet:

> Survey Process Tab

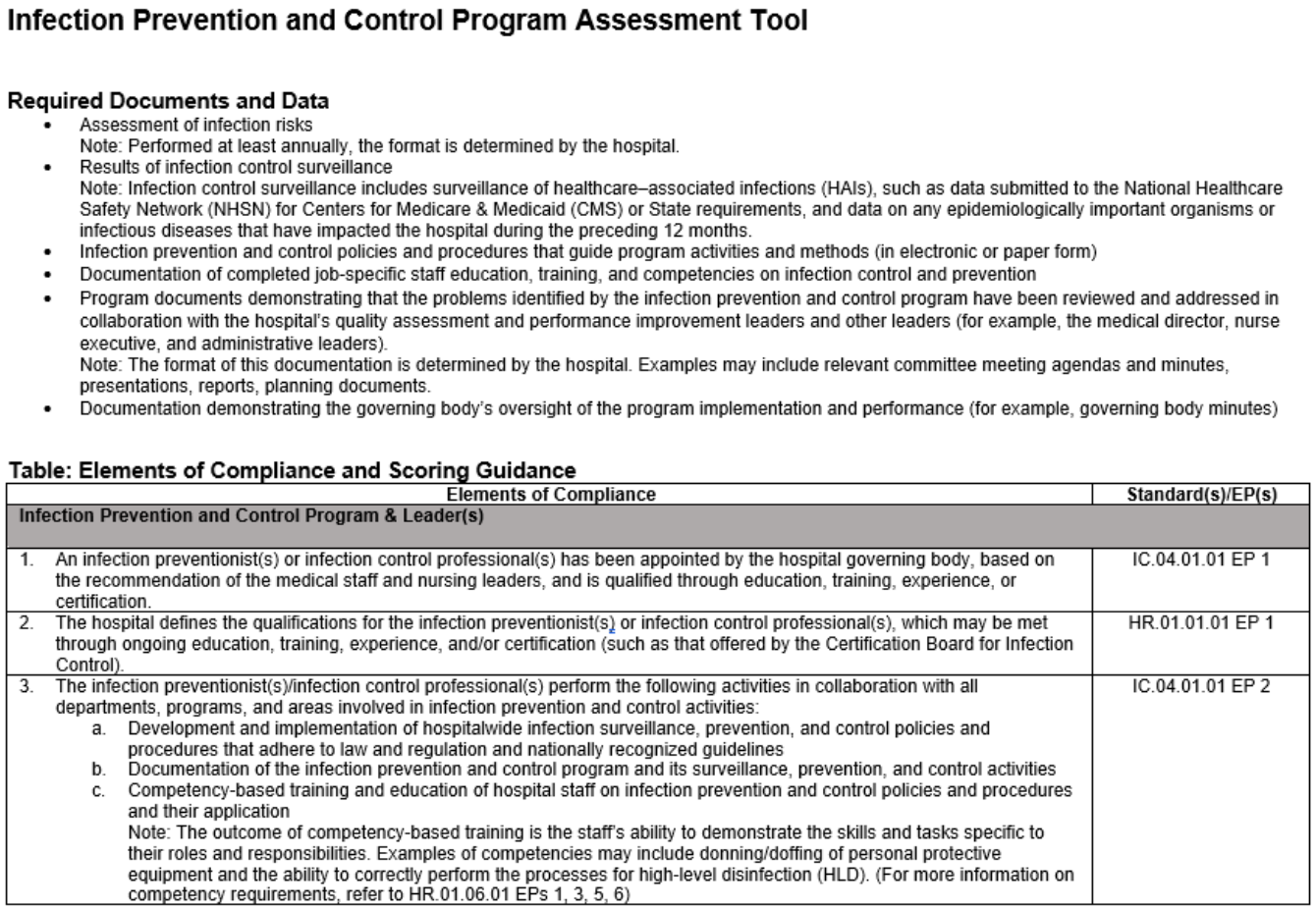
>> In Pre-Survey menu, click on "Survey Activity Guide"

>> Scroll down to "Additional Resources"

Will be available in the organization SAG in Spring 2024

Includes required components that could be evaluated during survey

Includes locations for scoring



Infection Prevention and Control Program Assessment Tool

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Infection Control Findings 2023

- Frequently Scored
- High Risk

Sterilization and High-Level Disinfection

#1 on the 2022 Most Frequently Cited Higher-Risk Accreditation Requirements

HAP, CAH, AHC, OBS

In the Top 10 Infection Control Findings

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

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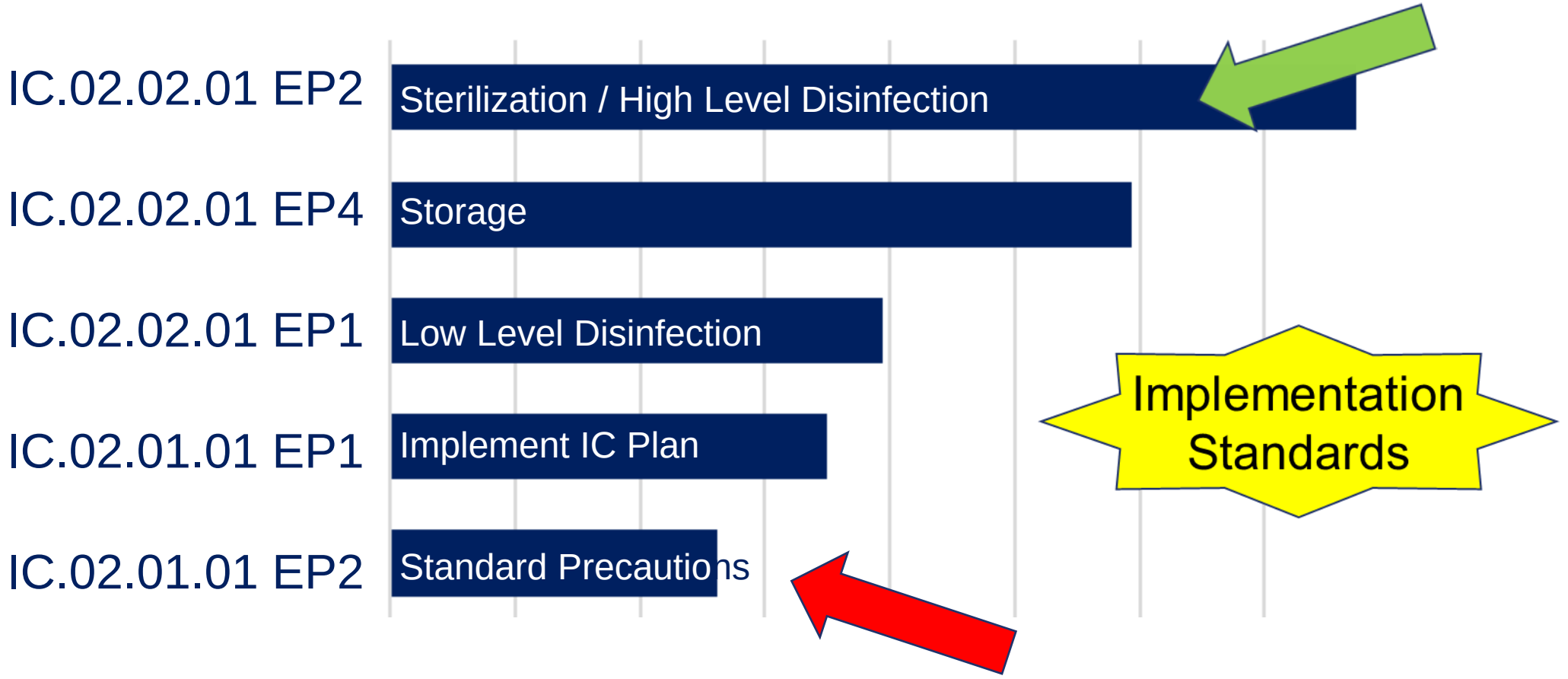
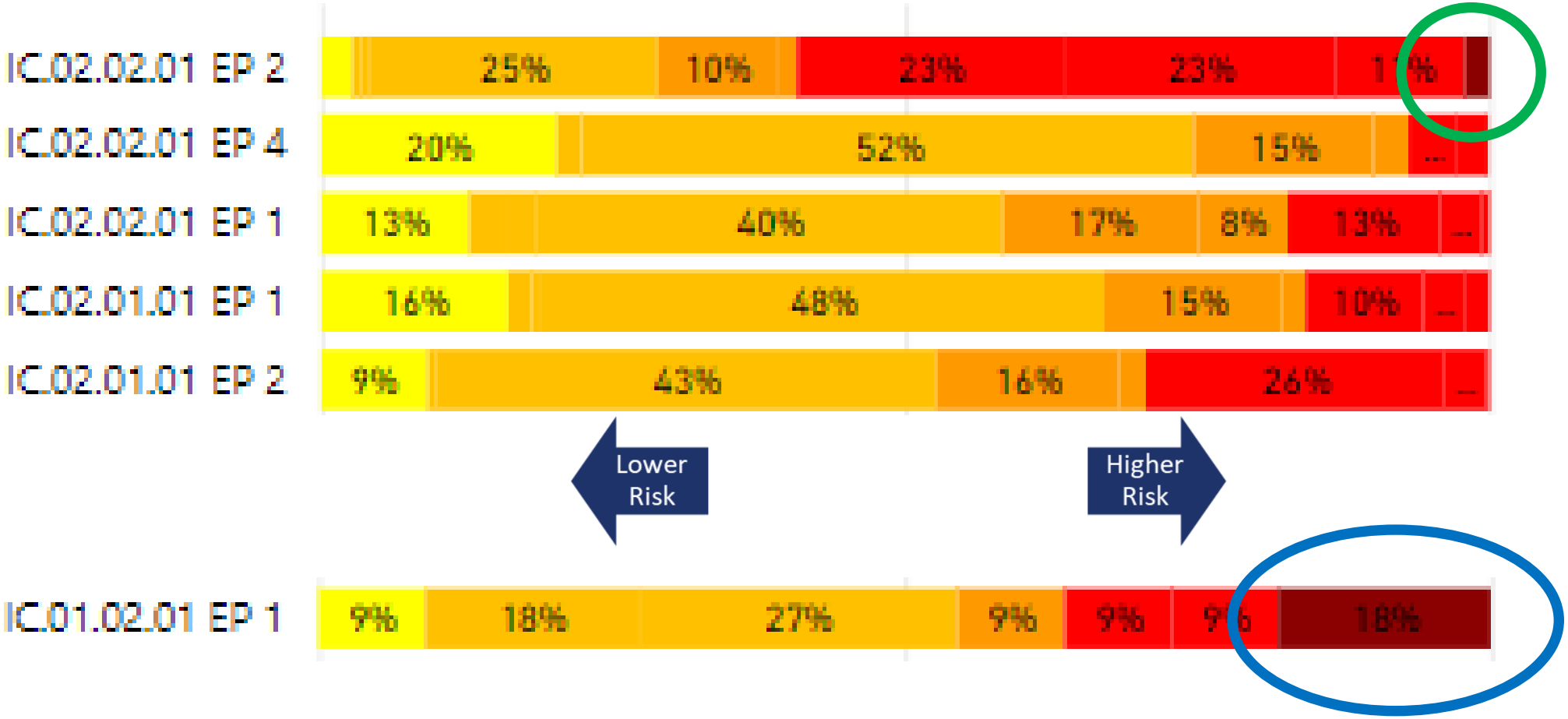
Top 5 Infection Control Findings 2023:

HAP/CAH Programs

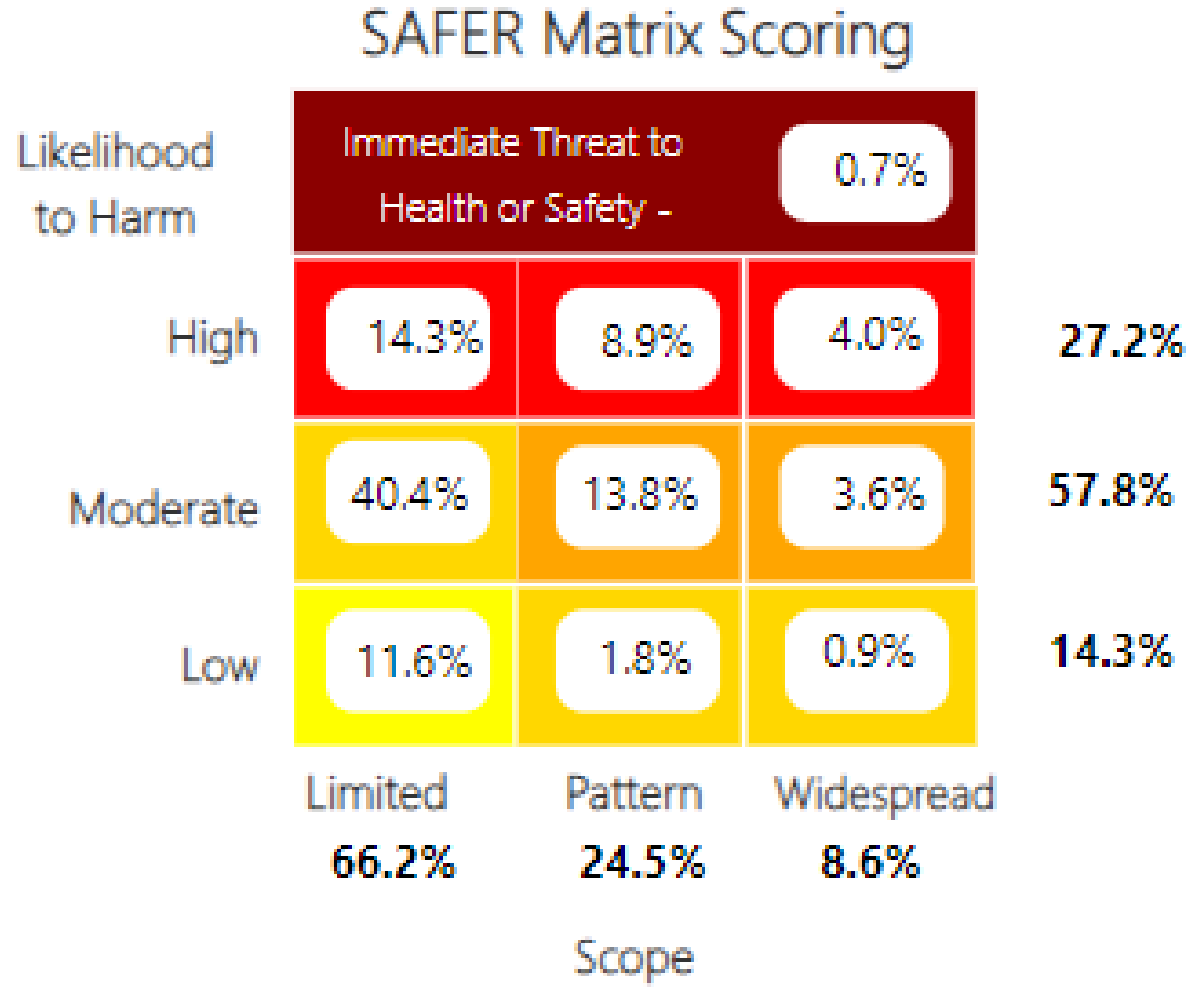


Proportion of Safer Placement 2023:

Top 5 Infection Control Findings (HAP/CAH)



Safer Matrix Scoring All IC Findings:
2023 HAP/CAH



Top 5 Scored IC Findings
Last 3 years HAP/CAH

2021	2022	2023
IC.02.02.01 EP2	IC.02.02.01 EP2	IC.02.02.01 EP2
IC.02.02.01 EP4	IC.02.02.01 EP4	IC.02.02.01 EP4
IC.02.01.01 EP1	IC.02.02.01 EP1	IC.02.02.01 EP1
IC.02.01.01 EP2	IC.02.01.01 EP1	IC.02.01.01 EP1
IC.02.02.01 EP1	IC.02.01.01 EP2	IC.02.01.01 EP2

IC.02.01.01 EP1 – Implementation of IC activities
IC.02.01.01 EP2 – Standard Precautions
IC.02.02.01 EP2 – High-Level Disinfection and Sterilization
IC.02.02.01 EP1 – Low-Level Disinfection
IC.02.02.01 EP4 – Storage

Frequently Cited Sterilization Observations

- Manufacturer’s Instructions for Use (MIFU) not available
- MIFU conflicts/ambiguity not clarified
- Supplies not available
- MIFU not followed
- Instruments/ devices not appropriate for sterilization
- Immediate Use Steam Sterilization

Frequently Cited High Level Disinfection Observations

- Manufacturer’s Instructions for Use (MIFU) not available
- Supplies not available
- MIFU not followed
- Not stored in a manner to protect from contamination/damage
- Contaminated probes not transported per OSHA Bloodborne Pathogen standard

Evaluating the Root Cause for Sterilization and High-Level Disinfection Non-Compliance

Where Does Reprocessing Occur in Your Organization?

High Level Disinfection

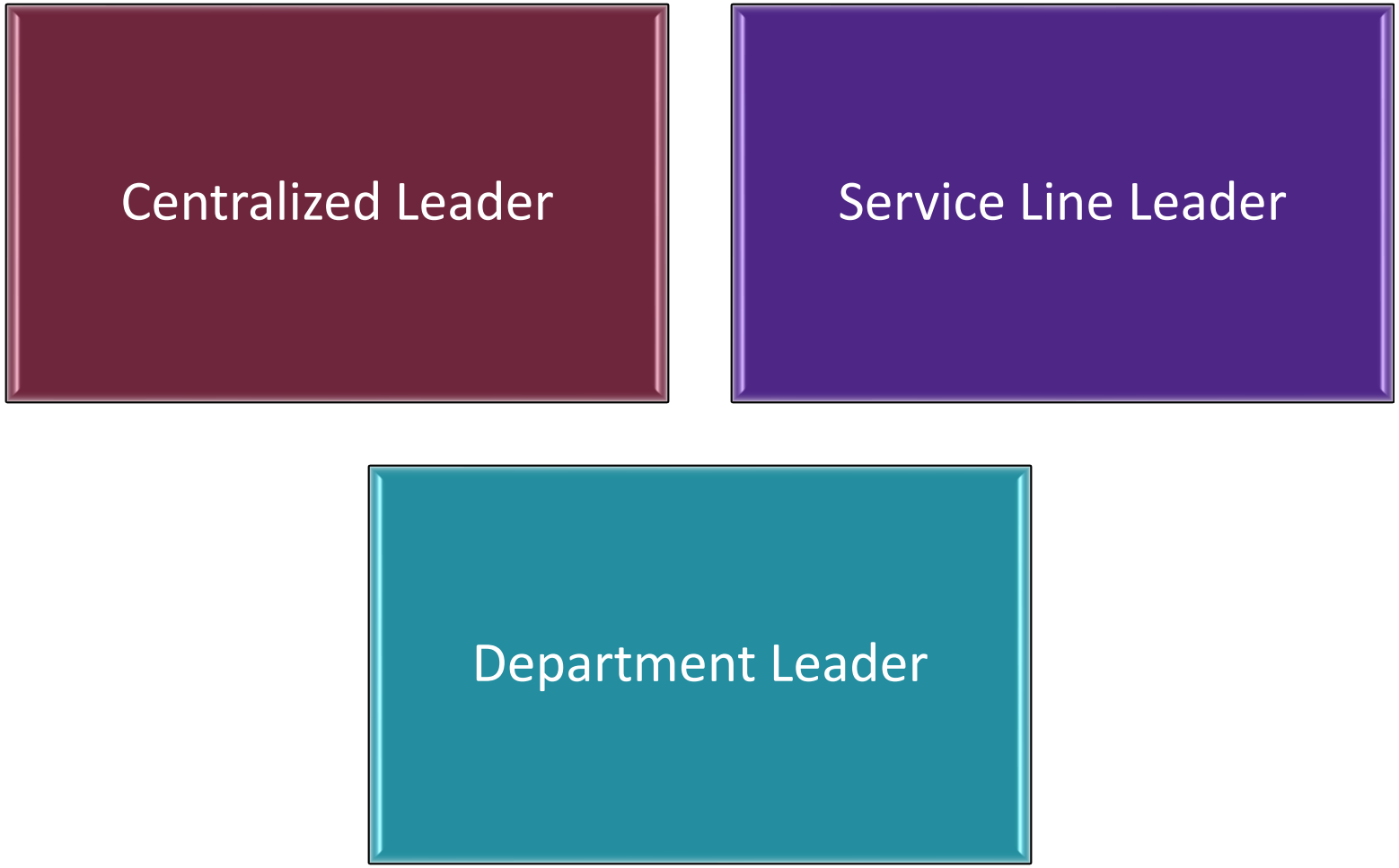
- Central Sterile Processing
- Radiology
  - Inpatient and Outpatient
- Women's Health locations
  - Inpatient Maternal Health (L&D triage, antepartum)
  - Outpatient OB/GYN
- GI services
  - Endoscopy department
  - GI Clinics
- Sleep Lab
- Speech Therapy
- Respiratory Therapy
- Ophthalmology Clinics
- Cardiology Clinics

Sterilization

- Central Sterile Processing
- Outpatient locations
  - Dental clinics
  - Wound clinics
  - OB/GYN clinics
  - Podiatry Clinics
  - Pain Clinics
  - Radiation Oncology Clinics
  - Ophthalmology Clinics

Offsite Centralized Reprocessing Site?

Who Provides Oversight for Reprocessing?



Wide Variety of Instruments and Devices Used in Healthcare Settings

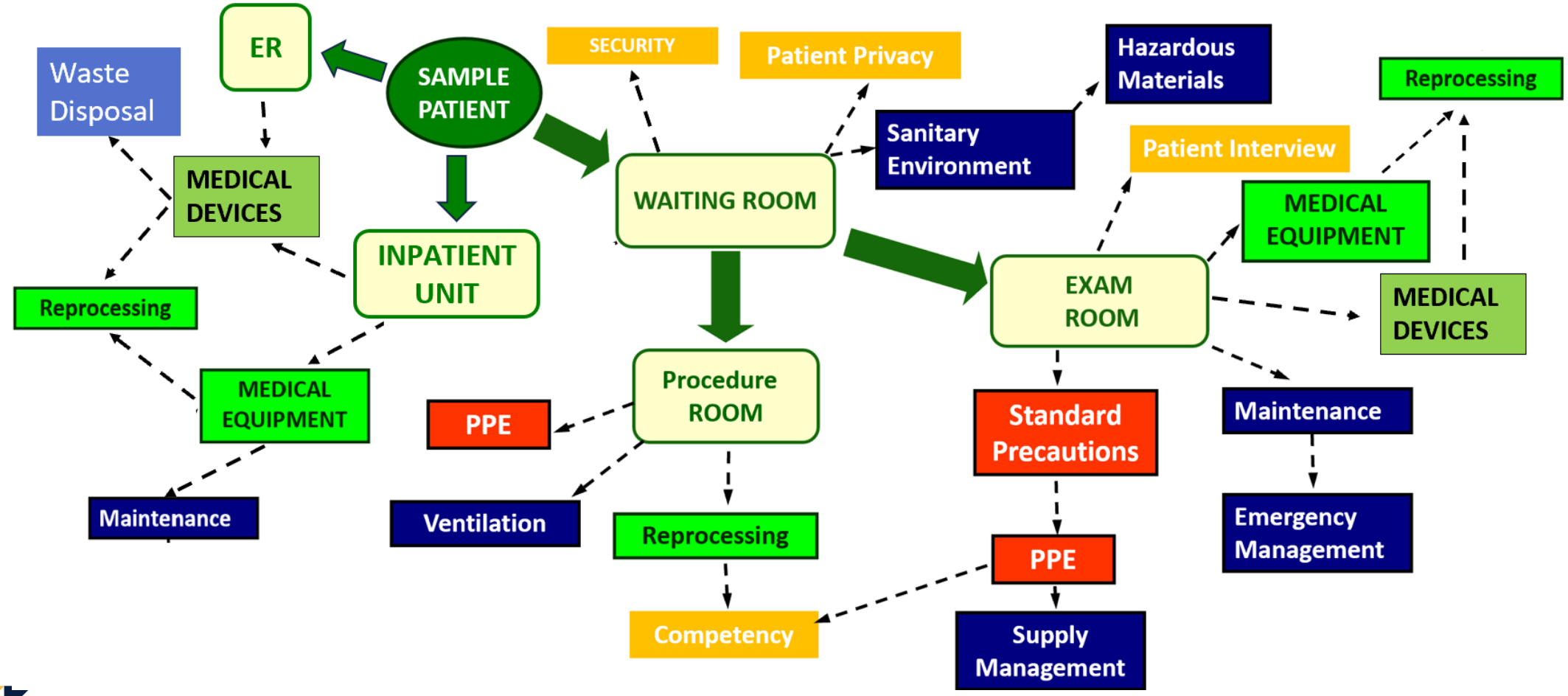
- Single use vs. reusable
- Varying levels of disinfection/sterilization required
- Varying levels of complexity
- Wide variation in reprocessing instructions

Spaulding Classification Determines Level of Reprocessing Required

Intended use Drives MINIMUM Reprocessing: FDA Uses Spaulding

Level	Risk of Infection	Description of Intended Use	Examples of Items	Reprocessing Methods
Critical	High	Item comes in contact with or enters sterile tissue, sterile body cavity, or the vascular system	Surgical and dental instruments, some endoscopes, inner surfaces of hemodialyzers, urinary catheters, biopsy forceps, implants, and needles	Sterilization
Semi-Critical	Moderate	Itemcomes in contactwith mucous membrane or non-intact skin	Respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades, esophageal manometry probes, vaginal ultrasound probes and specula, and diaphragm fitting rings	Minimum: High Level Disinfection (sterilization may be needed in certain cases*)
Non-critical	Low	Item comes in contact with skin	Patient care Items: bedpans, blood pressure cuffs, crutches, incubators Environmental Surfaces: bed rails, bedside tables, patient furniture, counters, and floor	Clean or disinfect

Evaluation of Reprocessing During Survey:
The Tracer Method



Key Elements of Reprocessing Evaluated During Survey

Available Resources

Manufacturer's Instructions For Use (MIFU) available

Supplies necessary for all steps of reprocessing

Personal Protective Equipment

Process Implementation

Conflicts within/between MIFU resolved

MIFU followed for all steps of the process

- Handling used items
- Cleaning
- Sterilization/High Level Disinfection
- Documentation
- Storage

Transporting

Organizational Policies, processes, procedures followed

Competent Employees

Staff who perform reprocessing are trained and competent

Staff who oversee process are competent to evaluate the process

Infection Prevention and Control

Process to audit adherence to policies, processes, procedures

Leadership Oversight

Leadership provide oversight and hold staff accountable

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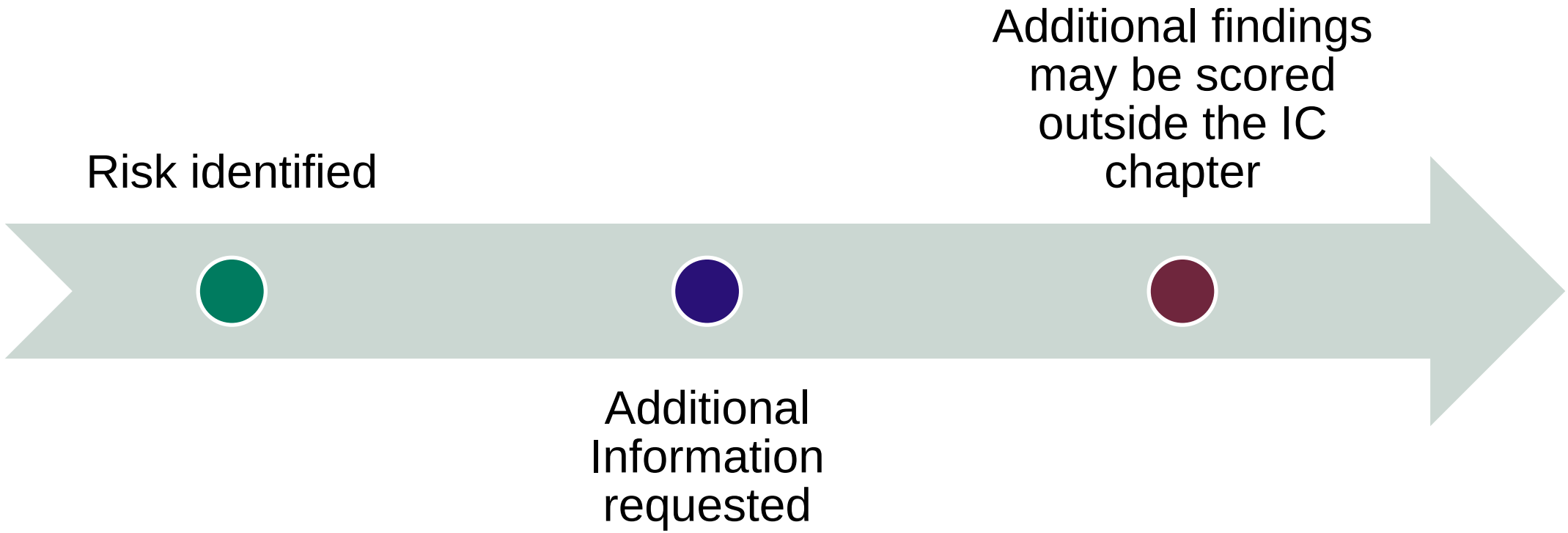
Evaluating Identified Risks



What is the Root Cause of Non-Compliance?

Resources

Accountability

Process Development

Process Oversight

Education/Training/Competency

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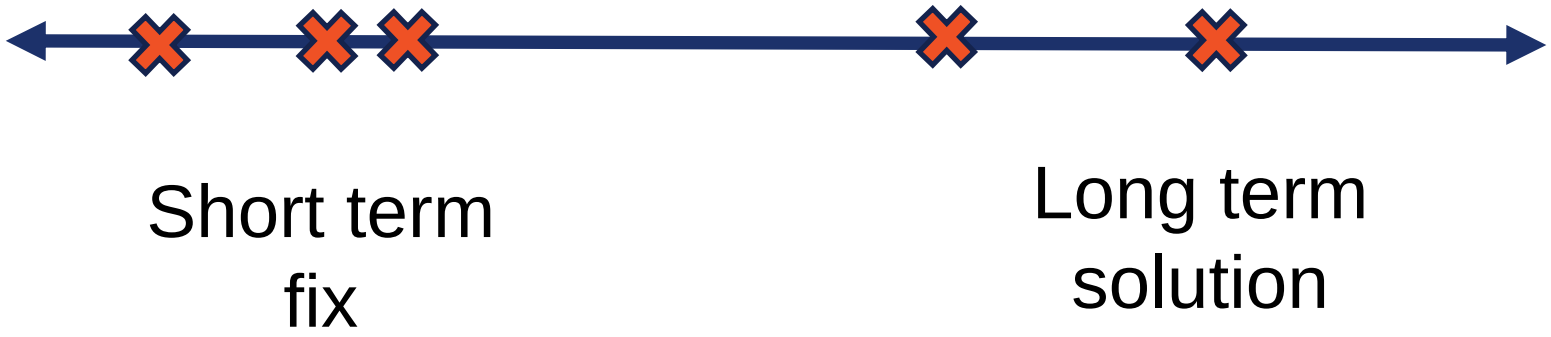
Other Locations Where Risks May Be Scored

Resources
Information
Equipment and Supplies

Leadership
Activity Management
Oversight

Human resources
Education
Training
Competency

Understanding the Root Cause Can Help Guide Activities and Resource Allocation



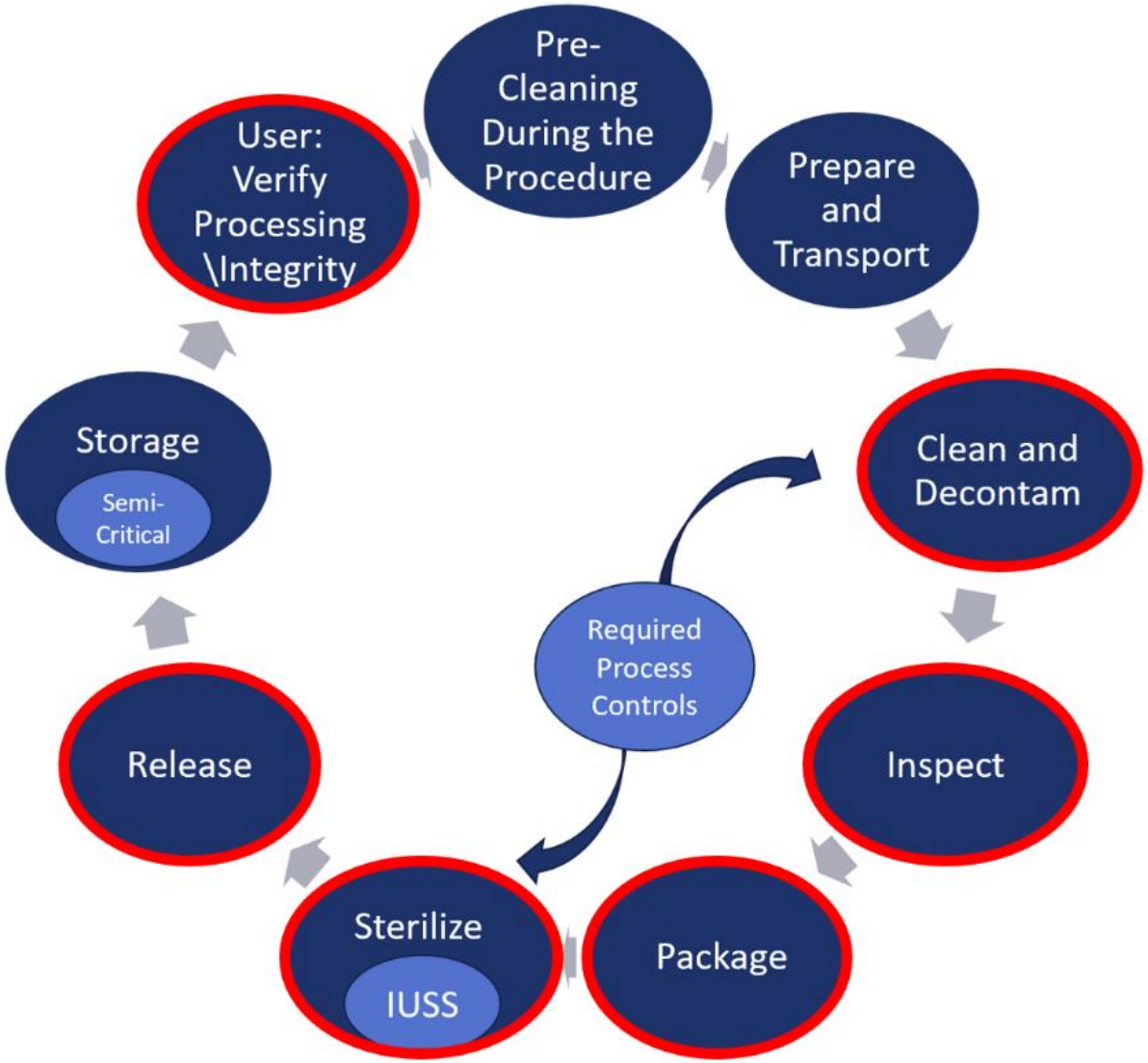
When Reprocessing Reusable Instruments, Devices and Equipment…

You must follow all local, state and federal regulations, CMS requirements, the manufacturers instructions for use for instruments, devices, equipment and products in use as well as your organization's policies, processes and procedures that have incorporated required or chosen Evidence Based Guidelines.

The following Infection Control Activities are examples of common elements of high-level disinfection and sterilization that are assessed during survey and are not intended to provide a comprehensive list of requirements for reprocessing.

Key Elements of Sterilization

Important Steps in the Sterilization Cycle



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Most Frequently Scored Observations Throughout the Sterilization Process

- Instructions for Use
- Cleaning/decontamination
- Instrument Inspection
- Pack and Prep
- Sterilization

Resources Available:

Manufacturers Instructions for Use for Instruments/Devices Being Reprocessed

Staff must have access to the MIFUs for all instruments, devices and/or equipment being reprocessed to ensure the processes are performed correctly

Having the MIFU is integral:

- Provides manufacturer validated instructions for all steps of reprocessing
- Includes validated methods for sterilization
- Identifies supplies / equipment needed for reprocessing
- Identifies required reprocessing steps / processes
- Identifies sequence of reprocessing steps / processes
- Identifies scenarios when items may no longer be usable due to loss of integrity or defect

MIFUs may be ambiguous, unclear or contain conflicting information

Resources Available:

Manufacturers Instructions for Use for Other Items Used Throughout the Sterilization Process

Most items utilized throughout the steps of reprocessing will have IFUs:

- Detergents
- Cleaning accessories
- Cleaning and decontamination equipment
- Sterilizers
- Chemical/low temperature sterilization equipment
- Accessories used for reprocessing (pouches, wraps, containers)
- Process indicators

Instructions for use for equipment may also contain additional important information including, but not limited to equipment verification testing, cleaning and disinfection, preventive maintenance and when servicing is indicated

MIFUs may be ambiguous, unclear or contain conflicting information

Example:
Ambiguity Within a MIFU

Example: Instruments/devices with multiple pieces

MIFU may contain instructions for:

- Disassembly prior to cleaning and decontamination
- Instructions for cleaning and decontamination
- Instructions for sterilization

May be ambiguous:

- May be silent on if the item should be sterilized disassembled or if it can be reassembled prior to sterilization

If there is a conflict within a MIFU or between MIFUs for items, or if a MIFU contains unclear or ambiguous information
Contact the Manufacturer for Clarification

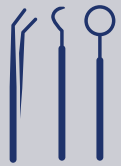
Example:
Confusing Manufacturers Instructions for Use

Example: Terminology used in the MIFU for Sterilization Accessories

- Maintenance of Package Integrity
- Real Time Testing
- Shelf Life
- Event related sterility
- Some MIFU refer end user to follow specific Evidence Based Guidance

Example:

Conflicts Between MIFUs



Instruments/Devices and Sterilization Accessories

Instruments/Devices and Sterilizers

If there is a conflict within a MIFU or between MIFUs for items, or if a MIFU contains unclear or ambiguous information

Contact the Manufacturer for Clarification

Resources Available:
Equipment and Supplies

- Personal Protective Equipment
- Manufacturer approved supplies
  - Supplies may vary based on manual vs automated process
- Additional equipment may be needed
  - Ultrasonic cleaner, flushing device
  - Equipment for instrument inspection
- Must use supplies and equipment according to the MIFU
- The use of incorrect supplies can lead to:
  - Instrument, device or equipment damage
  - Altered functionality
  - Inability to sterilize
- Lack of supplies can lead to missed steps in the process
  - Inability to sterilize

Evaluation of Adherence to MIFU Steps/Processes

Following all the steps/processes in the MIFU

1. Ensures proper cleaning and decontamination to prepare for sterilization
2. Validates integrity and functionality of instruments, equipment and devices
3. Ensures that items are correctly sterilized

Follow MIFU for:

- Cleaning solutions, supplies and equipment
- Instruments/devices
- Sterilization accessories
- Sterilizer/sterilization process

Ensure steps are performed in the correct sequence and as per the MIFU

Do not omit steps

Staff should know what next steps to take if there is a process failure

Evaluation of Cleaning and Decontamination Processes

- PPE for staff performing cleaning and decontamination
- Detergent
  - Dilution
  - Temperature requirements
- Brushes
  - Appropriate to task – type, size, lumens
  - Single use vs multi-use
- Use of additional equipment
  - Mechanical cleaning equipment
  - Ultrasonic
  - Flushing devices
- Lubricants

Are the Manufacturer's Instructions for Use followed for all steps of the process?

Evaluation of Instrument Inspection Process

Are instruments appropriate for sterilization?

Clean	Reusable or Single Use	Evidence of Oxidation
Pitting, cracking or corrosion	Tape applied correctly	Peeling or cracking tape

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Single-use Devices

Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA

"Single-use device: A single-use device, also referred to as a disposable device, is intended for use on one patient during a single procedure. This device is not intended to be reprocessed and used on

If you are unsure if an item is single use or reusable
Contact the Manufacturer for Clarification

https://www.fda.gov/search-fda-guidance-documents/labeling-recommendations-single-use-devices-reprocessed-third-parties-and-hospitals

How Do You Know if an Item is Single Use?

Single-use Surgical Instruments / Devices

- May have a single use or do not reuse symbol on the packaging

- Do not include manufacturer's instructions for use that provide instructions for reprocessing for use on a subsequent patient
- These items are not intended to be reprocessed, they often begin to show evidence of loss of integrity of the surfaces, which may manifest as oxidation, pitting or cracking

There may be single use items that are supplied unsterile and require sterilization prior to use – for these items, the provision of sterilization cycle and parameters alone does not imply the item is reusable

Evaluation of Instrument Compromise

- Instruments should be inspected for:
  - Oxidation
  - Corrosion
  - Pitting
  - Cracks
- Etching of instruments that leaves rough edges
  - Etching is acceptable if performed correctly
- Effective sterilization cannot be assured for:
  - Instruments with surface damage
  - Instruments with any type of rust

Figure 1. Images showing patterns of common changes seen within the instruments.

Figure 2. Images showing pits, cracks and corrosion affecting the instruments.

Figure 3. Images showing damages sustained within the instruments under magnification.

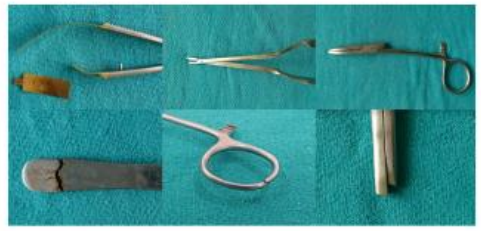

Figure 4. Images showing different sites of fractures sustained within the instruments.

Munakomi S, Shah R and Shrestha S. A pilot study comparing pattern of damage sustained among instruments from different surgical units in a tertiary care centre in Nepal – reappraising the role of instrument reprocessing in retaining their value [version 1; peer review: 2 approved]. F1000Research 2018, 7:102 (https://doi.org/10.12688/f1000research.13699.1)

Evaluation of Instrument Identification Tape or Coating

Evaluate:

- Product is approved for use with the sterilization process used
- Product applied according to manufacturer's IFU
  - Tape wrapping technique
- Presence of cracking, peeling, chipping, lifting, fading and/or frayed edges
- Tape adhesive left on instruments from previously applied instrument tape

Figure 1 Traditional Instrument Marking Techniques: Left panel – Instrument labeling using etching techniques which disrupts instrument surface; Center panel - Instrument body wrapped with surgical instrument label tape; Right panel – Instrument ends dipped in plastic coating in various stages of degradation.

Ipaktchi et al. Patient Safety in Surgery 2013, 7:31
http://www.pssjournal.com/content/7/1/31

Evaluation of Processes in Pack and Prep

Items packed disassembled if required by MIFU

Sterilization Accessories

- Container
- Tray
- Sterilization Wrap
- Peel Pouches

Sterilization Accessories are

- Compatible with the sterilization process used
- Clean
- Used per MIFU
  - Filled per MIFU
  - Double wrapped per IFU
  - No writing on “paper”

Chemical indicators

- Used/placed per IFU

Trackable: Load labels

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Evaluation of the Sterilization Process

The IFU of the MEDICAL DEVICE BEING STERILIZED determines the type of sterilization process and sterilization cycle parameters

Steam Sterilizers

- Gravity
- Dynamic air removal
  - Pre-vacuum
  - Steam Flush Pressure Pulse (SFPP)

Low temperature/chemical sterilizers are validated for the specific items being sterilized (may be device and sterilizer model specific)

Evaluation of Steam Sterilization Process Monitoring, Testing

Physical parameters were met – each cycle

1. Cycle, time, temperature, pressure

Biologic Indicator

1. At minimum weekly, and with each load that includes an implant and for sterilizer qualification testing
2. Include a positive control from the same lot with each processed BI

Chemical Indicator

External – Type 1	Bowie-Dick - Type 2	Internal – Type 3-6
Used on outside of package unless the internal CI is visible	Routine sterilizer testing (dynamic-air-removal sterilizers if applicable) Run each day in an empty sterilizer before the first processed load	Should be used inside each package Monitor critical process variables

Ensure the MIFU is followed for process monitoring supplies and ensure that the supply is appropriate for the type of sterilizer being used

These are general guidelines – Must follow MIFU or required / chosen EBG

Evaluation of Low Temperature/Chemical Sterilization Processes

Low temperature/chemical sterilization is compatible with the item(s) being sterilized

Follow MIFU for safe and effective use

- Manufacturer's recommended temperature and contact conditions are met

Compatible packaging materials

Process monitoring

- MIFU required methods to monitor the efficacy of the process
    - Physical monitors reflect the parameters of the automated processing equipment
    - Chemical monitoring
    - Biologic monitoring

Evaluating the Process for Release of Sterilized Instruments

Release is an active process

- Person removing items from the sterilizer should:
  - Verify cycle parameters match load content requirements
  - Review correct loading was done
  - Inspect packages for
    - Chemical indicator change
    - Damage
    - If visible, integrity of instruments
  - Verify load records are correct

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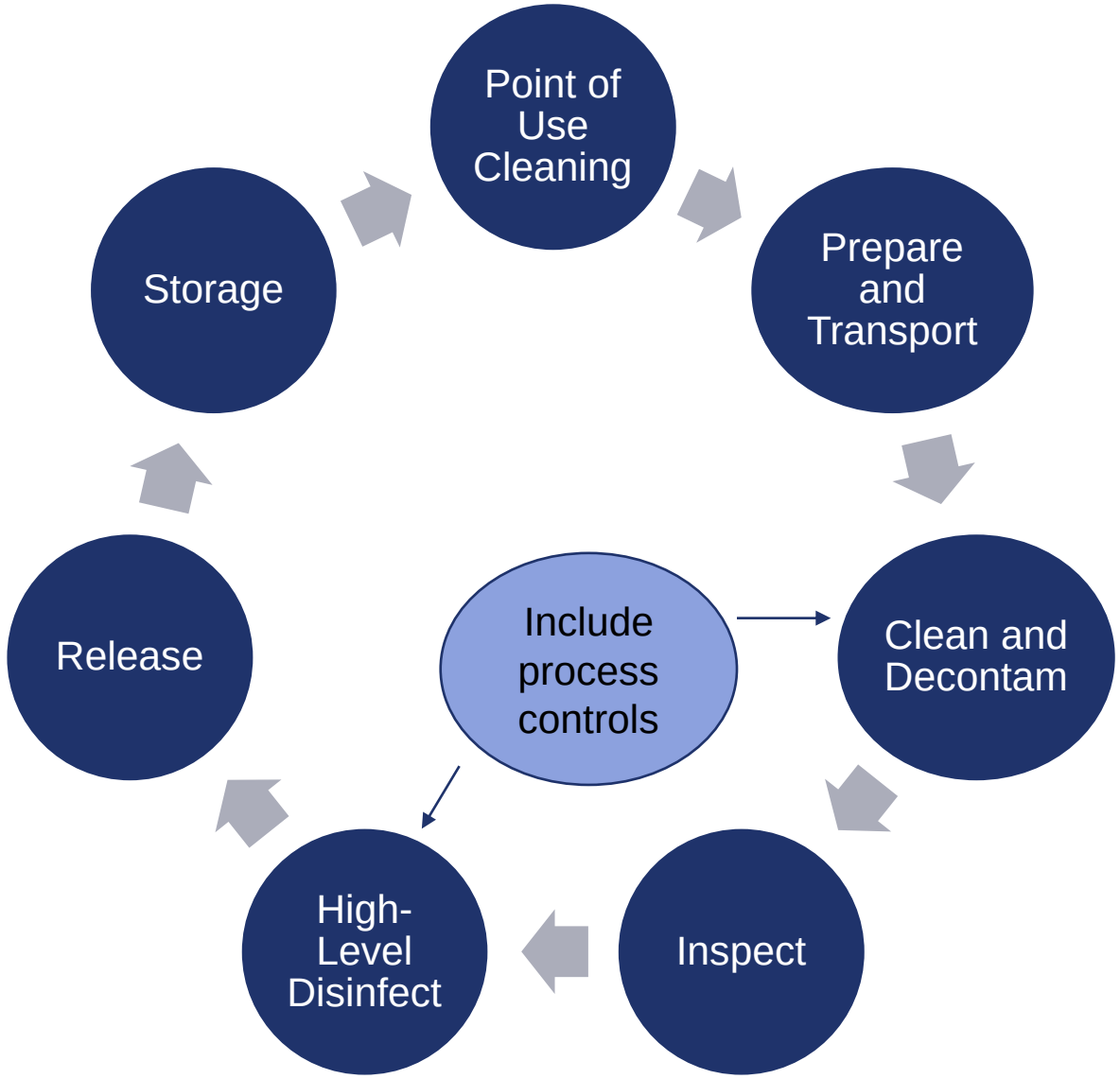
High Level Disinfection

Important Steps in the High-Level Disinfection Cycle



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Most Frequently Scored Processes Observations Throughout the High-Level Disinfection Process

Manufacturers Instructions for Use

Cleaning/decontamination

Critical Parameters

Resources Available:

Manufacturers Instructions for Use for Instruments/Devices Being Reprocessed

Staff must have access to the MIFUs for all instruments, devices and/or equipment being reprocessed to ensure the processes are performed correctly

Having the MIFU is integral:

- Provides manufacturer validated instructions for all steps of reprocessing
- Includes validated/compatible methods for High Level Disinfection
- Identifies supplies / equipment needed for reprocessing
- Identifies required reprocessing steps / processes
- Identifies sequence of reprocessing steps / processes
- Identifies scenarios when items may no longer be usable due to loss of integrity or defect

MIFUs may be ambiguous, unclear or contain conflicting information

Resources Available:

Manufacturers Instructions for Use for Other Items Used Throughout the High-Level Disinfection Process

Most items utilized throughout the steps of reprocessing will have IFUs

- Cleaning accessories
- Cleaning and decontamination equipment
- Leak testing equipment (where applicable)
- Products used for manual high-level disinfection
- High level disinfection equipment
- Process indicators

Instructions for use for equipment will also contain additional important information including, but not limited to verification testing, cleaning and disinfection, preventive maintenance and when servicing is indicated

MIFUs may be ambiguous, unclear or contain conflicting information

Resources Available:
Equipment and Supplies

- Personal Protective Equipment
- Manufacturer approved supplies
  - Supplies may vary based on manual vs automated process
- Additional equipment may be needed
  - Flushing device, leak testing equipment
- Must use supplies and equipment according to the MIFU
- The use of incorrect supplies can lead to:
  - Instrument, device or equipment damage
  - Altered functionality
  - Inability to high level disinfect
- Lack of supplies can lead to missed steps in the process
  - Inability to high level disinfect

Evaluation of Adherence to MIFU Steps/Processes

Following all the steps/processes in the MIFU

1. Ensures proper cleaning and decontamination to prepare for high level disinfection
2. Validates integrity and functionality of instruments, equipment and devices
3. Ensures that items are correctly high level disinfected

Follow MIFU for:

- Cleaning solutions, supplies and equipment
- Instruments/devices
- Manual high-level disinfection
- Automated high-level disinfection processes
- Preparation of devices to be sent for repair

Ensure steps are performed in the correct sequence and as per the MIFU

Do not omit steps

Staff should know what next steps to take if there is a process failure

Evaluation of Cleaning and Decontamination Processes

- PPE for staff performing cleaning and decontamination
- Detergent/cleaning products
  - Dilution
  - Temperature requirements
- Brushes
  - Appropriate to task – type, size, lumens
  - Single use vs multi-use
- Cloths specified by manufacturer
- Use of additional equipment
  - Flushing devices
  - Leak testing equipment
- Rinsing requirements
- Drying after rinsing

Are the Manufacturer's Instructions for Use followed for all steps of the process?

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Evaluation of Manual High-level Disinfection Processes

Verify critical parameters for the High-Level Disinfection Solution:

Physical Parameters

- Temperature directly measured prior to use to ensure manufacturer required minimum temperature is met
- Item submerged for manufacturer required immersion time

Chemical Monitoring

- Minimum effective concentration verified per MIFU

There may be other requirements:

Length of time a HLD solution is good for (primary container and secondary container)

Accessories for soaking (trays or other containers)

Rinsing requirements after HLD

- Type of water, volume of water for rinses, number of rinses

Drying after rinsing

Process for disposal of HLD solution (may require inactivation prior to disposal)

These are general guidelines – Must follow MIFU or required / chosen EBG

Evaluation of Automated High Level Disinfection Processes

Check Manufacturers Instructions for Use for device compatibility with the automated process

Follow MIFU for the device, equipment and chemical used

Physical Monitors
- Reflect the parameters of the automated processing equipment
- Validate the cycle parameters are met

Process Monitors
- Methods to monitor the efficacy of the process (e.g., solution monitoring, Chemical Indicators)

Staff should be able to demonstrate the actions to take for a failed cycle

Evaluation of Automated Endoscope Reprocessing

Check MIFU for device for compatibility with automated reprocessing equipment

Follow the MIFU for the device, equipment and chemical used

Confirm that correct connectors are being used for each scope model

Physical Monitors

- Reflect the parameters of the automated processing equipment
- Validate the cycle parameters are met

Process Monitors

- Methods to monitor the efficacy of the process (e.g., solution monitoring, Chemical Indicators)

Electronically stored data should be reviewed

Staff should be able to demonstrate the actions to take for a failed cycle

Critical Elements of Implementation

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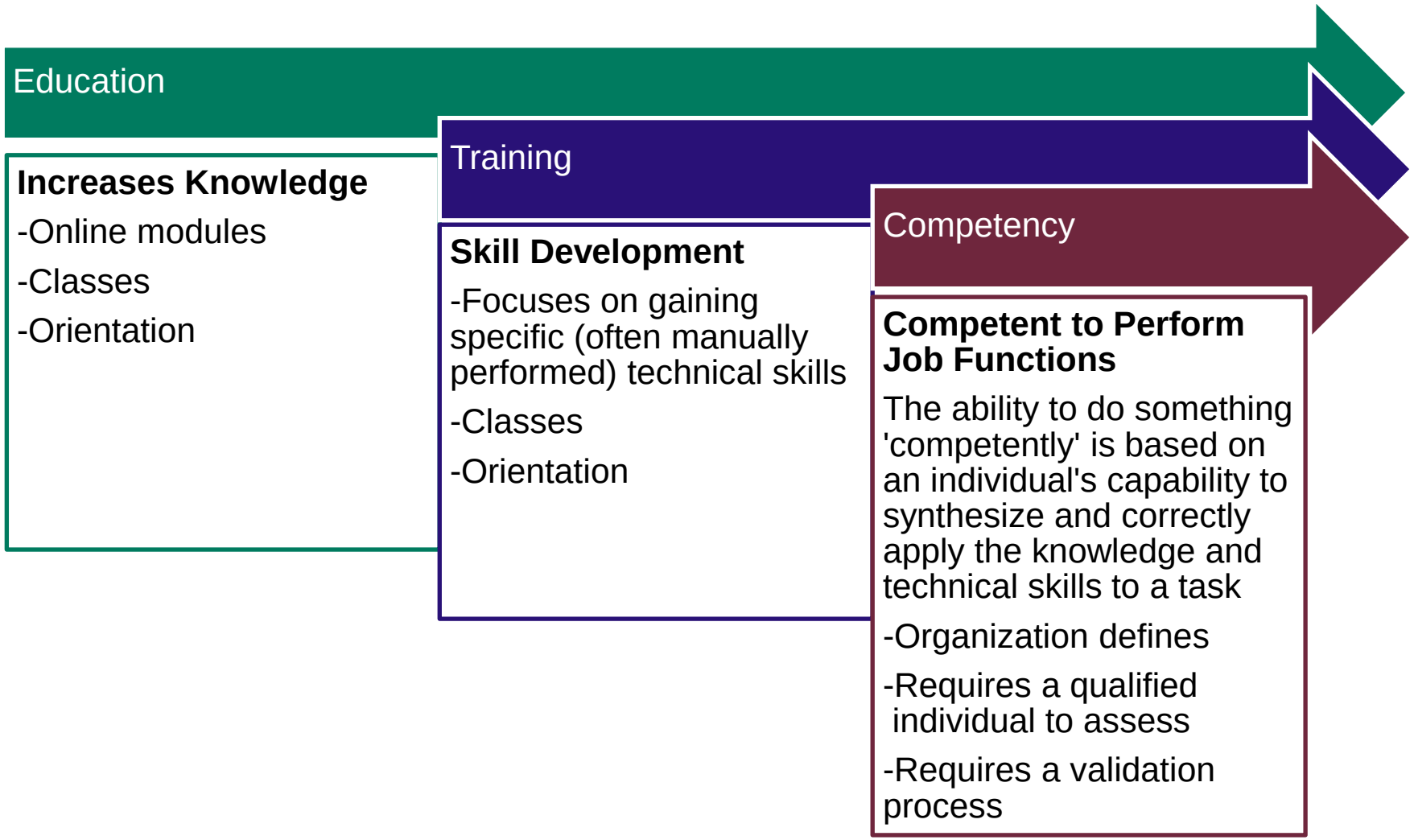
Education, Training and Competency



Staff Who Reprocess Devices and Instruments

- Devices, Instruments and Accessories

Low Complexity

Simple Instruments/ devices

Few items

Moderate Complexity

Few types of instruments/ devices

Additional reprocessing steps

High Complexity

Many different types of instruments/devices

Widely variable reprocessing instructions

- Education, training and competency may look different based on the types of items that are reprocessed and accessories and equipment needed

A one size fits all approach may not be appropriate!

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Process Oversight

Organization determines if processes should be monitored

Person Assigned to Oversight

Are they competent to provide oversight

Are staff held accountable

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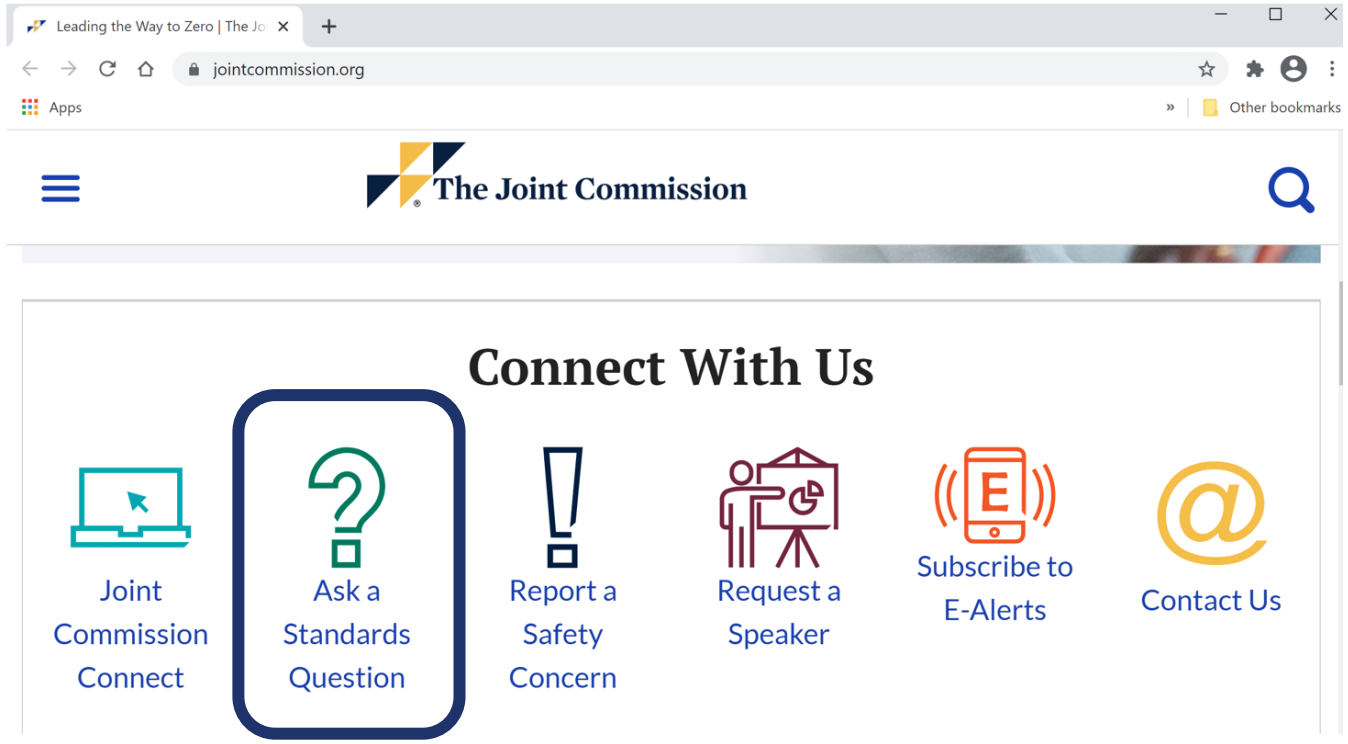
Summary

Follow the hierarchical approach to ensure compliance with IC standards

Provide the necessary resources

Ensure a culture of safety in which staff are held accountable to perform their job functions correctly, to ensure staff and patient safety

Have a Standards Question?



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Thank you for Keeping Patients Safe!