



Joint Commission Standards: Strengthening Reusable Instrument and Device Stewardship for Safe Management, Reprocessing, and Reuse

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Objectives



Describe the survey process for end-to-end tracing of reprocessed instruments between the Operating Room and Central Sterile Processing.



Recognize key opportunities to strengthen performance across the instrument reprocessing workflow between the Operating Room and Central Sterile Processing.



Identify standards that support collaboration and alignment among the Operating Room, Central Sterile Processing, and Infection Control teams.

Every Step Matters: Reprocessing and Patient Safety

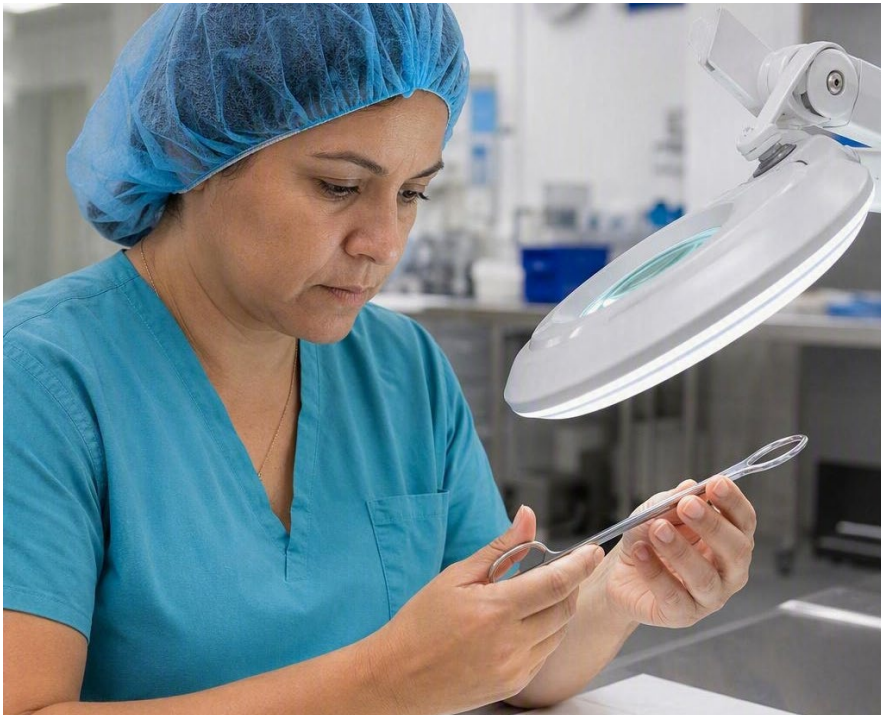
**The work you do is
important.**

**You are important to
patient safety.**



Why Reliable Reprocessing Processes Matter

What is at risk when reprocessing falls short?



Patient Infection or Complications

Impact on Patient Care and Workflow

Loss of Trust and Reputation

Financial Costs

Regulatory Implications

The Patient Safety Stories Behind the News Headlines

WHAT HAPPENS IN REPROCESSING IMPACTS PATIENTS

SAFEGUARDING CARE

“Procedures Paused to Protect Patients from Infection Risk”

Action taken before harm reached patients

OPPORTUNITY IDENTIFIED

“Review Highlights Areas to Strengthen Patient Safety”

Findings from state reviews

PROCESS BREAKDOWN

“Instrument Reprocessing Gaps Place Surgical Patients at Risk”

Where the process broke down

PATIENT COMMUNICATION

“Patients Notified of Potential Exposure Following Sterilization Lapses”

Transparency with those affected

Reprocessing of Reusable Medical Devices



...When the labeling instructions for reprocessing are completely and correctly followed after each use of the device, reprocessing results in a medical device that can be safely used more than once in the same patient, or in more than one patient.

Adequate reprocessing of reusable medical devices is vital to protecting patient safety.”



[Reprocessing of Reusable Medical Devices | FDA](#)

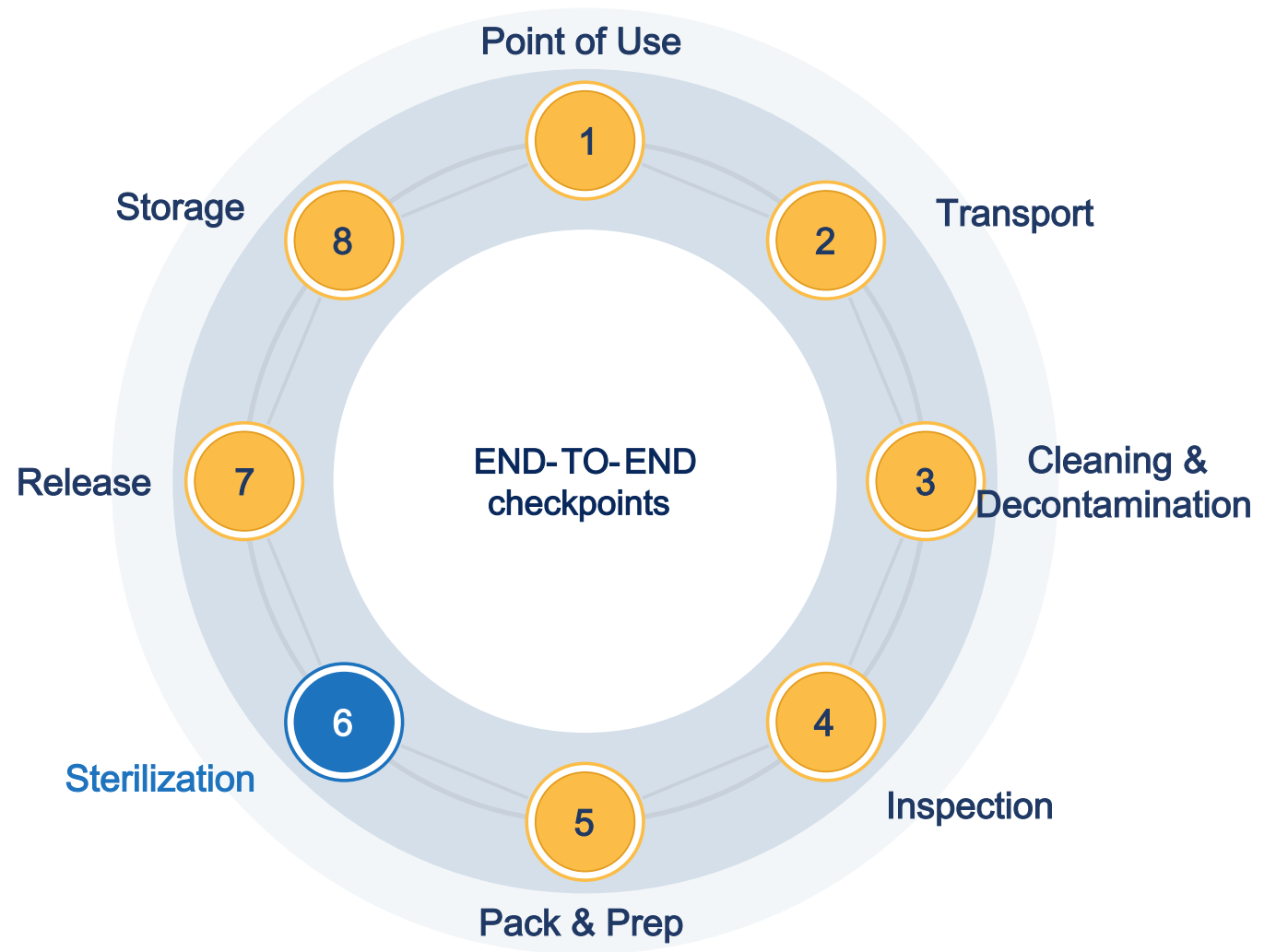
STERILIZATION

End to End

From point of use through storage

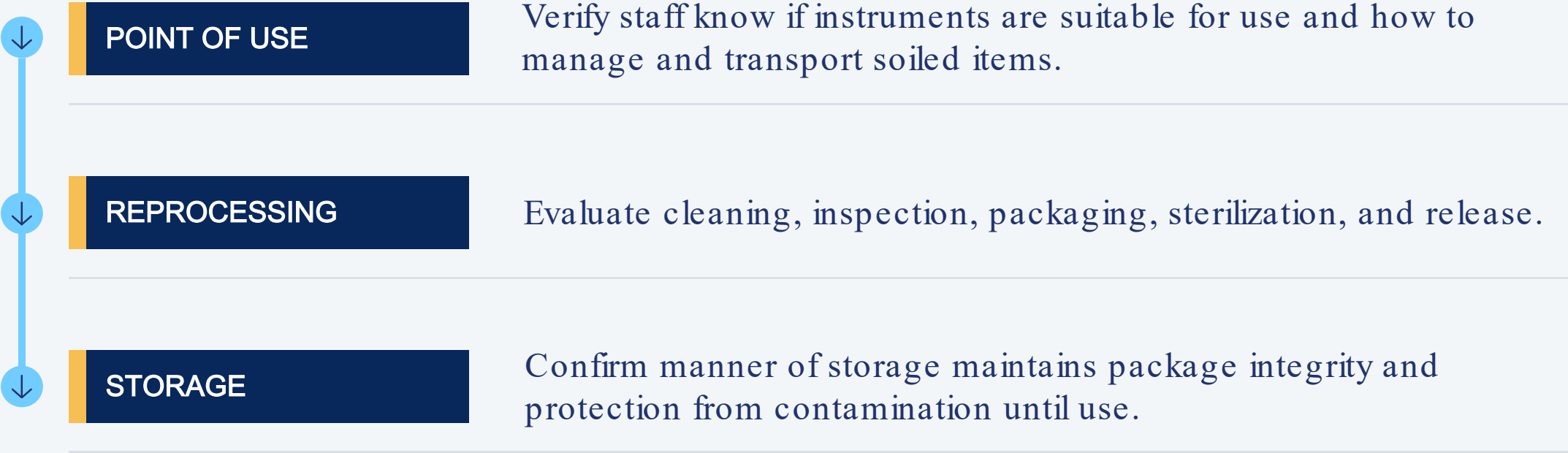
When each step in the process is done properly, the entire process succeeds

manufacturer validated instructions for use must be followed at every step



Where Evaluation Occurs Across the Lifecycle of a Sterilized Instrument or Device

Surveyors may evaluate items from point of use through all steps of reprocessing and storage



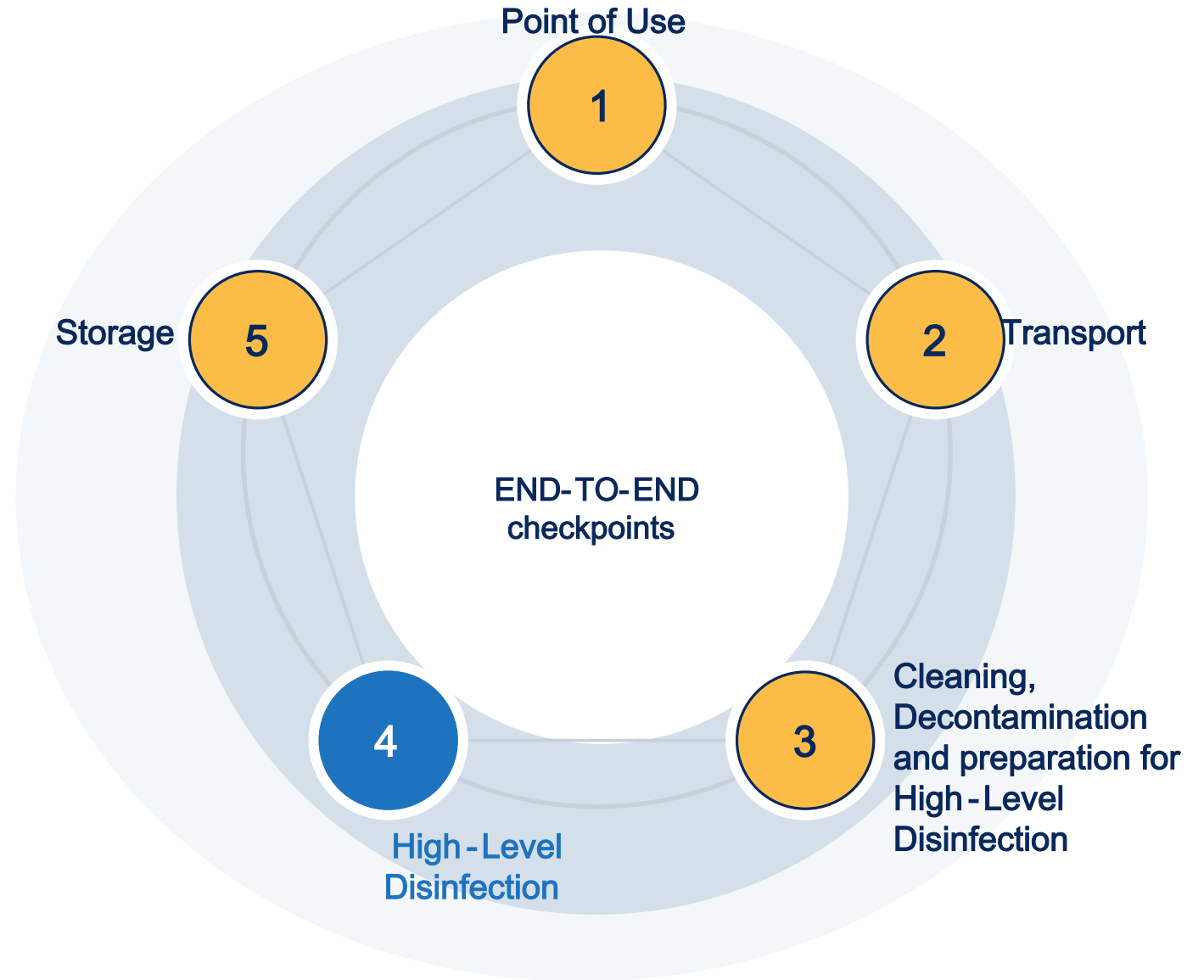
HIGH - LEVEL DISINFECTION

End to End

From point of use through
storage

When each step in the
process is done properly,
the entire process succeeds

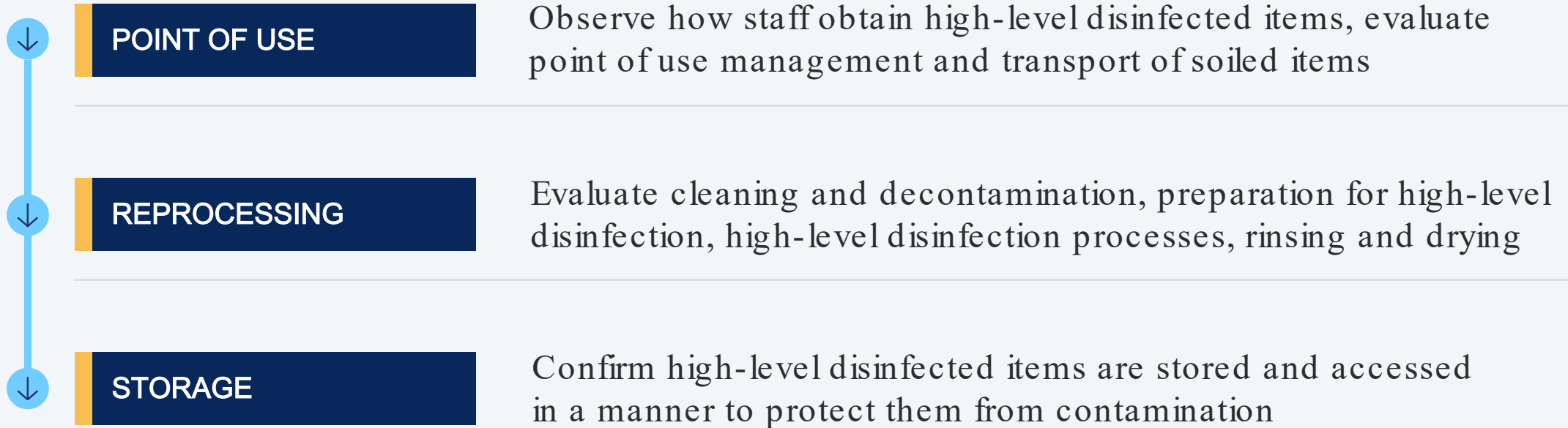
follow manufacturer
instructions for use for both the
device and the high -level
disinfectant at every step





Where Evaluation Occurs Across the Lifecycle of an Item

Surveyors may evaluate items from point of use through all steps of reprocessing and storage



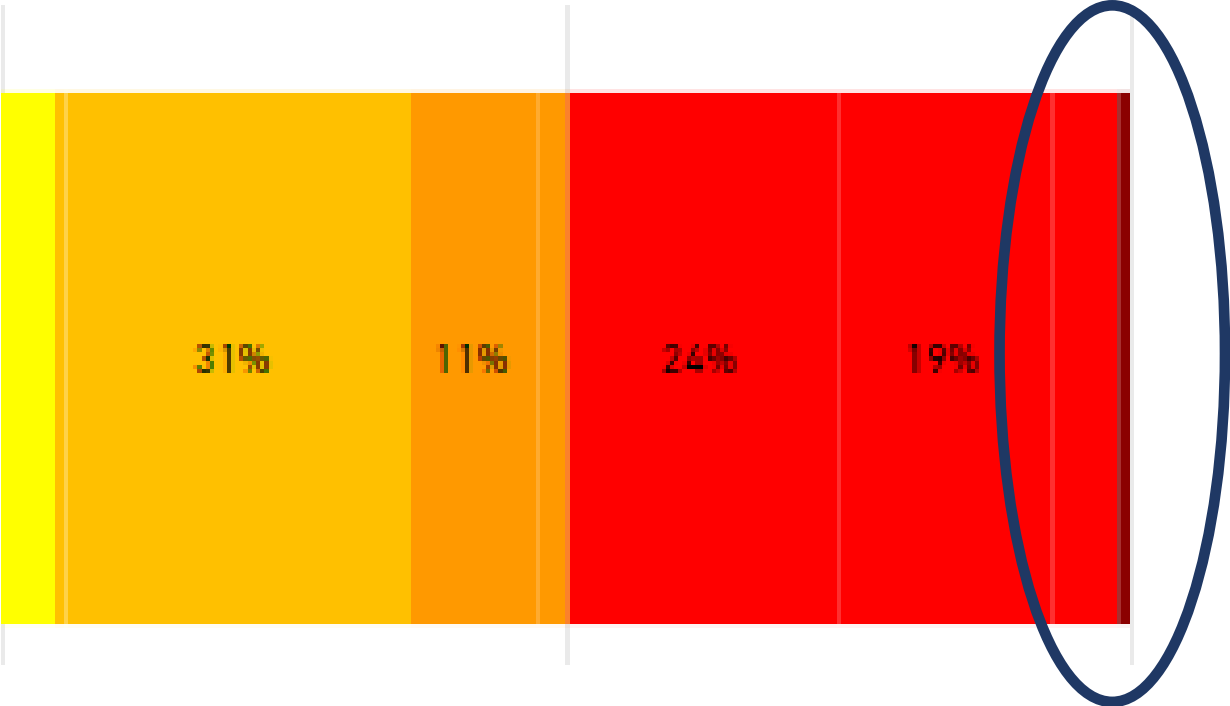
Opportunities to Strengthen Performance: Patterns and Trends Across Reprocessing

Implementation of Activities to Reduce Healthcare Associated Infections



Infection Control Process Defects Carry Higher Risk

Activities to Reduce HAIs (IC.06.01.01 EP 3)



High - Risk and Widespread Observations

Multiple steps in one process

Opportunities accumulate across the process



One process across several locations

The same opportunity repeats at multiple sites



One high - risk opportunity

A single significant breakdown is observed



WHAT IT SIGNALS

A single significant finding — or several observations together — can signal a process that is no longer reliable and greater patient risk

MAY LEAD TO

A condition level deficiency or an adverse accreditation decision

Patterns and Trends: Point of Use

PRIOR TO USE

Staff could not identify:

- Instruments that were not suitable for use
- Instruments in disrepair
- Identification tape applied incorrectly or not removed when evidence of lifting or degradation

Sterile instrument storage issues:

Not stored in a manner to protect the integrity of the packaging

- Holes or tears in packaging
- Visible evidence of soiling
- Are wet or have evidence of having been wet

POST PROCEDURE

Staff did not adhere to the manufacturer's instructions for use or organization policy/procedure:

- Preclean at the point of use if required
- Application of moisture maintaining product/process

Failure to contain soiled instruments/devices for transport per OSHA requirement

Point-of-use staff serve as gatekeepers —
keeping unsuitable instruments from patients and preparing devices for sterilization.

Patterns and Trends: Preparation for Sterilization

CLEANING / DECONTAMINATION

Enzymatic cleaner:

- Not diluted per MIFU
- Water temperature not measured as required by cleaner MIFU

Cleaning tools:

- Single-use brushes used multiple times
- Reusable brushes not reprocessed per MIFU
- Brushes not replaced per MIFU

Cleaning equipment:

- Not used when required by instrument/device MIFU
- Cleaning efficacy not validated per MIFU or organization policy
- Cleaning equipment not cleaned/maintained per MIFU

PACK & PREP

Instrument inspection:

- Failure to identify instruments/devices with degradation or visual color change requiring additional evaluation
- Failure to remediate instruments with identification tape not applied per MIFU or identification tape present in disrepair

Packing as per MIFU:

- Peel pouches not filled per MIFU
- Inner peel pack of a double peel-packed items folded which is not in alignment with the MIFU

Chemical indicator use/placement:

- Lack of internal chemical indicator

Key safeguard: Clean instruments per validated instructions and evaluate condition
Only clean instruments in good repair should proceed to sterilization

Patterns and Trends: Sterilization Processes

STERILIZATION PROCESS

Failure to follow manufacturer instructions for use (MIFU):

- Instrument manufacturer validated steam sterilization cycle/parameters not used
- Unapproved sterilization product/process used

Immediate use steam sterilization (IUSS) used for non -approved reasons

Sterilization of non -medical items

EQUIPMENT GAPS

Failure to follow MIFU:

- Leak test/Bowie Dick not performed per MIFU (Prevac)
- BI used to validate a cycle that the BI was not validated for

Failure to follow MIFU for cleaning of sterilization equipment

Failure to follow MIFU for preventive maintenance of sterilization equipment

Adequate sterilization requires following instrument/device MIFU for validated products/processes and **maintaining sterilizer function.**

Patterns & Trends: Preparation for High -Level Disinfection (HLD)

LEAK TEST

Endoscope leak test not performed per MIFU

TEE electric current leak test not performed per MIFU

Key safeguard: Protect patients by leak-testing devices and following MIFU-directed cleaning with correctly prepared solutions, appropriate tools, and maintained equipment.

CLEANING / DECONTAMINATION

Enzymatic cleaner:

- Not diluted per MIFU
- Water temperature not measured as required by cleaner MIFU

Cleaning tools:

- Single-use brushes used multiple times
- Reusable brushes not reprocessed per MIFU
- Brushes not replaced per MIFU

Cleaning equipment:

- Manual cleaning not performed when required by instrument/device MIFU
- Efficacy of cleaning/flushing equipment not validated per MIFU
- Cleaning equipment not maintained per MIFU

Patterns & Trends: : HLD Processes

HIGH-LEVEL DISINFECTION (HLD) PROCESS

Failure to follow manufacturer instructions for use (MIFU):

- Unapproved HLD product/process used
- Minimum effective concentration testing not performed per MIFU
- Temperature of HLD solution not measured prior to use
- Temperature of HLD solution did not meet the manufacturer minimum temperature at the time of use
- Instrument/device not immersed for the minimum immersion time per MIFU
- Automated HLD process failed and item not reprocessed prior to use on another patient

EQUIPMENT GAPS

Failure to follow MIFU for preventive maintenance of HLD equipment

Adequate high-level disinfection requires following instrument/device MIFU for validated products/processes and **maintaining function of automated high -level disinfection equipment.**

Patterns and Trends: Post Reprocessing

Documentation required by the organization	Incomplete Missing
Storage	High-level disinfected items not stored in a manner to protect them from contamination Sterilized items not stored in a manner to protect package integrity and sterility of the package contents

Why it matters:
Complete documentation creates traceability; proper storage ensures items remain safe for patient use

Patterns and Trends: Standard Precautions

STANDARD PRECAUTIONS OBSERVED GAPS

HAND HYGIENE REQUIREMENTS

Staff not adhering to hand hygiene requirements at key opportunities

PPE REQUIREMENTS

Staff not adhering to PPE requirements

Consistent implementation of hand hygiene and PPE requirements **helps protect staff from exposure** to blood, other potentially infectious material or other hazards identified by the organization.

Patterns and Trends: Supporting Structures

RESOURCES

Access to information:

- Staff could not access policies and procedures
- Staff did not have access to the Manufacturer's instructions for use
- Failure to clarify unclear or ambiguous information in a MIFU

Education/Training/Competency:

- Staff did not have evidence of education, training or competency required by the organization

Available Supplies:

- Staff did not have access to PPE required for decontamination
- Instrument/device specific brushes required for cleaning and decontamination not available

LEADERSHIP OVERSIGHT

Leadership Oversight:

- Leaders did not provide effective oversight of reprocessing processes

With optimal support structures in place,
reprocessing processes can be optimized.

Sterilization:

Scenarios That May Contribute to Condition Level Deficiencies

SCENARIOS EVALUATED

Process errors observed during cleaning/decontamination, pack & prep

Reusable instruments in disrepair were sterilized

Degraded or loose identification tape on instruments

Washer/decontaminator used after verification testing did not pass

Instruments requiring disassembly for sterilization were reassembled before sterilization

BI not approved for sterilization cycle used, not used at defined intervals, or not incubated per MIFU

Immediate Use Steam Sterilization (IUSS) used for non-approved reasons

- Insufficient instrument supply or vendor tray delivery delays

A condition -level deficiency may be identified for multiple defects in one process, multiple defects across locations, or one high-risk process defect.

High -Level Disinfection: Scenarios That May Contribute to Condition Level Deficiencies

SCENARIOS EVALUATED

Process gaps observed in high -level disinfection from point of use through storage

Opportunities observed in multiple steps of the process for preparing items for HLD

- Preparing for transport
- Transport process
- Cleaning

Process opportunities observed related to high level disinfection process

- Quality assurance (QA) of test strips not completed as per MIFU
- Process for minimum effective concentration (MEC) testing not performed per the MIFU

A condition -level deficiency may be identified
for multiple defects in one process, multiple defects across locations, or one high-risk process defect.

Sterilization:

Observations Evaluated for Immediate Threat to Health and Safety

SCENARIOS EVALUATED

Instruments not cleaned prior to sterilization

Single-use instruments requiring sterilization prior to use not sterilized prior to use

MIFU not followed for the instrument/device being sterilized

Non-medical devices sterilized and used for a critical procedure

- Sterilization cycle mismatch
- Minimum sterilization time and/or temperature not met

Unapproved sterilization product/process used to reprocess critical instruments/devices

Device used in a sterile body cavity without undergoing sterilization

High - Level Disinfection: Observations Evaluated for Immediate Threat to Health & Safety

SCENARIOS EVALUATED

Medical devices used for semi-critical purpose did not undergo HLD

- Endocavity probes
- Pessaries

Ultrasound probe/transducer used on mucous membranes did not undergo HLD after use for a patient, prior to use for the next patient

Manufacturer minimum requirements for the HLD solution used not met at the time of use (temp, time)

Non-medical device used for semi-critical purpose, intermediate level disinfected and used for a subsequent patient

Medical device with explicit instructions to not use on open wounds or non-intact skin, used on wounds and intermediate level disinfected

Supporting Implementation of Reprocessing Activities

Opportunities show consistent patterns across the same key areas

Year after year, the same five infection control themes rise to the top

2023

- HLD/Sterilization
- Device/Supply Storage
- Low Level Disinfection
- Implement IC Activities
- Standard Precautions

2024

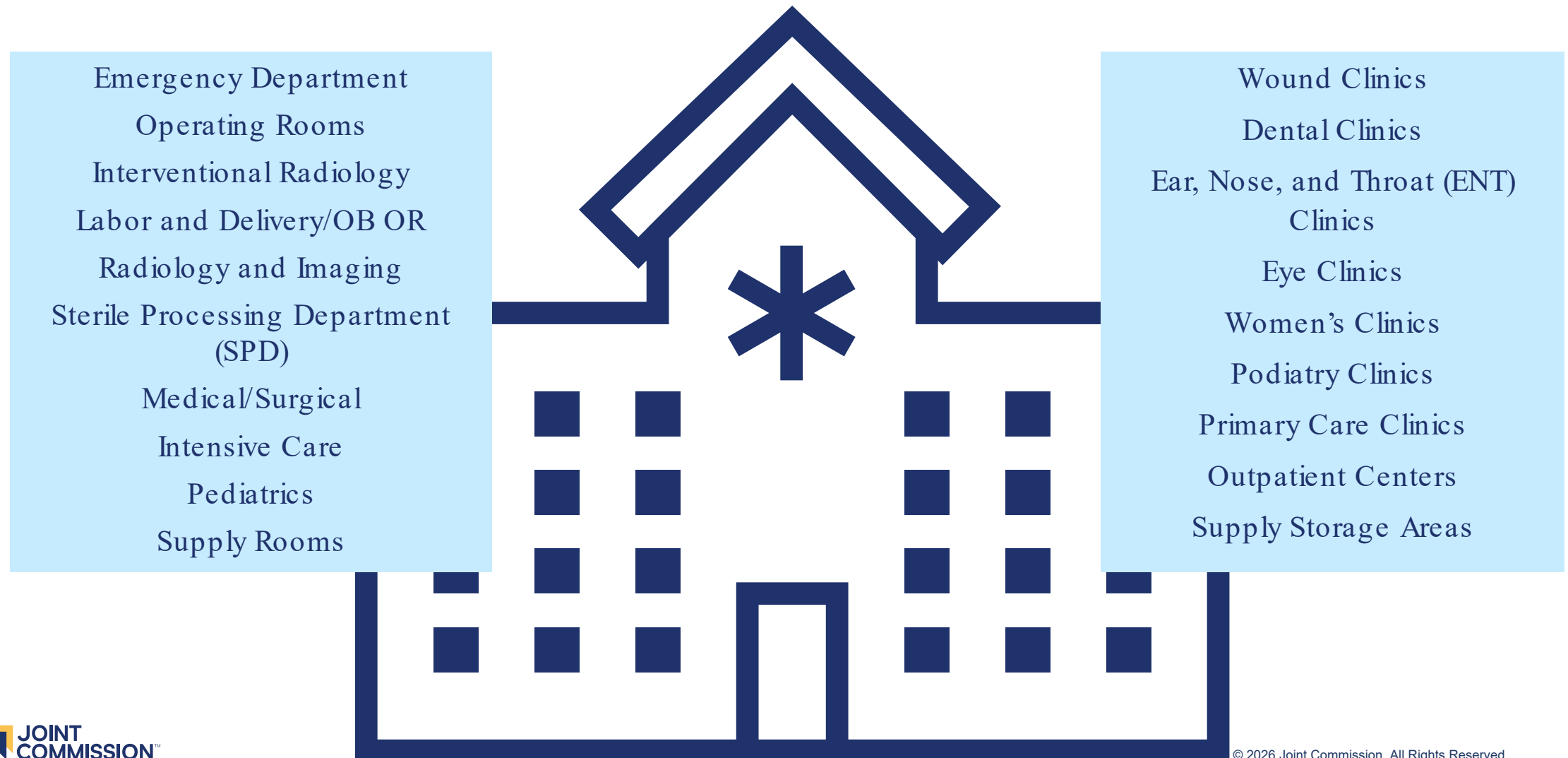
- HLD/Sterilization
- Device/Supply Storage
- Low Level Disinfection
- Standard Precautions
- Implement IC Activities

2025

- HLD/Sterilization
- Device/Supply Storage
- Low Level Disinfection
- Standard Precautions
- Implement IC Activities

Reprocessed Instrument and Devices are Found in Many Locations

Inpatient and Outpatient Locations, including but not limited to:



There Are Many Staff Who Play A Role In Managing Reusable Instruments



The diagram consists of five white rounded rectangular boxes arranged horizontally. Each box has a dark blue horizontal bar at the top. The text inside each box describes a role in managing reusable instruments. The roles are: Staff who obtain instruments and set up for procedure, Staff who use/handle instruments in use, Staff who prepare instruments for transport, Staff who perform sterile processing functions, and Supply management.

Staff who obtain
instruments and
set up for
procedure

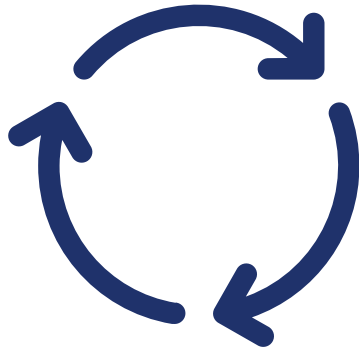
Staff who
use/handle
instruments in
use

Staff who
prepare
instruments for
transport

Staff who
perform sterile
processing
functions

Supply
management

What Do Repeat Patterns and Trends Tell Us About Process Rigor and Sustainability?



Focus is often placed on individual tasks or staff performance



This limits our ability to see end-to-end process failures



Sustainable improvement may require evaluating the entire process, not isolated steps

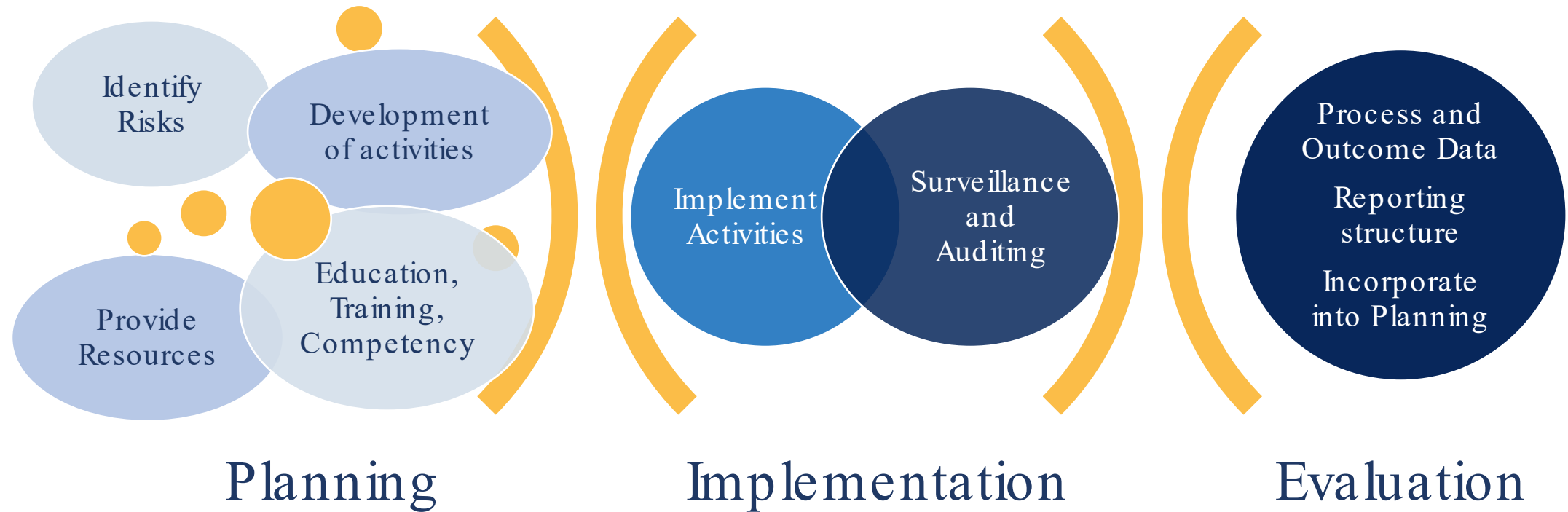


Strong processes support consistent outcomes, regardless of who performs the work



QAPI helps shift from reactive fixes to reliable, system-based performance

Successful Implementation of Reprocessing Activities is Multifactorial



Key Elements of Successful Implementation That Surveyors are Looking For



Process in Alignment with
IC Hierarchy



Competent Employees



Infection Prevention and
Control Involvement



Leadership Involvement



Available Resources

Implementation of Reprocessing Activities

SURVEYORS VERIFY

Activities are implemented...



As intended

Performed the way the process was designed



In all relevant locations

Every area where reprocessing occurs



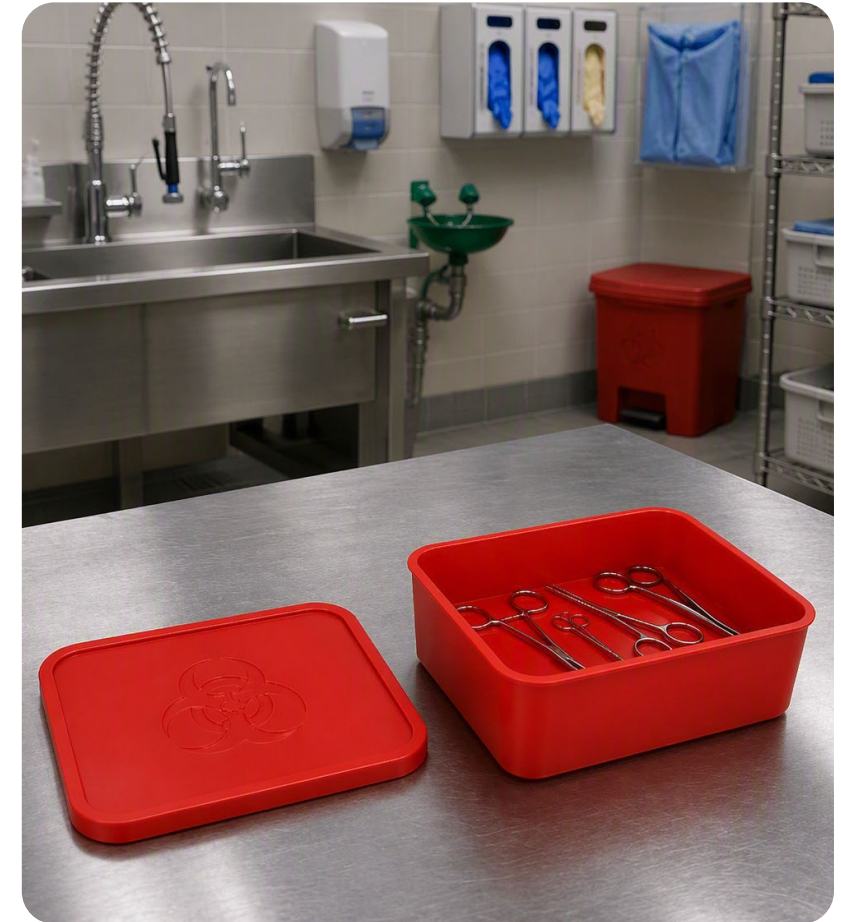
For all relevant staff

Everyone who performs the activity



With education, training & competency

As required by the organization

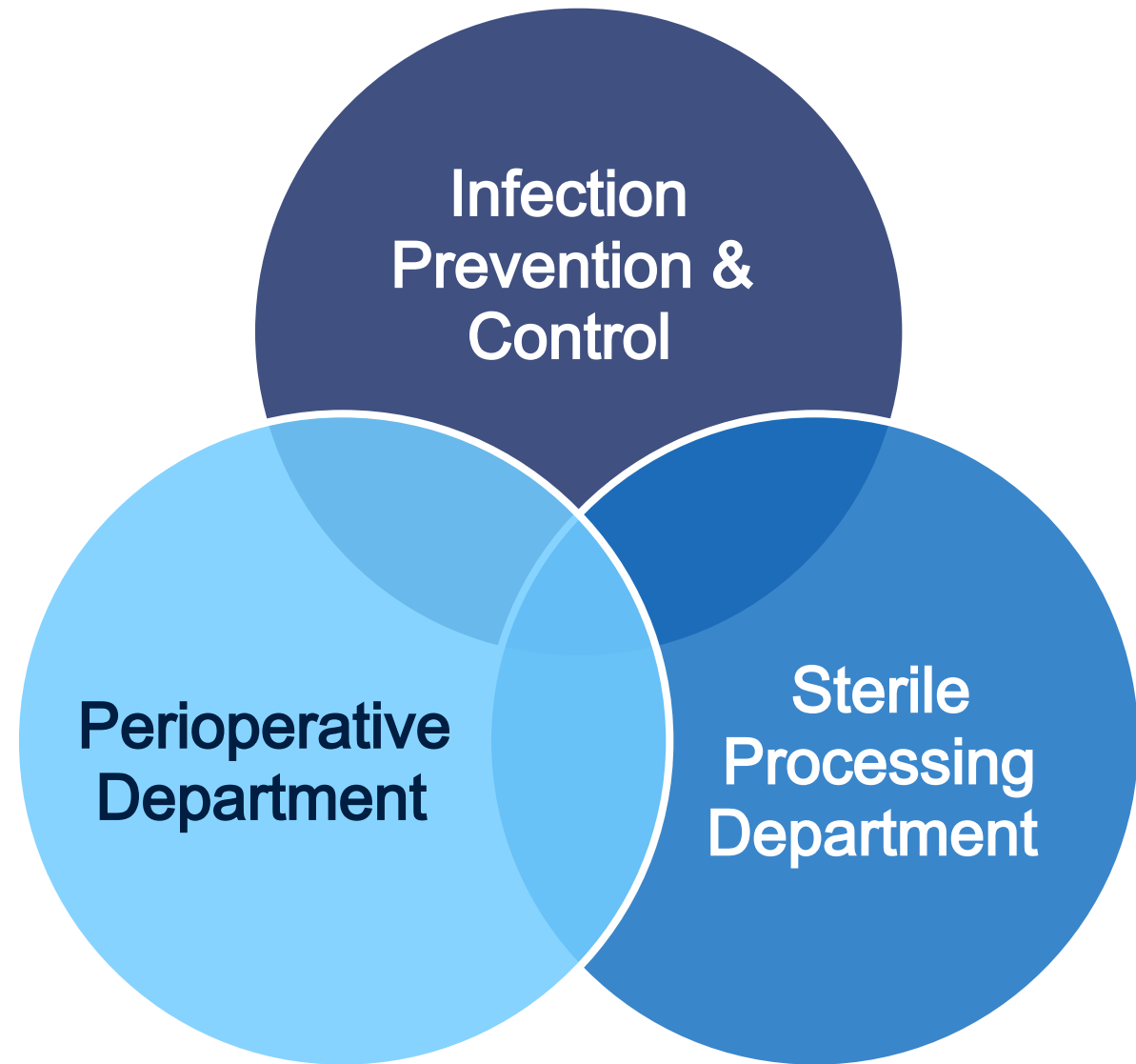


Using Quality Assessment & Performance Improvement to Support Reprocessing of Reusable Instruments & Devices

QAPI Starts With Leadership

QAPI is a leadership-driven, data-based framework that integrates Infection Prevention into organization-level improvement, accountability, and sustainability.

Effective QAPI in reprocessing depends on collaboration across departments



Collaboration Creates Synergy

The infection preventionist(s) or infection control professional(s) is responsible for the following:

01 Policies & Procedures

Development and implementation of hospitalwide infection surveillance, prevention, and control policies and procedures that adhere to law and regulation and nationally recognized guidelines

02 Program Documentation

Documentation of the infection prevention and control program and its surveillance, prevention, and control activities

03 Training & Education

Competency-based training and education of hospital personnel and staff, including medical staff and, as applicable, personnel providing contracted services in the hospital, on infection prevention and control policies and procedures and their application

04 Prevention & Auditing

Prevention and control of health care–associated infections and other infectious diseases, including auditing staff adherence to infection prevention and control policies and procedures

COLLABORATION AT THE CORE

Where synergy happens

- Communication and collaboration with all components of the hospital involved in infection prevention and control activities, including but not limited to the antibiotic stewardship program, sterile processing department, and water management program
- Communication and collaboration with the hospital's quality assessment and performance improvement program to address infection prevention and control issues

Using Quality Assessment & Performance Improvement to Support Reprocessing

Collect Data

Analyze Data

Take Action to Improve Performance

Monitor Improvement Activities

Impact : The best way to achieve better care is by first measuring the performance of processes that support care and then using that data to make improvements.

Quality Assessment and Performance Improvement Exists Along a Continuum

Not all risks require the same level of response



Some issues can be addressed with immediate, localized fixes

Others may require a formal performance improvement project

Consider:

Using data to determine scope, risk, and level of intervention
Aligning actions to drive sustained, system -level improvement

Evaluate High -Level Disinfection & Sterilization like a Surveyor

TRACE STERILIZATION

Tracing all steps of the sterilization process, in all locations

REVIEW INFORMATION

Verbal information provided by front line staff and written documents

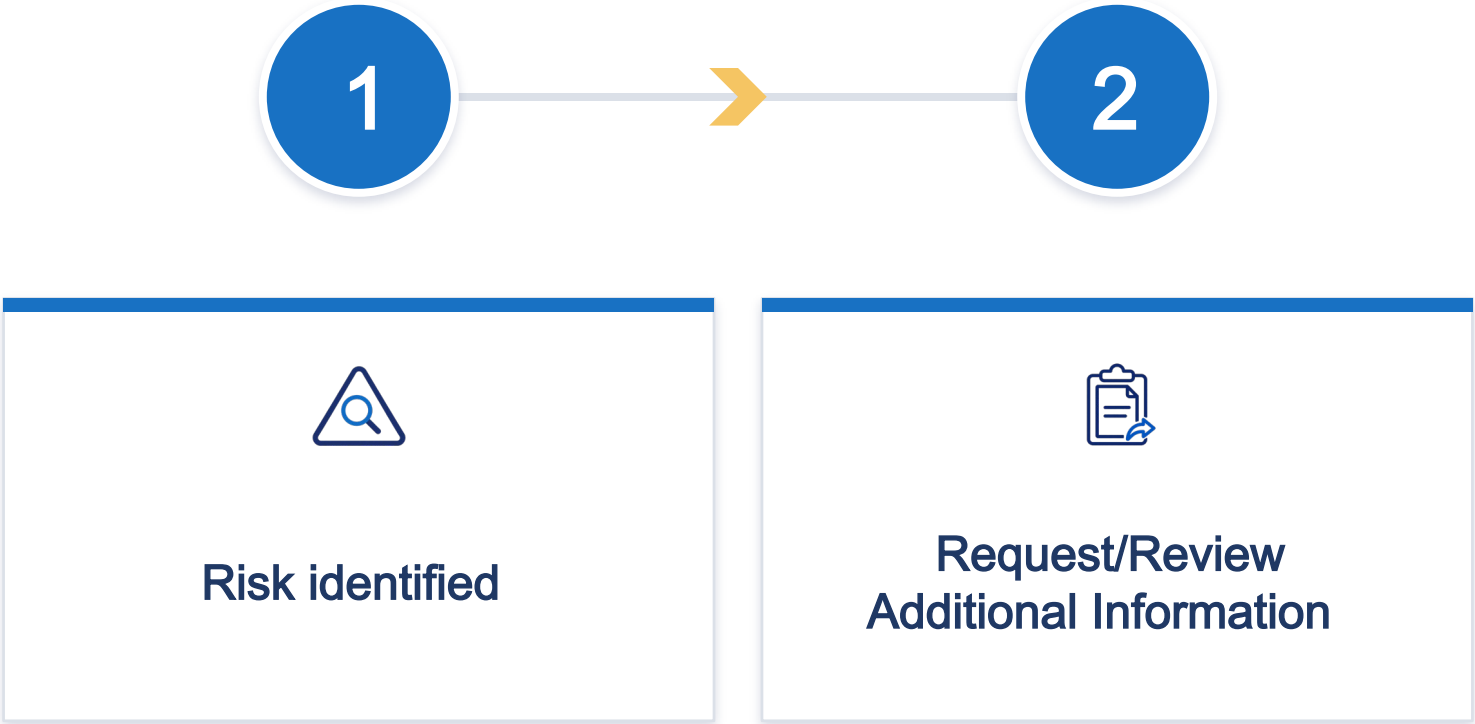
OBSERVE & INTERVIEW

Real-time observations and interviews

REVIEW DOCUMENTS

Review of documents

Evaluating Identified Risks



Look Beyond the Finding to Identify Contributing Factors

Available Resources

Process Developed is Compliant

Education, Training or Competency

Process Oversight

Staff Accountability



If You Find a Defect in a Process, Expand Your Evaluation

ASK

Are all activities implemented...

1

As intended

2

In all relevant locations

3

For all relevant staff

4

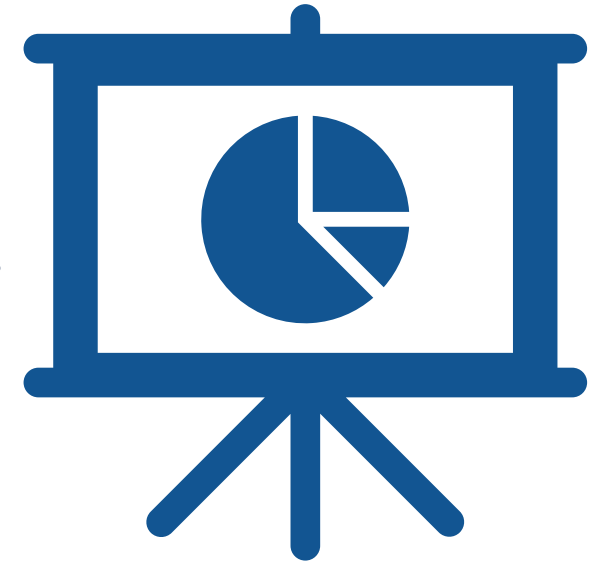
Includes education, training and/or competency if required by the organization



Shifting to a QAPI -Driven Approach

Consider:

- Moving beyond addressing individual RFIs
- Identifying system-level drivers and recurring process failures
- Analyzing trends across services, units, and time
- Prioritizing risks using data to guide improvement
- Implementing actions that support sustained performance and reliability



Why This Matters

Every step protects a patient

From point of use through storage, a single process defect can put a patient at risk.

Non-compliance follows patterns

The same themes drive sterilization and high-level disinfection findings year after year.

Resources enable safe practice

Ensuring staff have the resources they need supports sterilization processes.

QAPI supports improvement efforts

Auditing, action planning, and evaluation sustain the gains over time.

Managing Reprocessed Instruments & Devices is a Team Sport



Three Teams. One Mission. Stronger Together.

Infection Prevention and Control, Sterile Processing, and Perioperative Services are united by common goals, and working together produces the best outcomes for every patient

Infection Prevention & Control

Works hand in hand with Sterile Processing and Perioperative teams

Sterile Processing

Delivers safe, ready-to-use instruments

Perioperative Services

Puts safe practice into action in the OR





THE PATIENT PROMISE

Every patient deserves medical instruments and devices that have been flawlessly reprocessed for their care.

Additional Resources

Impact Accelerator Learning Series: 2026

ELEVATING CARE

Impact Accelerator: Learning Series

For 75 years, Joint Commission has conducted surveys and analyzed quality and safety risks across diverse healthcare settings. This sustained, system wide exposure gives us unique insight into patterns of recurring process gaps, and leading practices that reliably drive improvement and elevate care.

From this broad dataset, we see a consistent pattern of common and recurring Requirements for Improvement (RFIs). To address these issues head on with practical, evidence-based guidance, we are launching a new learning series that dives deeply into the most frequent RFIs. The objective is simple and focused: confront the most prevalent issues directly and equip healthcare organizations with actionable strategies to drive meaningful improvement.



High-Level Disinfection (HLD) and Sterilization

We are kicking off the series with **High-Level Disinfection (HLD) and Sterilization**—two of the most frequent and highest risk findings during surveys. Further, when HLD or sterilization issues do surface, they are often broad rather than isolated, indicating surveyors encounter them frequently and across multiple departments. Infection control findings, including HLD and sterilization, are consistently top-scoring problems in surveys.



Impact Accelerator Videos

To support improvement, we created concise videos that focus on what matters most—clear expectations, common gaps, and practical strategies. These videos, and future resources, are designed to support learning that leads to meaningful improvement where it matters most: in practice.

Elevating Care

High-Level Disinfection Practices



VIDEO

High-Level Disinfection Practices

Runtime: 5:13

Watch now

Elevating Care

Sterilization Practices



VIDEO

Sterilization Practices

Runtime: 5:48

Watch now



Webinars

On-demand webinars focused on real-world examples and lessons learned about high-level disinfection and sterilization.

Browse webinars

Impact Accelerator Resources

Explore our collection of complimentary resources that accompany this learning series—created to support your work and be there when you need a quick reference.

Browse resources



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COMMISSION™**

Impact Accelerator: Learning Series | Joint Commission

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HLD & Sterilization Resources

Available resources will expand over time

- A collection of practical, ready-to-use resources to complement the learning series
 - Posted to Impact Accelerator: Learning Series webpage
- Convey practical solutions as visual, distributable materials
 - Applicable Performance Strengths
 - HLD/Sterilization Tracers
 - Checklist
 - Complimentary publication
 - Infographics available for download
 - Replays of the HLD/Sterilization webinars

ELEVATING CARE

Impact Accelerator Resources

Explore our collection of complimentary, ready-to-use resources and successful practices from healthcare organizations. Check back often—new resources will be added regularly to support ongoing learning and improvement.



Filter Here

☐ Type Of Result ^

☐ Checklists

☐ Performance Strengths

☐ Publications

☐ Tracer Observation Forms

☐ Videos

☐ Webinars

Showing 10 Results per page

By Relevance

VIDEO

High-Level Disinfection Practices

This video discusses the HLD standards, frequent observations, strategies for success, a real-world example, and how organizations can avoid common survey findings.

March 31, 2026 | 5:13

Elevating Care

High-Level Disinfection Practices

Infection Prevention and Control Resource Center

JOINT COMMISSION

Accreditation Certification Products & Services Standards Knowledge Library About Us

Home > Knowledge Library > Infection Prevention and Control Resource Center

RESOURCE CENTER

Infection Prevention and Control & Antibiotic Stewardship

Effective infection prevention and control practices, along with antibiotic stewardship, are essential for preventing disease spread, safeguarding vulnerable populations, and maintaining a safe environment. This resource center supports organizations in developing comprehensive programs to protect the health and safety of patients and staff.



Creating the Foundation for Your Infection Prevention and Control Program and Activities

- Programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable.
- CMS regulations allow for flexibility and do not require organizations to adhere to a specific set of guidelines or best practices. Other federal, state and local regulations, however, may define specific requirements or require organizations to follow a specific guideline or national standard.
- Organizations must evaluate regulation and current evidence-based guidelines and national standards to design organizational policies and procedures to promote staff and patient safety.





Search by HAI Type

Adhering to evidence-based guidelines and best practices can improve patient outcomes and reduce the burden of HAIs. Regular monitoring and surveillance of infection rates allow healthcare organizations to identify trends, implement targeted interventions, and track progress in reducing HAIs.



Search by Setting

Start by selecting your accreditation program to find resources aligned with accreditation requirements.



Search by Joint Commission Standard

Joint Commission accreditation standards provide a framework that challenges healthcare organizations to strengthen their infection prevention and control practices. They guide healthcare professionals on the most effective approaches to patient care, infection prevention, and safety.



Search by Topic

There are resources that address many infection prevention and control-related topics. Staying informed and utilizing these resources is crucial for maintaining patient safety and preventing the spread of infections in healthcare settings.

[Infection Prevention and Control Resource Center | Joint Commission](#)

Standards FAQs | Joint Commission



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STANDARDS INTERPRETATION

Standards FAQs

Use the search below to browse our FAQ database to find answers to common questions regarding Joint Commission accreditation and certification standards.



[Standards FAQs | Joint Commission](#)

FAQs

STANDARDS FAQ

Who is responsible for ensuring that instructions for use are available and used by staff reprocessing equipment and devices?

STANDARDS FAQ

Do we need to monitor the temperature and humidity of the rooms where sterile supplies are stored?

Ask a Standards Question

Can't Find What You're Looking For?

If you do not find an answer to your question, please contact the Standards Interpretation Group (SIG).

Note: To provide adequate support to those organizations that are either accredited/certified or seeking accreditation/certification, we will only answer those questions submitted by those organizations seeking accreditation/certification or currently accredited/certified by the Joint Commission. The Joint Commission no longer answers questions submitted by students or vendors. Thank you for your understanding.

Ask a standards interpretation question



Standards Online Submission Form

Please consider reviewing the [Standards Interpretation FAQs page](#) prior to submitting a question. If you are Joint Commission accredited, click [Login](#) and then click "Joint Commission Connect". Then go to Resources and Tools, Standards Interpretation, and click on the online form link to submit your question. If you prefer to use this form, please complete Steps 1-3 below:

Joint Commission accredited? ☒ Yes ☐ No

Health Care Organization Information

Complete the three steps below. In Step 3, only health care organizations accredited/certified by The Joint Commission are included in the list. Step 3 is required if you selected Yes to the Joint Commission accredited question above.

Step 1. Select the state/territory: **Step 2.** Select the city: **Step 3.** Select the health care organization:

Select... ▼

▼

Required

▼

If you DID NOT find the name of the health care organization from the list in Step 3 above or the state/city is incorrect, please select "No" to "Joint Commission accreditation?" and complete the information below the question. If you are in the process of applying for accreditation, please select "Yes" to the "Are you in the process of becoming TJC accredited?" question and continue to fill out the rest of the information below.



For Keeping Patients Safe!