Updates from The Joint Commission: The 4-1-1 on Survey Enhancements
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The 411 on Survey Enhancements

Objectives

* Introduce a standardized approach to infection control standards
* Review the most problematic Joint Commission standards
* Identify how to decrease the likelihood of an IC finding
* Explain the process to follow if the facility disagrees with surveyor’s application of the standards
Standardized Approach to IC Related Standards

- Regulation
- Conditions of Participation/ Conditions for Coverage
- Manufacturer Instructions
- Evidence based standards or guidelines
- Consensus documents or position statements
- Incorporate into facility based risk assessment and policy

Some Sources

- Occupational Safety and Health Regulations
- Food and Drug Administration
- Department of Health and Human Services
- Centers for Medicare and Medicaid Service
- State or local Health Departments

State Operations Manual

### Program Specific State Operations Manual

#### Medicare State Operations Manual

**Appendix**

- Each appendix is a separate file that can be accessed directly from the SOM Appendix Table of Contents, as applicable.
- The appendix is an PDF. To access the appendix, please open the PDF in Adobe Reader. Click on the corresponding link at the top of the appendix.
- To return to the main page, left click on the return link on the navigation bar.

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Hospitals</td>
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<tr>
<td>AA</td>
<td>Psychiatric Hospitals</td>
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<tr>
<td>B</td>
<td>Home Health Agencies</td>
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<td>C</td>
<td>Laboratory and Laboratory Services</td>
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<tr>
<td>D</td>
<td>Home Care Service</td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>Integrated Care (Patient-Centric Service)</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>Physical Therapists in Independent Practice</td>
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<td>G</td>
<td>Rural Health Centers</td>
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</tr>
</tbody>
</table>

#### Other CMS Sources of IC Requirements

- Survey and Certification Letters
- Quality Safety & Oversight Memoranda

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**Other CMS Sources of IC Requirements**


**IC is integrated throughout!**
Want to Know What Facilities Are Being Cited for by CMS...

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Hospitals.html

- "...failed to follow current facility policy related to the cleaning of lobbies and corridors...dust noted in the area"
- "...sterilization equipment...policy, sterile processing technicians are responsible for cleaning sterilizers every week. Documentation...was requested." (no documentation available)

Manufacturer Instructions

- Must meet Spaulding classification requirements
- Read CAREFULLY

### Manufacturer Instructions

**Cleaning**
- Rinse: Immediately upon removal from patient’s eye, thoroughly rinse in cool or tepid water.
- Wash: Place a few drops of mild soap on a washcloth or paper towel, clean, and dry with a clean towel.
- Sterilize: Thoroughly rinse in cool or tepid water, then dry carefully with a sterile lint-free tissue.

**Disinfection**

<table>
<thead>
<tr>
<th>Solution</th>
<th>Rinse/Soak</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>2% or 3% aqueous solution</td>
<td>10% solution mixed on 1 part bleach to 9 parts cool tepid water</td>
<td>Recommended exposure time: 15 minutes</td>
</tr>
</tbody>
</table>

**Sterilization**

<table>
<thead>
<tr>
<th>Solution</th>
<th>Rinse/Soak</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene oxide</td>
<td>1% solution mixed on 1 part bleach to 9 parts cool tepid water</td>
<td>Recommended exposure time: 15 minutes</td>
</tr>
</tbody>
</table>

**Caution:** To avoid damaging the lens, do not exceed recommended exposure time.

**NOTE:** This lens is known to be compatible with: Acetone, Isopropanol, Ethanol, Chloroform, Trichloroethylene, 1-Propanol, 2-Propanol, Toluene, and DME.

**Caution:** If used on an assembled system, lens must be STERILIZED before next procedure.

Most Problematic Standards

June 1, 2017 to May 31, 2018

- Hospital
- Critical Access Hospitals
- Ambulatory Healthcare Centers
- Office Based Surgery Centers
- Nursing Care Centers
Most Problematic Standards: All Programs

- High Level Disinfection/ Sterilization*
- Storage
- Cleaning and Low Level Disinfection
- Standard Precautions
- Implementation of Infection Prevention and Control Program

*Rarely identified in NCC

Disinfection and Sterilization

IC.02.02.01 EP2: High Level Disinfection/ Sterilization Noncompliance 2012-2018 (half year)

Noncompliance 2012-2018 (half year):

<table>
<thead>
<tr>
<th>Year</th>
<th>AHC</th>
<th>CAH</th>
<th>HAP</th>
<th>OBS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>22.1%</td>
<td>27.3%</td>
<td>29.4%</td>
<td>25.6%</td>
</tr>
<tr>
<td>2013</td>
<td>28.7%</td>
<td>36.0%</td>
<td>32.6%</td>
<td>24.1%</td>
</tr>
<tr>
<td>2014</td>
<td>28.7%</td>
<td>46.0%</td>
<td>38.0%</td>
<td>33.6%</td>
</tr>
<tr>
<td>2015</td>
<td>35.7%</td>
<td>45.7%</td>
<td>46.9%</td>
<td>45.9%</td>
</tr>
<tr>
<td>2016</td>
<td>42.9%</td>
<td>57.8%</td>
<td>50.7%</td>
<td>53.4%</td>
</tr>
<tr>
<td>2017</td>
<td>47.9%</td>
<td>60.0%</td>
<td>54.3%</td>
<td>59.6%</td>
</tr>
<tr>
<td>2018</td>
<td>46.27%</td>
<td>52.31%</td>
<td>58.95%</td>
<td>71.43%</td>
</tr>
</tbody>
</table>

Percent Noncompliant:

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
Background: Spaulding Classification

<table>
<thead>
<tr>
<th>Level</th>
<th>Risk of Deficiency</th>
<th>Description</th>
<th>Examples of Items</th>
<th>Reprocessing Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>High</td>
<td>Item comes in contact with a sterile body cavity or the vascular system</td>
<td>Surgical and dental instruments, some endoscopes, inner surfaces of hemovacs, urinary catheters, laparoscopic forceps, implants, and needles</td>
<td>Sterilization</td>
</tr>
<tr>
<td>Semi-Critical</td>
<td>Moderate</td>
<td>Item comes in contact with mucous membrane or non-intact skin</td>
<td>Respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades, tracheal suction catheters, surgical instruments, and surgical devices</td>
<td>Minimum: High</td>
</tr>
<tr>
<td>Non-critical</td>
<td>Low</td>
<td>Item comes in contact with skin</td>
<td>Environmental surfaces, bed rails, bedside tables, patient furniture, counters, and floor</td>
<td>Clean or disinfect</td>
</tr>
</tbody>
</table>

The Sterilization Cycle

Divide into Key Steps with Emphasis on Risk

1. Confirm Ready for Use
2. Prepare for Transport
3. Transport to Point of Use
4. Sterilize
5. Clean and Disinfect
6. Inspect and Package
7. Transport to Decontamination Area
8. Wipe/Flush During the Procedure
9. Confirm Ready for Use

Key Risks for Sterilization Failure Leading the Way to Zero

- Sterilant cannot reach all surfaces
  - Cleaning and decontamination process
  - Maintenance and use of cleaning equipment
  - Disassembly and packaging
- Failure of the sterilizing equipment
  - Maintenance
  - Monitoring
- Staff does not recognize that product is not sterile
  - Load release
  - Product use
High Level Disinfection
Level of risk associated with complexity of equipment

Key Risks for High Level Disinfection
Failure: Endoscopes
Leading the Way to Zero
Outbreaks of infection, colonization and inflammation have been linked to:
Not following manufacturer’s instructions for use
- lack of precleaning endoscopes at point of use,
- inappropriate use or choice of detergent or disinfectant,
  - expired product,
  - shortened exposure time
  - incorrect temperature
  - below minimal effective concentration
- improper or inadequate cleaning procedures,
  - failure or inability to mechanically clean channels or disassemble instruments
  - insufficient flushing or brushing
- Not using or incorrect channel connectors when using automated endoscope reprocessor
- use of a untreated or contaminated water supply
- failure to completely dry channels
- lack of routine maintenance
- Flaws in the mechanical design

How to Avoid findings in IC.02.02.01
Frequent Survey Finding

- Frequent Finding
  - Dirty instruments were not prepared in a manner that prevented instruments from drying
  - Primarily cited in ambulatory areas (e.g., wound, podiatry, dental clinics) and inpatient wards

Prepare Instruments for Transport: Keep Moist

- Regulation
- Conditions of Participation (if deemed)
- Manufacturer instructions
- Evidence based guidelines and standards
  - Association for periOperative Registered Nurses (AORN)
  - AAMI
  - CDC
- Facility policy

Prepare Instruments for Transport: Keep Moist

Manufacturer Instructions

- **Manufacturer A**: Do not allow blood, debris or bodily fluids to dry on instruments. For best results... reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner...
- **Manufacturer B**: At point of use remove coarse contamination...and keep... moist for transit to the processing site.
- **Manufacturer C**: Immediately after procedure... cover with towel moistened with sterile distilled water... foam, spray, gel products are available...
- **Manufacturer D**: No instructions for point of use
AMMI (ST79 2017 6.3.5) states
Prior to transport, instruments should be prepared in such a way as to prevent organic soils from drying by
a) placing a towel moistened with water (not saline) over the instrument;
b) placing items inside a package designed to maintain humid conditions; or
c) applying a product designed for pretreatment

AORN 2017 Guideline for cleaning and care of surgical instruments states
III.g. Instruments should be kept moist until they are cleaned. A towel moistened with water placed over the instruments may be used. Saline should not be used. [3: Limited Evidence]
III.g.1. Instruments that cannot be cleaned immediately should be treated with an instrument cleaner according to the device and the instrument cleaner manufacturers' written IFU

Prepare Instruments for Transport: Keep Moist
Manufacturer Instructions
– **Enzymatic Detergent A**: Dispense gel over surgical tray of instruments to ensure soils are evenly covered. (No instruction to reapply)
– **Enzymatic Detergent B**: Place items in clearly marked decontamination area. Thoroughly spray directly onto instruments...reapply as needed to keep instruments moist.
– **Enzymatic Detergent C**: Spray directly on soiled instruments immediately after use. Allow foam to stay on instruments and scopes until ready for cleaning. Apply more as needed to keep moist.
Prepare Instruments for Transport: Keep Moist
Facility Policy and Procedure

- Facility makes the decision on how to maintain moisture of used instruments
- Follow manufacturer instructions for use
- In absence of instruction, follow evidenced based guidelines and national standards

Assessing Participant Knowledge
Facility Policy and Procedure – A or B

EXAMPLE A:
All instruments should have bioburden removed at point of use and should be sprayed with an enzymatic detergent. Enzymatic detergent A should be reapplied to maintain moisture as needed.

EXAMPLE B:
During operative procedures, instruments should be wiped with a gauze moistened with water and lumens should be flushed, as needed. Used instruments should be kept moist until they are cleaned in Decontamination. Moisture should be maintained by
- Placing a towel moistened with water (not saline) over the instrument
- Placing items inside a package designed to maintain humid conditions
- Applying a product designed for pretreatment

Assessing Participant Knowledge
Facility Policy and Procedure – A or B

EXAMPLE A:
All instruments should be placed in a rigid puncture proof container that is labeled with the biohazard symbol or red in color to signify that it contains soiled instruments

EXAMPLE B:
Soiled items must be contained to prevent injury and/or exposure to blood or other potentially infectious materials.
- Sharps (defined by OSHA as objects that can penetrate a worker’s skin, such as needles, scalpels, and the exposed ends of dental wires) must be placed in a leakproof, puncture-resistant container that is disposable and labeled red or with the biohazard symbol.
- Non-sharps must be contained in a way that contains contamination and is labeled with a biohazard symbol, the color red or equivalent warning.
Clarifying Standard Requirements:
Sterilization

<table>
<thead>
<tr>
<th>OLD FINDING</th>
<th>Moving Forward Will Score If</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visible bioburden and dried blood found on instruments</td>
<td>- Wiping / flushing of soiled instruments is not observed during a case in the operating room or procedure room and it is clinically appropriate or</td>
</tr>
<tr>
<td></td>
<td>- Item that is ready for use on a patient is visibly soiled</td>
</tr>
<tr>
<td>Enzymatic solution was not applied to maintain moisture on instruments</td>
<td>- There is no process for keeping used instruments moist, or</td>
</tr>
<tr>
<td></td>
<td>- Manufacturer instructions for products used to keep instruments moist were not followed, or</td>
</tr>
<tr>
<td></td>
<td>- The facility policy for keeping instruments moist was not followed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OLD FINDING</th>
<th>Moving Forward Will Score If</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instruments were not transported from the point of use in a leak proof puncture resistant container with the biohazard symbol or color red.</td>
<td>- Sharps are being transported in a manner that violates OSHA requirements (e.g., sharps not placed in puncture resistant container that is red or labeled biohazardous) or</td>
</tr>
<tr>
<td></td>
<td>- Non-sharps are transported in a way that could lead to people or staff contamination</td>
</tr>
<tr>
<td>Instruments in the closed position</td>
<td>- Packaged instruments awaiting sterilization are in the closed/ ratcheted position or</td>
</tr>
<tr>
<td></td>
<td>- Items that have just undergone sterilization are on the trolley or in the sterilizer in the closed/ ratcheted position or</td>
</tr>
<tr>
<td></td>
<td>- Items in preparation and packaging that have come through the washer or pass thru window have not been disassembled in accordance with manufacturer’s instructions</td>
</tr>
</tbody>
</table>
### Clarifying Standard Requirements: Sterilization

<table>
<thead>
<tr>
<th>OLD FINDING</th>
<th>Moving Forward Will Score If</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instruments are released prior to the biologic indicator being read.</td>
<td>- Routine sterilizer monitoring with a biologic indicator required by state or per EBG is not followed and recorded or&lt;br&gt;- Non-implant load is released without physical monitoring of cycle and external and internal chemical indicators or&lt;br&gt;- Implant loads are released without routine sterilizer monitoring, a biologic indicator and a type 5 integrating indicator (aka integrator) or&lt;br&gt;- Biologic indicator not read before implant release (unless allowed in emergent situations by facility policy and policy was followed)</td>
</tr>
</tbody>
</table>

### Clarifying Standard Requirements: High Level Disinfection

#### Old Finding Moving Forward Will Score If

<table>
<thead>
<tr>
<th>OLD FINDING</th>
<th>Moving Forward Will Score If</th>
</tr>
</thead>
<tbody>
<tr>
<td>Items that have been high level disinfected are stored in drawers.</td>
<td>- Container or location of storage is visibly soiled or staff are observed contaminating other high level disinfected products or&lt;br&gt;- Storage is not consistent with the items intended use (e.g., items that require minimum of high level disinfection may be stored in a way that protects from contamination even if they were sterilized) or&lt;br&gt;- Item is not stored in accordance with manufacturer instructions for use or&lt;br&gt;- Item is not stored in accordance with facility risk assessment / policy if no guidance was provided by the item manufacturer instructions for use</td>
</tr>
</tbody>
</table>

#### Stored Scopes exceeded the hang time.

<table>
<thead>
<tr>
<th>OLD FINDING</th>
<th>Moving Forward Will Score If</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility is not following Manufacturer IFU for drying or frequency of reprocessing.</td>
<td>Will NOT Score any finding related to hang time under IC Standards.</td>
</tr>
</tbody>
</table>
IC Blog Link: https://www.jointcommission.org/infection_prevention_control/

Storage

IC.02.02.01 EP4

Storage of Semi-Critical Items: Endocavity Probe at ASC in Wyoming

Using the standardized approach

Regulation
(e) All equipment and supplies shall be protected from contamination.

Conditions of Participation
CMS IC Infection Control Worksheet for ASC Page 15, “Following high level disinfection, items are placed in a designated clean area in a manner to prevent contamination.”

Manufacturers Instructions
Store the transducer so that it hangs freely and vertically, and observe the following precautions... Do not store the transducer in closed containers or where condensation may occur.
IC.02.02.01 EP4 Storage

Frequent Findings
- No impervious bottom to storage cart
- Storage visibly dirty
- Expired items
- Endoscopes stored with tip touching bottom of cabinet, in shipping case, or in other manner not recommended by manufacturer
- Open, stained, crushed, torn etc. sterile packages
- Incorrect temperature or other physical parameter
- Sterile storage in an unfinished room with exposed pipes, wires, insulation, unsealed concrete floor, and holes in walls
- Outside shipping containers with sterile supplies

IC.02.02.01 EP1 Cleaning and Low Level Disinfection

Frequent Findings
- Use of a detergent when a disinfectant is indicated
- Expired disinfectant being used
- Disinfectant not being used in accordance with manufacturer IFU (e.g., dilution, type of surface, contraindicated)
- Use of an antiseptic to clean environmental surfaces
- Failure to clean thermometer, blood pressure cuff, stethoscope or pulse oximeter, etc. after each patient
- Lack of environmental cleaning between patients in exam rooms, procedure rooms, operating rooms etc.
- Lack of cleaning in support areas
- Failure to monitor temperature or duration of contact with sanitizing agent or laundry
- Employees did not know....
Standard Precautions

IC.02.01.01 EP2

Refer to Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings – Recommendations of the Healthcare Infection Control Practices Advisory Committee states Standard Precautions include:

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

Frequent Findings

- Lack of hand hygiene
- Use of a hand hygiene sink for disposal or cleaning of equipment
- Use of a lancet, lancet pen, or insulin pen on multiple patients
- Use of a glucose monitor that is labeled for single patient use on more than one patient
- Use of single dose medication vials on multiple patients or availability for use after opening
- Taking a multi-dose vial into a patient room and then using it for a subsequent patient
- Failure to scrub the hub of an IV line or medication vial...
IC.02.01.01 EP2 Standard Precautions

Frequent Findings

- Not following state regulation, CoP, evidence-based guideline and/or facility policy regarding dress code in restricted areas (e.g., OR, pharmacy compounding)
- No documentation of Hepatitis B status for hemodialysis patients / Failure to follow CDC guideline for patients whose status was unknown
- Failure to provide PPE at point of use
- Failure to use or incorrect/inappropriate use of PPE
- Failure to follow aseptic technique

Implementation of Infection Prevention and Control Program

IC.02.01.01 EP1

Examples of Frequent Findings

- Failure to separate clean and dirty
- No surveillance over the cleaning, disinfection, or sterilization process by IC
- Not following facility policy related to infection control
- Not following manufacturer instructions, including performing routine maintenance
- Lack of air or surface sampling or follow-up of positive results in the compounding pharmacy
- Presence of surfaces that are not cleanable (e.g., foam, torn, delaminated)
- Failure to use appropriate disinfectants or water temperature (e.g., patient care surfaces, food services, laundry)
What is the issue in the statement below?

- The HCO was performing high level disinfection on the “dirty side” of the reprocessing area. They did not maintain required separation of clean and dirty in accordance with AORN which is their chosen evidence based guidelines.
Functional Area:
Centralized Decontamination

- Separate areas recommended for
  1. Reusable equipment
  2. Handwashing instruments
  3. Mechanical cleaning
  4. Cleaning and disinfection of endoscopes

Functional Area:
Centralized Decontamination and Prep/ Pack

One Room High Level Disinfection
Issue Resolution During Survey

- Ask surveyor what they are citing (e.g. regulation, CoP, IFU, EBG, etc.)
- Provide evidence of compliance (e.g. documentation)
  - Regulation
  - CoP / CfC
  - Manufacturer instruction
  - National Standard or Evidence based guideline
- At end of survey day clarification process
- Collaborative call with Central Office during survey

Post-Survey: Clarification

Organization can submit information as to why a finding should be removed during the clarification period
- Can challenge surveyors interpretation of the situation
- Survey process errors
- Findings that have been made in error
- **Cannot** clarify items that were document-related
  - All documentation related to compliance must be presented during survey
Some IC Breaches MUST be Reported

need an answer? Check Joint Commission FAQs

Questions and Comments?
Sgarcia-Houchins@jointcommission.org