CMS AND TJC UPDATES

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Statewide Program for Infection Control and Epidemiology (SPICE)

UNC School of Medicine

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OBJECTIVES

- Discuss the CMS Hospital Conditions of Participation (CoPs)
- Discuss the CMS revised infection control worksheet and survey process
- Review the standardized approach to infection control TJC standards
- Introduce the new TJC fully revised IPC chapter for hospitals and critical access hospitals

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CMS QUALITY, SAFETY AND OVERSIGHT GROUP (QSOG)

Federal

CMS Headquarters

10 Regional Offices

https://www.cms.gov/about-cms/where-we-are/regional-offices

State Agencies

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ORGANIZATION OF QUALITY, SAFETY AND OVERSIGHT GROUP (QSOG)

- Division of Acute Care Services (DACS)
  - Acute Care Hospitals, LTACs, CAHs, ASCs, Rehab, Psychiatric
- Division of Nursing Homes (DNH)
  - Nursing Homes
- Division of Continuing Care Providers (DCCP)
  - Home Health and Hospice, ESRD, Psychiatric Residential Treatment Facilities
- Clinical Laboratory Improvement Amendments (CLIA)

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CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Deemed organizations: Healthcare entities who participate must comply with:

Conditions of Participation (CoPs) - (hospitals, CAHs, ASCs)

Conditions for Coverage CfCs - (ESRD, LTC/NH, ASCs)

- Minimum health and safety **standards** that providers and suppliers must meet in order to be Medicare and Medicaid certified and receive reimbursement.
- The Interpretive Guidelines (IGs)provide instructions to the surveyors on how to survey the CoP. *Note: key are "should" versus "must" statements*

cms.gov

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CMS HOSPITAL INTERPRETIVE GUIDANCE – ORGANIZATIONAL POLICIES

- Designate in writing infection control officer(s)
  - ➢ Must be qualified
  - ➢ No specification on number of IPs or hours
- Develop and implement policies governing control of infections/communicable disease

§482.42 Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs

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WHERE TO SUBMIT A QUESTION OR INQUIRY TO CMS ?

Division of Acute Care Services (DACS)

- PFP.SCG@cms.hhs.gov

Division of Nursing Homes (DNHs)

- DNH_TriageTeam@cms.hhs.gov

ESRD Survey & Certification Group

- ESRDSurvey@cms.hhs.gov
- Find resources for compliance with the ESRD Conditions for Coverage here:
- www.cms.gov/GuidanceforLawsAndRegulations/05_Dialysis.asp

SCG General Information

- **http://www.cms.gov/SurveyCertificationGenInfo/**

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TJC HIERARCHICAL APPROACH TO INFECTION CONTROL RELATED STANDARDS

RULES AND REGULATIONS

CoPs and CfCs

Manufacturer's Instructions for Use (MIFU)

Evidence-based Guidelines and Standards

Consensus Documents

Organizational Infection Prevention and Control Policy and Procedures

For organizations that use deemed status the accrediting organizations must use the CoPs.

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RULES AND REGULATIONS

Common sources of infection control related regulation:

- Occupational Safety and Health administration(OSHA)
- Food and Drug Administration (FDA)
- Environmental Protection Agency (EPA)
- Local or state health authority having jurisdiction (AHJ)

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OSHA

1910.1030 - Bloodborne Pathogens Standard (1991) and the

2000 Needlestick Safety and Prevention Act,

– PPE, exposure control plans, engineering and work practice controls, hepatitis B vaccinations, hazard communication and training, and recordkeeping. deemed necessary to protect from exposure to blood and other potentially infectious materials linked to transmission of bloodborne pathogens

1910.134 - Respiratory Protection Standard (1994)

- Applies to PPE deemed necessary to protect workers from infectious disease that does not fall under coverage of the BBP standard (e.g., implementation of isolation)

- Respiratory Protection Program

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SCORING EXAMPLE

Observation: Quality minutes about staff in the ICU and emergency room being exposed to blood splashes of the face during emergency resuscitations on multiple occasions over the last year.

Survey Inquiry: What PPE employees were required to wear to prevent splash exposures?

Is this an issue for TJC compliance?

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IS THIS AN ISSUE FOR TJC COMPLIANCE?

Yes!

Answer: Organization did not evaluate the type of exposures anticipated and determine the type of PPE required based on the anticipated exposure.

Rationale: Despite documented staff exposures during emergency resuscitations, the organization had not evaluated the type of personal protective equipment that should be worn by staff to prevent exposure.

Finding under: IC.01.03.01 EP1

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FDA GUIDANCE FOR USERS

Reprocessing Patient Care Equipment

1. Check the label for date of issuance or the date of the latest revision

2. Contact the manufacturers technical service representatives for new instructions that comply with the FDA Reprocessing Guidance

3. Search the FDA 510(k) database

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

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CMS HOSPITAL INTERPRETIVE GUIDANCE

Infection Prevention and Control *and Antibiotic Stewardship Programs* must:

- Be incorporated into hospital-wide QAPI program
- Include nationally recognized practices, guidelines, and regulations
- Have active surveillance component covering patients and personnel that conduct surveillance facility-wide (all locations, departments, services, campuses), follow NHSN
- Develop and implement IC interventions to address issues identified through detection and monitor effectiveness of interventions.
- Appropriately monitor housekeeping, maintenance, and other activities to ensure sanitary environment

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CMS HOSPITAL INTERPRETIVE GUIDANCE

IP(s) must

- Demonstrate adherence to nationally recognized guidelines
- Implement best practice for improving antibiotic use and reduction of MDROs
- Develop and implement infection control measures for HCPs
- Mitigate risk (POA and HAI)
- Active surveillance
- Monitor compliance with policy and procedures
- Program evaluation and revision
- Report communicable diseases
- Maintain sanitary physical environment
- Competency-based training and education of hospital personnel and staff

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CMS – Joint Commission Crosswalk

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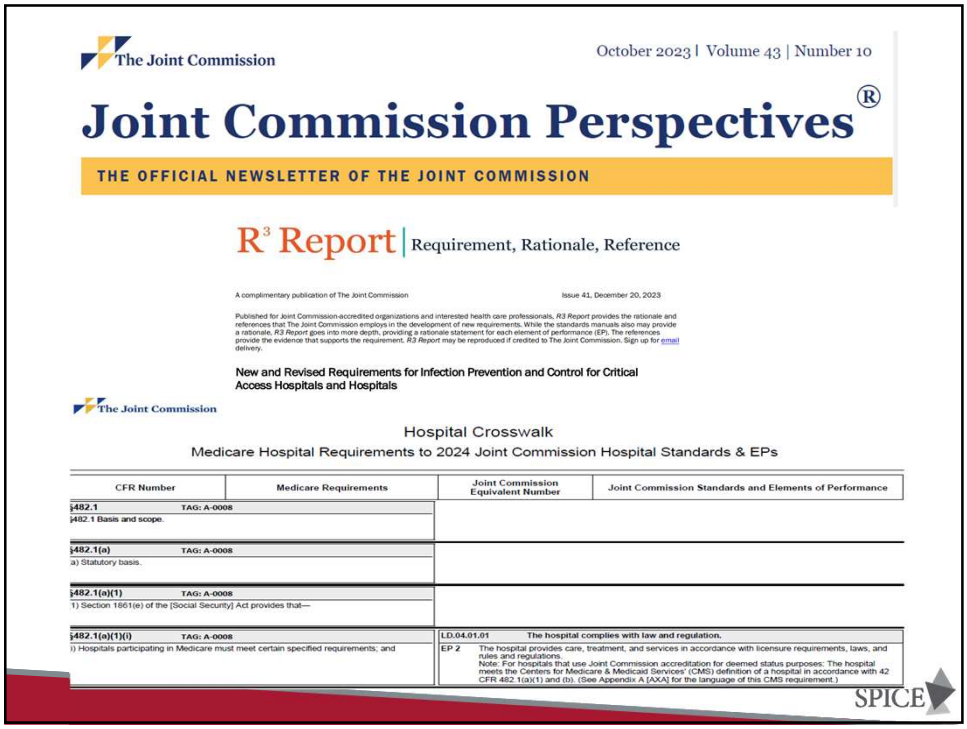
The Joint Commission
October 2023 | Volume 43 | Number 10
Joint Commission Perspectives®
THE OFFICIAL NEWSLETTER OF THE JOINT COMMISSION
R³ Report | Requirement, Rationale, Reference
A complimentary publication of The Joint Commission
Issue 41, December 20, 2023
Published for Joint Commission-accredited 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
The Joint Commission
Hospital Crosswalk
Medicare Hospital Requirements to 2024 Joint Commission Hospital Standards & EPs
CFR Number
Medicare Requirements
Joint Commission Equivalent Number
Joint Commission Standards and Elements of Performance
§482.1 TAG: A-0008
§482.1 Basis and scope.
§482.1(a) TAG: A-0008
a) Statutory basis.
§482.1(a)(1) TAG: A-0008
1) Section 1861(e) of the [Social Security] Act provides that—
§482.1(a)(1)(i) TAG: A-0008
i) Hospitals participating in Medicare must meet certain specified requirements; and
LD.04.01.01 The hospital complies with law and regulation.
EP 2 The hospital provides care, treatment, and services in accordance with licensure requirements, laws, and rules and regulations.
Note: For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital meets the Centers for Medicare & Medicaid Services' (CMS) definition of a hospital in accordance with 42 CFR 482.11(a)(1) and (b). (See Appendix A [AXA] for the language of this CMS requirement.)
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CMS TAG A-0747

- §482.42 Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Program
- The hospital must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic resistance organisms. Infection prevention and control problems and antibiotic use issues identified in the program must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.

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TJC CROSSWALK FOR TAG A-0747

- **EC.02.05.01 – Hospital manages risks associated with its utility systems.**
  - EP 1 – Designs and installs **utility systems** that meet patient care and operational needs. (Disruptions to grid, FGI Construction and Renovation Guidelines)
  - EP 15 – The ventilation system provides appropriate pressure relationships, air-exchange rates, filtration efficiencies, temperature and humidity. (Legionella, control of airborne pathogens; ventilation system provides appropriate pressure relationships, air-exchange rates, and filtration. Reprocessing and central sterile services have the right temp, humidity and AER monitored and documented.)

This is where current AORN Standards, ASHREA and AAMI standards are to be referenced by policy and followed.

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TJC CROSSWALK FOR CMS TAG A-0747

- **EC.02.05.05 - Hospital inspects, tests, and maintains utility systems**
  - EP 4 – Hospital inspects, test and maintains the following: infection control utility system components on the inventory. Activities are *documented.* (Air exchange rates, and filter banks changed per MIFU)

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TJC CROSSWALK FOR CMS TAG A-0747

- **EC.02.06.01 – Hospital establishes and maintains a safe, functional environment**
  - EP 20 – Areas used by patients are clean and free of offensive odors. **(Dust balls, tape on transport and patient care equipment)**
  - **Per LSC (Life Safety Code), NFPA (National Fire Protection Association) granting the 20% humidity waivers must validate equipment**

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TJC CROSSWALK FOR CMS TAG A-0747

EC.02.06.05 – Hospital manages its environment during demolition, renovation, and new construction to reduce the risk to those in the organization

EP 2 – When planning for demolition, construction, or renovation, hospital conducts a preconstruction risk assessment for air quality, infection control, utility systems, noise, vibration, and other hazards that affect care. (evidence of an ICRA documented and implemented)

EP 3 – Hospital takes actions based on its assessment to minimize risk during demolition, construction and renovation. (Was there a plan for moving immunocompromised patients from areas near or under construction? Daily review by IP? Is there education of outside contractors or a checklist for contractor to follow?)

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TJC CROSSWALK FOR CMS TAG A-0747

IC.01.02.01 – Hospital leaders allocate needed resources for IC program

EP 1 – Provides access to information (Intranet, training and education)

EP 2 – Provides laboratory resources (Outbreak DNA testing)

EP 3 – Provides equipment and supplies (Computer and surveillance programs)

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TJC CROSSWALK FOR CMS TAG A-0747

- **IC.01.03.01 – Hospital identifies risk for acquiring and transmitting infections**
- EP 1 – identifies risk for acquiring and transmitting infections based on: its geographic location, community, and population served (annual risk assessment: geographic, MDROs, community served…retirement, migrant, miners)
- EP 1 – Identifies s risk based on: The care treatment and services it provides. (surgical specialties, treatments)
- EP 1 – Identifies risk based on: analysis of surveillance activities and other IC activities (MDROs, CLABSI, SSI…)
- EP 2 – Reviews and identifies its risk at least annually and whenever significant changes occur with input from IPs, medical staff, nursing, leadership (ICC)

SPICE

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TJC CROSSWALK FOR CMS TAG A-0747

- **IC.01.05.01 – Hospital has an infection control plan (ICP)**
  - EP 1 – When developing plan, hospital uses evidence-based national guidelines, or expert consensus (e.g., CDC, AAMI)
  - EP 2 – ICP includes written description of the activities, including surveillance, to minimize, reduce, or eliminate risk of infection (PI programs for reducing CAUTI, Central line, SSI, Bundles, ASP)

SPICE

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TJC CROSSWALK FOR CMS TAG A-0747

- **IC.03.01.01 – Hospital evaluates the effectiveness of its infection control plan (ICP)**
- EP 1 – Evaluates the effectiveness of the ICP annually and whenever risks significantly change. Evaluation includes: ICP prioritized risks; goals and implementation of activities
- EP 6 – Findings from the evaluation are communicated at least annually to individuals or interdisciplinary group that manages the patient safety program
- EP 7 – Findings are utilized when revising the plan.

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INFECTION CONTROL RISK ASSESSMENT: REFERENCES

- Infection Control Risk Assessment
- https://www.cdc.gov/hai/prevent/infection-control-assessment-tools.html
- https://spice.unc.edu/resources/spice-ltc-infection-prevention-risk-assessment/

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FACILITY BASED RISK ASSESSMENT

There are some things that cannot be "risk-assessed."

Do NOT write a policy that conflicts with

- Regulations
- CoPs– look at interpretive guidelines or seek clarification from CMS (HospitalSCG@cms.hhs.gov)
- Manufacturer instructions for use – must resolve conflicts

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TJC CROSSWALK FOR CMS TAG A-0747

IC.02.01.01 – Hospital implements its ICP

- EP 1 – Hospital implements its IC activities, including surveillance, to reduce risk of infection. (other e.g., ASP, PI projects)
- EP 2 – Hospital uses Standard Precautions to reduce the risk of infection. (PPE availability at point of use, glove mouth and eye protection, surgical mask for epidural)
- EP 3 – Hospital implements Transmission-based Precautions. (Contact precautions for patients with epidemiologically significant multidrug-resistant organisms (MDROs)

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TJC CROSSWALK FOR CMS TAG A-0747

IC.02.01.01 – Hospital implements its ICP

- EP 6 – Minimizes risk of infection with storing and disposing of infectious waste (Follow state medical waste rules)
- EP 7 – Implements methods to communicate responsibilities for IC to LIPs, staff, visitors, patients, and families. (Implementation methods)
- EP 8 – Reports infection surveillance, prevention, and control information to the appropriate staff within hospital (also part of NPSGs of MDROs, SSI, HAI dashboards)

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TJC CROSSWALK FOR CMS TAG A-0747

IC.02.02.01 – Hospital reduces the risk of infection associated with medical equipment, devices and supplies

- EP 1 – Implements IC activities during: Cleaning and low-level disinfection (non-critical reusable patient care items using MIFU; can staff articulate the process?)
- EP 2 - Implements IC activities during: intermediate and high-level disinfection and sterilization (make sure the policy is consistent for ultrasound, TEE probes in outpatient areas)
- EP 3 – Disposing of medical equipment, devices, supplies (OSHA BBP, and state medical waste rules)
- EP 4 – Storing medical equipment devices and supplies. (Follow MIFU and CDC guidance for HLD including storage of scopes horizontally.)

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TJC CROSSWALK FOR CMS TAG A-0747

- IC.02.03.01 – Hospital works to prevent transmission of infectious disease among patients, LIPs, and staff
  - EP 1 – Makes screening for exposure/immunity to Infectious diseases available to LIPs and staff (CDC OCC Health Guidelines)
  - EP 2 – Refers/provides LIPs and staff with an infectious disease for assessment, testing, prophylaxis/treatment, and counseling…(OSHA BBP, TB, Meningococcemia per CDC OCC Health Guidelines)
  - EP 4 – Patients exposed to infectious diseases, hospital provides/refers for assessment, testing…

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TJC CROSSWALK FOR CMS TAG A-0748

- **IC.01.01.01 – Hospital identifies individual(s) responsible for the IC program**
  - EP 1 – Identifies individual(s) with clinical authority over the IC program
  - EP 2 – When individual with authority over IC program does not have expertise in IC, he or she consults with someone who has such expertise to make decisions…(LHD or APIC Consulting)

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TJC CROSSWALK FOR CMS TAG A-0748

- **IC.01.01.01 – Hospital identifies individual(s) responsible for the IC program.**
  - EP 3 – Hospital assigns responsibility for daily management of IC activities
  - EP 4 – Deemed status purposes: Individual with clinical authority is responsible for:

  -Developing polices
    - -Implementing policies
    - -Developing system for identifying reporting, investigating and control infections/CD

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TJC CROSSWALK FOR CMS TAG A-0749

- **HR.01.04.01 – Hospital provides orientation to staff**
  - EP 4 – The hospital orients staff on the following:
    - Specific job duties, including those related to infection prevention and control.
    - Orientation completion is documented

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TJC CROSSWALK FOR CMS TAG A-0749

- **IC.02.01.01 – Hospital implements IC plan**
  - EP 9 – Hospital reports infection surveillance, prevention, and control information to local, state, and federal public health authorities. (Communicable disease and outbreak reporting structure.)

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TJC CROSSWALK FOR CMS TAG A-0749

- **IC.01.01.01 – Hospital identifies individual(s) responsible for the IC program**
  - EP 3 – The hospital assigns responsibility for the daily management of infection prevention and control activities…(documentation)

Responsibilities of CEO, Medical Staff and Director of Nursing must:

1) Ensure that the hospital-wide QAPI program and training programs address problems identified by the infection control officer(s)
2) Be responsible for implementation and corrective actions

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TJC CROSSWALK FOR CMS TAG A-0749

LD Responsibilities of CEO, Medical Staff and Director of Nursing must:

1) Ensure that the hospital-wide QAPI program and training programs address problems identified by the infection control officer(s)
2) Be responsible for implementation and corrective actions

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1) Ensure that the hospital-wide QAPI program and training programs address problems identified by the infection control officer(s)
2) Be responsible for implementation and corrective actions

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VA3

ENVIRONMENTAL SERVICES

Environmental service worker PPE use

- Patient care area cleaning processes—high touch areas are cleaned daily
- Terminal Cleaning and removal of linen
- Use of cleaners and disinfectants reflect MIFU

Clean cloths for each patient room/corridor

- Mop head and cloth cleaning daily
- Blood and body fluid cleaning process--spills

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Slide 40

VA2 Not sure where these standards are? Cannot find
Vicki Allen, 3/31/2023

VA3 IC.02.02.01 addressing low level cleaning
Vicki Allen, 3/31/2023

ENVIRONMENTAL SERVICES

- Equipment cleaning schedules (HVAC, eyewash stations, ice machines, refrigerators, scrub sinks and on faucets)
- Handling of clean and dirty laundry with no potential for cross contamination
- Bagging and storage of dirty linen - Segregation of clean from dirty in laundry processing area

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NC DIVISION OF HEALTH SERVICES REGULATIONS
RULES AND REGULATIONS

NCDHHS

HOSPITALS: 10A NCAC 13B .1906 POLICIES AND PROCEDURES

The governing board shall assure written policies and procedures which are available to and implemented by staff. These policies and procedures shall cover at least the following areas:

(6) infection control which must include, but shall not be limited to, requirements for sterile, aseptic and isolation techniques; and communicable disease screening including, at a minimum, annual tuberculosis screening for all staff of the facility;…

https://info.ncdhhs.gov/dhsr/testrules.htm

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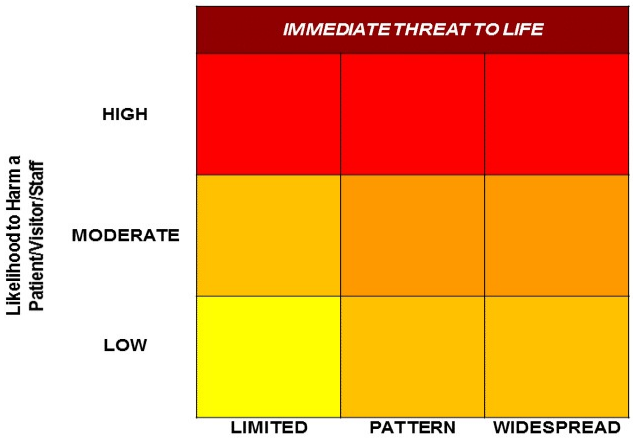
TJC SCORING

Survey Analysis for Evaluating Risk (SAFER) Matrix



The Joint Commission

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IMMEDIATE THREAT TO HEALTH & SAFETY (IJ)

– Expedited decision of Preliminary Denial of Accreditation (PDA) issued by The Joint Commission

– Results in notification of CMS and State Health Department – PDA remains in effect until corrective action is validated during on-site follow-up survey

– After corrective action is validated, organization's accreditation status will change to Contingent Accreditation pending follow-up survey to assess ongoing implementation of corrective action

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MANUFACTURER'S INSTRUCTIONS

Medical Device Manufacturers

- experts on their own devices
- responsible for validating the specific cleaning, disinfection and sterilization methods
- Biologic compatibility does not mean an item is chemical or functionally compatible
- Focus on areas where there is risk

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MANUFACTURER'S INSTRUCTIONS

- Organization must know how the item will be used
- Staff must have access to instructions
- When conflicts are identified, organization must resolve
  - Contact equipment manufacturer
  - Contact product manufacturer(s)

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MANUFACTURER'S INSTRUCTIONS

Examples of High Risk MIFU - HLD

- High Level Disinfection (HLD) tested before or after each use according to instructions.

- Cannot use beyond solution beyond expiration
- Test strips may be product specific
- Additional items may be necessary…watch/timer, paper towels
- Includes training instructions
- Follow each step as written
- Only FDA approved HLD and compatible with product

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MANUFACTURER'S INSTRUCTIONS

Process is often based on product choice!

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.

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EXAMPLE OF HOW SCORED

Observation: The facility was using a tonometer which touches the eye during use. The physician stated that he uses the item, wipes it with a pop-up wipe and places it back in the case.

Review of the pop-up manufacturer IFUs indicated that the disinfectant being used was not a high-level disinfectant.

Finding: IC.02.02.01 EP2

The tonometer which touches the eye was not being high-level disinfected after each use.

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EVIDENCE-BASED GUIDELINES AND NATIONAL STANDARDS (EBG)

Facilities must use evidence-based (EBG) guidelines and standardize infection prevention and control activities (IC.01.05.01 EP 1)

- EBG should be available (IC.01.02.01 EP 1)
- Facilities should be able to articulate the source of their IC practices if they are based on multiple EBG, a facility might choose:
  - AORN for dress code and aseptic practices in the OR
  - AAMI for reprocessing of sterile instruments
  - SGNA for reprocessing endoscopes
  - CDC Guidelines

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EVIDENCE BASED GUIDELINES AND NATIONAL STANDARDS (EBG)

CDC Core Practices: Standard Precautions

- Hand hygiene
- Environmental cleaning and disinfection
- **Injection and medication safety**
- Appropriate use of personal protective equipment
- Minimizing potential exposures
- Reprocessing of reusable medical equipment between each patient and when soiled

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EXAMPLE OF HOW SCORED

Observation: Three staff members (one in orthopedic clinic, one in the operating room and one in the ICU) did not disinfect the diaphragms of medication vials before inserting a needle into the vial.

Staff members did not adhere to standard precautions required when accessing a medication vial as described in CDC Core Practices for all Healthcare Settings: Standard Precautions

Finding: IC.02.01.01 EP2

"Disinfect the access diaphragms of medication vials before inserting a device into the vial".

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EVIDENCE BASED GUIDELINES AND NATIONAL STANDARDS (EBG)

Some EBGs ***<u>are required</u>*** by regulation or The Joint Commission standards

- CDC / WHO Hand Hygiene
- CDC Transmission based precautions
- CDC Standard Precautions

- Some EBGs are chosen: AORN, ASHRAE, SGNA, AAMI
  - Chosen EBGs cannot be less strict than regulation, CoPs, or IFUs

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EVIDENCE BASED GUIDELINES AND NATIONAL STANDARDS (EBG)

Your choice may affect your survey outcome, for example

"Hang-time" for endoscopes

- SGNA: "supports a 7-day storage interval for reprocessed endoscopes-but only if they were reprocessed and stored according to professional guidelines and manufacturer instructions."
- AAMI: "Due to the lack of consensus and evidence on the storage time, it is recommended that the health care facility conduct a risk assessment to determine the maximum storage time for an endoscope…"

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EVIDENCE BASED GUIDELINES AND NATIONAL STANDARDS (EBG)

Your Choice Guides Your Practices

AMMI (ST91 2021) states

4.2.1 General Considerations

11.2 Storage of reprocessed endoscopes

Design of processing area: physically separated from patient care areas and procedure rooms and designated for processing only. Should not use endoscopes that cannot be leak tested. Wet leak testing minimum observation of 60 seconds. The endoscope should be dry prior to storage. Never store scopes wet. Complete active drying cycle even after a scope has come out of an AER. AER's have an air purge, not drying. Cabinet should have minimum HEPA filtered air…Maximum storage time based on a risk assessment. Visually inspect cabinet for cleanliness, clean at least weekly (per IFU).

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EVIDENCE BASED GUIDELINES AND NATIONAL STANDARDS (EBG)

Your choice of Guidelines at Your Practice

AORN (Effective September 15, 2022) Guideline for Processing Flexible Endoscopes states

IX. Flexible endoscopes and endoscope accessories should be stored in a manner that minimizes contamination and protects the device or item from damage

IX.b. Flexible endoscopes should be stored in accordance with the endoscope and storage cabinet manufacturers' IFU.

IX.b.1.Flexible endoscopes should be stored in a drying cabinet

IX.b.2. If a drying cabinet is not available, flexible endoscopes may be stored in a closed cabinet with HEPA-filtered air that provides positive pressure and allows air circulation around the flexible endoscopes.

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CONSENSUS AND POSITION STATEMENTS

Guidelines for the cleaning and sterilization of intraocular surgical instruments

David F Chang[1], Nick Mamalis[2], Ophthalmic Instrument Cleaning and Sterilization Task Force

Abstract

These Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments were written by the Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force, comprised of representatives of the American Society of Cataract and Refractive Surgery, the American Academy of Ophthalmology, and the Outpatient Ophthalmic Surgery Society. These consensus subspecialty guidelines include evidence-based recommendations regarding issues that may be unique to the cleaning and sterilization of intraocular instrumentation. A newly published OICS Task Force study supports the safety of common short-cycle instrument processing practices for sequential same-day anterior segment surgery. Other studies substantiate the risk of toxic anterior segment syndrome from routine use of enzymatic detergent, whose microscopic residues are difficult to eliminate from intraocular instrumentation. Finally, based on published international outcomes and endophthalmitis rates, future studies should critically evaluate a variety of operating room protocols that may increase cost, waste, and carbon footprint, without any actual safety benefit.

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SCORING EXAMPLE

Observation: The organization was cleaning ophthalmology instruments with other surgical instruments. When asked which EBGs had been adopted, the CSP Manager stated that she was not aware of any recommendations specifically related to ophthalmology instrument reprocessing.

– The organization did not adopt evidence-based national guidelines or, in the absence of such guidelines, expert consensus guidance when developing IC activities…

Could be scored at IC.01.05.01 EP1

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FACILITY POLICY AND PROCEDURE

Facilities develop IC related policies and procedures that address the unique aspects of the organization

- Care settings
- Equipment, products and supplies
- Physical space
- Staffing
- Facilities in multiple states

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CMS IC WORKSHEET STRUCTURE

5 Modules

1 – Infection Control/Prevention Program

2 – General Infection Control Elements

3 – Equipment Reprocessing

4 – Patient Tracers

5 – Special Care Environments

- https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-1.pdf

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CMS ICW STRUCTURE

20 Sections

4 tracers

- Urinary Catheter Tracer
- Central Venous Catheter Tracer,
- Ventilator/Respiratory Therapy Tracer
- Surgical Procedure

Ideal self assessment tool for compliance with minimum standards (49 pages)

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-1.pdf

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Centers for Medicare & Medicaid Services

Hospital Infection Control Worksheet

Name of State Agency: _____

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the Infection Control Condition of Participation. Items are to be assessed by a combination of observation, interviews with hospital staff, patients and their family/support persons, review of medical records, and a review of any necessary infection control program documentation. **During the survey, observations or concerns may prompt the surveyor to request and review specific hospital policies and procedures. Surveyors are expected to use their judgment and review only those documents necessary to investigate their concern(s) or to validate their observations.**

The interviews should be performed with the most appropriate staff person(s) for the items of interest, as well as with patients, family members, and support persons.

Hospital Characteristics

1. Hospital name: _____
2. CMS Certification Number (CCN): ☐☐☐☐☐☐
3. Date of site visit: ☐☐ / ☐☐ / ☐☐☐☐ to ☐☐ / ☐☐ / ☐☐☐☐

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Module 1: Infection Prevention Program

Section 1.A. Infection Prevention Program and Resources

Elements to be assessed		Surveyor Notes
1.A.1 The hospital has designated one or more individual(s) as its Infection Control Officer(s).	☐ Yes ☐ No	
1.A.2 The hospital has evidence that demonstrates the Infection Control Officer(s) is qualified and maintain(s) qualifications through education, training, experience or certification related to infection control consistent with hospital policy.	☐ Yes ☐ No	
1.A.3 The Infection Control Officer(s) can provide evidence that the hospital has developed general infection control policies and procedures that are based on nationally recognized guidelines and applicable state and federal law.	☐ Yes ☐ No	
If no to any of 1.A.1 through 1.A.3, cite at 42 CFR 482.42(a) (Tag A-748)		
1.A.4 The Infection Control Officer can provide an updated list of diseases reportable to the local and/or state public health authorities.	☐ Yes ☐ No	
1.A.5 The Infection Control Officer can provide evidence that hospital complies with the reportable diseases requirements of the local health authority.	☐ Yes ☐ No	
No citation risk for questions 1.A.4 and 1.A.5		
1.A.6 The hospital has infection control policies and procedures relevant to construction, renovation, maintenance, demolition, and repair, including the requirement for an infection control risk assessment (ICRA) to define the scope of the project and need for barrier measures before a project gets underway.	☐ Yes ☐ No	
If no to 1.A.6, cite at 42 CFR 482.42(a) (Tag A-748)		

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SURVEY TIPS

- During Survey – Issue resolution session –Present all written documentation – Collaborative call with Central Office
- After Survey "After a survey event, organizations have the opportunity to submit clarifying ESC if they believe that their organization was in compliance with a particular standard at the time of Survey."

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EFFECTIVE JULY 2024

IPC CHAPTER FOR THE HOSPITAL AND CAH

- Fully revised IPC Chapter; 70% reduction of EPs in this chapter!
- Effective July 1, 2024
- TJC goal: help organizations develop a strong framework for their IPC programs, while aligning requirements more closely to law and regulation and the CMS CoPs.
- Focus on structures that support IC quality and safety.

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IPC CHAPTER: REWRITE

- Removed IPs related to waste management and responding to an influx of potentially infectious because they were redundant to existing EC and EM requirements
- Added new Standard IC.07.01.01 with its 2 new EPS to enhance preparedness for high-consequence infectious diseases or special pathogens.

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IC CHAPTER: REWRITE

- New IC Assessment tool that details the IC practices and structures needed to meet the IC requirements.
- More information about the revisions is available in the R3 Report as well as reference guide showing where concepts from the old EPs have moved in the new EPs.

https://www.jointcommission.org/standards/prepublication-standards/new-and-revised-requirements-for-the-infection-prevention-and-control-chapter/

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The Joint Commission

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

SPICE

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QUESTIONS?

SPICE

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