CMS AND TJC/DNV UPDATES

NC Statewide Program for Infection Control and Epidemiology (SPICE)

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OBJECTIVES

- Discuss the CMS Hospital Conditions of Participation (CoPs)
- Review TJC and DNV surveys for infection control and the process for accreditation
- Discuss the CMS infection control worksheet and survey process

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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*

https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107c01pdf.pdf

- Most Hospitals use a separate company to conduct surveys for these requirements rather than using CMS directly. The two most common are The Joint Commission (TJC) or Det Norske Veritas® (DNV). Hospitals contract with these companies for accreditation, and they report their findings to CMS for the hospitals.

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CMS HOSPITAL CONDITIONS OF PARTICIPATION AND INTERPRETIVE GUIDANCE

- Designate in writing infection control officer(s)
  - Must be qualified through education, training, experience or certification in infection control and prevention
  - Is **appointed by the governing body** as the infection preventionist(s) / infection control professional (s) responsible for the program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership
  - No specification on number of IPs or hours
- Develop and implement policies governing control of infections/communicable disease

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482

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

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ACCREDITATION 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.

https://digitalassets.jointcommission.org/api/public/content/01f83448fbb54ba7b9225048834e7247?v=4e3fcba2

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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

https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030

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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 or DNV compliance?

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IS THIS AN ISSUE FOR SURVEY 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.

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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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NC DIVISION OF HEALTH SERVICES REGULATIONS
RULES AND REGULATIONS

NCDHHS

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

The governing board shall ensure written policies and procedures that 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;…

HOSPITALS: 10a NCAC 13 B .3200 GENERAL HOSPITAL REQUIREMENTS - section .5100 Infection Control requirements

http://reports.oah.state.nc.us/ncac/title%2010a%20-%20health%20and%20human%20services/chapter%2013%20-%20nc%20medical%20care%20commission/subchapter%

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HOSPITAL CONDITIONS OF PARTICIPATION

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-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482

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THE INFECTION PREVENTIONIST(S)/INFECTION CONTROL PROFESSIONAL(S) IS RESPONSIBLE FOR:

- The development and implementation of hospital-wide infection surveillance, prevention, and control **policies and procedures** that adhere to nationally recognized guidelines.
- (ii) All **documentation**, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.
- (iii) Communication and collaboration with the **hospital's QAPI program** on infection prevention and control issues.
- (iv) Competency-based **training and education** of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of infection prevention and control guidelines, policies, and procedures.
- (v) The prevention and control of HAIs, including **auditing of adherence** to infection prevention and control policies and procedures by hospital personnel.
- (vi) Communication and **collaboration with the antibiotic stewardship program.**

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf

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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

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf

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AMS CONDITIONS OF PARTICIPATION

Standard: Antibiotic stewardship program organization and policies. The hospital must demonstrate that:

- (1) An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership;
- (2) The hospital-wide antibiotic stewardship program:
- (i) Demonstrates coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;
- (ii) Documents the evidence-based use of antibiotics in all departments and services of the hospital; and
- (iii) Documents any improvements, including sustained improvements, in proper antibiotic use;
- (3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and
- (4) The antibiotic stewardship program reflects the scope and complexity of the hospital services provided.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf

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DNV ACCREDITATION

- NIAHO® (National Integrated Accreditation for Healthcare Organizations) is the hospital accreditation program from DNV that validates Medicare compliance, ensures patient safety, and integrates ISO 9001 quality standards. It uses the CMS COPs directly and does not have additional requirements for Infection Control.

https://www.dnv.us/life-sciences/healthcare/

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TJC REVISION IN 2026

- The accreditation restructuring, titled “Accreditation 360: The New Standard,” includes a complete overhaul of the standards numbering system and elements of performance, making prior versions of the standards vastly different from the newly published standards.
- At first glance, it may seem that JC has reduced compliance requirements. However, these requirements have been consolidated, not eliminated, into broader standard categories, ensuring greater alignment with CMS’ Conditions of Participation as well as A-Tags from CMS’s Survey Operations Manual.
- The total number of standards and elements of performance has been reduced from 1,551 to 774 standards, simplifying compliance requirements.

https://www.jointcommission.org/en-us/accreditation/accreditation-360

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CFR Number §482.42	Medicare Requirements	Joint Commission Equivalent Number	Joint Commission Standards and Elements of Performance
§482.42	TAG: A-0747	IC.04.01.01	**The hospital has a hospitalwide infection prevention and control program for the surveillance, prevention, and control of health care–associated infections (HAIs) and other infectious diseases.**
§482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs. 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-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.		EP 2	The infection preventionist(s) or infection control professional(s) is responsible for the following: • Development and implementation of hospitalwide infection surveillance, prevention, and control policies and procedures that adhere to law and regulation and nationally recognized guidelines • Documentation of the infection prevention and control program and its surveillance, prevention, and control activities • 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 • Prevention and control of health care–associated infections and other infectious diseases, including auditing staff adherence to infection prevention and control policies and procedures • 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 Note: The outcome of competency-based training is the staff’s ability to demonstrate the skills and tasks specific to their roles and responsibilities. Examples of competencies may include donning/doffing of personal protective equipment and the ability to correctly perform the processes for high-level disinfection. (For more information on competency requirements, refer to HR.11.04.01 EP 1). (See also PE.04.01.05, EP 2)
		EP 3	The hospital’s infection prevention and control program has written policies and procedures to guide its activities and methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings. The policies and procedures are in accordance with the following hierarchy of references: a. Applicable law and regulation. b. Manufacturers’ instructions for use. c. Nationally recognized evidence-based guidelines and standards of practice, including the Centers for Disease Control and Prevention’s (CDC) Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings or, in the absence of such guidelines, expert consensus or best practices. The guidelines are documented within the policies and procedures. Note 1: Relevant federal, state, and local law and regulations include but are not limited to the Centers for Medicare & Medicaid Services’ Conditions of Participation, Food and Drug Administration’s regulations for reprocessing single-use medical devices; Occupational Safety and Health Administration’s Bloodborne Pathogens Standard 29 CFR 1910.1030, Personal Protective Equipment Standard 29 CFR 1910.132, and Respiratory Protection Standard 29 CFR 1910.134; health care worker vaccination laws; state and local public health

https://digitalassets.jointcommission.org/api/public/content/e38b871503004dd4ae4b2b30cd77f554?v=421a0663&_gl=1*ckmzhu*_gcl_au*MjA3OTQxMDU3My4xNzczNjc0NDgw*_ga*Njk4ODgxNTc5LjE3NzM2NzQ0ODE.*_ga_K31T0BHP4T*czE3NzQ2MjMwMzEkbzUkZzEkdDE3NzQ2MjMzNTckajYwJGwwJGgw

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TJC CROSSWALK FOR TAG A-0747

PE.04.01.01 The hospital addresses building safety and facility management.

EP 1 The hospital meets the applicable provisions and proceeds in accordance with the Health Care Facilities Code (NFPA 99-2012 and Tentative Interim Amendments [TIA] 12-2, 12-3, 12-4, 12-5, and 12-6). Note 1: Chapters 7, 8, 12, and 13 of the Health Care Facilities Code do not apply. Note 2: If application of the Health Care Facilities Code would result in unreasonable hardship for the hospital, the Centers for Medicare & Medicaid Services may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients. Note 3: All inspecting activities are documented with the name of the activity; date of the activity; inventory of devices, equipment, or other items; required frequency; name and contact information of person who performed the activity; NFPA standard(s) referenced for the activity; and results of the activity.

https://digitalassets.jointcommission.org/api/public/content/e38b871503004dd4ae4b2b30cd77f554?v=421a0663&_gl=1*ckmzhu*_gcl_au*MjA3OTQxMDU3My4xNzczNjc0NDgw*_ga*Njk4ODgxNTc5LjE3NzM2NzQ0ODE.*_ga_K31T0BHP4T*czE3NzQ2MjMwMzEkbzUkZzEkdDE3NzQ2MjMzNTckajYwJGwwJGgw

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TJC CROSSWALK FOR IP REQUIREMENTS

CFR Number §482.42(a)(1)	Medicare Requirements	Joint Commission Equivalent Number	Joint Commission Standards and Elements of Performance
§482.42(a)(1)	TAG: A-0748	HR.11.02.01	The hospital defines and verifies staff qualifications.
(1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;		EP 1	The hospital defines staff qualifications specific to their job responsibilities. Note 1: Qualifications for infection control may be met through ongoing education, training, experience, and/or certification (such as that offered by the Certification Board for Infection Control). Note 2: Qualifications for laboratory personnel are described in the Clinical Laboratory Improvement Amendments (CLIA), under Subpart M: "Personnel for Nonwaived Testing" §493.1351-§493.1495. A complete description of the requirement is located at https://www.ecfr.gov/cgi-bin/text-idx?SID=0854acca5427c69e771e5beb52b0b986&mc=true&node=sp42.5.493.m&rgn=div6. Note 3: For hospitals that use Joint Commission accreditation for deemed status purposes: Qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists, as defined in 42 CFR 484, provide physical therapy, occupational therapy, speech-language pathology, or audiology services, if these services are provided by the hospital. See Glossary for definitions of physical therapist, physical therapist assistant, occupational therapist, occupational therapy assistant, speech-language pathologist, and audiologist. Note 4: Qualifications for language interpreters and translators may be met through language proficiency assessment, education, training, and experience. The use of qualified interpreters and translators is supported by the Americans with Disabilities Act, Section 504 of the Rehabilitation Act of 1973, and Title VI of the Civil Rights Act of 1964. Note 5: If respiratory care services are provided, staff qualified to perform specific respiratory care procedures and the amount of supervision required to carry out the specific procedures is designated in writing.
		NPG.12.01.01	The hospital's leadership team ensures that there is qualified ancillary staff required to meet the needs of the population served and determines how staff function within the organization.
		EP 12	The hospital's governing body, based on the recommendation of the medical staff and nursing leaders, appoints an infection preventionist(s) or infection control professional(s) qualified through education, training, experience, or certification in infection prevention to be responsible for the infection prevention and control program.

https://digitalassets.jointcommission.org/api/public/content/e38b871503004dd4ae4b2b30cd77f554?v=421a0663&_gl=1*ckmzhu*_gcl_au*MjA3OTQxMDU3My4xNzczNjc0NDgw*_ga*Njk4ODgxNTc5LjE3NzM2NzQ0ODE.*_ga_K31T0BHP4T*czE3NzQ2MjMwMzEkbzUkZzEkdDE3NzQ2MjMzNTckajYwJGwwJGgw

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TJC CROSSWALK FOR CMS TAG A-7050

PE.01.01.01	**The hospital has a safe and adequate physical environment.**
EP 1	The hospital's building is constructed, arranged, and maintained to allow safe access and to protect the safety and well-being of patients. Note 1: Diagnostic and therapeutic facilities are located in areas appropriate for the services provided. Note 2: When planning for new, altered, or renovated space, the hospital uses state rules and regulations or the current Guidelines for Design and Construction of Hospitals published by the Facility Guidelines Institute. If the state rules and regulations or the Guidelines do not address the design needs of the hospital, then it uses other reputable standards and guidelines that provide equivalent design criteria.
PE.04.01.05	**The hospital has a water management program that addresses Legionella and other waterborne pathogens. Note: The water management program is in accordance with law and regulation.**
EP 1	The water management program has an individual or a team responsible for the oversight and implementation of the program, including but not limited to development, management, and maintenance activities.
EP 2	The individual or team responsible for the water management program develops the following: • A basic diagram that maps all water supply sources, treatment systems, processing steps, control measures, and end-use points Note: An example would be a flow chart with symbols showing sinks, showers, water fountains, ice machines, and so forth. • A water risk management plan based on the diagram that includes an evaluation of the physical and chemical conditions of each step of the water flow diagram to identify any areas where potentially hazardous conditions may occur (these conditions are most likely to occur in areas with slow or stagnant water) Note: Refer to the Centers for Disease Control and Prevention's "Water Infection Control Risk Assessment (WICRA) for Healthcare Settings" tool as an example for conducting a water-related risk assessment. • A plan for addressing the use of water in areas of buildings where water may have been stagnant for a period of time (for example, unoccupied or temporarily closed areas) • An evaluation of the patient populations served to identify patients who are immunocompromised • Monitoring protocols and acceptable ranges for control measures Note: Hospitals should consider incorporating basic practices for water monitoring within their water management programs that include monitoring of water temperature, residual disinfectant, and pH. In addition, protocols should include specificity around the parameters measured, locations where measurements are made, and appropriate corrective actions taken when parameters are out of range. (See also IC.04.01.01, EP 2)

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MOST CITED INFECTION CONTROL FINDINGS IN 2025

- Sterilization and high-level disinfection (HLD) of equipment, specifically failure to follow manufacturer instructions for use (MIFU), expired supplies, and improper storage.
- Other top findings involve inadequate infection control surveillance and staffing, alongside gaps in staff competence for sterilization and PPE use.

https://www.jointcommission.org/en-us/products-and-services/publications/most-cited-hospital-standards

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TOP 2025 INFECTION CONTROL FINDINGS & THEMES:

- Sterilization and High-Level Disinfection:
  - MIFU Non-compliance: Failure to follow manufacturer instructions for cleaning, sterilization, and HLD of instruments.
- Improper Storage: Soiled or soiled-adjacent storage areas, with clean supplies contaminated by improper handling or storage.
- Expired Items: Expired sterile supplies found in patient care areas.

https://www.jointcommission.org/en-us/products-and-services/publications/most-cited-hospital-standards

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TOP 2025 INFECTION CONTROL FINDINGS & THEMES:

- Risk Assessment: Failure to conduct, document, or act on a comprehensive annual infection risk assessment, including identifying risks from construction or regional pathogens.
- Staffing Shortages: High turnover and inadequate numbers of infection preventionists leading to gaps in surveillance and oversight.

Competency and Training:

- Lack of documented, observation-based training for staff performing high-level disinfection.
- Improper donning/doffing of PPE and failure to adhere to hand hygiene protocols.

Environmental Controls:

- Improper handling of soiled linens and inconsistent cleaning of equipment.

https://www.jointcommission.org/en-us/products-and-services/publications/most-cited-hospital-standards

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Key Focus Areas for Compliance:

- Rigorous Sterilization Audits: Focus on the process, not just the result.
- Documented Competencies: Ensure all staff performing disinfection are formally trained and checked.
- Environmental Monitoring: Active monitoring of cleaning protocols, including laundry and sanitation.

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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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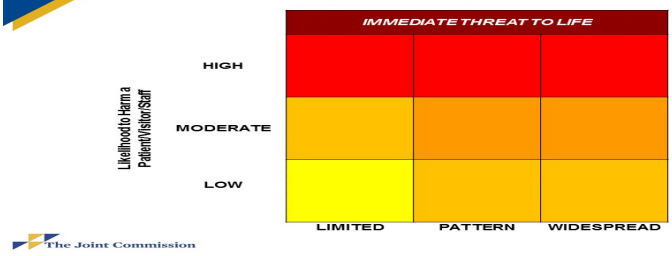
TJC SCORING (REVISED TO SAFEST TO IDENTIFY STRENGTHS)
SIMILAR PROCESS USED BY DNV

Survey Analysis for Evaluating Risk (SAFER) Matrix



https://www.jointcommission.org/en-us/knowledge-library/support-center/post-survey-or-review/safer-matrix

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IMMEDIATE THREAT TO HEALTH & SAFETY (IJ)

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

– 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

https://www.cms.gov/Regulations-and-guidance/Guidance/Manuals/downloads/som107ap_q_immedjeopardy.pdf

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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

https://www.jointcommission.org/standards/standard-faqs/hospital-and-hospital-clinics/leadership-ld/000002252/
https://www.jointcommission.org/standards/standard-faqs/ambulatory/infection-prevention-and-control-ic/000002250/

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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 or 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 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 FINDING

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 MIFUs indicated that the disinfectant being used was not a high-level disinfectant.

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

– EBG should be available

– 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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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 MIFUs

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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."
https://www.sgna.org/Portals/0/FAQ_Standards%20of%20Infection%20Prevention%20in%20Reprocessing%20Flexible%20Gastrointestinal%20Endoscopes.pdf

– 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…" https://array.aami.org/doi/10.2345/0899-8205-59.2.155
https://aami.org/standard/ansi-aami-st912021-pdf/

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

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

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ACCREDITATION 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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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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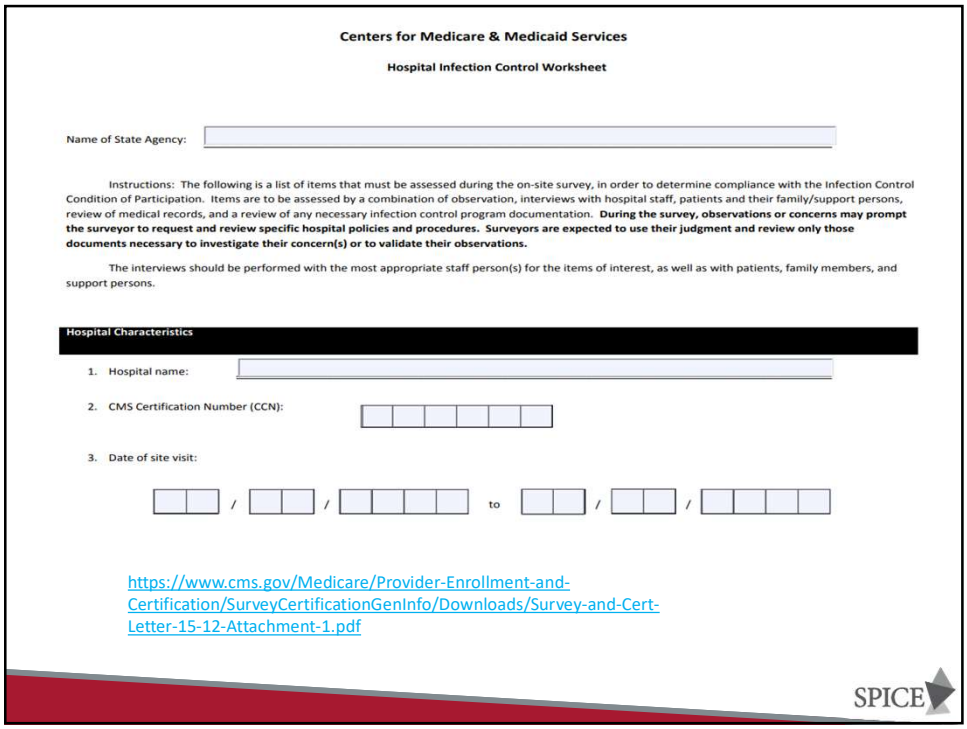

Centers for Medicare & Medicaid Services

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:

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

SPICE

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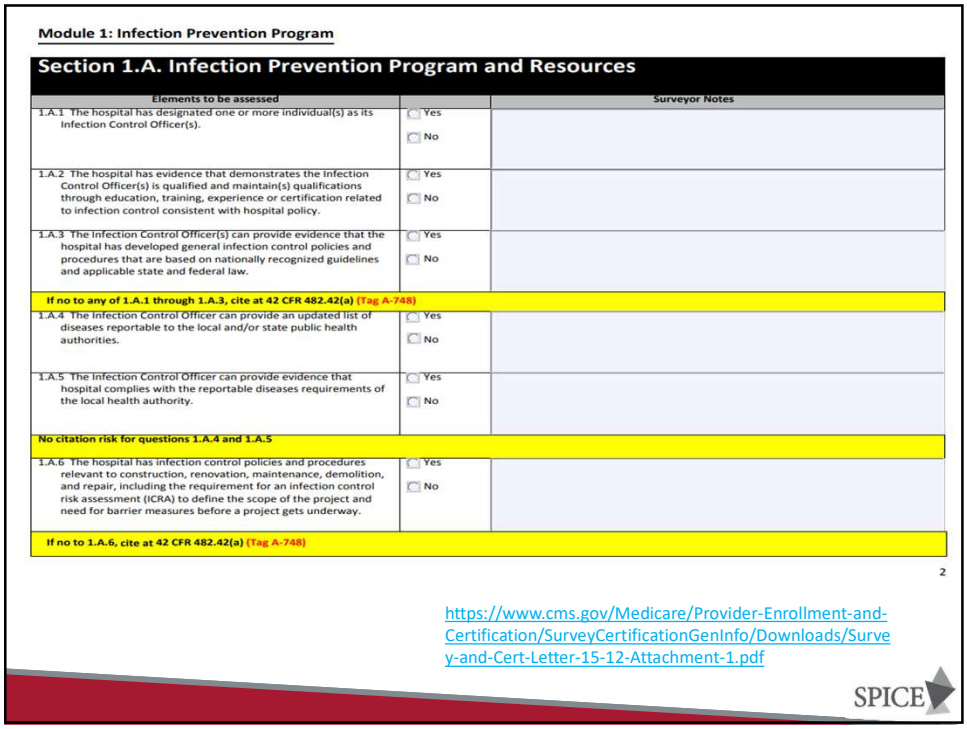

Module 1: Infection Prevention Program

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

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SURVEY TIPS

- Remain Calm – You are the expert in Infection Control and Prevention
- Have your documents organized and available. Know where MIFU are located (have department managers available to discuss their specific areas)
- During Survey – Issue resolution session –Present all written documentation – Collaborative call with Central Office
- After Survey - organizations may have the opportunity to submit clarifying evidence if they believe that their organization was in compliance with a particular standard at the time of the survey – work with your quality and regulatory staff to determine if this should be submitted.

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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:
  - https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-494
- SCG General Information
- **http://www.cms.gov/SurveyCertificationGenInfo/**

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QUESTIONS?

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