Nebraska Infection Control Network

Regulatory Preparation and Response

Jen Vogelsberg BS, MLS (ASCP), CIC

April 2025

PowerPoint created by: Terry Micheels, MSN, RN, CIC, FAPIC

1

Objectives

- Explore the CMS and Joint Commission infection prevention and control program regulatory requirements.
- Examine a variety of tools and processes to monitor organizational compliance with the infection control program and policies.
- Describe how to prepare a written response and measure of success to correct a survey finding.

2

Background

- Organizations seeking CMS approval may choose to be surveyed by either:
  - an accrediting body, such as the Joint Commission (TJC), DNV, and HFAP
  - state surveyors on behalf of CMS
- CMS Regulations →Crosswalk→ TJC standards
- The terms regulations and standards may be used interchangeably in this presentation to reflect program requirements.

3

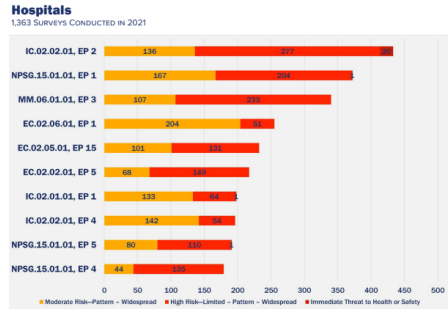
Background

- Infection prevention and control (IPC) practices have been a significant focus during CMS regulatory surveys and other volunteer accrediting agency surveys for many years.
- Attention has been given to:
  - Infection control practices
  - Hospital-acquired infections
  - Antibiotic stewardship

4

Top 10 Noncompliant Standards

- Acute Care and Critical Access Hospitals



- The hospital implements its infection prevention and control plan.
- The hospital reduces the risk of infections associated with medical equipment, devices, and supplies

Joint *Commission* Perspectives, 2022, 42(4), p. 3–30.

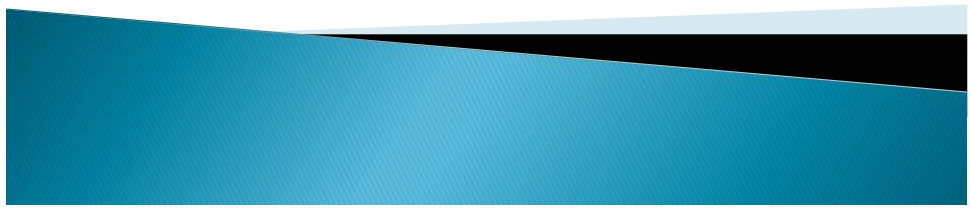
5

Key Survey Findings/Topics

- Intermediate and high-level disinfection and sterilization
- Following manufacturers' instructions for use
- Processes for cleaning equipment
- Minimizing infection risks
- Infection prevention surveillance
- Accurate documentation logs
- Soiled equipment
- No evidence of cleaning
- Safe storage of medical devices, equipment and supplies
- Ultrasound probes

6

Infection Prevention & Control Regulatory Requirements



7

CMS IPC Regulations

- CMS Conditions of participation:
  - CMS Critical Access Hospitals (CAH) and Swing-Beds in CAHs, SOM – Appendix W, pg. 208
    - https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_w_cah.pdf
  - CMS Hospital, SOM – Appendix A, pg. 383
    - https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_a_hospitals.pdf

8

New/Revised Requirements

- The Joint Commission New & Revised Requirements for Infection Prevention and Control Standards
  - Effective July 1, 2024, for Hospitals & CAH
    - All prior IC standards will be retired
    - New IC Standards will become effective
  - The IC chapter underwent a full rewrite
    - Simplified requirements that didn't add value
    - Provide a more meaningful evaluation of the hospital
    - Aligned requirements with CMS and CDC Core IPC Practices

9

New/Revised TJC Requirement

IC.04.01.01 The hospital has a hospital-wide IPC program for the surveillance, prevention, and control of HAIs and other infectious diseases.

IC.05.01.01 The hospital's governing body is accountable for the implementation, performance, and sustainability of the IPC program.

IC.06.01.01 The hospital implements its IPC program through surveillance, prevention, and control activities.

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

10

New/Revised TJC Requirement

- Additional NEW IC standard focusing on high consequence infectious diseases and/or special pathogens.
  - Standardize the approach to preparedness
  - Strengthen basic protocols and processes for routine IPC practices
- IC.07.01.01 The hospital implements processes to support preparedness for high-consequence infectious diseases or special pathogens

11

New/Revised TJC Requirement

IC.07.01.01

The hospital implements processes to support preparedness for high-consequence infectious diseases or special pathogens

EP1- Develop and implement protocols for high-consequence infectious diseases or special pathogens.

EP2 - Implement training & education, assess competency

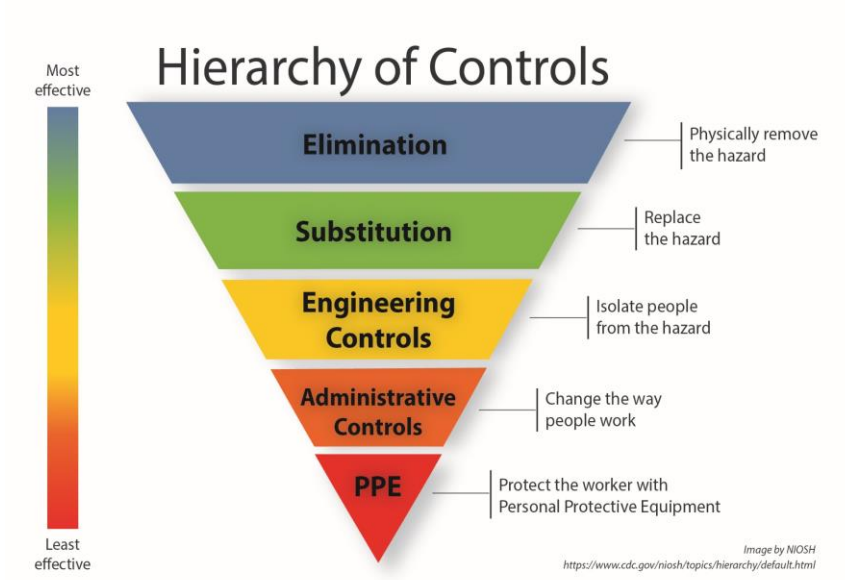
12

New/Revised TJC Requirement

IC.07.01.01, EP1 The hospital develops and implements protocols for high-consequence infectious diseases or special pathogens. Protocols are available for use at point of care and address the following:

- **Identify**
  - Screening at points of entry (ED, Urgent Care, Ambulatory settings)
- **Isolate**
  - Transmission-based precautions
- **Inform**
  - Key hospital leaders, staff, public health
- **PPE**
  - Required PPE, donning & doffing procedures
- **Hierarchy of controls**
  - Support safe provision of care

13



14

IPC Program Authority

- The hospital's governing body appoints an Infection Preventionist (IP) or IP professional responsible for the IPC Program
- Qualified through education, training, experience or certification in infection prevention.
  - Be prepared to review the IP file with surveyors
- Hospital governing body designates authority to take quick action when needed
- Should be defined in policy

15

IPC Program Risk Assessment

- Infection Control Risk Assessment
  - Establish a multidisciplinary team or advisory group
  - Establish a timeline
  - Gather data and information
    - Organizational data – Process & Outcome measures
    - Population-based data – community, state, region
  - Select a risk assessment tool that is easy to use
    - Need a ranking scheme
  - Perform risk assessment at least annually & rank order highest priorities
  - Disseminate the information

16

IPC Program Risk Assessment

EVENT	PROBABILITY	SEVERITY = (MAGNITUDE - MITIGATION)						RISK
		HUMAN IMPACT	PROPERTY IMPACT	BUSINESS IMPACT	PREPARED-NESS	INTERNAL RESPONSE	EXTERNAL RESPONSE	
	Likelihood this type infection / problems with this process will occur in our facility	Severity of this for the patient	Additional cleaning / isolation / staffing needs due to this infection / problem	Increased length of stay / cost to the facility due to this infection / problem	Identification & prevention of this disease / infection / process problem in place	Staff knowledge & compliance of plan for prevention of this particular problem	External support/ regulations for this type procedure problem - Public Health, CHS, Gov. Agencies, etc.	Relative threat*
SCORE	0 = N/A 1 = Low 2 = Moderate 3 = High	0 = N/A 1 = Low 2 = Moderate 3 = High	0 = N/A 1 = Low 2 = Moderate 3 = High	0 = N/A 1 = Low 2 = Moderate 3 = High	0 = N/A 1 = High 2 = Moderate 3 = Low or none	0 = N/A 1 = High 2 = Moderate 3 = Low or none	0 = N/A 1 = High 2 = Moderate 3 = Low or none	*0 - 100%*
Immediate Use Sterilization	1	2	1	1	1	1	1	13%
High Level Disinfection	2	2	2	2	1	2	1	37%

- Risk categories to include:
  - types of infections (HAIs), organisms of epidemiological significance, at-risk patients, geographical considerations, supply and equipment risks, communication risks, emergency preparedness, environmental issues, personnel risks, community considerations.

17

IPC Program Elements

What are the components of the IPC Program?

- Documentation focuses on a given time-period, such as annual
- Statement of identified risks and priorities
- Outline activities for surveillance, prevention and control of HAIs and other infectious diseases.

Which elements should be included in the IPC program document?

- IC program mission & vision
- Staffing & credentials, qualifications
- Scope of Hospital Services
- Population served
- Decision authority
- Risk assessment & priorities
- Surveillance plan
- Program to control HAIs, consistent use of standard precaution strategies, such as hand hygiene, environmental cleaning, and minimizing the infection risk from invasive medical devices and procedures.
- Program for detecting high-consequence infectious diseases and response plan
- Outbreak investigation
- Competency based education & training plan

18

Implementation of the IPC Program

- Applicable federal & state reporting requirements
  - CMS healthcare associated infection (HAI) surveillance
  - State surveillance & reporting requirements
    - Reportable diseases, MDROs, Outbreak investigations, syndromic surveillance
- Surveillance Plan monitors high risk, high volume events
  - Device associated infections
  - Surgical site infections
  - Sharps practices & injuries
  - Employee exposures
  - Organism-specific events

19

Implementation of the IPC Program

- Process Measures
  - Compliance with screening protocols
  - Hand Hygiene compliance
  - Standard Precautions & Respiratory Etiquette compliance
  - Compliance with transmission-based precautions
  - Safe injection processes
  - Medical equipment & devices
    - Point of use practices
    - Clean/disinfect/reprocessing, transport clean/dirty, storage
- Organizational reporting structure
  - Infection Control Committee
  - Quality Assurance Process Improvement (QAPI)
  - C-Suite

20

Strategies to Reduce Infection Risks

- HICPAC and SHEA Compendium Guidelines include performance-based measures
- Implement evidence-based practices across the organization
  - Category IA, IB and IC recommendations should be implemented as they are based on scientific evidence and epidemiological data
- Infection Control Basics
  - Hand Hygiene
  - Standard Precautions
  - Transmission-based Precautions (Isolation)
  - Environment of Care
  - Disinfection and Sterilization

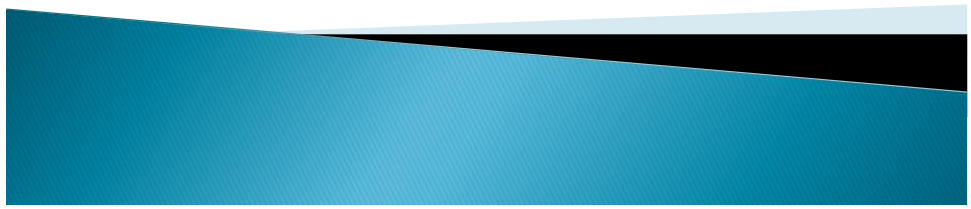
21

Evaluating the IPC Program

- Prepare an annual evaluation of the IPC Program
  - Summary of surveillance activities
    - HAI performance, including summary of auditing/monitoring
    - Special or Common-cause investigations, clusters of infections, outbreaks
    - Describe organizational process changes
  - Summary of IPC education & training competency
  - Describe barriers or challenges
  - What were your program's successes?
  - What opportunities remain for your IPC program?
- Sharing evaluation results organizationally
- Make IPC Program revisions

22

Tools and Processes to Assess Organizational Compliance



23

CMS IPC Hospital Survey

- CMS released revised survey tools on 11/18/2016 and 12/30/2020 to assess of infection control practices in hospitals.
- Free Internet access to the tool
  - https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-15-12-attachment-1.pdf
- Use this tool as a compliance self-check
  - What areas do you do well?
  - What areas do you need to explore further?
  - What areas do you have failures?

24

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)		

25

CDC Infection Control Assessment Tools

- CDC has Infection Control Assessment and Response (ICAR) tools to measure the basic elements of an infection prevention program in a hospital and guide quality improvement activities.
- There are 9 tools and associated resources that may be used to assess a hospital's IPC program.
- https://www.cdc.gov/hai/prevent/infection-control-assessment-tools.html

26

Tracers & Audits

- Measure current practices
  - When a GAP is identified investigate the practice in further detail.
  - Determine if the practice GAP is wide-spread?
  - Is it an Isolated incident?
  - What does the policy say the practice should be?
- Some tracers are performed by IPs, other audits by the unit leader or staff
- Tracer & Audit examples:
  - CDC's Targeted Assessment for Prevention (TAP) Strategy
    - https://www.cdc.gov/hai/prevent/tap.html
  - HLD
  - IC Compliance Rounds
  - Device rounds

27

IPC Unit-based EOC Rounds

(1-2x/yr. per Unit)

Location: | Contact Person:

Date:

This area performs: High Level Disinfection | Device Transport and send to SPD | Sterilization | Other: _____

Y	N	NA		Y	N	NA	
Reception and Waiting area				**Hand Hygiene (IC 02)**			
			Area Clean				Hand hygiene supplies are readily accessiblein patient care areas.
			Cover your cough sign posted (CMS)				Hand hygiene observation is completed regualrly and up to date
			Respiratory etiquette (sign posted, masks and sanitizer available) (CMS)				Lotions are hospital approved and no bigger than 6-8 oz.
			No touch waste receptables and tissues available (CMS)				Hand hygiene supplies not expired (IC 01)
			Front staff can speak to isolatoin procedures (IC 08)	**Environmental Cleaning**			
			Toys are cleaned according to policy (IC 14 appendix XVI)				PDI wipes available in every patient care area
							PDI wipes moist and not expired
Environment of care							orange)
			No missing, stained or broken ceiling tiles				Keyboards are wiped atleast once a shift
			No holes in the walls/floors/furniture				Reusable supplies (Blood pressure cuffs, thermometer...) are wiped between patient use
			No outside packing boxes are used to store supplies ANSI/AAMI ST 79 5.2.1 and 8.9.2	**Refrigerators/freezers (IC 08)**			
			No food in patient care areas (OSHA, IC 13, IC 01)				Refrigerators/freezers are clean, defrosted
			Drinks are in designated locations (no risk of contamination with BBP or toxic substances) (OSHA, IC 13, IC 01)				Patient food refrigerators have no medications
			Items are outside of 3 foot sink radius				No staff food in patient refrigerators
			Nothing stored beneath the sink				All food is labeled and dated in patient refrigerators
			Employee lounge clean				Temperature checks completed; response to variances recorded
			Equipment and wall mounted objects are free of dust				No food stored in medication refrigerators
PPE				**Point-of-Care Glucose Meters**			
			PPE is available and readily accessible to HCP.				Cleaned with bleach after every use
			Gowns, gloves and face masks are not used for more than one patient				Stored in a clean area
			Staff can speak to isolation procedures (IC 04)	**Sharps Containers**			
			Linen				Sharps containers secured

28

Hand Hygiene Audits

- Methods: Direct observations, hand hygiene actions detected by sensors, patient as an observer, product volume usage, audits of hand hygiene supplies.

Measurement	Numerator	Denominator	Stratification	Metric
Direct covert observations[a]	No. of adherent hand hygiene opportunities performed	No. of total opportunities	Unit HCP role	(Adherent HHOs)/(Total HHOs) ×100
AHHMS	Approximate no. of hand hygiene actions detected by sensors	Approximate no. of hand hygiene opportunities detected by sensors	Unit HCP role Individual	(Approximate hand hygiene actions)/(approximate HHOs) ×100[a]
Patient as observer	No. of patient reporting adherence	Total number of observations submitted by patients	Service area and/or HCP role	(No. reporting adherence observations)/(Total observations) ×100
Product volume	Volume of hand hygiene product used (eg, alcohol-based hand rub or liquid soap) for a specified period in a specified area	1,000 patient days during specified period in specified area, or number of patient visits for outpatient areas or emergency departments[185]	Unit Service area No stratification (ie, facility-wide)	Volume (mL) per 1,000 patient days or per patient visit
Audits of hand hygiene supplies	No. of hand hygiene stations with defects (eg, lack of adequate supplies or not functioning as intended)	No. of hand hygiene stations assessed	Unit Service area	(No. of hand hygiene stations without defects)/(No. of hand hygiene stations assessed) ×100

[a]Direct overt observation should not be used to calculate adherence.

SHEA/IDSA/APIC Practice Recommendation: Hand Hygiene, ICHE (2023) p. 1–22. doi:10.1017/ice.2022.304

29

Regular Device Rounds

- CMS Hospital Infection Control Survey tool adapted to use as an audit tool to assess staff practices.
- Process measure
- Unit-based performance metric

Urinary catheter access and maintenance:	
4.A.7 Hand hygiene is performed before and after manipulating catheter.	☐ Yes ☐ No ☐ Unable to observe
4.A.8 Urine bag is kept below level of bladder at all times.	☐ Yes ☐ No
4.A.9 Catheter tubing is unobstructed and free of kinking.	☐ Yes ☐ No
4.A.10 Urine bag is emptied using aseptic technique, using a separate, clean collection container for each patient; drainage spigot does not touch collecting container.	☐ Yes ☐ No ☐ Unable to observe

Process Audit

CMS Tracer: Indwelling Urinary Catheters

30

High Level Disinfection Competency & Process Audits

Ortho-Phthalaldehyde (Cidex OPA) Disinfection Tool

Employee Name	
Date	
Auditor	
Department	
Status	Competency Audit Other

PERSONAL PROTECTIVE EQUIPMENT (PPE)/DEVICES			
Nitrile Gloves	Yes	No	N/A
Full Face Protection: Select one	Yes	No	N/A
◻ Goggles/Mask ◻ Face Shield ◻ Mask with eye shield			
Fluid repellant gown	Yes	No	N/A

APPROPRIATE ENVIRONMENTAL CONTROLS			
Use with good ventilation per Safety Data Sheet (AAMI ST 58, AAMI ST 91 10 ACH)	Yes	No	N/A
Use manufacturer approved covered container	Yes	No	N/A
Knows how to use EYE WASH and understands the importance of having it near the work area: All must be selected ◻ Can locate and describe the use of an eye wash station ◻ Can state why and when to use an eye wash station ◻ Knows how to operate eye wash ◻ Understands the importance of having the safety devices immediately available at eh site of potential need. ◻ Eye Wash station tested per safety requirement (Weekly)	Yes	No	N/A

EMPLOYEE EDUCATION			
All must be selected: ◻ Training on use, safety, and exposure management will be done initially prior to product use and annually. ◻ Employee understands who to notify in the event of exposure/emergency. ◻ Competency check off will be completed prior to initial use, then annually thereafter. ◻ Know how to find the product safety data sheet (SDS), review the SDS at least annually. ◻ Employee has reviewed policies and procedures related to the use of Cidex OPA.	Yes	No	N/A

Chemical Audit

Cleaning Equipment and Accessories Needed:		
Enzymatic Cleaning Solution	60 mL syringe	70% Isopropyl Alcohol
Cleaning Basin or Sink	Soft, Lint free cloth	Pressure Compensation Cap (P/N:)
Flat Cleaning Brush (P/N:)	Lens Cleaner or Cotton Applicator	Leakage Tester (P/N:)

Removing Scope from Cabinet	**X**	**Initials/Date**
1. Open cabinet (2)		
2. Perform hand hygiene (wash hands or use hand sanitizer) (2)		
3. Put on gloves (2)		
4. Remove scope from cabinet, place in clean container, put lid on container (2)		
5. Transport to room (2)		
6. Leave in container with lid on for MD or case manager to set up (2)		
7. Prepare dirty container. Place blue bag with biohazard bag in container (2)		
8. Place completed patient label on blue bag (2)		

Bedside Pre-Cleaning (at point of use) Water Quality Recommendation: Utility Water *This step is to remove gross debris from the exterior of the Flexible Endoscope	**X**	**Initials/Date**
1. Put on gloves (2)		
2. Turn off the Light Source and detach the Flexible Endoscope from the Light Source (1)		
3. Wipe the entire exterior of the Flexible Endoscope with a soft, lint-free, cloth, moistened with water (1)		
4. Remove the Video Connection Cable from the Flexible Endoscope and from the camera control unit (1)		
5. Inspect the vent port and the Video Cable Connector area removing any visible debris on the external surface with a 70% isopropyl alcohol wipe (1)		
6. Place the Flexible Endoscope into labeled blue bag and place into dirty container (1,2)		
7. Remove gloves (2)		
8. Perform hand hygiene (wash hands or use hand sanitizer) (2)		
9. Place lid on dirty container (2)		
10. Transport the scope to the decontamination area (1, 2)		
11. Ensure the Flexible Endoscope is kept protected during transport (1)		
Note: Complete cleaning of the patient-used Flexible Endoscope should be started within two hours of the bedside pre-cleaning. If transit time is greater than 2 hours, ensure that additional manual cleaning (see Manual Cleaning Section) is performed if visible residual debris is still present (1)		

Device Audit

31

Construction IC Risk Assessment 2.0

Type A	**Inspection and non-invasive activities.** Includes but is not limited to: • Removal of ceiling tile for visual inspection-limited to 1 tile per 50 square feet with limited exposure time. • Limited building system maintenance (e.g., pneumatic tube station, HVAC system, fire suppression system, electrical and carpentry work to include painting without sanding) that does not create dust or debris. • Clean plumbing activity limited in nature.
Type B	**Small-scale, short duration activities that create minimal dust and debris.** Includes but is not limited to: • Work conducted above the ceiling (e.g., prolonged inspection or repair of firewalls and barriers, installation of conduit and/or cabling, and access to mechanical and/or electrical chase spaces). • Fan shutdown/startup. • Installation of electrical devices or new flooring that produces minimal dust and debris. • The removal of drywall where minimal dust and debris is created. • Controlled sanding activities (e.g., wet or dry sanding) that produce minimal dust and debris.
Type C	**Large-scale, longer duration activities that create a moderate amount of dust and debris.** Includes but is not limited to: • Removal of preexisting floor covering, walls, casework or other building components. • New drywall placement. • Renovation work in a single room. • Nonexisting cable pathway or invasive electrical work above ceilings. • The removal of drywall where a moderate amount of dust and debris is created. • Dry sanding where a moderate amount of dust and debris is created. • Work creating significant vibration and/or noise. • Any activity that cannot be completed in a single work shift.
Type D	**Major demolition and construction activities.** Includes but is not limited to: • Removal or replacement of building system component(s). • Removal/installation of drywall partitions. • Invasive large-scale new building construction. • Renovation work in two or more rooms.

Low Risk Non-patient care areas such as:	**Medium Risk** Patient care support areas such as:	**High Risk** Patient care areas such as:	**Highest Risk** Procedural, invasive, sterile support and highly compromised patient care areas such as:
• Public hallways and gathering areas not on clinical units. • Office areas not on clinical units. • Breakrooms not on clinical units. • Bathrooms or locker rooms not on clinical units. • Mechanical rooms not on clinical units. • EVS closets not on clinical units.	• Waiting areas. • Clinical engineering. • Materials management. • Sterile processing department - dirty side. • Kitchen, cafeteria, gift shop, coffee shop, and food kiosks.	• Patient care rooms and areas • All acute care units • Emergency department • Employee health • Pharmacy - general work zone • Medication rooms and clean utility rooms • Imaging suites: diagnostic imaging • Laboratory.	• All transplant and intensive care units. • All oncology units. • OR theaters and restricted areas. • Procedural suites. • Pharmacy compounding. • Sterile processing department - clean side. • Transfusion services. • Dedicated isolation wards/units. • Imaging suites: invasive imaging.

	Construction Project Type			
Patient Risk Group	**TYPE A**	**TYPE B**	**TYPE C**	**TYPE D**
LOW Risk Group	I	II	II	III*
MEDIUM Risk Group	I	II	III*	IV
HIGH Risk Group	I	III	IV	V
HIGHEST Risk Group	III	IV	V	V

32

Class of Precautions	Mitigation Activities (Performed Before and During Work Activity)
Class I	1. Perform noninvasive work activity as to not block or interrupt patient care. 2. Perform noninvasive work activities in areas that are not directly occupied with patients. 3. Perform noninvasive work activity in a manner that does not create dust. 4. Immediately replace any displaced ceiling tile before leaving the area and/or at end of noninvasive work activity.
Class II	1. Perform only limited dust work and/or activities designed for basic facilities and engineering work. 2. Perform limited dust and invasive work following standing precautions procedures approved by the organization. 3. This Class of Precautions must never be used for construction or renovation activities.
Class III	1. Provide active means to prevent airborne dust dispersion into the occupied areas. 2. Means for controlling minimal dust dispersion may include hand-held HEPA vacuum devices, polyethylene plastic containment, or isolation of work area by closing room door. 3. Remove or isolate return air diffusers to avoid dust from entering the HVAC system. 4. Remove or isolate the supply air diffusers to avoid positive pressurization of the space. 5. If work area is contained, then it must be neutrally to negatively pressurized at all times. *If negative pressure is required, refer to 9-11 guidance listed under Class IV precautions. 6. Seal all doors with tape that will not leave residue 7. Contain all trash and debris in the work area. 8. Nonporous/smooth and cleanable containers (with a hard lid) must be used to transport trash and debris from the construction areas. These containers must be damp-wiped cleaned and free of visible dust/debris before leaving the contained work area. 9. Install a sticky (dust collection) mat at entrance of contained work area based on facility policy. Sticky mats must be changed routinely and when visibly soiled. 10. Maintain clean surroundings when area is not contained by damp mopping or HEPA vacuuming surfaces.
Class IV	1. Construct and complete critical barriers meeting NFPA 241 requirements. Barriers must extend to the ceiling or if ceiling tile is removed, to the deck above. 2. All (plastic or hard) barrier construction activities must be completed in a manner that prevents dust release. Plastic barriers must be effectively affixed to ground and ceiling and secure from movement or damage. Apply tape that will not leave a residue to seal gaps between barriers, ceiling or floor. 3. Seal all penetrations in containment barriers, including floors and ceiling, using approved materials (UL schedule firestop if applicable for barrier type). 4. Containment units or environmental containment units (ECUs) approved for Class IV precautions in small areas totally contained by the unit and that has HEPA-filtered exhaust air. 5. Remove or isolate return air diffusers to avoid dust entering the HVAC system. 6. Remove or isolate the supply air diffusers to avoid positive pressurization of the space. 7. Negative airflow pattern must be maintained from the entry point to the anteroom and into the construction area. The airflow must cascade from outside to inside the construction area. The entire construction area must remain negatively pressurized. 8. Maintain negative pressurization of the entire workspace by use of HEPA exhaust air systems directed outdoors. Exhaust discharged directly to the outdoors that is 25 feet or greater from entrances, air intakes and windows does not require HEPA-filtered air. 9. If exhaust is directed indoors, then the system must be HEPA filtered. Prior to start of work, HEPA filtration must be verified by particulate measurement as no less than 99.97% efficiency and must not alter or change airflow/pressure relationships in other areas. 10. Exhaust into shared or recirculating HVAC systems, or other shared exhaust systems (e.g., bathroom exhaust) is not acceptable. 11. Install device (e.g., magnehelic, manometer, or digital monitoring) on exterior of work containment to continually monitor negative pressurization. The "ball in the wall" or similar apparatus are not acceptable. 12. Contain all trash and debris in the work area. 13. Nonporous/smooth and cleanable containers (with a hard lid) must be used to transport trash and debris from the construction areas. These containers must be damp-wiped cleaned and free of visible dust/debris before leaving the contained work area. 14. Worker clothing must be clean and free of visible dust before leaving the work area. HEPA vacuuming of clothing or use of cover suites is acceptable. 15. Workers must wear shoe covers prior to entry into the work area. Shoe covers must be changed prior to exiting the anteroom to the occupied space (non-work area). Damaged shoe covers must be immediately changed. 16. Install a sticky (dust collection) mat at entrance of contained work area based on facility policy. Sticky mats must be changed routinely and when visibly soiled. 17. Consider collection of particulate data during work to monitor and ensure that contaminates do not enter the occupied spaces. Routine collection of particulate samples may be used to verify HEPA filtration efficiencies.
Class V	1. Construct and complete critical barriers meeting NFPA 241 requirements. Barriers must extend to the ceiling or if ceiling tile is removed, to the deck above. 2. All (plastic or hard) barrier construction activities must be completed in a manner that prevents dust release. Plastic barriers must be effectively affixed to ground and ceiling and secure from movement or damage. Apply tape that will not leave a residue to seal gaps between barriers, ceiling or floor. 3. Seal all penetrations in containment barriers, anteroom barriers, including floors and ceiling using approved materials (UL schedule firestop if applicable for barrier type). 4. Construct anteroom large enough for equipment staging, cart cleaning, workers. The anteroom must be constructed adjacent to entrance of construction work area. 5. Personnel will be required to wear coveralls at all times during Class V work activities. Coveralls must be removed before leaving the anteroom. 6. Remove or isolate return air diffusers to avoid dust entering the HVAC system. 7. Remove or isolate the supply air diffusers to avoid positive pressurization of the space. 8. Negative airflow pattern must be maintained from the entry point to the anteroom and into the construction area. The airflow must cascade from outside to inside the construction area. The entire construction area must remain negatively pressurized. 9. Maintain negative pressurization of the entire workspace using HEPA exhaust air systems directed outdoors. Exhaust discharged directly to the outdoors that is 25 feet or greater from entrances, air intakes and windows does not require HEPA-filtered air. 10. If exhaust is directed indoors, then the system must be HEPA filtered. Prior to start of work, HEPA filtration must be verified by particulate measurement as no less than 99.97% efficiency and must not alter or change airflow/pressure relationships in other areas. 11. Exhaust into shared or recirculating HVAC systems, or other shared exhaust systems (bathroom exhaust) is not acceptable. 12. Install device (e.g., magnehelic, manometer, or digital monitoring) on exterior of work containment to continually monitor negative pressurization. The "ball in the wall" or similar apparatus are not acceptable. 13. Contain all trash and debris in the work area. 14. Nonporous/smooth and cleanable containers (with a hard lid) must be used to transport trash and debris from the construction areas. These containers must be damp-wiped cleaned and free of visible dust/debris before leaving the contained work area. 15. Worker clothing must be clean and free of visible dust before leaving the work area anteroom. 16. Workers must wear shoe covers prior to entry into the work area. Shoe covers must be changed prior to exiting the anteroom to the occupied space (non-work area). Damaged shoe covers must be immediately changed. 17. Install a sticky (dust collection) mat at entrance of contained work area based on facility policy. Sticky mats must be changed routinely and when visibly soiled. 18. Consider collection of particulate data during work to monitor and ensure that contaminates do not enter the occupied spaces. Routine collection of particulate samples may be used to verify HEPA filtration efficiencies.

Matrix of Precautions for Construction, Renovation and Operations

33

Targeted Assessment for Prevention (TAP)

- TAP is a framework for quality improvement developed by the CDC to use data for action to prevent healthcare-associated infections (HAIs).
- The TAP Strategy
  - Run TAP Reports in the National Healthcare Safety Network (NHSN) to target specific units (OR Facility) with an excess burden of HAIs.
  - Administer the TAP Assessment Tool to identify gaps in infection prevention in the targeted location(s).
  - Accessing infection prevention resources within the TAP Implementation Guides to address those gaps.
- Measure what is *currently in place* at the facility or unit in which the assessment is being administered.

34

Central Line-associated Bloodstream Infection (CLABSI) TAP

Training	
7. Does your facility provide *training* on **insertion** of central lines for all healthcare personnel with this responsibility at least once per year?	☐ Yes ☐ No ☐ Unknown
8. Does your facility conduct a *knowledge assessment* (e.g., quiz, test) on **insertion** of central lines for all healthcare personnel with this responsibility at least once per year?	☐ Yes ☐ No ☐ Unknown
9. Does your facility conduct a *skills assessment* (i.e., personnel demonstration of tasks) on **insertion** of central lines for all healthcare personnel with this responsibility at least once per year?	☐ Yes ☐ No ☐ Unknown
10. Does your facility provide *training* on **maintenance** of central lines for all healthcare personnel with this responsibility at least once per year?	☐ Yes ☐ No ☐ Unknown
11. Does your facility conduct a *knowledge assessment* (e.g., quiz, test) on **maintenance** of central lines for all healthcare personnel with this responsibility at least once per year?	☐ Yes ☐ No ☐ Unknown
12. Does your facility conduct a *skills assessment* (i.e., personnel demonstration of tasks) on **maintenance** of central lines for all healthcare personnel with this responsibility at least once per year?	☐ Yes ☐ No ☐ Unknown

Central Line-associated Bloodstream Infection (CLABSI) Targeted Assessment for Prevention (TAP) Facility Assessment Tool

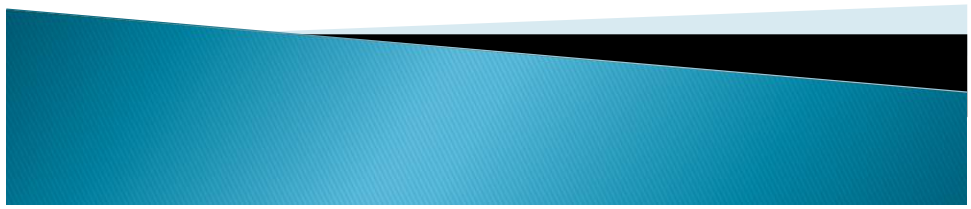
35

Buetti, N., et al. (2022). Strategies to prevent central line-associated bloodstream infections in acute-care hospitals: 2022 Update. *Infection Control & Hospital Epidemiology, 43*(5), 553-569. doi:10.1017/ice.2022.87

Guideline (Desired State)		Current State	Priority	Action Plan	Evaluation
Before accessing catheter hubs, needleless connectors, or injection ports, vigorously apply mechanical friction with an alcoholic chlorhexidine preparation, or 70% alcohol. (Quality of Evidence: MODERATE)	Not Met	Staff witnessed accessing needleless connector without prior disinfection.	High		

36

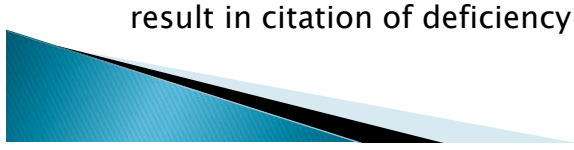
Responding to a Survey Finding



37

Types of CMS Surveys

- Certification/Recertification (routine) and Validation
  - Certification/Recertification Survey (routine) –
    - Unannounced
  - Validation Survey – CMS has right to do its own survey of "deemed" status hospital –
    - Random – Could be as a result of deficiencies identified in TJC survey – Unannounced
- Complaint/Allegation
  - Complaint = allegation of noncompliance with COPs
  - Allegation = assertion of improper care that could result in citation of deficiency with COPs



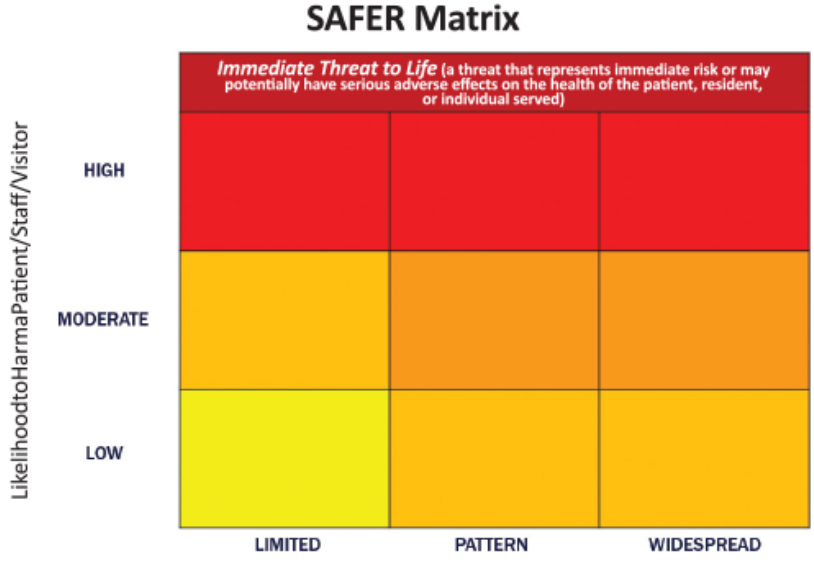
38

CMS Levels of Deficiency

- Standard Level Deficiencies –
  - Noncompliance with any single requirement or several requirements within a particular standard
- Condition Level Deficiencies –
  - Noncompliance with requirements in a single standard or several standards within the condition
  - Representing a severe or critical health or safety breach
  - 90 calendar day termination track
- Immediate Jeopardy –
  - Noncompliance with one or more requirements of participation, likely to cause serious injury, harm, impairment, or death
  - 23 calendar day termination track if not corrected before surveyors leave

39

SAFER Matrix



SOURCE: THE JOINT COMMISSION

40

Common CMS Findings

- Hand hygiene – Look at availability of dispensers, look at kitchen – immediate access as you enter food prep area. Don hair net then perform hand hygiene.
- Surgical Attire – hair coming out of head cover, mask around neck.
- Meds prepped within 3 feet of splash zone.
- Multi-dose meds cannot be used in Anesthesia carts.
- Eye drops and insulin should not be shared.

41

Common CMS Findings

- Transmission-based precautions-
  - What does sign say? What are staff wearing?
  - Need adequate supply of PPE.
  - Need staff to speak to air pressure requirements for Airborne. Is door closed?
- Low level disinfection – stethoscopes should be cleaned between patients. Train staff and providers.

42

Common CMS Findings – High Level Disinfection

- Reprocessing endoscopes – lack of maintenance, lack of adequate washing, lack of training
- Decentralization is a problem –less accountability.
- One sink is a problem – need minimum of 2 sinks for high level disinfection, 3 desired.
- Need airflow validated if performing HLD in a re-purposed room. Where is air exhausted?
- Store endoscopes in well-ventilated, dust free cabinet. Door closed to scope cabinet.
- Need eye-wash station
- Training – didactic & competency. What makes the trainer competent?

43

Written Response to a Survey Finding

- Plan of Correction:
  - Title of accountable person
  - Plan for correcting the deficiency
  - Procedure for correction
  - Monitoring correction
    - Measure of success
    - Is it sustainable?

44

Written Response to a Conditional Survey Finding – IC.02.02.01

EP 4: The hospital implements infection prevention and control activities when doing the following: medical equipment, devices and supplies.

- Finding: While conducting the building tour of the outpatient surgical facility, it was observed that oral airways were loose in the drawers in the pediatric resuscitation cart, anesthesia cart and supply room.
- Finding: While conduction the building tour of the outpatient surgical suites, it was observed that the bulk pack EKG pads on the resuscitation carts were opened and did not have adjusted expiration dates on the packaging materials.
- Finding: It was observed in Room 4342 (C-section Room) that EKG electrodes were hung and attached to the leads for the machine. There was no package available and an expiration date was not available (package discarded). The room did not have a scheduled patient for the remainder of the day.
- Finding: In 2 of 2 tracers conducted, it was observed that unwrapped EKG electrodes were undated and present in the resuscitation cart. These are considered expired. This was seen on the 8th Floor telemetry unit and in the operating suite.
  - WHO *is ultimately responsible for the corrective action?*
    Supply Chain Manager
  - WHAT *actions are needed to be completed to correct each finding?*
    Product replacement for individually wrapped oral airways and EKG electrodes
    Interim plan until supply is here - individually wrap airways and EKG electrodes from bulk supply
  - WHEN *will each of the actions completed?*
    Product here Sept. 26
    All supply drawers will be replaced with individually wrapped oral airways and EKG electrodes
    All Crash Carts and Anesthesia Cart supplies will be replaced with individually wrapped oral airways and EKG electrodes
  - HOW *will compliance be sustained?*
    Clean supplies will be single-patient use, individually wrapped & stocked daily by Supply Chain. Limited supplies are available in Pyxis and outdates are checked prior to stocking.

45

Measure of Success

ORAL AIRWAYS INDIVIDUALLY WRAPPED

Outpatient Surgical Center - Anesthesia Cart			
Date	**Number of Audits**	**# of Oral Airways in Compliance**	**Percent of Compliance**
October	21	21	100%
November	21	21	100%
December	21	21	100%
January	18	18	100%

WOMEN'S SERVICES C-SECTION ROOM 4338			
Date	**Number of Audits**	**# of EKG in Compliance**	**Percent of Compliance**
October	26	22	84%
November	25	23	92%
December	29	29	100%
January	15	15	100%

46

47

Key Resources for Implementation

- Centers for Disease Control
  - Your one-stop-shop for everything you need
  - https://www.cdc.gov/infectioncontrol/guidelines/index.html
- Agency for Healthcare Research & Quality
  - CUSP & TeamSTEPPS, CAUTI, CLABSI, VAE, *Clostridium difficile*, CRE Prevention Toolkit
  - https://www.ahrq.gov/
- OSHA https://www.osha.gov/
- Association for the Advancement of Medical Instrumentation (AAMI)
- Association of periOperative Registered Nurses Recommended Practices (AORN)
- Facility Guidelines Institute (FGI)
- US Food and Drug Administration Guidance – Medial Devices Section https://www.fda.gov/MedicalDevices/

48

References

- July 2022 TJC Manual for Hospitals
- CMS crosswalk
- Joint Commission Resources IC Risk Assessment
- https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-09.pdf pg. 21-64

49