# Healthcare Regulatory Insights: Will You Comply?

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The Joint Commission

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## Objectives

- Describe the approach for ensuring compliance with Joint Commission Infection Control Standards
- Review infection risks associated with the environment and key interventions
- Identify best practices to decrease infection risks
- Provide examples of situations that could lead to survey findings and adverse accreditation decisions

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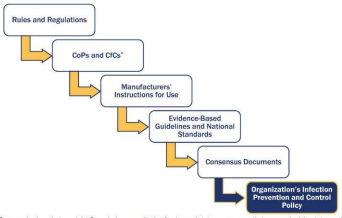
## Hierarchical Approach to IC Standards




* For organizations that use Joint Commission accreditation for deemed status purposes or that are required by state regulation or directive, Conditions of Participation (CoPs) and/or Conditions for Coverage (CfCs) should be reviewed for applicable mandatory requirements.

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Source: *Perspectives* April 2019



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# Regulations

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## Regulations

- Common sources of infection control related regulation
  - Local, state and federal building code requirements
  - Occupational Safety and Health administration (OSHA)
  - Food and Drug Administration (FDA)

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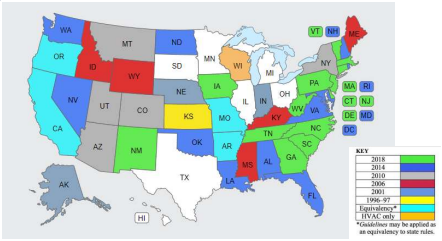
## Regulations

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## Regulations: OSHA

Bloodborne Pathogens Standard (1991)

- Applies to PPE necessary to protect from exposure to blood and other potentially infectious materials linked to transmission of bloodborne pathogens

Personal Protective Equipment for General Industry (1994)

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

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# Conditions of Participation



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## State Operations Manual


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https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984.html?DLPage=1&DLSort=0&DLSortDir=ascending

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## Program Specific State Operations Manual

**Medicare State Operations Manual**
**Appendix**

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.
- The appendices are in PDF format, which is the format generally used in the IOM to display files. **Click on the corresponding letter in the "Appendix Letter" column to see any available file in PDF.**
- To return to this page after opening a PDF file on your desktop use the browser "back" button. This is because closing the file usually will also close most browsers.

| Appendix Letter | Description |
|---|---|
| A | Hospitals |
| AA | Psychiatric Hospitals |
| B | Home Health Agencies |
| C | Laboratories and Laboratory Services |
| D | Portable X-Ray Service |
| E | Outpatient Physical Therapy or Speech Pathology/Services-Interpretive Guidelines |
| F | Physical Therapists in Independent Practice - **Deleted** |
| G | Rural Health Clinics (RHC's) |

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## Program Specific State Operations Manual

**State Operations Manual**
**Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals**

Table of Contents
*(Rev. 176, 12-29-17)*

Transmittals for Appendix A

Survey Protocol

Introduction
- Task 1 - Off-Site Survey Preparation
- Task 2 - Entrance Activities
- Task 3 - Information Gathering/Investigation
- Task 4 - Preliminary Decision Making and Analysis of Findings
- Task 5 - Exit Conference
- Task 6 – Post-Survey Activities

Psychiatric Hospital Survey Module
Psychiatric Unit Survey Module
Rehabilitation Hospital Survey Module
Inpatient Rehabilitation Unit Survey Module
Hospital Swing-Bed Survey Module

Regulations and Interpretive Guidelines

§482.1 Basis and Scope
§482.2 Provision of Emergency Services by Nonparticipating Hospitals
§482.11 Condition of Participation: Compliance with Federal, State and Local Laws
§482.12 Condition of Participation: Governing Body

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## Program Specific State Operations Manual

Hospitals

Regulation

**§482.41(a) Standard: Buildings**

The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

Interpretive Guidelines

**Interpretive Guidelines §482.41(a)**

…routine and preventive maintenance and testing activities are performed as necessary, in accordance with *Federal and State laws, regulations, and guidelines and manufacturer's recommendations*, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas or equipment in need of repair…

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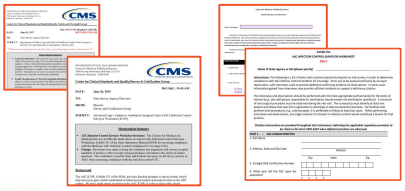
## More CMS Requirements

- Survey and Certification Letters
- Quality Safety & Oversight Memoranda





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https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html



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## Joint Commission Standards Tie into CMS Standards

| Nbr | Elements of Performance (EPs) | CMS | New | FSA | MOS | CR | DOC | SC | ESP |
|---|---|---|---|---|---|---|---|---|---|
| 1 | The hospital implements infection prevention and control activities when doing the following: Cleaning and performing low-level disinfection of medical equipment, devices, and supplies. * Note: Low-level disinfection is used for items such as stethoscopes and blood glucose meters. Additional cleaning and disinfecting is required for medical equipment, devices, and supplies used by patients who are isolated as part of implementing transmission-based precautions. Footnote *: For further information regarding cleaning and performing low-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html. | §482.42(a) §482.51 §482.51(b)(3) | N | M | | | C | |
| 2 | The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. * (See also EC.02.04.03, EP 6) Note: Sterilization is used for items such as implants and surgical instruments. High-level disinfection may also be used if sterilization is not possible, as is the case with flexible endoscopes. Footnote *: For further information regarding performing intermediate and high-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention | §482.42 §482.51 §482.51(b)(3) | N | | | | A | |

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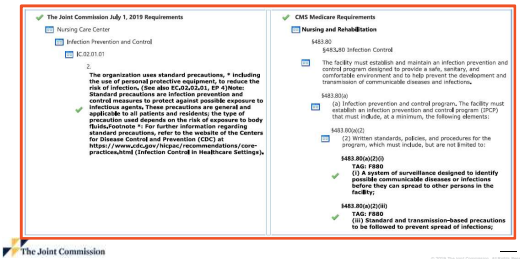
## Blue Links in E-dition Tie to CMS TAGs and CoPs




## Manufacturer Instructions for Use

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## Manufacturer Instructions

13. SYSTEM DRAIN . The opening of the facility drain must be at least 1-1/2-inch (3.8 cm) in diameter to accommodate one machine drain hose **with an air gap**.

Source: Installation Instructions
Automated Endoscope Reprocessor

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# Evidence-Based Guidelines



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## Evidence Based Guideline

- Guidelines for Environmental Infection Control in Health-Care Facilities (2003)
- Key recommendations
  - infection-control impact of ventilation system
  - establishment of a multidisciplinary team to conduct infection-control risk assessment;
  - use of dust-control procedures and barriers during construction, repair, renovation, or demolition;
  - environmental infection-control measures



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# Water Management Program



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Legionella Bacteria Found in New York City Hospital: Officials

Published at 9:35 PM EDT on Jul 28, 2018 | Updated at 2:46 PM EDT on Jul 29, 2018

'Inadequate disinfection' blamed in Legionnaires' outbreak

4 Cases of Legionnaires' Disease Investigated at Hospital

Health officials warn of possible Legionnaires' exposure at Missouri cancer center

Vets' Home Legionnaires' Outbreaks Spur New Disease Notification Law

Legionella outbreak investigated by Hawaii Health Department

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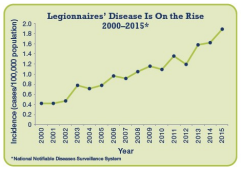
## What's the risk?

- More Legionella pneumophila in the environment
- More susceptible patient population
- Increased awareness and testing
- 1 in 4 patients who acquire their infection in healthcare facility will die




In the United States, reported cases of Legionnaires' disease have increased by nearly four and a half times since 2000. More illness occurs in the summer and early fall but can happen any time of year.

Source: https://www.cdc.gov/legionella/downloads/toolkit.pdf

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## Other Waterborne Pathogens

- Hospitals water systems
- Showers
- Faucets
- Sinks
- Ice Machines
- Water baths
- Birthing tubs

Source: Hajime Kanamori, David J. Weber, William A. Rutala, Healthcare Outbreaks Associated With a Water Reservoir and Infection Prevention Strategies, *Clinical Infectious Diseases*, Volume 62, Issue 11, 1 June 2016, Pages 1423–1435, https://doi.org/10.1093/cid/ciw122

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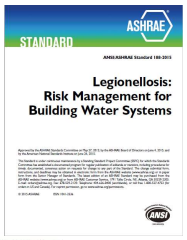
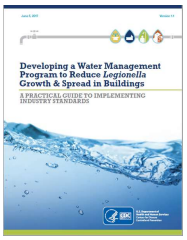
## How to Reduce Risk

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## Key Elements

**Facility risk assessment**

- CDC Toolkit provides step by step direction

**Water management program**

- Establish a water management team
- Describe the building's current water system
- Identify where Legionella and other pathogens can grow
- Determine control measures and how to monitor (DOES NOT require cultures)
- Establish interventions when clinical limits are not met
- Make sure the program is functioning as designed and effective
- Document and communicate

**Testing protocols and acceptable ranges for control measures**

- Results of testing and corrective actions taken when control limits are not maintained

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## Sylvia's tips





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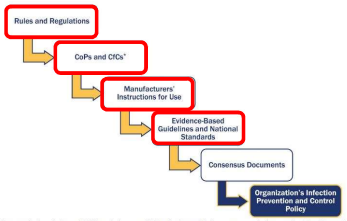
## What's Joint Commission's Approach

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Source: April 2019 *Perspectives*

## Regulations

- New York Department of Health: *Protection Against Legionella* Effective date: 7/6/16
  - Cooling Tower: < 20 CFU/mL
  - Healthcare Facilities:
    - Sampling sites determined by environmental assessment
    - Water cultures every 90 days for first year or if water system serves hematopoietic stem cell transplant or solid organ transplant patients every 90 days
- New Jersey Senate Bill S1108, introduced January 25, 2018: Requires registration, inspection, testing, cleaning, and disinfection of cooling towers to control outbreaks of Legionnaire's Disease

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## Regulation

- "General Duty Clause" Section 5(a)(1) of the Occupational Safety and Health (OSH) Act of 1970, 29 USC 654(a)(1),
  - Employers should know the hazards and risks with having water sources in the workplace and maintain all systems to prevent *Legionella* growth.
- Other OSHA standards and regulations
  - Personal Protective Equipment (PPE) (29 CFR 1910.132)
  - Respiratory Protection (29 CFR 1910.134) standards.
  - Hazard Communication standard (29 CFR 1910.1200): Chemicals for cleaning and water system disinfection
  - Section 11(c) of the OSH Act, 29 USC 660(c), prohibits employers from retaliating against workers for raising concerns about safety and health conditions.

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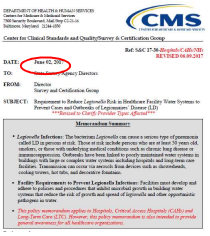
## Survey and Certification S&C 17-30 Legionella

- Applies to
  - Hospitals
  - Critical Access Hospitals
  - Long-Term Care
- Implement plan that reduces
  - Legionella
  - Other opportunistic water pathogens


DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS

Centers for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C 17-30-Hospitals/CAHs/NHs
REVISED 06.09.2017

DATE: June 02, 2017

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Requirement to Reduce Legionella Risk in Healthcare Facility Water Systems to Prevent Cases and Outbreaks of Legionnaires' Disease (LD)
***Revised to Clarify Provider Types Affected***

Memorandum Summary

- Legionella Infection: The bacterium Legionella can cause a serious type of pneumonia called LD in persons at risk. Those at risk include persons who are at least 50 years old, smokers, or those with underlying medical conditions such as chronic lung disease or immunosuppression. Outbreaks have been linked to poorly maintained water systems in buildings with large or complex water systems including hospitals and long-term care facilities. Transmission can occur via aerosols from devices such as showerheads, cooling towers, hot tubs, and decorative fountains.
- Facility Requirements to Prevent Legionella Infections: Facilities must develop and adhere to policies and procedures that inhibit microbial growth in building water systems that reduce the risk of growth and spread of legionella and other opportunistic pathogens in water.
- *This policy memorandum applies to Hospitals, Critical Access Hospitals (CAHs) and Long-Term Care (LTC). However, this policy memorandum is also intended to provide general awareness for all healthcare organizations.*

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## Manufacture Instructions

**Tower Cleanliness**

An unclean tower can be an amplifier of unhealthy biological agents…**periodically inspect** an operating cooling tower for good biological control. The inspection should include, at a minimum, **visual evaluation of the condition of the water and the distribution basins**. Good biological control is indicated by clean, clear water with no green or brown algae below the water line. Poor control is detected by…

**Drift (Mist) Eliminators**

Cleanliness and effectiveness of drift eliminators are critical in preventing the spread of *Legionella pneumophila* bacteria. Make sure that all air passages are clear of debris, and as clean as possible. Check that all components are properly installed. Check condition of seals to assure that water can't bypass the eliminators through deteriorated or missing seals.

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Source: Marley M92-1474C ISSUED 4/2013 User Manual: Cooling Tower Inspection Tips

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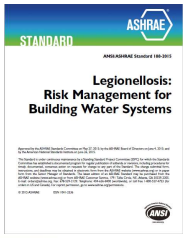
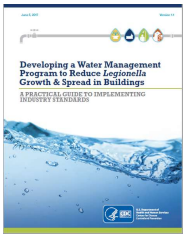
## Evidence Based Guidelines

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## The Joint Commission Standards

**Standard EC.01.01.01**
- The hospital has a written plan for managing its utility system

**Standard EC.02.01.01**
- The organization manages safety and security risks.

**Standard EC.02.05.01**
- The organization manages risks associated with its utility systems

**Standard EC.02.05.05**
- The organization inspects, tests, and maintains utility systems

**Standard IC.01.03.01**
- The organization identifies risks for acquiring and transmitting infections

**Standard IC.01.05.01**
- The organization has an infection prevention and control plan

**Standard IC.02.01.01**
- The organization implements its infection prevention and control plan

**Standard IC.03.01.01**
- The organization evaluates the effectiveness of its infection prevention and control plan

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## EC.02.05.01 EP14: Examples

- No evidence of a plan to manage legionella and other waterborne pathogen risks associated with the water management processes, including testing protocols and acceptable ranges for control measures
- No evidence that a risk assessment was conducted for the infection control utilities system components associated with legionella and other waterborne pathogens
- The organization could not demonstrate how evidence-based control measures were incorporated into the water management program.

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## Scoring


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# Mold Prevention



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## What's the Risk?

- "…Concentrations below 1cfu/m$^3$ was enough to cause infection in high-risk patients. Virtually all outbreaks of nosocomial aspergillosis are attributed to airborne sources, usually construction…"
- Fatality rate was 57.6% in high risk patients and 39.4% in patients without severe immunodeficiency.


Source: Vonberg R-P, Gastmeier, P. Nosocomial aspergillosis in outbreak settings. Journal of Hospital Infection (2006) 63, 246-254

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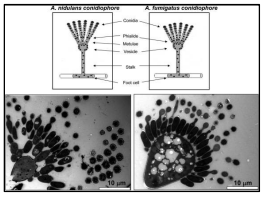
## Background

Mold spores versus active mold replication

- Spores drift through the air all the time (think dust)
- To change into its replicative state spores require
  - Nutrients
  - Moisture
  - The right temperature




Source: Yu J. H. (2010). Regulation of Development in Aspergillus nidulans and Aspergillus fumigatus. *Mycobiology, 38*(4), 229-37.

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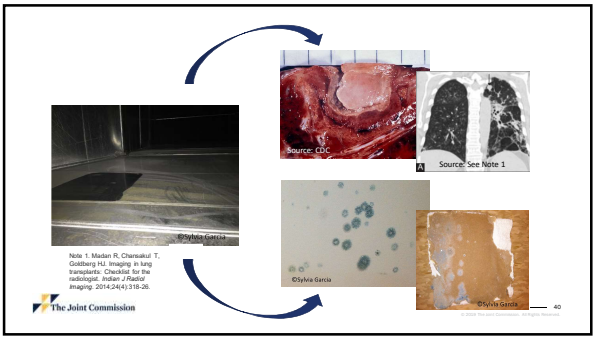


## Other Implications of Mold

- Sensitive to molds
  - Stuffy nose
  - Wheezing
  - Red or itchy eyes/ skin
- Allergic to molds/ asthmatics
  - Fever
  - Shortness of breath
- Exposure to mold may lead to development of asthma

Source: https://www.cdc.gov/mold/faqs.html#affect

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## Release of Mold Spores

- ANY work that generates dust
- Drilling through walls or ceilings
- Coring through floors, removing floor tile or carpet
- Air movement over the tops of ceiling tiles
- Anything that stays wet for >72 hours is a potential mold source (e.g., Wet ceiling tiles)
- Disruption of air supply or incorrect pressurization
- Improper filter installation
- Open windows or doors (lack of airlocks)
- Cleaning air supply or exhaust grills and ducts
- Vacuum cleaners
- Plants or fresh flowers

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## How do we reduce risk?

- American Institute of Architects (now Facilities Guideline Institute - FGI) addressed the issue in 2001 last revision 2014
- Joint Commission followed with related EC standard in 2002
- CDC published Guidelines for Environmental Infection Control in Health-Care Facilities (2003) – Available at https://www.cdc.gov/infectioncontrol/guidelines/environmental/

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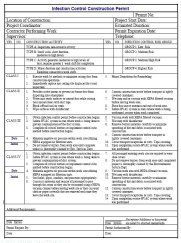
## Risk Mitigation Document



Infection Control Construction Permit

| Low Risk | Medium Risk | High Risk | Highest Risk |
|---|---|---|---|
| • Office areas | • Cardiology<br>• Echocardiography<br>• Endoscopy<br>• Nuclear Medicine<br>• Physical Therapy<br>• Radiology/MRI<br>• Respiratory Therapy | • CCU<br>• Emergency Room<br>• Labor & Delivery<br>• Laboratories (specimens)<br>• Newborn Nursery<br>• Outpatient Surgery<br>• Pediatrics<br>• Pharmacy<br>• Post Anesthesia Care Unit<br>• Surgical Units | • Any area caring for immunocompromised patients<br>• Burn Unit<br>• Cardiac Cath Lab<br>• Central Sterile Supply<br>• Intensive Care Units<br>• Medical Unit<br>• Negative pressure isolation rooms<br>• Oncology<br>• Operating rooms including C-section rooms |

Shortcomings:

- Does not work well for multiple phase projects
- Does not include all elements specified in FGI or CDC
- May be too general for implementation

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## Key Elements

**Planning and Monitoring**

- ❑ Involve Infection Preventionist from concept through commissioning
- ❑ Ensure **all** elements outlined in FGI 2014 are addressed
- ❑ Project specific protective measures including the responsibilities of each party (governing body, designer, contractor, and facility staff)
- ❑ Assigned responsibility for monitoring compliance
- ❑ Written procedures for suspension of work

**Ventilation of Construction Zone**

- ❑ Dedicated (isolated) ventilation\exhaust system for the construction area
- ❑ Barriers maintained at 0.03 inches of water with airflow from clean to dirty with visual display (FGI 2014)
- ❑ System cleaned prior to occupancy if existing building HVAC system used

**Disaster Plans for Emergencies**

- ❑ Written plans for HVAC shutdown, water outage or leaks, etc

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## Sylvia's Tips

- Ensure your IP is knowledgeable and competent to perform risk assessment and develop mitigation strategies
- Use a blueprint as the starting point of your assessment and mitigation plan
- Train staff in the area to report problems and have 24 hour coverage to respond
- Consider contractual penalties for not complying with ICRA requirements

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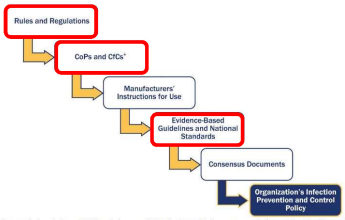
## What's The Joint Commission's Approach

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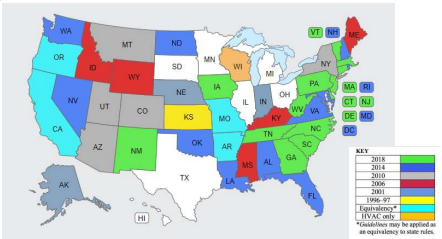
## Regulations

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https://www.fgiguidelines.org/guidelines/state-adoption-fgi-guidelines/

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## FGI 2014: Two Types of Risk Assessment Required

1. ICRA: Planning, Design, Construction and Commissioning
   - "…infection control risk assessment shall be part of the integrated facility planning, design, construction, and commissioning activities and shall be incorporated into the safety risk assessment."
2. Infection Control Risk Mitigation
   - Plans that describes the specific methods by which transmission of contaminants will be avoided during maintenance, renovation, construction and commissioning

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## FGI: Planning Elements

- Number, location, type of airborne isolat… protective environment rooms
- Special HVAC needs
- Water/plumbing system
  - Minimum hand h… first aid equipment
  - Water mana… program
- Selection… als for surfaces and furnishings
- Test… ertification of installed systems
- Ass… ment of external and internal construction activities
- Location of known hazards

Be prepared to talk about the process

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## FGI: Infection Control Risk Mitigation

- **Written plan** that includes
  - Patient placement
  - Standards for barriers
  - Construction
    - Plumbing systems
    - Water related equipment (e.g., ice machines, sterilizers)
    - HVAC
  - Staff training
  - Bathrooms and breaks for construction staff
  - Commissioning and occupancy

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## Monitoring and Planning

- Written procedures for suspension of work
- Protective measures including the respons… limitations of each party (governing body, designer, cont… monitor)
- Governing body shall provide … plans for effective application of ICRMRs, may place resp… n (and/or)
  - Infection Prevention…
  - Epidemiolog…
  - Const… ators
  - C…
  - In… dent outside consultants

Be prepared to talk about the process

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## Disaster Plans for Emergencies

- **Written plan** for
  - HVAC shutdown
  - Water outage
    - Location of supplies
    - Who is responsible for what
    - Who will be notified
  - Water leak

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## CMS Condition of Participation

Hospital Infection Control Worksheet
Cite: 42 CFR 482.42(a)
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.

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## Evidence Based Guideline

Guidelines for Environmental Infection Control in Health-Care Facilities (2003)

- Key recommendations
  - infection-control impact of ventilation system
  - establishment of a multidisciplinary team to conduct infection-control risk assessment;
  - use of dust-control procedures and barriers during construction, repair, renovation, or demolition;
  - environmental infection-control measures
  - establish and maintain surveillance for airborne environmental disease

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## Infection Surveillance

- Establish and maintain surveillance for airborne environmental disease (e.g., aspergillosis) as appropriate during construction, renovation, repair, and demolition activities
  - Monitor for airborne fungal infections in immunocompromised patients.
  - Periodically review the facility's microbiologic, histopathologic, and postmortem data
  - If cases of health-care–associated airborne fungal infections occur, aggressively pursue the diagnosis

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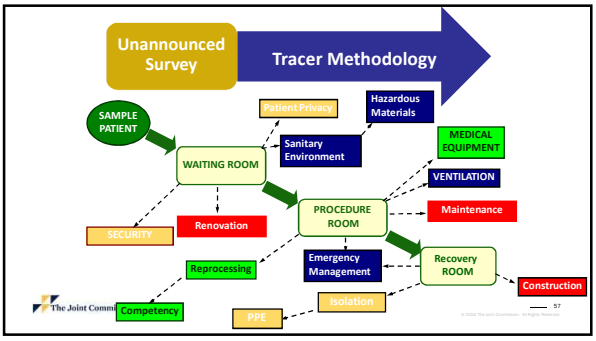

## Standard EC.02.06.05

EP 1 Must use
- State rules and regulations
- Guidelines for Design and Construction of Health Care Facilities, 2014

EP 2 Preconstruction risk assessment
- Demolition
- Construction
- Renovation

EP 2 Preconstruction risk assessment addresses
- air quality requirements
- infection control
- utility requirements
- noise, vibration, and other hazards

EP 3 Take action based on risk assessment

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**Where is the ICRA for this project?**

**How was IC involved in the planning and design of this project?**

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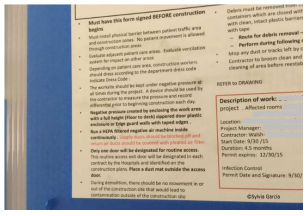


**Is there an ICRA posted but it is not being followed?**

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What does the ICRA say about pressurization and barriers?


- FGI: Barriers maintained at 0.03 inches of water with airflow from clean to dirty
- CDC: Establish negative pressure

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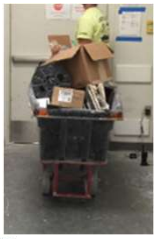
What does the ICRA say about construction waste?



- FGI: ICRM must included impact of movement of debris, traffic flow, clean-up, elevator use for construction materials and workers, and construction worker routes
- CDC: Mist debris and cover disposal carts before transport

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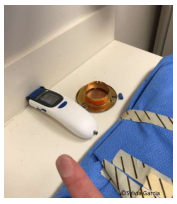
Have staff started to stock supplies and hang curtains before dust removed?



- FGI: ICRA must address commissioning
- CDC: Remove dust generated during construction

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Do staff know what an ICRA is and the steps to take if it is not followed?

Are staff walking past a barrier that is not correct?



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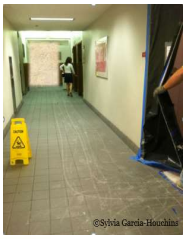
Are construction workers aware of the importance of adhering to infection control measures during the project?





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## Scoring EC.02.06.05

2018

| Likelihood to Harm a Patient/Staff/Visitor | Immediate Threat to Health and Safety 0% | | | |
|---|---|---|---|---|
| HIGH | 1.72% | 5.17% | 6.90% | 13.79% |
| MODERATE | 27.59% | 5.17% | 0% | 32.76% |
| LOW | 43.10% | 6.90% | 3.45% | 53.45% |
| | 72.41% LIMITED | 17.24% PATTERN | 10.34% WIDESPREAD | Scope |

2019

| Likelihood to Harm a Patient/Staff/Visitor | Immediate Threat to Health and Safety 3.92% | | | |
|---|---|---|---|---|
| HIGH | 5.88% | 3.92% | 0% | 9.80% |
| MODERATE | 43.14% | 17.76% | 7.84% | 62.75% |
| LOW | 21.57% | 0% | 1.96% | 23.53% |
| | 70.59% LIMITED | 15.69% PATTERN | 9.80% WIDESPREAD | Scope |

Number of observations for first half of 2019 equal to all of calendar year 2018

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# Barrier Details








Barrier with Solid Top








Barrier that goes to drop ceiling


If drop ceiling, MUST cover inside of barrier to prevent penetration of dust outside of barrier


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What about this one?


Take a closer look from the inside

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# Maintaining Negative Pressure: HEPA Filters

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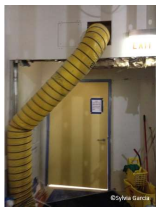
## Where are these HEPA Filters exhausting?





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## Where to Exhaust HEPA Filters

- Must NOT exhaust
  - directly into a return
  - into the space above a dropped ceiling

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## Filters

- Placed prior to system start up
- Final filters gasketed and clipped
- Inspected once system startup occurs


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## Conclusion

- Facilities staff should understand the risks and their role in preventing infections.
- Effective management of the physical environment is necessary to prevent related disease
- It is not easy to link exposure to disease but when disease does occur it usually results in significant adverse patient outcomes (illness and/or death)

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Thank you for Keeping Patients Safe!

Questions and Comments
sgarcia-houchins@jointcommission.org

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