



FOR PROVIDERS.
BY PROVIDERS.

Critical Access Hospital 2023 Standard Revisions

Customer Education

Objectives



- Provide ACHC customers with an overview of new and revised Critical Access Hospital Standards that align with CMS.
- ACHC revised standards are tentatively effective as of March 1, 2023.

Important to Note



- The 2023 CAH Manual contains.
 - New Standards
 - Revised Standards
 - New or revised Required Elements
- All revisions or new additions to the standards are in **BOLD** in the prepublication version, pending CMS approval

Chapter 2 Emergency Services



Chapter 2: Updates

- 02.00.00 Condition of Participation
- 02.00.03 Equipment availability

Chapter 2: 02.00.00

02.00.00 Condition of Participation: Emergency Services - Scoring revised

- The CAH follows its own policies and procedures, evidenced through a sample of records for patients treated in the emergency services department.

Chapter 2: 02.00.03

02.00.03 Equipment Availability – Revised

Required Elements

The organization has a policy or process which defines what supplies and equipment are required for medical emergencies. Policies should address:

- How contents are secured after use and during transport to be restocked.
- Individuals authorized to transport carts
- Process to clean and restock carts
- Secure locations with limited access where carts may be stored prior to use by floors/departments
- Policy defines the process and frequency of checking for outdated supplies in carts and emergency trays/boxes
- Frequency of cart/tray/box lock check (at minimum once per day)

Adequate equipment must be available to respond to emergencies in more than one location simultaneously.

Chapter 2: 02.00.03

02.00.03 Equipment Availability – Revised

Required Elements cont.

Adequate equipment must be available to respond to all patients' populations under the scope of services, e.g., if the facility treats bariatric, neonatal or pediatrics patients, appropriately sized resuscitation equipment is immediately available.

At a minimum the following equipment must be available:

- Defibrillator
- Oxygen tank
- Suction equipment/ vacuum
- Bag valve mask (BVM) device
- Medication (as applicable, based on type of emergency cart)

Chapter 2: 02.00.03

02.00.03 Equipment Availability – Revised

Scoring Revised

- Verify:
 - Policy or process defining emergency equipment required
 - Adequate supplies are available
 - Supplies encompass all patient populations.

Chapter 3 Physical Environment



Chapter 3: Updates

- 03.02.01 Building Security
- 03.04.02 Fire drills – quarterly
- 03.06.03 Water management plan (NEW STANDARD)
- ~~03.06.07 Potable water~~
- ~~03.06.12 Water temperature control~~

Chapter 3: 03.02.01

- 03.02.01 Building Security
- The organization shall have policies and other measures in effect to identify and minimize security risks to patients, visitors, and staff.
- **The organization's security features are based on nationally recognized standards to ensure the safety of vulnerable patients.**
- **Access to non-clinical rooms identified as hazardous locations must be secured to prevent patient and visitor entry.**
 - Required Elements / Additional Information
 - Policies, procedures, and systems shall be developed to monitor and reduce security concerns. Examples of security issues include theft of personal or commercial items, abduction, and assaults of individuals in and outside the facilities.
 - **Security risks include locations in which hazardous materials are located. Examples of such locations include, but are not limited to, boiler and fuel fired heater rooms, electrical rooms, clean and dirty storage rooms.**

Chapter 3: 03.04.02

- 03.04.02 Fire drills – quarterly
 - Fire drills shall be conducted at least quarterly on all shifts in all buildings classified as healthcare occupancy or ambulatory healthcare occupancy.
 - For buildings classified as business occupancy (or other occupancies), fire drills are conducted annually on all shifts.
 - **The transmission of a fire alarm signal shall be tested quarterly during fire drills from the alarm panel in the protected premise, to the emergency response force.**
 - All fire drills are documented.

Chapter 3: 03.04.02

- 03.04.02 Fire drills – quarterly
 - Required Elements / Additional Information
 - The fire plan is practiced without prior warning to the occupants of the building(s). Observers document actual reactions to the enactment.
 - Fire drill expectations include:
 - Simulation of emergency fire conditions.
 - A coded announcement is permitted between 9:00 pm and 6:00 am in lieu of activating the audible notification devices on the fire alarm system, but the fire alarm system still needs to be activated for each drill.
 - Actual patients are not required to be moved during drills.
 - Evacuation of simulated patients to the nearest smoke compartment barrier door.
 - Non-customary shifts such as 12-hour shifts and weekend staffing patterns.
 - Staff participation in the drills inasmuch as the CAH's fire response plan requires their response to fire alarms.
 - **Quarterly, the transmission of the fire alarm signal and simulation of fire conditions must be tested during fire drills per NFPA 101 Life Safety Code (2012 edition), 18/19.7.1.4.**
 - **For Fire alarm systems – transmitting signal, see standard 14.02.03.**

Chapter 3: 03.04.02

- 03.04.02 Fire drills – quarterly
 - Scoring Procedure
 - Participation is based upon staff's role in accordance with the Fire Control Plan, which may be at the point of alarm and away from the point of alarm.
 - Review logs to ensure each healthcare occupancy and each ambulatory healthcare occupancy had one drill per shift per quarter.
 - Review logs to ensure off-site business occupancies have had annual fire drills on each shift.
 - **Review CAH fire drill records to determine whether the fire alarm system signal is transmitted quarterly from the fire alarm panel to the emergency response force when fire drills are conducted. Note: A deficiency in transmitting the signal during a fire drill is cited at 14.02.03.**

Chapter 3: 03.06.03

- 03.06.03 Water management plan (NEW STANDARD)
 - **Monitoring of water quality and temperatures are identified as control points in the water management program.**
 - **Potable water is tested annually and treated as necessary.**
 - **The hospital takes precautions to monitor the temperature of water.**
- Required Elements / Additional Information
 - **Reports for water testing quality monitoring will be reported to the water management team and safety committee.**
 - **The facility leader will attend the scheduled water management team meetings with reports for water testing and monitoring.**
 - **For specific water management program compliance activities, refer to Infection Prevention and Control standard 18.02.06.**
 - **Precautions are taken to assure compliance with state and local standards related to domestic hot water temperature to protect patients against scalding or burning.**

Chapter 3: 03.06.03

- 03.06.03 Water management plan (NEW STANDARD)
 - Scoring Procedure
 - **Verify water reports and annual testing are submitted to the water management team and Safety Committee.**
 - **Interview maintenance director to verify support for water management plan, that domestic hot water temperature is maintained based on state and local standards and talk with risk manager to assess any incidents or patient safety incident-related reports.**

Chapter 3: 03.06.07 & 03.06.12

- ~~03.06.07 Potable water~~
- ~~03.06.12 Water temperature control~~

- Requirements moved to 11.06.03 Water management plan

Chapter 4 Organizational Structure



Chapter 4: 04.01.02

04.01.02 Oversight of Patient Care Supplies – New Standard

The governing body is responsible for ensuring adequate patient care supplies are available to support services offered to patients. Supplies are not outdated or contaminated.

Policies and procedures are in place for an effective product recall system that includes the following:

1. Receipt and distribution of recall notices.
2. Identification of product availability within the CAH.
3. Notification of recalls to appropriate departments/staff.
4. Verification of recall of all available products.

Required Elements

A recall log is maintained to verify all elements of the process are completed.

The supplies are of the sizes and quantities needed to accommodate patient care.

Chapter 4: 04.01.02

04.01.02 Oversight of Patient Care Supplies – New Standard

Scoring

- Verify:
 - A policy covers each standard requirement.
 - The policy has been implemented.
 - Staff are aware of the process for notification and recall of products.
 - A recall log is maintained
 - Non-expired supplies are available throughout the CAH.

Chapter 5 Staffing



Chapter 5: 05.02.01

05.02.01 Rapid Response Team – Revised

Required Elements

Clinical deterioration is the physiological decompensation that occurs when a patient experiences worsening conditions or an acute onset of a serious physiological disturbance.

Early response to clinical deterioration may reduce cardiopulmonary arrests and patient mortality.

The organization has a policy and procedure that addresses:

1. Identification of and response to clinical deterioration.
2. Written criteria for assessment(s) and when to seek additional assistance, e.g., activation of a Rapid Response System
3. Documentation requirements for vital signs, treatments, medications, and patient response to treatments addressing clinical deterioration.
4. Coordination of care if assessment identifies the need to transfer the patient to another level of care.

Chapter 5: 05.02.01

05.02.01 Rapid Response Team – Revised

Scoring

- Written policies and procedures are approved by the medical staff.
- The policy describes the required assessments and identifies all required elements.
- Medical records meet documentation requirements.
- Procedures clearly indicate communication method for and documentation of response to patient deterioration.

Chapter 06 Provision of Services



Chapter 6: Updates

- 06.01.27 Medication Reconciliation
- 06.03.09 **New Standard-** Lighting, Ventilation, and Temperature Control
- 06.08.08 Identifying Patients Correctly
- 06.10.01 Notification of Rights

Chapter 06.01: 06.01.27

06.01.27 Medication Reconciliation-Revised

Required Elements

Removed 3rd paragraph of current required elements. No other revisions.

Chapter 06.03: 06.03.09

06.03.09 Lighting, Ventilation, and Temperature Control-New Standard

Standard

1. Food products are stored under appropriate conditions (e.g., time, temperature, packaging, location), consistent with nationally accepted guidelines (i.e., Food and Drug Administration (FDA), United States Department of Agriculture (USDA), Hazard Analysis and Critical Control Point (HACCP), etc.).
2. The air supply should flow from clean (food preparation) to dirty (cleanup/ garbage).
3. Daily temperatures are consistent with USDA guidelines and recorded for refrigerator and freezer units.
4. Hot foods are maintained at appropriate temperatures.
5. If dish machines are used, dish machine temperatures are recorded for each cycle.
6. Food preparation areas have adequate lighting.
7. Ceiling light bulbs are shielded.

Chapter 06.03: 06.03.09

06.03.09 Lighting, Ventilation, and Temperature Control-New Standard

Required Elements

VENTILATION HOOD SYSTEMS AND FILTERS

- Processes are in place to ensure proper ventilation throughout the food preparation area. Usually, the hospital maintenance department provides oversight for these processes.
- Ventilation of sufficient capacity is provided to keep the area free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes.
- Ventilation hood systems or other grease extracting equipment shall be designed to prevent grease or condensation from dripping onto food, equipment, and utensils. Ventilation hoods should be readily removable for cleaning and replacement if not designed to be cleaned in place.
- Intake and exhaust air ducts shall be cleaned, and filters changed so they are not a source of contamination by dust, dirt, and other materials.
- The air supply flows from clean to dirty areas of the kitchen.
- Dust is not permitted to accumulate around the ventilation grilles.

Chapter 06.03: 06.03.09

06.03.09 Lighting, Ventilation, and Temperature Control-New Standard

Required Elements (Cont.)

FOOD TEMPERATURE DANGER ZONE

The food temperature danger zone is between 41° F and 135° F. To avoid bacterial growth:

- Store cold foods at 40° Fahrenheit (5° Celsius) or less.
- Hot foods should be held and stored at 135° Fahrenheit (60° Celsius) or greater

MAINTAIN PROPER REFRIGERATOR/FREEZER TEMPERATURES

1. There are daily records of food refrigerator and freezer temperatures. Such records are to be maintained for all patient food regardless of the location of the equipment or the department/service distributing the product.
2. The log provides space to document the date, time, and person recording the temperature. The desired refrigerator/freezer temperature is indicated on the log.
3. The internal temperature for refrigerators/freezers are checked and recorded consistent with State and public health rules and regulations, but at least daily.

Chapter 06.03: 06.03.09

06.03.09 Lighting, Ventilation, and Temperature Control-New Standard

Required Elements (Cont.)

4. A process is in place for adjusting refrigerators in a timely manner when the temperature is out of range. The temperature is rechecked following adjustments.
5. If food is above 45°, discard it. If frozen food has thawed, do not refreeze.

REFRIGERATOR TEMPERATURES

Refrigerator temperatures should be maintained:

- Between 32° – 40° Fahrenheit (0° to 5° Celsius) for all refrigerated goods.
- For fresh meat, poultry, and seafood: 30° – 34° Fahrenheit (minus 1° to 1° Celsius).

FREEZER TEMPERATURES

Freezer temperatures should be maintained:

- Between minus 10° to minus 0.4° Fahrenheit (minus 23° to minus 18° Celsius) for dairy, ice cream, frozen vegetables, meat, poultry and seafood.
- For ice cream in scooping cabinets: Between minus 0.4° to 10° Fahrenheit (minus 18° to minus 12° Celsius).

Chapter 06.03: 06.03.09

06.03.09 Lighting, Ventilation, and Temperature Control-New Standard

Required Elements (Cont.)

Dishwashing Machines

Records are kept of the dishwasher temperatures.

Setting the right temperature for your commercial dishwasher is critical to ensure cookware, dishes and utensils are properly sanitized to prevent foodborne illnesses.

Temperatures:

- Dishwasher temperatures are maintained per manufacturer's guidelines and in accordance with nationally recognized standards of practice (e.g., ANSI, FDA) for both:
 - High temperature settings with hot water sanitation
 - Low temperature setting with chemical sanitation
 - Hospitals are in compliance with any federal, state, and local regulations.

Chapter 06.03: 06.03.09

06.03.09 Lighting, Ventilation, and Temperature Control-New Standard

LIGHTING

There is sufficient lighting in the food handling area to ensure safety.

LIGHT BULBS

- The Food and Drug Administration (FDA) requires ceiling light bulbs to be shielded, coated, or otherwise shatter-resistant in areas where there is food, clean equipment, and utensils.
- Shielding of light bulbs is not required in areas that are used only for storing food in unopened packages if:
 - The integrity of the packages cannot be affected by broken glass falling onto them.
 - The packages are capable of being cleaned of debris from broken bulbs before the packages are opened.

Chapter 06.03: 06.03.09

06.03.09 Lighting, Ventilation, and Temperature Control-New Standard

Scoring

- Request dishwasher temperature guidelines.
- Verify that Food Service policies and employee orientation both cover the listed issues.
- During the kitchen walk through, observe for adherence to these principles. Observe the receiving, food preparation, cooking, cooling, and reheating flow of food, if possible.

Chapter 06.03: 06.03.09

06.03.09 Lighting, Ventilation, and Temperature Control-New Standard

- Verify:
 - Proper ventilation and air flow is provided throughout the food service area. Ventilation hoods and filters are clean and free of dust and grease.
 - Refrigerator and freezer temperatures are maintained according to guidelines. Daily records are in place.
 - Dishwasher temperatures are maintained per guidelines. Temperature recordings are in place for the wash and rinse cycles. Dishes, glassware, and utensils are free of water spots.
 - Federal, state, and local regulations are followed.
 - Interview nutritional services personnel about proper dishwashing temperatures.
 - Interview food services personnel about proper dishwashing temperatures.
 - There is adequate lighting in the food preparation area. Ceiling light bulbs are shielded.

Chapter 06.08: 06.08.08

06.08.08 Identifying Patients Correctly-Revised

Standard

The CAH has a written patient safety policy that requires at least two methods for patient identification prior to medication administration, testing, treatment, and procedures.

Chapter 06.10: 06.10.01

06.10.01 Notification of Rights-Revised

Standard:

CFR added §489.20(q)

Required Elements:

EMERGENCY DEPARTMENT PATIENT RIGHTS

Emergency department patient rights must be posted in a conspicuous place(s) likely to be noticed by all individuals seeking care.

Section 1866(a)(1)(N)(iii) of the Social Security Act requires the posting of signs which specify the rights of individuals with Emergency Medical Conditions (EMCs) and women in labor.

Suspicion of EMTALA violations would be reported to the appropriate agency within the Centers for Medicare and Medicaid Services.

Scoring:

Are the emergency department patient rights posted in a conspicuous place?

Chapter 7 Medical Records



Chapter 7 Updates

- 07.01.04 Electronic Patient Event Notifications

Chapter 7: 07.01.04

07.01.04 Electronic Patient Event Notifications-Revised

CFR References

§485.638(d)

§485.638(d)(1-5)

Chapter 8 Surgical Services



Chapter 8: Updates

- 08.00.05 Pre-operative history and physical
- 08.00.10 Required equipment in the operating suite
- 08.03.05 Anesthesia policies
- 08.03.07 Monitoring the physical environment

Chapter 8: 08.00.05

08.00.05 Pre-Operative History and Physical-Revised

Scoring

- Review a sample of medical records of surgical patients to verify that a complete history and physical examination is completed and authenticated by a surgeon prior to surgery, except in an emergency, and in accordance with the methodology described.

Chapter 8: 08.00.10

08.00.10 Required Equipment in the Operating Room Suite-Revised

Standard

The Surgical Services maintains an adequate inventory of instrumentation, supplies, and equipment. *The following equipment must be available to the operating room suites.*

- Call-in system (intercom or equivalent)
- Cardiac monitor
- Resuscitator (ventilator)
- Defibrillator
- Aspirator (suction equipment/vacuum)
- Tracheotomy set

Chapter 8: 08.00.10

08.00.10 Required Equipment in the Operating Room Suite-Revised

Required Elements

Systems and processes shall be in working order and available for emergency communication and for patient care crises. The availability of oxygen is essential. The use of pulse oximetry and immediate availability of blood gas analysis should be considered as "standard."

Note: A cricothyroidotomy set is not a substitute for a tracheotomy set.

The term "resuscitator" refers to a hand-held bag type of device; a mechanical ventilator is not required.

Age-specific resuscitation equipment is required to meet the emergency needs of the patient. If the facility treats neonatal/pediatric patients, neonatal/pediatric sized resuscitation equipment is immediately available.

Chapter 8: 08.00.10

08.00.10 Required Equipment in the Operating Room Suite-Revised

Required Elements (cont.)

The organization has a policy that defines:

- Supplies and equipment required for emergencies
- The process and frequency of checking for outdated supplies in carts
- How all types of emergency carts are managed after use and during transport to be restocked to ensure security of supplies and medications. Emergency carts may include, but are not limited to:
 - Resuscitation Carts
 - Medication Carts
 - Anesthesia Carts
 - OB Hemorrhage Carts
 - Malignant Hyperthermia Carts
- Individuals authorized to transport carts
- Secure locations in which carts may be stored prior to use by floors/departments
- Frequency of cart lock check
- Management of carts when a unit is closed. Carts must be stored in a secure location.

Chapter 8: 08.00.10

08.00.10 Required Equipment in the Operating Room Suite-Revised

Scoring

- All required systems in surgical and invasive procedure rooms are working.
- All required equipment is readily available with adequate inventory for patient care.
- Age-specific resuscitation equipment is readily available. If the facility treats neonatal/pediatric patients, ensure neonatal/pediatric size endotracheal tubes/tracheostomy set are immediately available.

Chapter 8: 08.03.05

08.03.05 Anesthesia Policies-Revised

Required Elements

Patient care policies are reviewed every two years.

The medical record must contain documentation of the patient consent for anesthesia. This may be accomplished through a separate written informed consent for the administration of anesthesia or may be integrated into the surgical informed consent given that the practitioner responsible for the administration of anesthesia has participated in the informed consent process and discussion of the planned anesthesia care.

Hospital policy defines the categories of practitioners that are able to obtain informed consent for the delivery of anesthesia. Informed consent requires a discussion of the risks, benefits, and alternatives to anesthesia. Therefore, it is critical that an individual acting within their scope of practice participate in the discussion with the patient and/or representative regarding the anesthesia plan of care, risks, benefits, and alternatives.

Scoring

Policies have received approval in the past two years

Chapter 8: 08.03.07

08.03.07 Monitoring the Physical Environment-Revised

Required Elements

Medication Carts

Due to their mobility, mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing drugs or biologicals (hereafter, all referred to as “carts”) must be locked in a secure area when not in use. Hospital policies and procedures are expected to address the security and monitoring of carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety.

Chapter 11 Swing Beds



Chapter 11: Updates

- 11.02.04 Transfer and Discharge: Facility Requirements

Chapter 11: 11.02.04

11.02.04 Transfer and Discharge: Facility Requirements-Revised

Required Elements

- Transfer and discharge documentation may be completed by a physician extender unless prohibited by state law or facility policy.

Scoring

- Review medical records of patients who were transferred to confirm that the reason for transfer was documented by a physician or physician extender.

Chapter 14 Life Safety



Chapter 14: Updates

- 14.00.05 Facility Demographic Report (FDR)
- 14.02.03 Fire alarm system – transmitting signal
- 14.03.05 Fire pumps: Annual test

Chapter 14: 14.00.05

- 14.00.05 Facility Demographic Report (FDR)
 - Required Elements / Additional Information
 - ACHC does not set qualifications for the designated individual; however, since the FDR is technical in manner, a person with technical knowledge must be designated.
 - The CAH must complete the ACHC Facility Demographic Report on at least an annual basis, or more often as needed, **for example, when construction or renovations are completed for areas more than 50% of a smoke compartment or 4500 square feet.** An FDR must be completed for each facility identified as a healthcare occupancy or as an ambulatory healthcare occupancy and maintain the accuracy of the information.
 - Business occupancies do not require an FDR.
 - Scoring Procedure
 - **Has the FDR been updated because of renovations or construction?**

Chapter 14: 14.02.03

- 14.02.03 Fire alarm system – transmitting signal
 - The fire alarm system shall transmit an appropriate signal to an offsite monitoring station, or directly to the emergency response force.
 - This signal shall be tested annually from the alarm panel in the protected premise, to the emergency response force.
 - **The transmission of a fire alarm signal shall be tested quarterly during fire drills from the alarm panel in the protected premise, to the emergency response force.**
 - All results of the tests are documented.

Chapter 14: 14.02.03

- 14.02.03 Fire alarm system – transmitting signal
 - Required Elements / Additional Information
 - This standard does not require the fire alarm system to transmit all three signals, but when the fire alarm system activates an alarm signal, supervisory signal, or a trouble signal, it must be transmitted to an approved location, such as an Auxiliary Fire Alarm System, a Central Station, a Proprietary System, or a Remote Supervising Station.
 - Manual reporting systems and methods are not permitted.
 - Annually, the off-premises monitoring transmission equipment must be tested to ensure the local fire-responding agency received an alarm signal, even if the transmission of that signal is through a third-party entity.
 - **Quarterly, the transmission of the fire alarm signal and simulation of fire conditions must be tested during fire drills per NFPA 101 Life Safety Code (2012 edition), 18/19.7.1.4.**
 - NFPA 72 (2010 edition) Table 14.4.2.2 (18) (a) through (e) and Table 14.4.5 (22) describes in detail the methods and procedures to follow for each type of system.

Chapter 14: 14.02.03

- 14.02.03 Fire alarm system – transmitting signal
 - Survey Procedure
 - Review CAH records to determine whether the fire alarm system signal is transmitted annually from the fire alarm panel to the emergency response force.
 - **Review CAH fire drill records to determine whether the fire alarm system signal is transmitted quarterly from the fire alarm panel to the emergency response force when fire drills are conducted.**

Chapter 14: 14.03.05

- 14.03.05 Fire pumps: Annual test
 - Required Elements / Additional Information
 - A CAH is not required to have a fire pump installed, but if present, the fire pump must be tested according to the standard.
 - An annual water-flow test is required for all fire pumps, which consists of:
 1. A churn test.
 2. The pump operated at design flow (100% nameplate capacity).
 3. The pump operated at peak flow (150% nameplate capacity).
Note: If available suction supplies do not allow flowing of 150 percent of the rated pump capacity, the fire pump shall be permitted to operate at maximum allowable discharge.
 4. During peak flow, a power failure is simulated on electric motor-driven pumps equipped with automatic transfer switches to ensure emergency power supply is connected, and confirmation of peak flow continues.
 5. After peak flow has been confirmed and documented, normal power is restored to ensure circuit protection devices have not opened.
 - Additional readings and measurements are required during this annual flow test.
 - If peak flow is not attainable due to limitations in water supply, that shall not constitute an unsuccessful test.

Chapter 16 Restraints



Chapter 16: Updates

Chapter Restructured, Renumbered, & Retitled Standards

- 16.00.00 Restraints and seclusion
- 16.00.05 Least restrictive interventions
- 16.00.07 Restraint or Seclusion: Modification of the Plan of Care
- 16.00.08 Orders for Restraint or Seclusions
- 16.00.09 Use of Standing or PRN orders
- 16.00.10 Physician Notification of Restraint and Seclusion Use
- 16.00.11 Non-violent Restraint: Renewal Orders
- 16.00.14 Violent Restraint and/or Seclusion: One-hour Face-to Face Assessment
- 16.00.15 Violent Restraint and/or Seclusion: One-hour Face-to-Face Components
- 16.00.17 Monitoring of the Patient
- 16.00.18 Discontinuation of Restraints
- 16.00.22 Training Intervals
- 16.00.23 Training content
- 16.00.28 Training requirements: patient monitoring
- 16.00.29 Training requirements: CPR training
- 16.00.30 Trainer Requirements
- 16.00.32 Death Related to Restraint or Seclusion: Reporting Requirements

Chapter 16: 16.00.00

16.00.00 Restraint and Seclusion-Revised

Required Elements

The intent of this standard is to eliminate the inappropriate use of restraint or seclusion.

The safety of the patient, staff, or others is the basis for initiating and discontinuing the use of restraint or seclusion.

The use of restraint is inherently risky.

The use of restraints for management of patient behavior should not be considered a routine part of care.

For example...

A history of falling without a current clinical basis for a restraint intervention is inadequate to demonstrate the need for restraint.

Scoring

- Verify the facility has an accurate process to track patients in restraints and/or seclusion.
- Does the number of patients who are restrained or secluded increase on weekends, on holidays, at night, on certain shifts; where contract nurses are used; in one unit more than other units? Such patterns of restraint or seclusion use may suggest that the intervention is not based on the patient's need, but on issues such as convenience, inadequate staffing or lack of staff training. Obtain nursing staffing schedules during time periods in question to determine if staffing levels impact the use of restraint or seclusion.

Chapter 16: 16.00.05

16.00.05 Least Restrictive Interventions-Revised

Standard Consolidated into one Standard 16.00.05 Least Restrictive Interventions

16.00.06 Effective restraints

16.00.24 Requirements for documentation

16.00.25 Requirements for documentation

16.00.26 Requirements for documentation

16.00.27 Requirements for documentation

Chapter 16: 16.00.05

16.00.05 Least Restrictive Interventions-Revised

Standard

Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.

The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:

- A description of the patient's behavior and the intervention used.
- Alternatives or other less restrictive interventions attempted (as applicable).
- The patient's condition or symptom(s) that warranted the use of the restraint or seclusion.
- The patient's response to the interventions(s) used, including the rationale for continued use of the intervention.

§482.13(e)(2-3)

§482.13(e)(16)(ii-v)

Chapter 16: 16.00.05

16.00.05 Least Restrictive Interventions-Revised

Required Elements

The patient's behavior should be documented in descriptive terms to evaluate the appropriateness of the interventions used.

The documentation should include a detailed description of the patient's physical and mental status assessments, and of any environmental factors (e.g., physical, milieu, activities, etc.) that may have contributed to the situation at the time of the intervention.

The use of restraint or seclusion must be selected only when less restrictive measures have been judged to be ineffective to protect the patient or others from harm.

It is not always appropriate for less restrictive alternatives to be attempted prior to the use of restraint or seclusion.

When a patient's behavior presents an immediate and serious danger to him- or herself, or others, immediate action is needed.

- For example, when a patient physically attacks someone, immediate action is needed.

While staff should be mindful of using the least intrusive intervention, it is critical that the intervention selected be effective in protecting the patient or others from harm.

A comprehensive, individualized patient assessment is necessary to identify the most appropriate intervention to effectively manage a patient's condition or symptom(s).

When using a restraint or seclusion intervention, the patient's condition or symptom(s) must be identified and documented in the patient's medical record.

Chapter 16: 16.00.05

16.00.05 Least Restrictive Interventions-Revised

Scoring

- Is there clear documentation in the patient's medical record describing the steps or interventions used prior to the use of the needed restraint or seclusion? That is, what documentation is in the medical record to explain the rationale for the use of restraint or seclusion?
- If the time of restraint or seclusion use is lengthy, look for evidence that the symptoms necessitating the use of restraint or seclusion have persisted.
- Is there evidence to indicate that the staff have evaluated whether or not the restraint or seclusion can be safely discontinued?
- Does the patient's medical record include a clear description of the patient's behavior that warranted the use of restraint or seclusion?
- Was the intervention employed appropriate for the identified behavior?
- What was the effect of less restrictive interventions, if attempted by staff?
- Does the patient's medical record include descriptions of the impact of the intervention on the patient behavior that resulted in the use of restraint or seclusion?
- Does the patient's medical record include a detailed assessment of the patient's response to the intervention and a well-reasoned plan for the continued use of restraint or seclusion?

Chapter 16: 16.00.07

16.00.07 Restraint or Seclusion: Modification of the Plan of Care-Revised

Required Elements

An order for restraint or seclusion must result in a modification of the individualized plan of care.

Scoring

- Does the plan of care or treatment reflect a process of assessment, intervention, and evaluation when restraint or seclusion is used? Is there evidence of assessment of the identified problem or of an individual patient assessment?
- Has the plan of care been modified to reflect the use of restraint or seclusion based on the patient assessment?
- Has the plan of care been reviewed and updated according to hospital policy?

Chapter 16: 16.00.08

16.00.08 Orders for Restraint or Seclusions-Revised

Required Elements

Removed first and last paragraph of current required elements. No other revisions

Scoring

Do physician's or other LIP's orders specify the reason for restraint or seclusion, the type of restraint, and the duration of restraint or seclusion?

Chapter 16: 16.00.09

16.00.09 Use of Standing or PRN orders-Revised

Required Elements

- Removed first sentence of 3rd paragraph of current required elements. No other revisions.

Scoring

- Ensure there are no restraint orders written on a PRN or as standing orders.

Chapter 16: 16.00.10

16.00.10 Physician Notification of Restraint and Seclusion Use-Revised

Required Elements

This provision does not specify that consultation with the attending physician be face-to-face. The consultation can occur via telephone.

Scoring

- Review a random sample of medical records for patients who have been restrained or secluded.
- Review the patient's medical record for documentation that the attending physician was notified immediately if the attending physician did not order the restraint or seclusion.

Chapter 16: 16.00.11

16.00.11 Non-violent Restraint: Renewal Orders-Revised

Required Elements Revised

When the physician or LIP renews an order or writes a new order authorizing the continued use of restraint or seclusion, there must be documentation in the medical record that describes the patient's clinical needs and supports the continued use of restraint or seclusion.

While hospitals have the flexibility to determine time frames for the renewal of orders for restraint of the non-violent, non-self-destructive patient, renewal order timeframes should support an ongoing evaluation of the need for continued use of restraints. It is recommended that renewal orders are obtained each calendar day.

Scoring

- Does CAH policy align with medical record documentation of restraint duration orders?

Chapter 16: 16.00.12

16.00.12 Violent restraint and/or seclusion: Time limited renewal orders- Revised

Scoring

- Review a random sample of medical records for patients who have been restrained or secluded.

Chapter 16: 16.00.14

16.00.14 Violent Restraint and/or Seclusion: One-hour Face-to Face Assessment-Revised

Standards 16.00.18, 16.00.20, and 16.00.23 consolidated into 16.00.14

Standard

When restraint or seclusion is used, there must be documentation in the patient's medical record of the one-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior.

§482.13 (e)(16)(i)

Chapter 16: 16.00.14

16.00.14 Violent Restraint and/or Seclusion: One-hour Face-to Face Assessment-Revised

Standard (cont.)

When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention --

- i. By a
 - A. Physician or other licensed independent practitioner; or
 - B. Registered nurse or physician assistant who has been trained in accordance with the requirements specified in 42 CFR 482.13(f).

§482.13(e)(12) §482.13(e)(12)(i)(A-B)

States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of 42 CFR 482.13. §482.13(e)(12)

Required Elements

States are free to have requirements that are more restrictive regarding the types of practitioners who may conduct the one-hour face-to-face evaluation.

Generally, states may have more restrictive requirements if they do not conflict with federal requirements.

Chapter 16: 16.00.14

16.00.14 Violent Restraint and/or Seclusion: One-hour Face-to Face Assessment-Revised

Scoring

Review clinical records of patients who recently required restraint or seclusion to verify:

- The patient's medical record includes documentation of the 1 hour face-to-face medical and behavioral evaluation when restraint or seclusion is used to manage violent or self-destructive behavior?
- Review CAH policy regarding the one-hour face-to-face evaluation.
 - Does the policy identify categories of practitioners authorized to conduct the one-hour face-to-face evaluation?
- Interview staff to verify that practice is consistent with hospital policy.
- Prior to the survey, determine whether there are state provisions governing the use of restraint or seclusion that are more restrictive than those found in this section. When state requirements are more restrictive, apply those requirements instead of those found in this chapter.

Chapter 16: 16.00.15

16.00.15 Violent Restraint and/or Seclusion: One-hour Face-to-Face Components-Revised

Standard

When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen...

Required Elements

Training for an RN or PA to conduct the one-hour face-to-face evaluation would include competency to assess items A-D of this standard and all of the training requirements in standards 16.00.22-29 [§482.13(f)].

Chapter 16: 16.00.17

16.00.17 Monitoring of the Patient-Revised

Required Elements

Policies

CAH policies are expected to guide staff in determining the type of restraint or seclusion used and appropriate intervals for assessment and monitoring based on the individual needs of the patient.

Taking into consideration variables such as the patient's condition, cognitive status, risks associated with the use of the chosen intervention, and other relevant factors.

CAH policies should address:

1. Frequencies of monitoring and assessment as appropriate for patient condition. ACHC recommends that patients with violent or self-destructive behavior are monitored at least every 15 minutes, although patient condition may warrant continuous monitoring. The recommendation for non-violent patients in restraints is monitoring at least every two hours.

Chapter 16: 16.00.18

16.00.18 Discontinuation of Restraints-Revised

Required Elements

3rd paragraph of current required elements deleted as redundant with 16.00.05

Chapter 16: 16.00.22

16.00.22 Training Intervals-Revised

Required Elements

Removed 2nd and 3rd paragraph of current required elements. Content relocated to 16.00.23.

Chapter 16: 16.00.23

16.00.23 Training Content-Revised

Required Elements

Training for an RN to conduct the one-hour face-to-face evaluation would include all the training requirements in standards 15.02.29-.39 (§482.13(f)) as well as content addressing:

- evaluation of the patient's immediate situation.
- the patient's reaction to the intervention.
- the patient's medical and behavioral condition.
- the need to continue or terminate the restraint or seclusion.

An evaluation of the patient's medical condition would include:

- complete review of systems assessment.
- behavioral assessment.
- review and assessment of the patient's history, medications, most recent lab results, etc.

Chapter 16: Redundancy Removed

Standard **16.00.24** Training requirements: Nonphysical interventions

Standard **16.00.28** Training requirements: patient monitoring

Standard **16.00.29** Training requirements: CPR training

Standard **16.00.30** Trainer Requirements

Required Elements

Information deleted as redundant with the standard. No additional Information.

Chapter 16: 16.00.32

16.00.32 Death Related to Restraint or Seclusion: Reporting Requirements- Revised

Required Elements

After reviewing the submitted information, the CMS location (Regional Office) will determine whether an on-site investigation of the circumstances surrounding the patient's death is warranted and will may direct the State Survey Agency to conduct a survey if applicable.

CAH RESTRAINT DEATH LOG

The two-point soft wrist restraint death report must be entered into the internal log or tracking system within seven days of the patient's death.

Refer to CMS electronic form "CMS-10455"

Chapter 17

Emergency Management

Chapter 17: Updates

- 17.00.01 – Condition of Participation: Emergency Preparedness
- 17.00.02 – Hazard Vulnerability Analysis
- 17.00.03 – Emergency Operations Plan
- 17.00.05 – Services
- 17.00.06 – Continuity of Operations
- 17.01.01 – Policies & Procedures
- 17.01.03 – Supplies
- 17.01.04 – Utilities
- 17.01.06 – Evacuation
- 17.02.02 – Contact information
- 17.02.06 – CAH Information
- 17.03.01 – Emergency Training
- 17.03.02 – Emergency Exercises

Chapter 17: 17.00.01

- 17.00.01 – Condition of Participation: Emergency Preparedness
 - Required Elements / Additional Information
 - **The term “comprehensive” in this requirement is to ensure that facilities do not choose only one potential emergency that may occur in their area, but rather demonstrate that they have considered multiple events during development of the program.**
 - **As emerging infectious disease outbreaks may affect any facility in any location across the country, a comprehensive Emergency Preparedness Program should include emerging infectious diseases and pandemics during a public health emergency (PHE).**
 - **The program’s plan for emerging infectious disease should encompass how facilities will plan, coordinate, and respond to a localized and widespread pandemic, similar to the 2019 Novel Coronavirus (COVID-19) PHE. Facilities should ensure their Emergency Preparedness Programs are aligned with their state and local emergency plans/pandemic plans.**

Chapter 17: 17.00.02

- 17.00.02 – Hazard Vulnerability Analysis
 - **The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every two years. The plan must:**
 - **Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.**
 - The CAH conducts a risk assessment (i.e., Hazard Vulnerability Analysis) to ascertain conceivable threats and disasters that could affect the ability to operate the facilities of the organization, or to provide services to their patients, and the probability of those events occurring.
 - The CAH's Hazard Vulnerability Analysis (HVA) must be shared with the community's emergency response agencies. The CAH must identify likely hazards for their community service area (e.g., natural disaster, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel, nuclear accidents, industrial accidents, other likely mass casualties, **unforeseen widespread communicable diseases**, etc.) and develop appropriate responses that will assure that safety and wellbeing of patients.
 - The HVA is documented and reviewed by the oversight committee on emergency management for relevancy and accuracy on a biennial basis.

Chapter 17: 17.00.02

- 17.00.02 – Hazard Vulnerability Analysis
 - Required Elements / Additional Information
 - When meeting the requirements for the all-hazards risk assessment (HVA), CAHs must consider the following:
 1. Identification of all business functions essential to the CAHs' operations that should be considered during an emergency.
 2. Identification of all risks or emergencies that the CAH may reasonably expect to confront.
 3. Identification of all contingencies for which the CAH should plan.
 4. Consideration of the CAH's location, including all locations where the CAH delivers patient care or services, or has business operations.
 5. Assessment of the extent to which natural or man-made emergencies may cause the CAH to cease or limit operations.
 6. Determination of what arrangements with other CAHs, other healthcare providers or suppliers, or other entities might be needed to ensure that essential services could be provided during an emergency.
 - 7. **For public health emergencies, such as emerging infectious diseases (EID) or pandemics: Facilities should consider risk assessments to include the needs of the patient population they serve in relation to a communicable or EID outbreak. Planning should include a process to evaluate the facility's needs based on the specific characteristics of an EID that includes, but is not limited to:**
 - **Increased need for PPE.**
 - **Considerations for screening patients and visitors; which may also include testing considerations for staff, visitors, and patients for infectious diseases.**
 - **Transfers and discharges of patients.**
 - **Home-based healthcare settings.**
 - **Physical environment, including but not limited to changes needed to achieve distancing, isolation, or capacity/surge.**

Chapter 17: 17.00.02

- 17.00.02 – Hazard Vulnerability Analysis
 - **The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every two years. The plan must:**
 - **Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.**
 - The CAH conducts a risk assessment (i.e., Hazard Vulnerability Analysis) to ascertain conceivable threats and disasters that could affect the ability to operate the facilities of the organization, or to provide services to their patients, and the probability of those events occurring.
 - The CAH's Hazard Vulnerability Analysis (HVA) must be shared with the community's emergency response agencies. The CAH must identify likely hazards for their community service area (e.g., natural disaster, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel, nuclear accidents, industrial accidents, other likely mass casualties, **unforeseen widespread communicable diseases**, etc.) and develop appropriate responses that will assure that safety and wellbeing of patients.
 - The HVA is documented and reviewed by the oversight committee on emergency management for relevancy and accuracy on a biennial basis.

Chapter 17: 17.00.03

- 17.00.03 – Emergency Operations Plan
 - A written Emergency Operations Plan (EOP) is developed, maintained, and available to the staff for crisis preparation and response.
 - The Emergency Operations Plan must include **strategies for addressing emergency events identified by the risk assessment.**
 - The EOP is based on the priorities established in the current Hazard Vulnerability Analysis (HVA) to determine the strategies and activities designed to reduce the risk associated with emergency events. The EOP is reviewed with the community's emergency response agencies to synchronize responses to common emergency events.
 - **The CAH develops or makes revisions to its emergency preparedness plan that considers EIDs as potential threats that can impact operations and continuity of care within the healthcare setting.**
 - The EOP is reviewed every two years (biennially) by the emergency management committee to ensure relevancy and accuracy. Adjustments are documented and changes made based on lessons learned during actual emergency events and during planned exercises.

Chapter 17: 17.00.03

- 17.00.03 – Emergency Operations Plan
 - Required Elements / Additional Information
 - **Emerging infectious diseases (EIDs) such as Influenza, Ebola, Zika Virus, COVID-19 or SARS-CoV-2 and others.**
 - **These EIDs may require modifications to facility protocols to protect the health and safety of patients, such as location and personal protective equipment (PPE) measures.**
 - **EMERGING INFECTIOUS DISEASES (EIDs)**
 - **The type of infectious diseases to consider or the care-related emergencies that are a result of infectious diseases are not specified. Adding EIDs within a facility's risk assessment ensures that facilities consider having infection prevention personnel involved in the planning, development, and revisions to the EOP, as these individuals would likely be coordinating activities within the facility during a potential surge of patients.**
 - **Some examples of EIDs may include but are not limited to:**
 - **Potentially infectious bio-hazardous waste.**
 - **Bioterrorism.**
 - **Pandemic influenza.**
 - **Highly communicable diseases (such as Ebola, Zika Virus, SARS, or novel COVID-19 or SARS-CoV-2) EID's may be localized to a certain community or be widespread (as seen with the COVID-19 PHE) and therefore plans for coordination with local, state, and federal officials are essential. Facilities should engage and coordinate with their local healthcare systems and healthcare coalitions, and their state and local health departments when deciding on ways to meet surge needs in their community.**

Chapter 17: 17.00.03

- 17.00.03 – Emergency Operations Plan
 - Required Elements / Additional Information
 - **Surge Planning**
 - **CAHs must have policies and procedures which include emergency staffing strategies and plan for emergencies resulting in a surge of patients. These strategies encompass procedures to preserve the healthcare system while continuing to provide care for all patients at an appropriate level (e.g., home-based care, outpatient, urgent care, emergency room, or hospitalization). Facilities must have policies which address their ability to respond to a surge in patients. As required, these policies and procedures must be aligned with a facility's risk assessment and should include planning for EIDs. Concentrated efforts will be required to mobilize all aspects of the healthcare system to reduce transmission of disease, direct people to the right level of care, and decrease the burden on the healthcare system.**
 - **Surge Planning During Natural Disasters**
 - **In most circumstances, staffing strategies and surge planning for natural disasters are event-specific and focus on evacuations, transfers, and staffing assistance from areas that are not impacted by the emergency.**
 - **Surge Planning for Infectious Diseases/Pandemics**
 - **Infectious diseases may rise to the level of pandemic, causing severe impact to response and staffing strategies within the healthcare system. The primary goals in planning for infectious disease pandemics are to:**
 - **Reduce morbidity and mortality.**
 - **Minimize disease transmission.**
 - **Protect healthcare personnel.**

Chapter 17: 17.00.03

- 17.00.03 – Emergency Operations Plan
 - Required Elements / Additional Information
 - **Preserving CAH/system functioning**
 - **Facilities are encouraged to consider developing policies and procedures that could be implemented during an emergency to reduce non-essential healthcare visits and slow surge within the facility, such as:**
 - **Instructing patients to use available telehealth options, advice lines, patient portals, and/or on-line self-assessment tools.**
 - **Call options to speak to an office/clinic staff member and identification of staff to conduct phone interactions with patients.**
 - **Development of protocols for rapid triage and assessment.**
 - **Algorithms to identify which patients can be managed by telephone and advised to stay home, and which patients will need to be sent for emergency care or come to the facility.**
 - Scoring Procedure – added
 - **The EOP addresses widespread infection control outbreak or pandemic.**

Chapter 17: 17.00.05

- 17.00.05 – Services
 - The Emergency Operations Plan (EOP) must address the type of services the CAH has the ability to provide in an emergency.
 - **The EOP also addresses services needed that cannot be provided by the facility during an emergency as part of continuity of operations and services.**

- Scoring Procedure
 - The EOP identifies the types of services that the CAH has the ability to provide during an emergency.
 - **The EOP addresses plan for services needed that cannot be provided during an emergency?**

Chapter 17: 17.00.06

- 17.00.06 – Continuity of Operations
 - Required Elements / Additional Information
 - **The emergency plan must identify which staff would assume specific roles in another’s absence through succession planning and delegations of authority.**
 - **Succession planning is a process for identifying and developing internal people with the potential to fill key positions in the CAH. Succession planning increases the availability of experienced and capable employees that are prepared to assume these roles as they become available.**
 - **During times of emergency, facilities must have employees who are capable of assuming various critical roles in the event that current staff and leadership are not available.**
 - **At a minimum, there should be a qualified person who “is authorized in writing to act in the absence of the administrator or person legally responsible for the operations of the facility.”**

Chapter 17: 17.00.06

- 17.00.06 – Continuity of Operations
 - Scoring Procedure
 - The EOP provides for the continuity of operations.
 - **The EOP addresses how the CAH plans to continue to provide these services during an emergency.**
 - The EOP addresses the delegation of authority during the emergency event, and the succession of that authority.

Chapter 17: 17.01.01

- 17.01.01 – Policies & Procedures
 - Required Elements / Additional Information
 - **Contracts with vendors and suppliers are to be renewed annually or when vendors/suppliers are changed.**
 - **Real-time electronic tracking systems of current and former staff members are deemed to meet the requirement for semi-annual updates to the call-back roster.**
 - **Facilities should also consider updates to their emergency preparedness policies and procedures during the course of a disaster, including planning for an emergency event with a duration longer than expected (for instance, during public health emergencies such as pandemics, the Centers for Disease Control and Prevention (CDC) and other public health agencies may issue periodic, on-going, event-specific guidance and recommendations to healthcare workers).**
 - **Facilities should ensure their programs have policies in place to update or provide additional emergency preparedness procedures to staff. This may include a policy delegating an individual to monitor guidance by public health agencies and issuing directives and recommendations to staff such as use of PPE when entering the building; isolation of patients under investigation (PUIs); and any other applicable guidance in a public health emergency.**

Chapter 17: 17.01.03

- 17.01.03 – Supplies
 - Required Elements / Additional Information
 - **Anticipate Supply Shortages**
 - **CAH policies identify:**
 - **Actions to take when the organization experiences shortages of medications or supplies.**
 - **Strategies recommended by state and federal health agencies including how to access the national stockpile of medications and supplies.**
 - **Medications and doses used to treat the communicable disease.**
 - **Pharmaceutical sources and suppliers of the medications.**
 - **Suppliers of the emergency equipment and supplies, and when possible, back-up suppliers.**
 - **In advance of a communicable disease outbreak or pandemic, the CAH determines the types and quantities of equipment, supplies, and medications needed for continuity of patient care. While stockpiling is not required, the CAH determines the quantities of supplies needed for a one-month period of time:**
 - **Beds**
 - **Ventilators PPE: Facemasks, gowns, gloves**
 - **Hand sanitizer**
 - **Cleaning supplies**
 - **Paper products, such as toilet paper, paper towels**
 - **Others**

Chapter 17: 17.01.03

- 17.01.03 – Supplies
 - Required Elements / Additional Information
 - **PERPETUAL INVENTORY**
 - **During a widespread communicable disease outbreak or pandemic, a shortage of supplies should be anticipated.**
 - **The CAH has a process to update the Incident Command Center regarding available equipment/supplies, such as:**
 - **beds**
 - **ICU beds**
 - **ventilators**
 - **gloves, facemasks, gowns**
 - **IV infusion pumps**
 - **Quantities of medications used to treat the communicable disease.**
 - **The organization considers an electronic report of the current availability of supplies to post on the facility's intranet. Facilities have flexibility to identify appropriate tools for tracking of inventory, however facilities may consider electronic tracking tools consistent with state recommendations and guidelines.**

Chapter 17: 17.01.03

- 17.01.03 – Supplies
 - Scoring Procedure
 - Medical supplies, pharmaceutical supplies, and general equipment are inventoried and stored for the immediate response of an emergency, as confirmed by interview with the person in charge of emergency management.
 - The organization has reviewed and updated the inventory of emergency response supplies on a semi-annual basis.
 - P&P provide for the supplies and equipment needed in the initial phase of an emergency event.
 - P&P have been reviewed and updated per standard 17.01.01.
 - **The organization has a policy that includes the anticipation of supply shortages and contingencies in the event of a communicable disease outbreak or pandemic.**
 - **Review written agreements with vendors and/or suppliers to verify that they have been updated annually.**
 - **The organization has a process for providing updates to the Incident Command Center regarding availability of equipment/supplies.**

Chapter 17: 17.01.04

- 17.01.04 – Utilities
 - Required Elements / Additional Information
 - At a minimum, the quantity of fuel maintained for the emergency generators **must be calculated to include all these elements per the specifics under NFPA 72, 2010 edition, sections 10.5.6.3 and 10.5.10.6:**
 - **At least a 24-hour supply to maintain the fire alarm system under non-alarm conditions.**
 - **An additional amount of fuel for continuance under alarm operation for five minutes.**
 - **An additional amount for six months of generator testing.**
 - **If used, portable generators are connected to a facility's electrical circuits via a power transfer system, as recommended by the generators' manufacturer. A power transfer system typically consists of a transfer switch, generator power cord and power inlet box in accordance with manufacturer instructions and NFPA 70, Article 400.8. Extension cords or other temporary wiring devices may not be used to connect electrical equipment in the facility to a portable and mobile generator.**

Chapter 17: 17.01.06

- 17.01.06 – Evacuation
 - Required Elements / Additional Information
 - **Patient safety is the priority and any existing guidance on patient rights and safe setting (e.g., §482.13(c)(2) for CAHs) should be continued. Facilities should consider how they would address a situation where a patient/resident refuses to evacuate; leaving a patient in an unsafe environment is not acceptable.**
 - Scoring Procedure
 - The P&P consider multiple transportation options for patient evacuation needs.
 - **Ask how staff would handle a situation in which a patient refused to evacuate.**

Chapter 17: 17.02.02

- 17.02.02 – Contact information
 - Required Elements / Additional Information
 - **Emergency preparedness officials may include, but are not limited to, emergency management agencies which may be local to the community and local officials who support the Incident Command System depending on the nature of the disaster (e.g., fire, police, public health, etc.).**
 - **Additionally, emergency management officials also include state public health departments, federal emergency preparedness officials (FEMA, ASPR, DHS, CMS, etc.), and tribal emergency officials, as applicable.**
 - Scoring Procedure
 - **Staff rosters are current and reflect semi-annual updates.**
 - **Verify that the facility has contact information for the State Survey Agency and/or public health departments.**

Chapter 17: 17.02.06

- 17.02.06 – CAH Information
 - Required Elements / Additional Information
 - **Reporting Facility Needs**
 - **Generally, in small community emergency disasters, reporting the facility's needs will be coordinated through established processes to report directly to local and state emergency officials. Reporting needs may include but are not limited to shortages in PPE; need to evacuate or transfer patients; requests for assistance in transport; temporarily loss of part or all facility function; and staffing shortages.**
 - **In large scale emergency disasters or pandemics, reporting of needs specific to a facility may be altered by local, state, and federal public health and emergency management officials due to the potential volume of requests. Some emergency management officials at all levels of governance may require facilities to report specific data or slow reporting to manage volume.**

Chapter 17: 17.02.06

- 17.02.06 – CAH Information
 - Required Elements / Additional Information
 - **Reporting the Ability to Provide Assistance**
 - **During widespread disasters, reporting a facility's ability to provide assistance is critical within a community. Pre-planning and collaborating with emergency officials before an emergency to determine what assistance may be necessary directly supports surge planning within a community.**
 - **During widespread disasters, facilities may be required to report the following to local officials:**
 - **Ability to care for patients requiring transfer from different healthcare settings.**
 - **Availability of PPE.**
 - **Availability of staff who may be able to assist in a mass casualty incident.**
 - **Availability of electricity-dependent medical and assistive equipment, such as ventilators and other oxygen equipment (BiPAP, CPAP, etc.), renal replacement therapy machines (e.g., home and facility-based hemodialysis, peritoneal dialysis, continuous renal replacement therapy and other machines, etc.), and wheelchairs and beds.**

Chapter 17: 17.03.01

- 17.03.01 – Emergency Training
 - **Required Elements / Additional Information**
 - **The training provided by the facility must be based on the facility’s risk assessment policies and procedures as well as the communication plan. The intent is that new and existing staff, volunteers, and individuals providing services at the facility are familiar and trained on the facility’s processes for responding to an emergency.**
 - **Training should include individual-based response activities in the event of a natural disaster, such as what the process is for staff in the event of a forecasted hurricane. It should also include the policies and procedures on how to shelter-in-place or evacuate.**
 - **Training should include how the facility manages the continuity of care to its patient population, such as triage processes and transfer/discharge during mass casualty or surge events. Furthermore, the facility must train staff based on the facility’s risk assessment.**
 - **Training for staff should mirror the facility’s emergency plan and should include training staff on procedures that are relevant to the hazards identified. For example, for EID’s this may include proper use of PPE, assessing needs of patients and how to screen patients and provide care based on the facility’s capacity and capabilities and communications regarding reporting and providing information on patient status with caregiver and family members.**

Chapter 17: 17.03.01

- 17.03.01 – Emergency Training
 - **Required Elements / Additional Information**
 - **Facilities must also be able to demonstrate additional training when the emergency plan is significantly updated. CAHs that have changed their EOP should plan to conduct initial training to all staff on the new or revised sections of the plan.**
 - **If a facility determines the need to add additional policies and procedures based on a new risk identified in the facility's risk assessment, the facility must train all staff on the new policies and procedures and the staff responsibilities. Facilities are not required to retrain staff on the entire emergency plan but can choose to train staff on the new or revised element of the emergency preparedness program.**
 - **For example, a facility identifies during an influenza outbreak that additional policies and procedures and adjustments to the risk assessment are needed to address a significant influx of patients/clients/residents. The facility identifies clinical locations in which contagious patients can be triaged in a manner to minimize exposure to non-infected individuals.**
 - **The training for this new or revised policy can be done without needing to re-train staff on the entire program.**

Chapter 17: 17.03.02

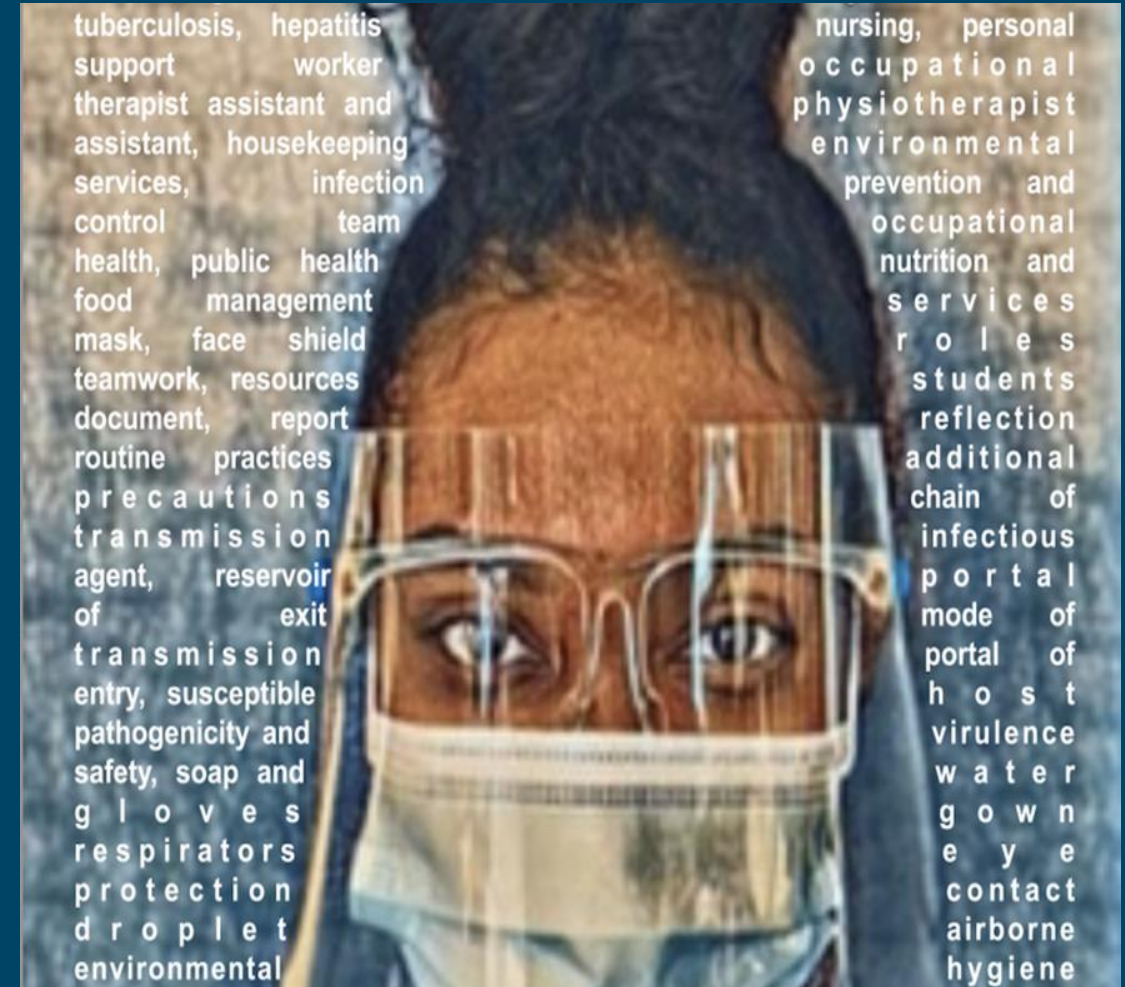
- 17.03.02 – Emergency Exercises
 - **Required Elements / Additional Information**
 - **Participation**
 - **Regulations do not specify a minimum number of staff, or the roles of staff in the exercises, but it is strongly encouraged that facility leadership and department heads participate. If an exercise is conducted at the individual facility-based level and is testing a particular clinical area, staff in this clinical area should participate to develop a clear understanding of their roles and responsibilities.**
 - **Facilities can review which members of staff participated in the previous exercise to ensure participation in the subsequent exercises. A sign-in roster for the exercise is acceptable to substantiate staff participation.**
 - **A sufficient number of staff should participate in the exercise to thoroughly assess the risk, policy, procedure, or plan being tested.**

Chapter 17: 17.03.02

- 17.03.02 – Emergency Exercises
 - Required Elements / Additional Information
 - **EXEMPTION BASED ON ACTUAL EMERGENCY**
 - **An actual emergency event or response of sufficient magnitude to require activation of the relevant emergency plans meets the full-scale exercise requirement and exempts the facility from the next community-based full-scale exercise or individual, facility-based exercise following the actual event.**
 - **Facilities must be able to demonstrate this through written documentation that may include, but is not limited to, an 1135 waiver issued to the facility (time limited and event-specific); documentation alerting staff of the emergency; documentation of facility closures; meeting minutes addressing event-specific information. The facility must also complete an after-action report and integrate corrective actions into their emergency preparedness program.**
 - **Example: If a CAH completed the full-scale exercise in January 2020 and is scheduled to conduct an exercise of choice in November 2020 but experiences an actual emergency in March 2020 which required activation of its emergency plan, the hospital is exempt from the next required full-scale exercise in January 2021 but must complete the exercise of choice.**
 - **If the CAH conducted an exercise of choice prior to the actual emergency and had a full-scale exercise scheduled for November 2020, then the hospital would be exempt from that full-scale exercise.**

Chapter 18

Infection Prevention and Control/ Antibiotic Stewardship



Chapter 18: Updates

- 18.00.00 Condition of Participation
- 18.02.01 Risk Mitigation Measures for Infection Prevention
- 18.02.06 Reduce Risk of Legionella in Water Systems
- 18.02.07 Prevention of Infections: Central Venous Catheters
- 18.02.08 Surgical Site Infections (SSI)
- 18.02.09 Recall Process
- 18.03.03 Employee Health: Vaccinations for Healthcare Workers
- 18.04.01 Decontamination and Sterilization Policies
- 18.04.02 Decontamination of Reusable Items and Reuse of Single Use Items
- 18.04.03 **NEW STANDARD:** High-Level Disinfection/Sterilization and Processing of Endoscopes
- 18.04.05 Sterilization and Decontamination Devices
- 18.05.04 Maintenance of ceilings
- 18.06.01 Soiled linen management
- 18.07.01 Extermination program
- Renumbered Standards

Chapter 18: 18.00.00

18.00.00 Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship-Revised

Required Elements

To prevent, control and investigate infections and communicable diseases, the CAH's program must include an active surveillance component that covers both CAH patients and personnel working in the CAH. Surveillance includes infection detection, data collection and analysis, monitoring, and evaluation of preventive interventions.

The CAH must conduct surveillance on a hospital-wide basis to identify infectious risks or communicable disease problems at any particular location. This does not imply "total hospital surveillance," but it does mean that hospitals must have reliable sampling or other mechanisms in place to permit identifying and monitoring infections and communicable diseases occurring throughout the CAH's various locations or departments. The CAH must document its surveillance activities, including the measures selected for monitoring, and collection and analysis methods. Surveillance activities should be conducted in accordance with recognized infection control surveillance practices, such as, for example, those used by the CDC's National Healthcare Safety Net (NHSN).

The hospital must develop and implement appropriate infection control interventions to address issues identified through its detection activities, and then monitor the effectiveness of interventions through further data collection and analysis.

The infection control program includes processes to reduce the risk of growth and spread of legionella and other opportunistic pathogens in building water systems.

The CAH's infection prevention and control program must be integrated into its Quality Assurance and Performance Improvement (QAPI) program. (See 42 CFR 482.42(b)(1).)

Chapter 18: 18.02.01

18.02.01 Risk Mitigation and Infection Prevention-Revised

Required Elements

MAINTENANCE OF SANITARY ENVIRONMENT

- Techniques for infection control risk mitigation for corrugated cardboard boxes.

HOSPITAL STAFF-RELATED MEASURES

- Risk mitigation measures are implemented to decrease infectious risk associated with corrugated containers to ensure a safe, sanitary environment. Diligence is demonstrated to remove corrugated containers throughout the facility, including from high-risk areas, such as Central Sterile, Procedural Areas, Compounding Pharmacy, specialty patient care units, etc. Receiving, breakdown, and distribution of supplies is an important aspect of sterility. Infection risk assessments should be conducted for specific items which cannot be removed from corrugated boxes which stratifies the risk of potential infection to the loss or damage of product.

Chapter 18: 18.02.06

18.02.06 Reduce Risk of Legionella in Water Systems-Revised

Standard

The infection control plan includes processes to reduce the risk of growth and spread of legionella and other opportunistic pathogens in building water systems including:

- The Infection Control Leader collaborates with a multi-disciplinary team to reduce the risk of growth and spread of legionella and other opportunistic pathogens in the water systems.

§485.640 Tag C-1200

§485.635(a)(3)(vi)

Chapter 18: 18.02.06

18.02.06 Reduce Risk of Legionella in Water Systems-Revised

Required Elements

Outbreaks generally are linked to environmental reservoirs in large or complex water systems, including those found in healthcare facilities such as hospitals and long-term care facilities.

The hospital must implement a water management program that considers the ASHRAE industry standard and the CDC toolkit, and includes control measures such as physical controls, temperature management, disinfectant level control, visual inspections, and environmental testing for pathogens.

The Infection Control Committee (function):

- Verifies the water management plan has been implemented as designed.
- Reviews and approves the hospital risk assessment to identify where legionella and other opportunist waterborne pathogens could grow and spread.
- Reviews and approves the water management program, including actions taken to reduce the growth and spread of legionella and other opportunist water pathogens.
- Validates conditions and outcomes to ensure the water management program is effective. This validation must be completed and documented annually.

Procedures for measuring and monitoring the water system are implemented and testing is conducted based on the hospital risk assessment and in accordance with hospital policy and nationally recognized standards of practice.

Once the water management plan has been implemented, a communication plan is developed and shared with the staff on a routine basis as established by the hospital policy.

Chapter 18: 18.02.06

18.02.06 Reduce Risk of Legionella in Water Systems-Revised

Scoring

- A water management multi-disciplinary team has been identified and roles developed.
- A description of the building water system is available in text and diagram formats.
- A risk assessment has been completed that identifies patient risks, and water sources that are opportunistic to pathogen growth.
- Control points have been identified with measures and monitoring procedures have been implemented.
- Outbreak and contingency plans have been developed and implemented.
- A communication plan is developed and provided to hospital staff as per the hospital policy.
- The infection control plan addresses the water management program.

Chapter 18: 18.02.07

18.02.07 Prevention of Infections: Central Venous Catheters-Revised

Standard

The organization adheres to effective methods of preventing central venous catheter-related blood stream infections.

Organizational policies and procedures reflect evidence-based strategies for infection reduction and processes to monitor compliance and infection rates.

Required Elements

Vascular catheter-related infections are the leading cause of hospital-associated blood stream infections and are associated with significant morbidity in critically ill patients.

Most central venous catheter-related infections are considered preventable. Evidence shows that most central venous catheter-related infections are caused by organisms that colonize the skin at the insertion site and migrate down the extra luminal surface of the catheter through the transcutaneous tract created at the time of insertion.

IMPLEMENTATION APPROACHES

“Before insertion” practices, include:

- Use of aseptic technique during central line insertion.
- Disinfecting skin with an appropriate antiseptic before catheter insertion and at the time of dressing changes—preferably with a 2% chlorhexidine-based preparation; alternatively use tincture of iodine, and iodophor or 70% alcohol in accordance with evidence-based guidelines.

“After insertion” practices include:

- Disinfection of catheter hubs and injection ports before accessing the ports.

Chapter 18: 18.02.07

18.02.07 Prevention of Infections: Central Venous Catheters-Revised

Scoring

- Verify the facility has taken actions to prevent central line-associated bloodstream infection by implementing evidence-based practices.
- Review the policy for central catheter insertion and care. It must:
 - Reflect evidence-based strategies for infection reduction, and
 - Define a process to monitor compliance and infection rates.
- Review patient records to determine compliance with the policy.

Chapter 18: 18.02.08

18.02.08 Surgical Site Infections (SSI)-Revised

Standard

The organization adopts nationally recognized clinical practice guidelines that are identified as effective in improving patient safety through the reduction of surgical site infections.

Required Elements

The organization ensures the evaluation of each preoperative patient in light of his or her planned surgical procedure for the risk of SSI and implements appropriate antibiotic prophylaxis and other preventive measures based on that evaluation.

Organizational policies and procedures are in place regarding the prevention of SSI's, including selection, timing, and discontinuation of antibiotics.

Antibiotic prophylaxis should be given according to nationally recognized guidelines. Feedback to the surgical team and OR staff of surgical infection rates is important for ongoing infection-reduction efforts. Infection trends are monitored, and corrective actions are taken when appropriate.

Chapter 18: 18.02.08

18.02.08 Surgical Site Infections (SSI)-Revised

Scoring

- Verify the facility has taken actions to prevent surgical-site infection by implementing evidence-based practices.
- Review policies on prevention of surgical site infections for content. The policies should, at minimum, address:
 - Evidence-based strategies for infection reduction
 - A defined process to monitor compliance and infection rates.
- Review inpatient and outpatient surgical records to determine if:
- The risk assessment for SSI was completed.
- The appropriate plan of care and intervention was documented as completed.

Chapter 18: 18.02.09

18.02.09 Recall Process-Revised

Standard

There is a process for the recall and disposal or reprocessing of outdated or contaminated patient care supplies/ equipment.

Chapter 18: 18.03.03

18.03.03 Employee Health: Vaccinations for Healthcare Workers-Revised

Standard

Vaccinations will be made available to all healthcare workers in accordance with state and federal law. The vaccination status of all employees will be maintained.

There is a process in place for ensuring all employees are vaccinated as required by hospital policy or have been granted an exemption.

Required Elements

Healthcare workers (HCWs) are at risk for exposure to serious, and sometimes deadly, diseases. HCWs who work directly with patients or handle material that could spread infection, get appropriate vaccines to reduce the chance that they will get or spread vaccine-preventable diseases.

Recommended vaccines for HCWs include:

- Hepatitis B: Serologic evidence of immunity or complete Hep B vaccine series
- Flu (Influenza): One dose annually
- MMR (Measles, Mumps, & Rubella): Serologic evidence of immunity or MMR vaccine
- Varicella (Chickenpox): Serologic evidence of immunity or prior vaccine
- Tdap (Tetanus, Diphtheria, Pertussis): Tdap and booster every 10 years. Pregnant HCWs should have Tdap during pregnancy.
- COVID-19

Chapter 18: 18.03.03

18.03.03 Employee Health: Vaccinations for Healthcare Workers-Revised

Scoring

- Employee health policies and procedures include:
- There is a process in place for ensuring all employees are vaccinated or have been granted an exemption.
- All employees have been offered the recommended vaccinations.
- Employee exemption from vaccination is documented.

Chapter 18: 18.04.01

18.04.01 Decontamination and Sterilization Policies-Revised

Required Elements

A policy identifies when sterilization, low-level, high-level disinfection, or chemical disinfection is acceptable and delineates the steps of **each** disinfection processes used in the hospital.

The policies address the equipment used for manual and automated processes. The policies are based on the manufacturer's instructions for use, nationally recognized organizational guidelines such as AST and IAHCMM. Policies and procedures are easily accessible to personnel.

After use, instruments are properly cleaned and sterilized.

The hospital provides appropriate education/ and training/competence to staff handling, cleaning, sterilizing, and storing instrumentation and assesses competency with these tasks.

Hinged instruments should be opened as wide as possible for proper cleaning. The use of decontamination stringers may be helpful in keeping hinged instruments open throughout the cleaning process.

To protect sharp and delicate instruments, approved instrument protectors should be used. Heavy items should be placed below lighter, more delicate items. Every effort should be made to evenly distribute the weight within the tray to facilitate sterilant contact, as well as even heating and drying in steam sterilization processes.

To protect sharp and delicate instruments, approved instrument protectors should be used. Heavy items should be placed below lighter, more delicate items. Every effort should be made to evenly distribute the weight within the tray to facilitate sterilant contact, as well as even heating and drying in steam sterilization processes.

When peel packaging items for sterilization, care should be taken to keep hinged instruments opened and ensure there is adequate space in the package for the sterilant to contact all parts of the instrumentation. Care should also be taken to help ensure excess stress is not placed on the sides or seals of the peel pack.

Chapter 18: 18.04.01

18.04.01 Decontamination and Sterilization Policies-Revised

SCORING

Verify:

- Policies and procedures address disinfection and sterilization procedures.
- Documentation that the infection control committee has reviewed, at least annually, the departmental policies regarding decontamination and sterilization. and made ongoing revisions.
- Verify practices are consistent with CDC guidelines, OSHA, state, and local laws, and evidence-based guidelines.
- Through observation and interview, that staff are familiar with policies and procedures and follow them.

Chapter 18: 18.04.02

18.04.02 Decontamination of Reusable Items and Reuse of Single Use Items

Standard

First sentence removed. No other changes.

Required Elements

First sentence deleted.

Second sentence revised: Sterilization may be provided via a contracted vendor.

Chapter 18: 18.04.03

18.04.03 High Level Disinfection/Sterilization and Processing of Endoscopes- NEW STANDARD

Standard

Reusable flexible endoscopes are visually inspected and evaluated for cleanliness, missing parts, clarity of lenses, integrity of seals and gaskets, moisture, damage, and function after disinfection/sterilization and again before use. Flexible endoscopes and endoscope accessories are stored to minimize contamination and protects the device or item from damage.

Required Elements

The hospital has policies and procedures consistent with nationally accepted guidelines for processing and high-level disinfection/sterilization of that address:

- Precleaning of flexible endoscopes
- Transport of endoscope to ensure compliance with infection control practices and to maintain integrity of the scope
- Leak testing
- Manual cleaning
- Mechanical processing

Chapter 18: 18.04.03

18.04.03 High Level Disinfection/Sterilization and Processing of Endoscopes-NEW STANDARD

Required Elements (cont.)

After processing is complete, endoscopes should be stored according to manufacturer recommendation and hospital policy in an appropriate cabinet.

The hospital maintains records of endoscope processing including date, time, scope details, method, verification, identity of mechanical processor if indicated, lot numbers of solutions, and identity of the individual performing processing.

A multidisciplinary team that includes infection preventionists, endoscopists, endoscopy processing personnel, and other identified individuals may evaluate the need to implement a surveillance program for endoscopes through the QAPI Program to ensure appropriate handling and storage of chemicals used during sterilization.

The hospital follows recommendations of nationally recognized practices from CDC, APIC, AAMI, etc.

Chapter 18: 18.04.03

18.04.03 High Level Disinfection/Sterilization and Processing of Endoscopes-NEW STANDARD

Scoring

Verify:

- The policy on processing endoscopes includes precleaning, leak testing, manual cleaning including appropriate rinsing, inspection of scopes, mechanical cleaning, transport and storage (including the length of time scopes may be stored before recleaning is required).
- Cleaning and sterilization of endoscopes for adherence to policy and manufacturer's IFU.
- Expiration dates and loads and lot number validation for chemicals and test strips used for cleaning and disinfection/sterilization and appropriate storage of each.
- Through interview that there is a process used to ensure effective processing and sterilization of endoscopes.
- Determine if incorporated into QAPI program.

Chapter 18: 18.04.05

18.04.05 Sterilization and Decontamination Devices-Revised

Standard

Policies and/or procedures describe the use of devices to monitor sterilization or decontamination results in compliance with manufacturer's instructions.

Required Elements

The FDA provides guidance on sterilization: <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices>.

Chapter 18: 18.05.04

18.05.04 Maintenance of ceilings-Revised

SCORING

- In the sensitive areas noted above, determine the risk of contamination from the ceilings.

Chapter 18: 18.06.01

18.06.01 Soiled linen management-Revised

SCORING

- Policies address each element of the standard and are approved by the infection control committee (function).

Chapter 18: 18.07.01

18.07.01 Extermination program-Revised

SCORING

Verify:

- Records of pest control.
- Availability of MSDS precautions for any chemicals.
- Observe for exposure of patients and staff to hazardous conditions.
- Measures taken to prevent pest entry.



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Thank you