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National Integrated Accreditation for Healthcare Organizations  
(NIAHO®)  
Accreditation Requirements  
Interpretive Guidelines and Surveyor Guidance for  
Critical Access Hospitals  
REV 9.2 [PROPOSED 10-25-2016]

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## PHYSICAL ENVIRONMENT (PE)

### PE.1 FACILITY

The facility shall be constructed, arranged, and maintained to ensure patient safety, and to provide adequate space and will appropriate for the services provided.

The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of services. **485.623 (a)**

SR.1 The condition of the physical plant and the overall CAH environment must be developed and maintained through housekeeping and preventive maintenance programs in such a manner that the safety and well-being of patients, visitors, and staff are assured. 485.623(a)

SR.1a All essential mechanical, electrical, and patient-care equipment shall be maintained in safe operating condition. **485.623(b)(1)**

SR.1b The premises are clean and orderly in where patients and staff can function safely

**485.623(b)(4)** SR.2 The CAH must maintain adequate facilities for its services.

SR.2a Diagnostic and therapeutic facilities must be located for the safety of patients.

SR.2b Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

SR.2c The extent and complexity of facilities must be determined by the services offered.

SR.3 The CAH shall have a process in place, as required and/or recommended by local, State, and national authorities or related professional CAHs, to maintain a safe environment for the CAH's patients, staff, and others.

SR.4 The CAH shall have a written policies and procedures to define how unfavorable occurrences, incidents, or impairments in the facility's infrastructure, Life Safety, Safety, Security, Hazardous Material/Waste, Emergency, Medical Equipment, and Utilities Management are prevented, controlled, investigated, and reported throughout the CAH.

SR.5 The CAH shall evaluate the facility's physical environment management systems at least annually. This evaluation shall be forwarded to Quality Management oversight.

SR.6 Occurrences, incidents, or impairments shall be measured and analyzed to identify any patterns or trends.

SR.7 The CAH, through its senior leadership shall ensure that the physical environment and associated processes adequately address issues identified throughout the CAH and there are prevention, correction, improvement and training programs to address these issues.

SR.8 Significant physical environment data/information shall be disseminated regularly to Quality Management oversight.

SR.9 Except as otherwise provided in this section, the CAH must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6). **485.623 €**

SR.10 Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a CAH. **485.623(e)(i)**

SR.11 If application of the Health Care Facilities Code required under paragraph (e) of this section would result in unreasonable hardship for the CAH, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients **485.623(e)(2)**

**Interpretive Guidelines:**

*The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:*

*[http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.* **485.623(f)**

*(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, [www.nfpa.org](http://www.nfpa.org), 1.617.770.3000.* **485.623(f)(1)**

*(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.* **485.623(f)(1)(i)**

*(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.* **485.623(f)(1)(ii)**

*(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.* **485.623(f)(1)(iii)**

*(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.* **485.623(f)(1)(iv)**

*(v) TIA 12-5 to NFPA 99, issued August 1, 2013.* **485.623(f)(1)(v)**

*(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.* **485.623(f)(1)(vi)**

*(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;* **485.623(f)(1)(vii)**

*(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.* **485.623(f)(1)(viii)**

*(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.* **485.623(f)(1)(ix)**

*(x) TIA 12-3 to NFPA 101, issued October 22, 2013.* **485.623(f)(1)(x)**

*(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.* **485.623(f)(1)(xi)**

*(2) [Reserved]*

*[58 FR 30671, May 26, 1993, as amended at 62 FR 46036, 46037, Aug. 29, 1997; 68 FR 1387, Jan. 10, 2003; 69 FR 49271, Aug. 11, 2004; 70 FR 15239, Mar. 25, 2005; 71 FR 55341, Sept. 22, 2006; 77 FR 29076, May 16, 2012; 81 FR 26901, May 4, 2016]*

*Section 1820(c)(2)(B)(iii) of the Social Security Act, codified at 42 USC 1395i-4(c)(2)(B)(iii) limits a CAH to a maximum of 25 inpatient beds that can be used for inpatient acute care or swing bed services. The statute also requires CAHs to provide inpatient acute care limited, on an annual average basis, to 96 hours per patient (see interpretive guidelines for §485.620(b)).*

*Section 1820(c)(2)(E) of the Act also permits a CAH to operate a 10-bed psychiatric distinct part unit (DPU) and a 10-bed rehabilitation DPU, without counting these beds toward the 25-bed inpatient limit.*

*The limit applies to the number of inpatient beds; not to the number of inpatients on any given day. CAHs that were larger hospitals prior to converting to CAH status may not maintain more than 25 inpatient beds, plus a maximum of 10 psychiatric DPU inpatient beds, and 10 rehabilitation DPU inpatient beds.*

*This standard shall apply to all locations of the CAH, all campuses, and all off-site facilities, all provider-based activities. The CAH's department that is responsible for the CAH's buildings and equipment (both facility equipment and patient care equipment) must be evaluated for maintaining the appropriate work environment and related infrastructure to be safe for all staff, patients and visitors.*

*The CAH must ensure that the condition of the physical plant and overall CAH environment is developed and maintained in a manner to ensure the safety and wellbeing of patients. This includes ensuring that 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. The routine and preventive maintenance and testing activities should be incorporated into the CAH's quality management oversight.*

*"Adequate facilities" means the CAH has facilities that are:*

- Designed and maintained in accordance with Federal, State and local laws, regulations and guidelines; and*
- Designed and maintained to reflect the scope and complexity of the services it offers in accordance with accepted standards of practice.*

*Certain areas of the CAH may be required to have external sources responsible for maintaining treatment areas and the CAH will ensure that these services are provided to provide a safe environment for all staff, patient and visitors.*

*The CAH'S departments or services responsible for the CAH'S building and equipment maintenance (both facility equipment and patient care equipment) must be incorporated into the CAH'S quality management oversight and be in compliance with the requirements.*

*"Clean and orderly" means an uncluttered physical environment where patients and staff can function safely. Equipment and supplies are stored in proper spaces, not in corridors. Spills are not left unattended. There are no floor obstructions. The area is neat and well kept. There is no evidence of peeling paint, visible water leaks, or plumbing problems*

#### **Surveyor Guidance:**

*The survey team will delegate one surveyor to review and evaluate the physical environment of the CAH. However, each surveyor, during their respective review of areas within the CAH, should assess the CAH's compliance with the physical environment standards. If warranted, based upon the size and complexity of services provided, the Life Safety Code may be reviewed and evaluated separately by a qualified surveyor.*

*Verify that the condition of the CAH is maintained in a manner to assure the safety and wellbeing of patients (e.g., condition of ceilings, walls, and floors, presence of patient hazards, etc.).*

*Review the CAH's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.*

*Verify that the CAH has developed and implemented a comprehensive plan to ensure that the safety*

*and wellbeing of patients are assured during emergency situations.*

*Observe the facility layout and determine if the patient's needs are met. Toilets, sinks, specialized equipment, etc. should be accessible.*

**PE.2 LIFE SAFETY MANAGEMENT 485.623(d)**

SR.1 Except as otherwise provided in this section—

a. The CAH must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.) **485.623(d)(i)**

b. Notwithstanding paragraph (d)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors. **485.623(d)(1)(ii)**

SR.2

(a) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a CAH, but only if the waiver will not adversely affect the health and safety of the patients.

**485.623(d)(2)**

(b) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

**485.623(d)(3)**

SR.3 The CAH must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with firefighting and emergency management authorities; including training of staff in the following areas: **485.623(c)(1)**

SR.3a Use of alarms

SR.3b Transmission of alarm to fire department

SR.3c Response to alarms

SR.3d Isolation of fire

SR.3e Evacuation of immediate

area SR.3f Evacuation of smoke  
compartment

SR.3g Preparation of floors and building for  
evacuation SR.3h Extinguishment of fire

SR.4 The Life Safety Management System shall have procedures for the proper routine storage and prompt disposal of trash. **485.623(b)(2)**

SR.5 The CAH shall maintain written evidence of regular inspection and approval by State or local fire control agencies. **485.623(d)(4)**

SR.6 Health care occupancies shall conduct unannounced fire drills, but not less than one (1) drill per shift per calendar quarter that transmits a fire alarm signal and simulates an emergency

fire condition. When fire drills are conducted between 9:00 p.m. (2100 hours) and 6:00 a.m. (0600 hours), a coded announcement shall be permitted to be used instead of audible alarms. Business occupancies shall conduct at least one unannounced fire drill annually per shift.

SR.6a Fire drills must be thoroughly documented and evaluate the CAH's knowledge to the items listed in PE.2, SR.3

SR.6a(1) At least annually, the CAH shall evaluate the effectiveness of the fire drills, The report of effectiveness shall be forwarded to Quality Management oversight

SR.7 The CAH shall address applicable Alternative Life Safety Measures (ALSM) that shall be implemented whenever life safety features, systems, or processes are impaired or deficient are created or occur. Thorough documentation is required.

SR.7a All alternative life safe measures must be approved by the authority having local jurisdiction. Life safety measures for redundant and/or common minor renovations/repairs/testing may be pre-approved for the specific task by the AHJ

SR.8 The CAH shall require that Life Safety systems (e.g., fire suppression, notification, and detection equipment) shall be tested and inspected (including portable systems).

SR.9 When a sprinkler system is shut down for more than 10 hours, the CAH must: **485.623 (d)(6)**

- a. Evacuate the building or portion of the building affected by the system outage until the system is back in service, or **485.623 (d)(6)(i)**.
- b. Establish a fire watch until the system is back in service. **485.623 (d)(6)(ii)**.

SR.10 Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement. **485.623 (d)(7)**

- a. The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours. **485.623 (d)(7)(i)**
- b. Special nursing care areas of new occupancies shall not exceed 60 inches. **485.623 (d)(7)(ii)**

SR.11 The CAH shall require a process for reviewing the acquisition of bedding, draperies, furnishings and decorations for fire safety.

SR.12 Construction, Repair, and Improvement operations shall involve the following activities:

SR.12a During construction, repairs, or improvement operations, or otherwise affecting the space, *the Guidelines for Design and Construction of Hospitals and Health Care Facilities*, 2006 edition, published by the American Institute of Architects shall be consulted for designing purposes.

SR.12b The CAH shall assess, document, and minimize the impact of construction, repairs, or improvement operations upon occupied area(s). The assessment shall include, but not be limited to, provisions for infection control, utility requirements, noise, vibration, and alternative life safety measures (ALSM).

- SR.12c In occupied areas where construction, repairs, or improvement operations occur, all required means of egress and required fire protection features shall be in place and continuously maintained or where alternative life safety measures acceptable to the authority having local jurisdiction are in place.

NFPA 241-1996, *Standard for Safeguarding Construction, Alteration, and Demolition Operations* shall be referenced in identifying and implementing alternative life safety measures.

- SR.12d All construction, repairs, or improvement operations, shall be in accordance with applicable NFPA 101-2000 standards, and State and local building and fire codes. Should standards and codes conflict, the most stringent standard or code shall prevail.

SR.13 The CAH shall require that a tobacco-free policy be developed and enforced campus-wide. Substantial progress toward complete conformity shall be demonstrated over time.

***Interpretive Guidelines:***

*The CAH, regardless of size or number of beds, shall meet the applicable provisions of the 2000 edition of the Life Safety Code® of the National Fire Protection Association for all inpatient care locations, emergency departments, and outpatient care locations.*

*Additionally, the CAH must be in compliance with all applicable codes referenced in the Life Safety Code®, such as, NFPA-99: Health Care Facilities.*

*Note: In order for SR.3 to be applicable, the appropriate supporting documentation must be in place.*

*The CAH will maintain and update, as necessary, a fire control plan that includes the elements of SR.4. The CAH will also have supporting documentation to verify the regular inspection and approval by State or local fire control agencies.*

*The Life Safety Management System shall:*

- *address applicable Alternative Life Safety Measures to be implemented whenever life safety systems, processes, or deficiencies are created or occur;*
- *require that Life Safety systems (e.g., fire alarm and detection equipment) shall be is tested and inspected (including portable systems);*
- *require a process for reviewing bedding, draperies, furnishings and decorations for fire safety; and,*
- *require that a tobacco-free policy be developed and enforced campus-wide. Substantial progress toward complete conformity shall be demonstrated over time.*

*When construction, repairs, or improvement operations affect the space where CAH processes are carried out, the Guidelines for Design and Construction of Hospitals and Health Care Facilities, 2006 edition (or newer revision if in publication), NFPA 101-2000 standards, and State and local building and fire codes shall be used.*

*When construction, repairs, or improvement operations impacts occupied areas, the CAH will also make provisions to include, as appropriate, infection control practices to be followed, utility requirements, and account for noise and vibration. The CAH may have also implemented appropriate*

*alternative life safety measures which are required to be approved by the authority having local jurisdiction.*

*The term trash refers to common garbage as well as biohazardous waste. The storage and disposal of trash must be in accordance with Federal, State and local laws and regulations (i.e., EPA, OSHA, CDC, State environmental, health and safety regulations). The Radiology requirements address handling and storage of radioactive materials.*

*Medicare-participating CAHs, regardless of size or number of beds, must comply with the CAH/healthcare Life Safety Code requirements for all inpatient care locations. CAH departments and locations such as emergency departments, outpatient care locations, etc. must comply with CAH/healthcare Life Safety Code Requirements. Additionally, the CAH must be in compliance with all applicable codes referenced in the Life Safety Code, such as NFPA-99: Health Care Facilities.*

*Medicare-participating CAHs must be in compliance with chapter 19.3.6.3.2 of the 2000 Edition of NFPA 101 beginning March 13, 2006. Exception number 2 of chapter 19.3.6.3.2 will not be allowed in Medicare-participating CAHs. CAHs should develop plans for compliance with this requirement so that in all applicable locations roller latches have been replaced by positive latches prior to March 13, 2006.*

*Beginning March 13, 2006, Medicare-participating CAHs must be in compliance with Chapter 19.2.9 of the 2000 Edition of NFPA 101. After March 13, 2006 a CAH with doors in service with roller latches or with emergency lighting systems with less than 1-1/2 hour batteries will not be in compliance and will be cited at 485.623(d)(1).*

**Surveyor Guidance:**

*When applicable, verify the consideration, assessment, and recommendation for waivers of specific Life Safety Code® provisions have been handled by the Fire Authority surveyor as part of the Life Safety Code® survey process.*

*Review and validate the CAH's written fire control plans to verify they contain the required provisions of the Life Safety Code® or State law.*

*Review and verify that CAH staff has a process in place to report all fires as required to State officials.*

*In the review of respective areas of the CAH, interview staff throughout the facility to verify knowledge of their role and responsibilities during a fire.*

*Review and validate the documentation of inspection and approval reports from State and local fire control agencies. Review and validate that the Life Safety Management System addresses the elements as described within the Interpretive Guidelines.*

*Verify that CAH staff reported all fires as required to State officials.*

*The surveyor should validate compliance with the inspection, testing, and maintenance of fire detection, notification, and suppression equipment and systems.*

*Review areas where current construction, repairs, or improvement operations are taking place and validate that the Guidelines for Design and Construction of Hospitals and Health Care Facilities, NFPA 101-2000, standards, and State and local building and fire codes are being followed.*

*If construction, repairs, or improvement operations are taking place and affects occupied areas, verify that the CAH has made provisions for the respective elements as described in the Interpretive Guidelines (above).*



*If there is no renovation or construction taking place within the CAH, verify that the CAH follows a process to follow the Guidelines for Design and Construction of Hospitals and Health Care Facilities, implements alternative life safety measures and includes the infection control practitioner and has the resources to account for utility requirements, and eliminating, to the extent possible, noise and vibration.*

*Validate there was documentation:*

- *That the means of egress were checked daily.*
- *That the means of egress were continuously maintained free from obstructions or impediments.*
- *That an assessment was performed of work relating to the impact on the occupied area(s) shall be conducted and include provisions for infection control, utility requirements, noise, vibration, and alternate life safety measures*
- *That the authority having local jurisdiction approved the alternate life safety measures.*

*Verify that the CAH has developed and implemented policies for the proper storage and disposal of trash. Verify through observation that staff adhere to these policies and that the CAH has signage, as appropriate.*

*Survey the entire building occupied by the CAH unless there is a 2-hour firewall separating the space designated as the CAH from the remainder of the building. A 2-hour floor slab does not count; it must be a vertical firewall to constitute a separate building or part of a building.*

*Review staff training documents and in-service records to validate training.*

*Interview staff throughout the facility to verify their knowledge of their responsibilities during a fire (this is usually done during the LSC survey, but health surveyors may also verify staff knowledge).*

### **PE.3 SAFETY MANAGEMENT**

SR.1 The CAH shall have processes in place to maintain safe and adequate facilities for its services. Diagnostic and therapeutic facilities must be located for the safety of patients and drugs and biologicals are appropriately stored.

**485.623 (b)(3)**

SR.2 The CAH shall require that facilities, supplies, and equipment be maintained and ensure an acceptable level of safety and quality and that the premises are clean and orderly. The extent and complexity of facilities shall be determined by the services offered.

**485.623(b)(4)**

SR.3 The CAH shall require proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas. **485.623(b)(5)**

SR.4 The CAH shall maintain an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries.

SR.5 The CAH shall require periodic surveillance of the CAH facilities and grounds to observe and correct safety issues that may be identified.

SR.6 The Safety Management System shall address safety recalls and alerts.

***Interpretive Guidelines:***

*The CAH will maintain safe and adequate facilities that are designed and maintained in accordance with Federal, State and local laws, regulations and guidelines and reflect the scope and complexity of the services it offers in accordance with accepted standards of practice.*

*The Safety Management System will require:*

- *That facilities, supplies, and equipment be maintained and ensure an acceptable level of safety and quality;*
- *The CAH maintains an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries; and,*
- *A process for addressing safety recalls and alerts.*

*The CAH shall require periodic surveillance of the CAH grounds to observe safety issues that may be identified and make corrective/preventive action(s) as needed.*

*There must be proper ventilation in at least the following areas:*

- *Areas using ethylene oxide, nitrous oxide, guteraldehydes, xylene, pentamidine, or other potentially hazardous substances;*
- *Locations where oxygen is transferred from one container to another;*
- *Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.);*
- *Pharmaceutical preparation areas (hoods, cabinets, etc.); and*
- *Laboratory locations.*

*There must be adequate lighting in all the patient care, food and medication preparation areas.*

*Temperature, humidity and airflow in the operating rooms must be maintained within acceptable standards to inhibit bacterial growth and prevent infection, and promote patient comfort. Each operating room should have separate temperature control. Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the American Institute of Architects (AIA) should be incorporated into CAH policy.*

*The CAH must ensure that an appropriate number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer's recommendations (pharmaceuticals).*

***Surveyor Guidance:***

*Review and verify that diagnostic, treatment, and other specialized services are provided in areas appropriate for the service provided.*

*Review and verify that the physical facilities are large enough and properly equipped for the scope of services provided and the number of patients served.*

*Where corrective/preventive action(s) have been taken, review and verify the documentation in place to ensure the effectiveness of action(s) taken.*

*Verify that all food and medication preparation areas are well lit and that pharmaceuticals are stored at temperatures recommended by the product manufacturer.*

*Verify that each operating room has temperature and humidity control mechanisms, reviewing temperature and humidity tracking logs to ensure that appropriate temperature and humidity levels are maintained.*

*Verify that the CAH is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving*

*Verify that the CAH has developed and implemented a comprehensive plan to ensure the safety and wellbeing of patients during local emergency situations.*

*Verify that food products are stored under appropriate conditions (e.g., time, temperature, packaging, location) based on nationally-accepted sources such as the United States Department of Agriculture, the Food and Drug Administration, or other nationally-recognized standard.*

#### **PE.4 SECURITY MANAGEMENT**

SR.1 The CAH shall have processes in place that provides for a secure environment. SR.2 The CAH shall provide for identification of patients, employees and others.

SR.3 The CAH shall address issues related to abduction, elopement, visitors, workplace violence, and investigation of property losses.

SR.4 The CAH shall establish emergency security procedures to include all

hazard events SR.5 The CAH shall require vehicular access to emergency service areas.

SR.6 The CAH shall require a process for reporting and investigating security related issues.

#### ***Interpretive Guidelines:***

*The organization should have a written, comprehensive workplace violence control and prevention program based on guidelines from national authorities such as the OSHA Publication 3148-01R 2004 Guidelines for Preventing Workplace violence for Healthcare and Social Workers.*

*Elements of a Workplace Violence Prevention Program should include but not limited to:*

- *A Clearly Written Company Workplace Violence Policy Statement*
- *Establishment of a Threat Assessment Team*
- *Hazard Assessments*
- *Workplace Hazard Control and Prevention*
- *Training and Education*
- *Incident Reporting, Investigation, Follow-up and Evaluation*
- *Recordkeeping*

#### ***Surveyor Guidance:***

*Review and validate the Security Management System to ensure that it addresses the respective elements as stated within SR.1 – SR.6.*

## **PE.5 HAZARDOUS MATERIAL (HAZMAT) MANAGEMENT**

- SR.1 The CAH shall have processes in place to manage hazardous materials and waste.
- SR.2 The CAH shall provide processes to manage the environment, selection, handling, storing, transporting, using, and disposing of hazardous materials and waste.
- SR.3 The CAH shall provide processes to manage reporting and investigation of all spills, exposures, and other incidents.
- SR.4 The CAH monitors staff exposure levels in hazardous environments and report the results of the monitoring to the Quality Management oversight.
- SR.5 A CAH may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access. **485.623(d)(5)**
- SR.6 In anesthetizing locations, which use alcohol-based skin preparations, have implemented effective fire risk reductions measures which include:
- SR.6a The use of unit dose skin prep solutions.
- SR.6b Application of skin prep follows manufacture/supplier instructions and warnings.
- SR.6c Sterile towels are used to absorb drips and runs during the application and then removed from the anesthetizing location prior to draping.
- SR.6d Verifying that all of the above has occurred prior to initiating the surgical procedure.
- SR.7 All compressed gas cylinders in service and in storage shall be individually-secured and located to prevent mechanical shock from falling or being knocked over.

### ***Interpretive Guidelines:***

*The term waste refers to common garbage, hazardous material as well as biohazardous wastes. The storage and disposal of trash must be in accordance with Federal, State and local laws and regulations (i.e., EPA, OSHA, CDC, DOT, State environmental, health and safety regulations). The Conditions of Participation for Radiology and Nuclear Medicine Services address handling and storage of radioactive materials.*

*There must be proper ventilation in at the following areas: Areas using ethylene oxide, nitrous oxide, gluteraldehydes, xylene, pentamidine, formalin or other potentially hazardous substances;*

**Surveyor Guidance:**

*Verify that the CAH has developed and implemented policies and processes for the selection, handling, storing, transporting, using, and disposing of hazardous materials and waste in accordance with Federal, State and local laws and regulations (e.g. EPA, OSHA, CDC, State environmental, health and safety regulations).*

*Review and verify that processes are in place for the reporting and investigation of all spills, exposure and other incidents involving hazardous materials.*

*Ensure that alcohol-based hand rub dispensers are installed, located and managed in accordance with*

*PE.5; SR.5. Review documents to ensure employee and environmental monitoring is being conducted.*

**PE.6 EMERGENCY MANAGEMENT 485.623(c)**

- SR.1 The CAH must have a process in place to coordinate with local authorities for emergencies in the CAH or within the community and region that may impact the CAH's ability to provide services. This may include requirements for the CAH to have appropriate measures in place to account for particular conditions, potential hazards, or other concerns with respect to the location of the CAH. **485.623 (c) (4)**
- SR.2 The CAH shall have processes in place for addressing alternative means to support essential building functions such as electricity, water, ventilation, fuel, medical gas and vacuum systems, and other identified utilities.
- SR.3 The CAH will have coordinate with local and regional healthcare facilities and public health agencies in cases of CAH, community, or regional crisis for utilization of resources (space, personnel, and equipment). The CAH will have memorandums of understanding or provisions through other arrangements for utilization of resources as necessary.
- SR.4 The CAH shall have policies, procedures, and decision criteria for the determination of protection in place or evacuation of patients in the event of a disaster.

**Interpretive Guidelines:**

*Assuring the safety and wellbeing of patients would include developing and implementing appropriate emergency preparedness plans and capabilities. The CAH must develop and implement a plan to ensure that the safety and wellbeing of patients are assured during emergency situations. The CAH should coordinate with Federal, State, regional, and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel; nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and to develop appropriate responses that will assure the safety and wellbeing of patients. The following issues should be considered when developing the comprehensive emergency plans(s):*

- The differing needs of each location where the certified CAH operates;*
- The special needs of patient populations treated at the CAH (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.);*

- *Security of patients and walk-in patients;*
- *Security of supplies from misappropriation;*
- *Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;*
- *Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, community officials, other healthcare facilities if transfer of patients is necessary, etc.);*
- *Communication among staff within the CAH itself;*
- *Qualifications and training needed by personnel, including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures;*
- *Identification, availability and notification of personnel that are needed to implement and carry out the CAH emergency plans; • Identification of community resources, including lines of communication and names and contact information for community emergency preparedness coordinators and responders; • Transfer or discharge of patients to home, other healthcare settings, or other hospitals; • Transfer of patients with CAH equipment to another CAH or healthcare setting; and • Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs.*
- *Provisions if gas, water, electricity supply is shut off to the community;*

*The CAH must provide for a Emergency Management System in order to respond to emergencies in the CAH or that occur in the community that impact the CAH's ability to provide services.*

*The hospitals must comply with the applicable provisions of the Life Safety Code®, National Fire Protection Amendments (NFPA) 101, 2012 Edition and applicable references, such as, NFPA-99: Health Care Facilities, Chapter 12, Emergency Management, as applicable.*

*In order to prepare for such an emergency, the CAH must conduct a hazard vulnerability analysis to identify potential emergencies or other circumstances that may impact the CAH and the community. The CAH must maintain documentation that this analysis has been conducted and that the CAH has prioritized activities to address and prepare for these vulnerabilities.*

*Emergency management exercises shall be based upon the most probable emergencies or other circumstances that may impact the CAH and the community. A report, After Action Report, shall be created after each exercise documenting opportunities for improvement. The CAH's emergency management plan shall be revised based upon the identified opportunities for improvement.*

*The "community" represents local, regional, State, Federal public safety forces and/or public health agencies.*

#### **Surveyor Guidance:**

*Review and verify that the CAH has developed and implemented a comprehensive plan to ensure that the safety and wellbeing of patients are assured during local emergency situations. This plan must address the elements listed above within the Interpretive Guidelines.*

*Review and validate that the CAH has conducted a hazard vulnerability analysis to identify potential emergencies in the CAH and the community. Determine the method used to prioritize and made preparations to address the potential hazards to the CAH and community.*

*Review and validate:*

- *That the CAH has conducted or involved in appropriate emergency management exercises.*
- *That after action reports identified opportunities for improvements*
- *That the CAH revised its emergency management plan according to the identified opportunities for improvement.*

*How does the CAH ensure that all personnel on its staff, including new additions to the staff, are trained to manage non-medical emergencies?*

## **PE.7 MEDICAL EQUIPMENT MANAGEMENT**

- SR.1 The CAH shall establish processes for the acquisition, safe use, and the appropriate selection of equipment.
- SR.2 The CAH shall address issues related to the CAH's initial service inspection, the orientation, and the demonstration of use for rental or physician owned equipment.
- SR.3. The CAH shall address criteria for the selection of equipment.
- SR.4 The CAH shall address incidents related to serious injury or illness or death (See SMDA 1990).
- SR.5 The CAH shall have a process in place for reporting and investigating equipment management problems, failures, and user errors.
- SR.6 The CAH shall have a process in place for determining timing and complexity of medical equipment maintenance. §485.623(b)
- SR.7 The CAH shall have a process in place for receiving and responding to recalls and alerts.

### ***Interpretive Guidelines:***

*The CAH will ensure that the facilities are maintained to ensure an acceptable level of safety and quality.*

*There must be a regular periodic maintenance and testing program for medical devices. A qualified individual such as a clinical or biomedical engineer, or other qualified maintenance person must monitor, test, calibrate and maintain the equipment periodically in accordance with the manufacturer's recommendations, [risk assessments](#) and Federal and State laws and regulations. Equipment maintenance may be conducted using CAH staff, contracts, or through a combination of CAH staff and contracted services.*

*Equipment includes both facility equipment (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment (e.g., biomedical equipment, radiological equipment, patient beds, stretchers, IV infusion equipment, ventilators, laboratory equipment, etc.).*

*The equipment to be maintained would encompass the CAH's need for medical equipment (e.g. biomedical equipment, radiological equipment, patient beds, stretchers, IV infusion equipment, ventilators, laboratory equipment) for both day-to-day operations and equipment that would be needed in likely emergency/disaster situations such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, and that the CAH makes adequate provisions to ensure the availability of that equipment when needed.*

*The CAH will have a process in place to effectively manage medical equipment that addresses the following:*

- *Issues related to use of demonstration or rental equipment and how appropriate training is*

- provided to ensure safe operation;*
- *Defined criteria for the selection of equipment;*
- *The process of reporting and investigating incidents related to serious injury or illness or death (See SMDA 1990);*
- *A process for reporting and investigating equipment management problems, failures, and user errors;*
- *a process for determining timing and complexity of medical equipment maintenance; and,*
- *a process of receiving and responding to recalls and alerts.*

**Surveyor Guidance:**

*Review and validate that there is a process in place to address the repair/periodical maintenance program for equipment.*

*Review and validate, through a document sampling, that a clinical or biomedical engineer routinely checks medical devices and equipment.*

*Review and verify that the CAH maintains maintenance logs for significant medical equipment (e.g. cardiac monitors, IV infusion pumps, ventilators).*

*Interview the person in charge of medical equipment and determine if there is an adequate repair/periodical maintenance program.*

*Verify that all medical devices and equipment are routinely checked by a clinical or biomedical engineer.*

*Review maintenance logs for significant medical equipment (e.g., cardiac monitors, IV infusion pumps, ventilators, etc.).*

*Verify that supplies maintained in such a manner as to ensure that safety Verify that supplies are stored as recommended by the manufacturer*

*Verify that supplies are stored in such a manner as to not endanger patient safety*

*Verify that the CAH has identified supplies and equipment that are likely to be needed in emergency situations Verify that the CAH made adequate provisions to ensure the availability of supplies and equipment when needed*

**PE.8 UTILITY MANAGEMENT**

- SR.1 The CAH shall ensure that processes are in place to provide for a safe and efficient that reduces the opportunity for CAH-acquired illnesses.
- SR.2 The CAH shall have a process in place to evaluate critical operating components.
- SR.3 The CAH shall develop maintenance, testing, and inspection processes for critical



utilities.

SR.4 The CAH shall have a process in place to address medical gas systems and HVAC systems (e.g., includes areas for negative pressure).

SR.5 The CAH shall provide for emergency processes for utility system failures or disruptions.

SR.6 The CAH shall provide for reliable emergency power sources with appropriate maintenance as required.

SR.7 The CAH shall require proper ventilation, light and temperature controls in operating rooms, sterile supply rooms, special procedures, isolation and protective isolation rooms, pharmaceutical, food preparation, and other appropriate areas.

SR.8 There shall be emergency power and lighting in at least the operating, recovery, intensive care, emergency rooms, and in other areas where invasive procedures are conducted, stairwells, and other areas identified by the CAH (e.g., blood bank refrigerator, etc.). In all other areas not serviced by the emergency supply source, battery lamps and flashlights shall be available.  
**485.623(c)(2)**

SR.9 There shall be facilities for emergency fuel and water supply.

**485.623(c)(3)** SR.10 All relevant utility systems shall be maintained inspected and tested.

### ***Interpretive Guidelines:***

*The CAH must ensure that the condition of the physical plant and overall CAH environment is developed and maintained in a manner to ensure the safety and wellbeing of patients, visitors, and staff. The CAH will ensure that 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 in need of repair.*

*There should be proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas;*

*The CAH will maintain, and regularly test and inspect, emergency power and lighting in at least the operating, recovery, in other areas where invasive procedures are conducted, intensive care, and emergency rooms, stairwells, and other areas identified by the CAH (e.g. blood bank refrigerator) to comply with the applicable Life Safety Code (101). Where areas are not supplied with an emergency supply source, the CAH will make provisions for battery lamps and flashlights.*

*The CAH must have systems for emergency gas and water needs to provide care to inpatients and other persons who may come to the CAH in need of care. This includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas. The CAH should consider nationally accepted references or calculations made by qualified staff when determining the need for at least water and gas. For example, one source for information on water is the Federal Emergency Management Agency (FEMA).*

*Emergency gas includes fuels such as propane, natural gas, fuel oil, liquefied natural gas, as well as any gases the CAH uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc.*

*The CAH should have a plan to protect these limited emergency supplies, and have a plan for prioritizing their use until adequate supplies are available. The plan should also address the event of a disruption in supply (e.g., disruption to the entire surrounding community).*

*The CAH must comply with the applicable provisions of the Life Safety Code, National Fire Protection Amendments (NFPA) 101, 2000 Edition and applicable references such as NFPA-99: Health Care Facilities, for emergency lighting and emergency power.*

*The CAH must have a system to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the CAH in need of care. This includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas. Emergency gases include fuels such as propane, natural gas, fuel oil, liquefied natural gas, as well as any gases the CAH uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc.*

*The CAH should have a plan to protect these limited emergency supplies, and have a plan for prioritizing their use until adequate supplies are available. The plan should also address the event of a disruption in supply (e.g., disruption to the entire surrounding community).*

**Surveyor Guidance:**

*Review and validate the CAH's process for managing utilities to ensure that there is a process in place to provide for a safe and efficient facility that reduces the opportunity for CAH-acquired illnesses.*

*Review and validate the condition of the CAH and that it is maintained in a manner to assure the safety and wellbeing of patients (e.g. condition of ceilings, walls, and floors, presence of patient hazards).*

*Review and validate the CAH's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary corrective/preventive action(s) are taken.*

*Review and verify that the facility layout is appropriate to meet patient's needs. Toilets, sinks, specialized equipment should be accessible.*

*The CAH will maintain, test and inspect their utility systems and have adequate facilities for emergency gas and water supply, to provide safe care for patients.*

*Verify that the process for managing utilities provides for:*

- *A process to evaluate critical operating components;*
- *A means of addressing medical gas systems and HVAC systems;*
- *A means for providing emergency processes for utility system failures or disruptions; and,*
- *A means for providing for reliable emergency power sources with appropriate maintenance.*
- *Verify that the quality of the water supply and distribution system has been deemed acceptable for its intended use (drinking water, irrigation water, lab water, dialysis);*
- *Emergency gases have been deemed acceptable and can be adequately supplied as needed; and,*
- *Review the system used by CAH staff to determine the CAH's emergency needs for gas and water. Verify that the system accounts for not only inpatients, but also staff and other persons who come to the CAH in need of care during emergencies.*

- *Determine the source of emergency gas and water supplies, Review the quantity and availability of these supplies to the CAH, and that they are available within a short time through period additional deliveries.*
- *Verify that arrangements have been made with utility companies and others for the provision of emergency sources of critical utilities, such as water and gas.*
- *Verify that the utility systems have been tested, inspected and maintained for the safety of patient care and applicable to the services provided.*

*Review and verify that proper ventilation is in place in at least the following areas:*

- *Areas using ethylene oxide, nitrous oxide, guteraldehydes, xylene, pentamidine, formaldehyde , or other potentially hazardous substances;*
- *Locations where oxygen is transferred from one container to another;*
- *Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH);*
- *Pharmaceutical preparation areas (hoods, cabinets); and,*

*Review and verify that adequate lighting is in place in all the patient care areas, and food and medication preparation areas.*

*Temperature, humidity and airflow in the operating rooms must be maintained within acceptable standards to inhibit bacterial growth and prevent infection, and promote patient comfort.*

*Review and verify that each surgical suite has separate temperature control.*

*Review and verify that food products are stored under appropriate conditions (e.g. time, temperature, packaging, location) based on nationally accepted sources such as the United States Department of Agriculture, the Food and Drug Administration, or other nationally recognized standard.*

*Review and verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer and according to CAH policy.*

*Review the system used by CAH staff to determine the CAH'S emergency needs for gas and water. Verify that the system accounts for not only inpatients, but also staff and other persons who come to the CAH in need of care during emergencies.*

*Determine the source of emergency gas and water, both the quantity of these supplies readily available at the CAH, and that are needed within a short time through additional deliveries.*

*Verify that arrangements have been made with utility companies and others for the provision of emergency sources of critical utilities, such as water and gas.*