

NATIONAL INTEGRATED ACCREDITATION FOR HEALTHCARE ORGANIZATIONS (NIAHO®)

Interpretive Guidelines and Surveyor Guidance - Version 11.1 [PROPOSED]

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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 areas for diagnosis and treatment and for special organization services appropriate to the needs of the community.

SR.1 The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients, visitors, and staff are assured.

SR.2 The hospital 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 Except as otherwise provided in this section, the hospital 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).

- a. Chapters 7 and 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a hospital.
- b. If application of the Health Care Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the hospital, 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.

SR.4 The organization shall have policies, procedures and processes in place to manage staff activities, as required and/or recommended by local, State, and national authorities or related professional organizations, to maintain a safe environment for the organization's patients, staff, and others.

SR.5 The organization shall have a documented process, 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 Systems are prevented, controlled investigated, and reported throughout the organization.

SR.6 The organization shall evaluate the facility's physical environment management systems at least annually. This evaluation shall be forwarded to Quality Management oversight.

SR.7 Occurrences, incidents, or impairments shall be measured and analyzed to identify any patterns or trends.

SR.8 The organization, through its senior leadership shall ensure that the physical environment and associated management systems adequately address issues identified throughout the organization and there are prevention, correction, improvement and training

programs to address these issues.

SR. 9 Significant physical environment data/information shall be disseminated regularly to Quality Management oversight.

SR. 10 The organization, through its senior leadership shall ensure that a tobacco-free policy be developed and enforced campus-wide. Substantial progress toward complete conformity shall be demonstrated over time.

DNV GL- Healthcare will permit temporary tobacco use in the areas of the hospital where patient visits may be abbreviated, in behavioral health units and other areas near the main campus that are not under hospital control. In order for this to be permissible the hospital must obtain from the local and/or state fire prevention agencies (Authority Having Jurisdiction or AHJ) written documentation stating that these areas can be used for smoking while the hospital continues to demonstrate progression toward a tobacco-free campus over time. (See the PE.1 Interpretive Guidelines for specific direction on this procedure.)

Interpretive Guidelines

PE.1, SR.10 IG

In order to apply for areas in which smoking is acceptable

1. *The documented AHJ permission must list:*

- a. *which specific patients populations are permitted to participate in smoking*
- b. *what specific areas will be included in the policy*
- c. *any specific applicable controls (e.g. smokers could be under physician's orders and/or accompanied by a security guard in specific approved areas.)*
- d. *all arrangements/precautions/restrictions that pertain to this special permission*

2. *The hospital must also perform a documented risk assessment of the area in which tobacco use is proposed including:*

- a. *the specific areas where smoking will be allowed*
- b. *the smoking areas are designed and built to resist fire, including but not limited to the landscaping in the immediate area*
- c. *the smoking areas are located adequately from windows, air intakes and entrances to the facility*
- d. *the hospital areas are compliant with NFPA 101, 2012 Chapter 18/19: 18.7.4* or 19.7.4**

Once it is established that the arrangements described in the inquiry are endorsed/permitted by the local/state fire prevention agency or AHJ documentation, then the hospital can continue demonstrate progression towards a tobacco-free campus while using the AHJ-approved specific areas for smoking described in the hospital tobacco-free policy and the AHJ documentation. The hospital policy must also include plans and/or processes that will be developed and maintained to demonstrate continual progress in achieving a tobacco-free campus

Interpretive Guidelines:

Facilities

The hospital must ensure that the condition of the physical plant and overall hospital

environment is developed and maintained in a manner that provides an acceptable level of safety and well-being of patients, staff and visitors.

Supplies

The hospital must ensure that supplies are maintained to provide an acceptable level of safety and quality for patients. Among other things, this means that the hospital identifies the supplies required to meet its patients' needs for both day-to-day operations as well as those supplies that are likely to be needed in likely emergency situations, such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, etc. Further, the hospital must make adequate provisions to ensure the availability of those supplies when needed.

Supplies must be stored in such a manner to ensure their safety (protection against theft or damage, contamination, or deterioration), as well as that the storage practices do not violate fire codes or otherwise endanger patients (storage of flammables, blocking passageways, storage of contaminated or dangerous materials, safe storage practices for poisons, etc.).

Equipment

In order to ensure an acceptable level of safety and quality, the hospital must identify the equipment required to meet its patients' needs for both day-to-day operations and in a likely emergency/disaster situation, such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, etc. In addition, the hospital must make adequate provisions to ensure the availability and reliability of equipment needed for its operations and services. Equipment includes both facility equipment, which supports the physical environment of the hospital (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment, which are devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the hospital (e.g., IV infusion equipment, ventilators, laboratory equipment, surgical devices, etc.).

All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades.

All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. Equipment maintenance activities may be conducted using hospital personnel, contracted services, or through a combination of hospital personnel and contracted services. Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified. The hospital maintains records of hospital personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified.

All equipment maintenance policies, procedures and programs, as well as specific equipment maintenance inventories, activities and schedules fall under the purview of the hospital's clinical maintenance personnel, safety department personnel or other personnel who have been assigned responsibility for equipment maintenance by hospital leadership.

Hospitals comply with this regulation when they follow the manufacturer-recommended

maintenance activities and schedule. Hospitals may choose to perform maintenance more

frequently than the manufacturer recommends, but must use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer's recommendations, the hospital must maintain documentation of those recommendations and the hospital's associated maintenance activity for the affected equipment.

Alternate Equipment Management (AEM) Program

A hospital may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer. Hospitals that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the hospital associated with the use of facility or medical equipment. The AEM program must be based on generally accepted standards of practice for facility or medical equipment maintenance. An example of guidelines for a medical equipment maintenance program may be found in the American National Standards Institute/ Association for the Advancement of Medical Instrumentation document: ANSI/AAMI EQ 56:1999/ (R) 2013, Recommended Practice for a Medical Equipment Management Program. Likewise, an example of guidelines for physical plant equipment may be found in the American Society for Healthcare Engineering (ASHE) 2009 document: Maintenance Management for Health Care Facilities. There may be similar documents issued by other nationally recognized organizations which hospitals might choose to reference.

Decision to Place Equipment in an AEM Program

The determination of whether it is safe to perform facility or medical equipment maintenance without following the equipment manufacturer recommendations must be made by qualified personnel, regardless of whether they are hospital employees or contractors.

In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program.

In the case of facility equipment, a Healthcare Facility Management professional (facility manager, director of facilities, vice president of facilities) would be considered qualified.

The hospital must maintain records of the qualifications of hospital personnel who make decisions on placing equipment in an AEM program, and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.

In determining whether or not to include equipment in an AEM program, and which maintenance strategies to use in developing maintenance activities and frequencies for particular equipment, the hospital must take into account the typical health and safety risks associated with the equipment's use. Note that the risk may vary for the same type of equipment, depending on the patient care setting within the hospital where it is used.

A hospital is expected to identify any equipment in its AEM program which is "critical equipment," i.e., biomedical or physical plant equipment for which there is a risk of serious

injury or death to a patient or staff person should the equipment fail. Surveyors must focus their review of a hospital's AEM program on critical equipment in that program and the hospital's documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

Factors for a hospital to consider when evaluating the risks associated with a particular type of equipment include, but are not limited to:

- How the equipment is used and the likely consequences of equipment failure or malfunction - would failure or malfunction of the equipment hospital-wide or in a particular setting be likely to cause harm to a patient or a staff person?*
- How serious is the harm likely to be? For example, a slightly miscalibrated scale in an adult internal medicine outpatient clinic might not present significant risk of harm. However, a miscalibrated scale in a neonatal intensive care unit could have very serious consequences for patient care.*
- How widespread is the harm likely to be? For example, are many patients exposed to the equipment, resulting in harm due to failure impacting more patients or staff? If harm would be widespread, even if the harm to each affected individual is not serious, this would be a cause for concern.*

Information, if available, on the manufacturer's equipment maintenance recommendations, including the rationale for the manufacturer's recommendations;

- Maintenance requirements of the equipment:
 - Are they simple or complex?*
 - Are the manufacturer's instructions and procedures available in the hospital, and if so can the hospital explain how and why it is modifying the manufacturer's instructions?*
 - If the manufacturer's instructions are not available in the hospital, how does the hospital assess whether the AEM uses appropriate maintenance strategies?*
 - How readily can the hospital validate the effectiveness of AEM methods for particular equipment? For example, can the hospital explain how it ensures there is no reduction in the quality of the performance of biomedical equipment subjected to alternate maintenance methods?*
 - The timely availability of alternate devices or backup systems in the event of equipment failure or malfunction; and*
 - Incident history of identical or very similar equipment – is there documented evidence, based on the experience of the hospital (or its third party contractor), or on evidence publicly reported by credible sources outside the hospital, which:
 - Provides the number, frequency and nature of previous failures and service requests?*
 - Indicates use of an AEM strategy does not result in degraded performance of the equipment?***

Generally multiple factors must be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The hospital is expected to be able to demonstrate to a surveyor the factors it considered in its risk

assessment for equipment placed in its AEM program.

Equipment not Eligible for Placement in the AEM Program:

Some equipment may not be eligible for placement in the AEM program, for one or more of the following reasons:

- *Other Federal law (for example, regulations promulgated by another Federal agency) or State law may require that facility or medical equipment maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or may establish other, more stringent maintenance requirements. In these instances, the hospital must comply with these other Federal or State requirements, but State Surveyors conducting Federal surveys assess compliance only with the hospital Conditions of Participation (CoPs).*
- *Other CoPs require adherence to manufacturer's recommendations and/or set specific standards which preclude their inclusion in an AEM program. For example:*
 - *The National Fire Protection Association Life Safety Code (LSC) requirements incorporated by reference at 42 CFR 482.41(b) has some provisions that are pertinent to equipment maintenance, and compliance with these requirements are assessed on Federal surveys. Further, §482.41(b)(9)(v) requires hospitals to adhere to the manufacturer's maintenance guidelines for alcohol-based hand-rub dispensers. Compliance with these requirements is assessed on Federal surveys.*
 - ***Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes, is governed by 42 CFR 482.26(b)(2) and must be maintained per manufacturer's recommendations.***
- *The equipment is a medical laser device. It should be noted that for medical lasers the U.S. Food and Drug Administration requires manufacturers to provide a schedule of maintenance and adequate instructions for service adjustments and service procedures to purchasers and, at cost, to any other parties requesting them.*
- *New equipment for which sufficient maintenance history, either based on the hospital's own or its contractor's records, or available publicly from nationally recognized sources, is not available to support a risk-based determination must not be immediately included in the AEM program. New equipment must be maintained in accordance with manufacturer recommendations until a sufficient amount of maintenance history has been acquired to determine whether the alteration of maintenance activities or frequencies would be safe. If a hospital later transitions the equipment to a risk-based maintenance regimen different than the manufacturers' recommendations, the hospital must maintain evidence that it has first evaluated the maintenance track record, risks, and tested the alternate regimen.*

Alternative Maintenance Frequencies or Activities

Maintenance strategies are various methodologies used for determining the most efficient and effective maintenance activities and frequencies. Manufacturers' recommendations may be

based on one or more such strategies. A hospital may also use one or more maintenance strategies for its AEM program in order to determine the appropriate maintenance, inspection, and testing activities and frequencies, based upon the nature of the equipment and the level of risk it presents to patient or staff health and safety. The risk to patient health and safety that is considered in developing alternative maintenance strategies must be explained and documented in the AEM program.

In developing AEM maintenance strategies hospitals may rely upon information from a variety of sources, including, but not limited to: manufacturer recommendations and other materials, nationally recognized expert associations, and/or the hospital's (or its third party contractor's) own experience. Maintenance strategies may be applied to groups or to individual pieces of equipment.

The hospital is expected to adhere strictly to the AEM activities or strategies it has developed.

Background Information on Types of Maintenance Strategies

- **Preventive Maintenance (Time-based Maintenance)** – a maintenance strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance. Most preventive maintenance is “interval-based maintenance” performed at fixed time intervals (e.g., annual or semi-annual), but may also be “metered maintenance” performed according to metered usage of the equipment (e.g., hours of operation). In either case, the primary focus of preventive maintenance is reliability, not optimization of cost-effectiveness. Maintenance is performed systematically, regardless of whether or not it is needed at the time. Example: Replacing a battery every year, after a set number of uses or after running for a set number of hours, regardless.
- **Predictive Maintenance (Condition-based Maintenance)** – a maintenance strategy that involves periodic or continuous equipment condition monitoring to detect the onset of equipment degradation. This information is used to predict future maintenance requirements and to schedule maintenance at a time just before equipment experiences a loss of performance. Example: Replacing a battery one year after the manufacturer's recommended replacement interval, based on historical monitoring that has determined the battery capacity does not tend to fall below the required performance threshold before this extended time.
- **Reactive Maintenance (Corrective, Breakdown or Run-to-Failure Maintenance)** – a maintenance strategy based upon a “run it until it breaks” philosophy, where maintenance or replacement is performed only after equipment fails or experiences a problem. This strategy may be acceptable for equipment that is disposable or low cost, and presents little or no risk to health and safety if it fails. Example: Replacing a battery after equipment failure when the equipment has little negative health and safety consequences associated with a failure and there is a replacement readily available in supply.
- **Reliability-Centered Maintenance** – a maintenance strategy that not only considers equipment condition, but also considers other factors unique to individual pieces of equipment, such as equipment function, consequences of equipment failure, and the operational environment. Maintenance is performed to optimize reliability and cost

effectiveness. Example: Replacing a battery in an ambulance defibrillator more frequently than the same model used at a nursing station, since the one in the ambulance is used more frequently and is charged by an unstable power supply.

Maintenance Tools

Tools (e.g., hand tools, test equipment, software, etc.) necessary for performing equipment maintenance must be available and maintained to ensure that measurements are reliable. Tools used for maintenance are not required to be those specifically recommended by the manufacturer, but tools utilized must be capable of providing results equivalent to those required by the equipment manufacturer.

AEM Program Documentation

For each type of equipment subject to the AEM program, there must be documentation indicating:

- The pertinent types and level of risks to patient or staff health and safety;*
- Alternate maintenance activities, and the maintenance strategy and any other rationale used to determine those activities; the differences from the manufacturer's recommended maintenance activities are made explicit, unless the hospital is unable to obtain the manufacturer's maintenance recommendations, due to the age of the equipment or the manufacturer's restricting the availability of its recommendations;*
- Alternate maintenance frequencies to be used, if any, and the maintenance strategy and any other rationale used to determine those frequencies. For equipment identified as presenting a very low risk to patient or staff safety, it could be acceptable to not set a particular frequency but instead indicate a less specific approach, for example, an interval range, such as "every 12 – 24 months." It could also be acceptable to employ periodic "departmental sweeps" for such very low risk equipment, where equipment functioning is sampled and operators are polled about its functionality.*
- The date when AEM program maintenance activities were performed and, if applicable, further actions required/taken; and*
- Documentation of any equipment failures (not including failures due to operator error), including whether there was resulting harm to an individual. (Note: equipment failure that is due to operator error and which results in an adverse event or near miss must be documented in accordance with the QAPI CoP, as part of the hospital's required tracking of patient safety-related incidents. However, there is no requirement to include operator failures in equipment maintenance documentation.)*

When the hospital has multiple identical equipment items, the documentation may be generic to that type of equipment, except that documentation of maintenance activities performed must be specific to each item of equipment.

Evaluating Safety and Effectiveness of the AEM Program

The hospital must have policies and procedures which address the effectiveness of its AEM program. In evaluating the effectiveness of the AEM program the hospital is expected to address factors including, but not limited to:

- *How equipment is evaluated to ensure there is no degradation of performance, particularly for equipment where such degradation may not be readily apparent to staff using the equipment, e.g., miscalibration.*
- *How incidents of equipment malfunction are investigated, including:*
 - *whether or not the malfunction could have been prevented, and what steps will be taken to prevent future malfunctions; and*
 - *how a determination is made whether or not the malfunction resulted from the use of an AEM strategy;*
- *The process for the removal from service of equipment determined to be unsafe or no longer suitable for its intended application; and*
- *The use of performance data to determine if modifications in the AEM program procedures are required.*

Equipment Inventory

All hospital facility and medical equipment, regardless of whether it is leased or owned, and regardless of whether it is maintained according to manufacturer recommendations or is in an AEM program, is expected to be listed in an inventory which includes a record of maintenance activities. For low cost/low risk equipment, such as housekeeping cleaning equipment, it is acceptable for the inventory to indicate under one item the number of such pieces of equipment in the hospital, e.g., "15 vacuum cleaners for cleaning patient rooms and common areas."

If the hospital is using an AEM program, the equipment managed through that program must be readily separately identifiable as subject to AEM. Critical equipment, whether in an AEM program or not, must also be readily identified as such.

To facilitate effective management, a well-designed equipment inventory contains the following information for all equipment included. However, hospitals have the flexibility to demonstrate how alternative means they use are effective in enabling them to manage their equipment.

- *A unique identification number;*
- *The equipment manufacturer;*
- *The equipment model number;*
- *The equipment serial number;*
- *A description of the equipment;*
- *The location of the equipment (for equipment generally kept in a fixed location);*
- *The identity of the department considered to "own" the equipment;*
- *Identification of the service provider;*

- *The acceptance date; and*
- *Any additional information the hospital believes may be useful for proper management of the equipment.*

This standard shall apply to all locations of the hospital, all campuses, and all off-site facilities.

The hospital's department that is responsible for the hospital'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.

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

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

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. 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.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11,

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

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

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

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

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

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

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

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

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

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

(2) [Reserved]

[51 FR 22042, June 17, 1986, as amended at 53 FR 11509, Apr. 7, 1988; 68 FR 1386, Jan. 10, 2003; 69 FR 49267, Aug. 11, 2004; 70 FR 15238, Mar. 25, 2005; 71 FR 55340, Sept. 22, 2006; 81 FR 26899, May 4, 2016; 81 FR 42548, June 30, 2016]

Surveyor Guidance:

The survey team will delegate one surveyor to review and evaluate the physical environment of the hospital. However, each surveyor, during their respective review of areas within the hospital, should assess the hospital'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 hospital is maintained in a manner to assure the safety and wellbeing of patients (e.g., condition or ceilings, walls, and floors, presence of patient hazards, etc.).

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

Verify that the hospital 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.

Interview personnel in charge of facility, supplies and equipment maintenance to verify:

- supplies are maintained in such a manner as to ensure an acceptable level of safety and quality.
- supplies are stored as recommended by the manufacturer.
- supplies are stored in such a manner as not to endanger patient safety.
- the hospital has identified supplies and equipment that are likely to be needed in emergency situation.
- the hospital has made adequate provisions to ensure the availability of those supplies and equipment when needed.
- Interview equipment users when surveying the various units/departments of the hospital to determine if equipment failures are occurring and causing problems for patient health

or safety.

- Determine if there is a complete inventory of equipment required to meet patient needs, regardless of ownership.
- Is critical equipment readily identified?
- If the hospital employs an AEM program, is equipment in this program readily identified?
- Determine if the hospital has documentation of the qualifications (e.g., training certificates, certifications, degrees, etc.) of hospital personnel responsible for the AEM program (if one is being used by the hospital) as well as for those performing maintenance.
- Determine if the hospital is able to demonstrate how it assures contractors use qualified personnel.

If the hospital is following the manufacturer-recommended equipment maintenance activities and frequencies:

- In addition to reviewing maintenance records on equipment observed while inspecting various hospital locations for multiple compliance assessment purposes, select a sample of equipment from the hospital's equipment inventory to determine whether the hospital is following the manufacturer's recommendations. Critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc. should make up the sample majority.

For the sample selected, determine if:

- The hospital has available manufacturer's recommendations (e.g., manufacturer's operation and maintenance manual, standards, studies, guidance, recall information, service records, etc.);
- Maintenance is being performed in accordance with manufacturer's recommendations.

If a hospital is using an AEM for some equipment:

- *Does the hospital's inventory include equipment, for example, any diagnostic imaging or therapeutic radiologic equipment, which is not eligible for AEM?*
- *Determine if the hospital's development of alternate maintenance activities and frequencies for equipment in the AEM program as well as AEM activities are being performed by qualified personnel*
- *Verify the hospital has documented maintenance activities and frequencies for all equipment included in the AEM program;*
- *Verify the hospital is evaluating the safety and effectiveness of the AEM program.*
- *If there is equipment on the inventory the hospital has identified as having such a very low level of risk that it has determined it can use a broad interval range or departmental "sweeps," ask the hospital for the evidence used to make this determination. Does it seem reasonable?*

Select a sample of equipment in the AEM program. The majority of the sample must include critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc. For the sample selected:

- *Ask the responsible personnel to explain how the decision was made to place the equipment in an AEM program. Does the methodology used consider risk factors and make use of available evidence?*
- *Ask the responsible personnel to describe the methodology for applying maintenance strategies and determining alternative maintenance activities or frequencies for the sampled equipment. Can they readily provide an explanation and point to sources of information they relied upon?*
- *Determine if maintenance is being performed in accordance with the maintenance activities and frequencies defined in the AEM program.*
- *Verify the hospital is evaluating the safety and effectiveness of the AEM maintenance activities for this equipment and taking corrective actions when needed.*

PE.2 LIFE SAFETY MANAGEMENT SYSTEM

SR.1 The hospital 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.) Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.

- a. Notwithstanding paragraph (b)(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.

- b. 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 hospital, but only if the waiver will not adversely affect the health and safety of the patients.
- c. The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals

SR.2 reserved

SR.3 The organization shall maintain written evidence of regular inspection and approval by State or local fire control agencies.

SR.4 The organization must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel, and visitors; evacuation; and cooperation with firefighting authorities.

The fire control plan shall provide for the following (NFPA 101-2012, 18.7.2.2 & 19.7.2.2):

SR.4a Use of alarms

SR.4b Transmission of alarms to fire department

SR.4c Emergency phone call to fire department

SR.4d Response to alarms

SR.4e Isolation of fire

SR.4f Evacuation of immediate area

SR.4g Evacuation of smoke compartment

SR.4h Preparation of floors and building for evacuation

SR.4i Extinguishment of fire

SR.5 The Life Safety Management System shall include in the elements of SR.4e a written barrier protection plan for the preservation of the integrity of hospital smoke and fire barriers. The plan shall include:

- a. Name(s) of Responsible hospital staff for barrier protection program
- b. Requirement for written permission for anyone (including all hospital staff, contractors and vendors) to penetrate a smoke or fire barrier wall, ceiling or floor
- c. Input from Infection Control and Prevention Practitioner on critical clinical areas prior to issuance of written permit for performing work on barriers
- d. Establishment of monitoring process to ensure all work is completed correctly

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. (NFPA 101-2012, 18.7.1.7. & 19.7.1.7).

SR.6a. Business occupancies shall conduct at least one unannounced fire drill annually per shift.

SR.6b. Fire drills must be thoroughly documented and evaluate the organization's knowledge to the items listed in PE.2, SR.4.

SR.6c. At least annually, the organization shall evaluate the effectiveness of the fire drills, The report of effectiveness shall be forwarded to Quality Management oversight.

SR.7 The Life Safety Management System shall address applicable Alternative Life Safety Measures (ALSM) that shall be implemented whenever life safety features, systems, or processes are impaired or deficiencies 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 When a sprinkler system is shut down for more than 10 hours, the hospital must:

- a. Evacuate the building or portion of the building affected by the system outage until the system is back in service, or
- b. Establish a fire watch until the system is back in service

SR.9 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.

- a. The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.
- b. The sill height in special nursing care areas of new occupancies must not exceed 60 inches.

SR. 10 The Life Safety Management System shall require that Life Safety systems (e.g., fire suppression, notification, and detection equipment) shall be tested and inspected (including portable systems).

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

SR.12 All sleeping rooms shall be equipped with an approved, single station smoke alarm.

Note: NFPA 101, 2012 9.6.2.10.1.4: System smoke detectors in accordance with NFPA 72, National Fire Alarm and Signaling Code, and arranged to function in the same manner as single-station or multiple-station smoke alarms shall be permitted in lieu of smoke alarms.

SR.13 Construction, Repair, and Improvement operations shall involve the following activities:

SR.13a. During construction, repairs, or improvement operations, or otherwise affecting the space, *the Guidelines for Design and Construction of Hospitals and Health Care Facilities*, 2014 Edition, published by the American Institute of Architects shall be consulted for designing purposes.

SR.13b. The organization 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.13c. 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 241-2009, *Standard for Safeguarding Construction, Alteration, and Demolition Operations* shall be referenced in identifying and implementing alternative life safety measures.

SR.13d. All construction, repairs, or improvement operations, shall be in accordance with applicable NFPA 101-2012 standards, and State and local building and fire codes. Should standards and codes conflict, the most stringent standard or code shall prevail.

Interpretive Guidelines:

The hospital, regardless of size or number of beds, shall meet the applicable provisions of the 2012 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 hospital 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.2 to be applicable, the appropriate supporting documentation must be in place.

The hospital will maintain and update, as necessary, a fire control plan that includes the elements of SR.4. The hospital 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 tested and inspected (including portable systems);*
- *require a process for reviewing bedding, draperies, furnishings and decorations for fire safety; and,*

When construction, repairs, or improvement operations affect the space where hospital processes are carried out, the Guidelines for Design and Construction of Hospitals and Health Care Facilities, 2014 edition (or newer revision if in publication), NFPA 101- 2012 standards, and State and local building and fire codes shall be used.

When construction, repairs, or improvement operations impacts occupied areas, the hospital will also make provisions to include, as appropriate, infection control practices to be followed, utility requirements, and account for noise and vibration. The hospital may have also implemented appropriate alternative life safety measures which are required to be approved by the authority having local jurisdiction.

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 hospital's written fire control plans to verify they contain the required provisions of the Life Safety Code® or State law.

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

In the review of respective areas of the hospital, 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.

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 101-2012, 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 hospital 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 hospital, verify that the hospital 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.*

PE.3 SAFETY MANAGEMENT SYSTEM

SR.1 The organization shall provide a Safety Management System that shall maintain safe and adequate facilities for its services. Diagnostic and therapeutic facilities must be located for the safety of patients.

SR.2 The Safety Management System shall require that facilities, supplies and equipment be maintained and ensure an acceptable level of safety and quality. The extent and complexity of facilities shall be determined by the services offered.

SR.3 The Safety Management System shall require proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas.482.41 (d)(4)

SR.4 The Safety Management System shall require that the organization maintain an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries.

SR.5 The Safety Management System shall require periodic surveillance of the hospital grounds to observe and correct safety issues that may be identified.

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

SR.7 All eyewashes and emergency showers shall be tested and maintained according to the ANSI Z358.1-2009 Standard.

SR.8 The hospital must have procedures for the proper routine storage and prompt disposal of trash.

Interpretive Guidelines:

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

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.

PE.4 SECURITY MANAGEMENT SYSTEM

SR.1 The organization shall develop a Security Management System that provides for a secure environment.

SR.2 The organization shall meet the requirements set forth in NFPA 99, 2012 Chapter 13, Security Management.

SR.3 The Security Management System shall require that the organization conduct a security vulnerability assessment (SVA) and shall implement procedures and controls in accordance with the risks identified by the SVA.

SR.4 The Security Management System shall at a minimum:

SR.4a. Provide for identification of patients, employees and others.

SR.4b. Address issues related to abduction, elopement, visitors, workplace violence, and investigation of property losses.

SR.4c. Develop a written, comprehensive workplace violence control and prevention program based on guidelines from national authorities such as the *OSHA Publication 3148-04R 2015 Guidelines for Preventing Workplace Violence for Healthcare and Social Workers*.

SR.4d. Establish emergency security procedures to include all hazard events identified in the SVA.

SR.4e. Require vehicular access to emergency service areas.

SR.4f. Require a process for reporting and investigating security related issues.

Interpretive Guidelines:

From NFPA 99, 2012, Chapter 13

13.2 Security Vulnerability Assessment (SVA).

13.2.1 The health care facility shall conduct a security vulnerability assessment (SVA).*

13.2.2 The SVA shall evaluate the potential security risks posed by the physical and operational environment of the health care facility to all individuals in the facility.

13.2.3 The facility shall implement procedures and controls in accordance with the risks identified by the SVA.

These include but may not be limited to:

(1) Provide identification for patients, staff, and other people entering the facility

(2) Control access in and out of security-sensitive areas

(3) Define and implement procedures as follows:

(a) Security incident

(b) Hostage situation

*(c) *Bomb (explosive device or threat)*

(d) Criminal threat

(e) Labor action

(f) Disorderly conduct

(g) Workplace violence

(h) Restraining order

(i) Prevention of, and response to, infant or pediatric abduction

(j) Situations involving VIPs or the media

(k) Maintenance of access to emergency areas

(l) Civil disturbance

- (m) Forensic patients
- (n) Patient elopement
- (o) Homeland Security advisory system (threat level changes)
- (p) Suspicious powder or substance
- (q) Use of force policy
- (r) Security staffing augmentation

- (4) Provide security at alternate care sites or vacated facilities
- (5) Control vehicular traffic on the facility property
- (6) Protect the facility assets, including property and equipment
- (7) Provide policy for interaction with law enforcement agencies
- (8) Comply with applicable laws, regulations, and standards regarding security management operations
- (9) Educate and train the facility security force to address the following:
 - (a) Customer service
 - (b) Use of physical restraints
 - (c) Use of force
 - (d) Response criteria
 - (e) Fire watch procedures
 - (f) Lockdown procedures
 - (g) Emergency notification procedures
 - (h) Emergency communications procedures

For general information regarding the SVA and premises security, see NFPA 730, *Guide for Premises Security*.

Elements of a Workplace Violence Prevention Program should include but not be 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 PE.4, SR.1 – SR.4.

PE.5 HAZARDOUS MATERIAL (HAZMAT) MANAGEMENT SYSTEM

SR.1 The organization shall provide a Hazmat Management System to manage hazardous materials and waste.

SR.2 The HAZMAT Management System shall provide processes to manage the environment, selection, handling, storing, transporting, using, and disposing of hazardous materials and waste.

SR.3 The HAZMAT Management System shall provide processes to manage reporting and investigation of all spills, exposures, and other incidents.

SR.4 The organization shall monitor staff exposure levels in hazardous environments and report the results of the monitoring to the Quality Management System.

SR.5 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.

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 A hospital may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

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 least the following areas: Areas using ethylene oxide, nitrous oxide, gluteraldehydes, xylene, pentamidine, formaldehyde or other potentially hazardous substances;

Surveyor Guidance:

Verify that the hospital 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, DOT, 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.

Review documents to ensure employee and environmental monitoring is being conducted.

PE.6 EMERGENCY MANAGEMENT SYSTEM

SR.1 The organization must provide a comprehensive Emergency Management System to respond to emergencies in the organization or within the community and region that may impact the organization's ability to provide services.

SR.2 The organization shall meet the requirements set forth in NFPA 99 (2012), Chapter 12,

Emergency Management.

SR.3 The organization 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 in accordance with NFPA 99, 2012. The organization must develop and implement a comprehensive plan to ensure that the safety and wellbeing of patients are assured during emergency situations

The organization must 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. In addition to or in alignment with the text in NFPA 99, 2012 Chapter 12, the following issues should be considered when developing the comprehensive emergency plans(s):

- The differing needs of each location where the certified hospital operates;*
- The special needs of patient populations treated at the hospital (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 hospital 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 hospital's 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 hospital equipment to another hospital 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 hospital must provide for a comprehensive Emergency Management System in order to respond to emergencies in the organization or that occur in the community that impact the hospital'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, 2012: Health Care Facilities, Chapter 12, Emergency Management.

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

The organization's emergency management plan shall be revised based upon the identified opportunities for improvement.

Surveyor Guidance:

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

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

Review and validate:

- *That the organization has conducted appropriate and timely emergency management exercises.*
- *That after action documentation identified opportunities for improvements.*
- *That the organization revised its emergency management plan according to the identified opportunities for improvement.*

PE.7 MEDICAL EQUIPMENT MANAGEMENT SYSTEM

SR.1 The organization shall establish a Medical Equipment Management System that provides processes for the acquisition, safe use, and the appropriate selection of equipment.

SR.2 The Medical Equipment Management System shall address issues related to the organization's initial service inspection, the orientation, and the demonstration of use for rental or physician owned equipment.

SR.3. The Medical Equipment Management System shall address criteria for the selection of equipment.

SR.4 The Medical Equipment Management System shall address incidents related to serious injury or illness or death (See SMDA 1990).

SR.5 The Medical Equipment Management System shall have a process for reporting and investigating equipment management problems, failures, and user errors.

SR.6 The Medical Equipment Management System shall address a process for determining timing and complexity of medical equipment maintenance.

SR.7 The Medical Equipment Management System shall address the process of receiving and responding to recalls and alerts.

Interpretive Guidelines:

Medical Equipment must be maintained to ensure an acceptable level of safety and quality.

In order to ensure an acceptable level of safety and quality, the hospital must identify the equipment required to meet its patients' needs for both day-to-day operations and in a likely emergency/disaster situation, such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, etc. In addition, the hospital must make adequate provisions to ensure the availability and reliability of equipment needed for its operations and services. Equipment includes both facility equipment, which supports the physical environment of the hospital (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment, which are devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the hospital (e.g., IV infusion equipment, ventilators, laboratory equipment, surgical devices, etc.).

All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades.

All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. Equipment maintenance activities may be conducted using hospital personnel, contracted services, or through a combination of hospital personnel and contracted services. Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified. The hospital maintains records of hospital personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified.

All equipment maintenance policies, procedures and programs, as well as specific equipment maintenance inventories, activities and schedules fall under the purview of the hospital's clinical maintenance personnel, safety department personnel or other personnel who have been assigned responsibility for equipment maintenance by hospital leadership.

Hospitals comply with this regulation when they follow the manufacturer-recommended maintenance activities and schedule. Hospitals may choose to perform maintenance more frequently than the manufacturer recommends, but must use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer's recommendations, the hospital must maintain documentation of those recommendations and the hospital's associated maintenance activity for the affected equipment.

Alternate Equipment Management (AEM) Program

A hospital may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer. Hospitals that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the hospital associated with the use of facility or medical equipment. The AEM program must be based on generally accepted standards of practice for facility or medical equipment maintenance.

An example of guidelines for a medical equipment maintenance program may be found in the American National Standards Institute/ Association for the Advancement of Medical Instrumentation document: ANSI/AAMI EQ 56: 1999/ (R) 2013, Recommended Practice for a Medical Equipment Management Program. Likewise, an example of guidelines for physical plant equipment may be found in the American Society for Healthcare Engineering (ASHE) 2009 document: Maintenance Management for Health Care Facilities. There may be similar documents issued by other nationally recognized organizations which hospitals might choose to reference.

Decision to Place Equipment in an AEM Program

The determination of whether it is safe to perform facility or medical equipment maintenance without following the equipment manufacturer recommendations must be made by qualified personnel, regardless of whether they are hospital employees or contractors.

In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program.

In the case of facility equipment, a Healthcare Facility Management professional (facility manager, director of facilities, vice president of facilities) would be considered qualified.

The hospital must maintain records of the qualifications of hospital personnel who make decisions on placing equipment in an AEM program, and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.

In determining whether or not to include equipment in an AEM program, and which maintenance strategies to use in developing maintenance activities and frequencies for particular equipment, the hospital must take into account the typical health and safety risks associated with the equipment's use. Note that the risk may vary for the same type of equipment, depending on the patient care setting within the hospital where it is used.

A hospital is expected to identify any equipment in its AEM program which is "critical equipment," i.e., biomedical or physical plant equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail. Surveyors must focus their review of a hospital's AEM program on critical equipment in that program and the hospital's documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

Factors for a hospital to consider when evaluating the risks associated with a particular type of equipment include, but are not limited to:

- *How the equipment is used and the likely consequences of equipment failure or malfunction - would failure or malfunction of the equipment hospital-wide or in a particular setting be likely to cause harm to a patient or a staff person?*
- *How serious is the harm likely to be? For example, a slightly miscalibrated scale in an adult internal medicine outpatient clinic might not present significant risk of harm. However, a miscalibrated scale in a neonatal intensive care unit could have very serious consequences for patient care.*
- *How widespread is the harm likely to be? For example, are many patients exposed to the equipment, resulting in harm due to failure impacting more patients or staff? If harm would be widespread, even if the harm to each affected individual is not serious, this would be a cause for concern.*
- *Information, if available, on the manufacturer's equipment maintenance recommendations, including the rationale for the manufacturer's recommendations;*

Maintenance requirements of the equipment:

- *Are they simple or complex?*
- *Are the manufacturer's instructions and procedures available in the hospital, and if so can the hospital explain how and why it is modifying the manufacturer's instructions?*
- *If the manufacturer's instructions are not available in the hospital, how does the hospital assess whether the AEM uses appropriate maintenance strategies?*
- *How readily can the hospital validate the effectiveness of AEM methods for particular equipment? For example, can the hospital explain how it ensures there is no reduction in the quality of the performance of biomedical equipment subjected to alternate maintenance methods?*
- *The timely availability of alternate devices or backup systems in the event of equipment failure or malfunction; and*
- *Incident history of identical or very similar equipment – is there documented evidence, based on the experience of the hospital (or its third party contractor), or on evidence publicly reported by credible sources outside the hospital, which:*
 - *Provides the number, frequency and nature of previous failures and service requests?*
 - *Indicates use of an AEM strategy does not result in degraded performance of the equipment?*

Generally multiple factors must be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The hospital is expected to be able to demonstrate to a surveyor the factors it considered in its risk assessment for equipment placed in its AEM program.

Equipment not Eligible for Placement in the AEM Program:

Some equipment may not be eligible for placement in the AEM program, for one or more of the following reasons:

- *Other Federal law (for example, regulations promulgated by another Federal agency) or*

State law may require that facility or medical equipment maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or may establish other, more stringent maintenance requirements.

- In these instances, the hospital must comply with these other Federal or State requirements, but State Surveyors conducting Federal surveys assess compliance only with the hospital Conditions of Participation (CoPs).*
- Other CoPs require adherence to manufacturer's recommendations and/or set specific standards which preclude their inclusion in an AEM program. For example:*
 - The National Fire Protection Association Life Safety Code (LSC) requirements incorporated by reference at 42 CFR 482.41(b) has some provisions that are pertinent to equipment maintenance, and compliance with these requirements are assessed on Federal surveys. Further, §482.41(b)(9)(v) requires hospitals to adhere to the manufacturer's maintenance guidelines for alcohol-based hand-rub dispensers. Compliance with these requirements is assessed on Federal surveys.*
 - Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes, is governed by 42 CFR 482.26(b)(2) and must be maintained per manufacturer's recommendations.*
- The equipment is a medical laser device. It should be noted that for medical lasers the U.S. Food and Drug Administration requires manufacturers to provide a schedule of maintenance and adequate instructions for service adjustments and service procedures to purchasers and, at cost, to any other parties requesting them.*
- New equipment for which sufficient maintenance history, either based on the hospital's own or its contractor's records, or available publicly from nationally recognized sources, is not available to support a risk-based determination must not be immediately included in the AEM program. New equipment must be maintained in accordance with manufacturer recommendations until a sufficient amount of maintenance history has been acquired to determine whether the alteration of maintenance activities or frequencies would be safe. If a hospital later transitions the equipment to a risk-based maintenance regimen different than the manufacturers' recommendations, the hospital must maintain evidence that it has first evaluated the maintenance track record, risks, and tested the alternate regimen.*

Alternative Maintenance Frequencies or Activities

Maintenance strategies are various methodologies used for determining the most efficient and effective maintenance activities and frequencies. Manufacturers' recommendations may be based on one or more such strategies. A hospital may also use one or more maintenance strategies for its AEM program in order to determine the appropriate maintenance, inspection, and testing activities and frequencies, based upon the nature of the equipment and the level of risk it presents to patient or staff health and safety. The risk to patient health and safety that is considered in developing alternative maintenance strategies must be explained and documented in the AEM program.

In developing AEM maintenance strategies hospitals may rely upon information from a variety of sources, including, but not limited to: manufacturer recommendations and other materials,

nationally recognized expert associations, and/or the hospital's (or its third party contractor's) own experience. Maintenance strategies may be applied to groups or to individual pieces of equipment.

The hospital is expected to adhere strictly to the AEM activities or strategies it has developed.

Background Information on Types of Maintenance Strategies

- **Preventive Maintenance (Time-based Maintenance)** – a maintenance strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance. Most preventive maintenance is “interval-based maintenance” performed at fixed time intervals (e.g., annual or semi-annual), but may also be “metered maintenance” performed according to metered usage of the equipment (e.g., hours of operation). In either case, the primary focus of preventive maintenance is reliability, not optimization of cost-effectiveness. Maintenance is performed systematically, regardless of whether or not it is needed at the time. Example: Replacing a battery every year, after a set number of uses or after running for a set number of hours, regardless.
- **Predictive Maintenance (Condition-based Maintenance)** – a maintenance strategy that involves periodic or continuous equipment condition monitoring to detect the onset of equipment degradation. This information is used to predict future maintenance requirements and to schedule maintenance at a time just before equipment experiences a loss of performance. Example: Replacing a battery one year after the manufacturer's recommended replacement interval, based on historical monitoring that has determined the battery capacity does not tend to fall below the required performance threshold before this extended time.
- **Reactive Maintenance (Corrective, Breakdown or Run-to-Failure Maintenance)** – a maintenance strategy based upon a “run it until it breaks” philosophy, where maintenance or replacement is performed only after equipment fails or experiences a problem. This strategy may be acceptable for equipment that is disposable or low cost, and presents little or no risk to health and safety if it fails. Example: Replacing a battery after equipment failure when the equipment has little negative health and safety consequences associated with a failure and there is a replacement readily available in supply.
- **Reliability-Centered Maintenance** – a maintenance strategy that not only considers equipment condition, but also considers other factors unique to individual pieces of equipment, such as equipment function, consequences of equipment failure, and the operational environment. Maintenance is performed to optimize reliability and cost effectiveness. Example: Replacing a battery in an ambulance defibrillator more frequently than the same model used at a nursing station, since the one in the ambulance is used more frequently and is charged by an unstable power supply.

Maintenance Tools

Tools (e.g., hand tools, test equipment, software, etc.) necessary for performing equipment maintenance must be available and maintained to ensure that measurements are reliable. Tools used for maintenance are not required to be those specifically recommended by the

manufacturer, but tools utilized must be capable of providing results equivalent to those required by the equipment manufacturer.

AEM Program Documentation

For each type of equipment subject to the AEM program, there must be documentation indicating:

- The pertinent types and level of risks to patient or staff health and safety;
- Alternate maintenance activities, and the maintenance strategy and any other rationale used to determine those activities; the differences from the manufacturer's recommended maintenance activities are made explicit, unless the hospital is unable to obtain the manufacturer's maintenance recommendations, due to the age of the equipment or the manufacturer's restricting the availability of its recommendations;
- Alternate maintenance frequencies to be used, if any, and the maintenance strategy and any other rationale used to determine those frequencies. For equipment identified as presenting a very low risk to patient or staff safety, it could be acceptable to not set a particular frequency but instead indicate a less specific approach, for example, an interval range, such as "every 12 – 24 months." It could also be acceptable to employ periodic "departmental sweeps" for such very low risk equipment, where equipment functioning is sampled and operators are polled about its functionality.
- The date when AEM program maintenance activities were performed and, if applicable, further actions required/taken; and
- Documentation of any equipment failures (not including failures due to operator error), including whether there was resulting harm to an individual.) (Note: equipment failure that is due to operator error and which results in an adverse event or near miss must be documented in accordance with the QAPI CoP, as part of the hospital's required tracking of patient safety-related incidents. However, there is no requirement to include operator failures in equipment maintenance documentation.)

When the hospital has multiple identical equipment items, the documentation may be generic to that type of equipment, except that documentation of maintenance activities performed must be specific to each item of equipment.

Evaluating Safety and Effectiveness of the AEM Program

The hospital must have policies and procedures which address the effectiveness of its AEM program. In evaluating the effectiveness of the AEM program the hospital is expected to address factors including, but not limited to:

- How equipment is evaluated to ensure there is no degradation of performance, particularly for equipment where such degradation may not be readily apparent to staff using the equipment, e.g., miscalibration.
 - How incidents of equipment malfunction are investigated, including:
 - whether or not the malfunction could have been prevented, and what steps will be taken to prevent future malfunctions; and
 - how a determination is made whether or not the malfunction resulted from the use of an AEM strategy;
- The process for the removal from service of equipment determined to be unsafe or no longer suitable for its intended application; and

- *The use of performance data to determine if modifications in the AEM program procedures are required.*

Equipment Inventory

All hospital facility and medical equipment, regardless of whether it is leased or owned, and regardless of whether it is maintained according to manufacturer recommendations or is in an AEM program, is expected to be listed in an inventory which includes a record of maintenance activities. For low cost/low risk equipment, such as housekeeping cleaning equipment, it is acceptable for the inventory to indicate under one item the number of such pieces of equipment in the hospital, e.g., "15 vacuum cleaners for cleaning patient rooms and common areas."

If the hospital is using an AEM program, the equipment managed through that program must be readily separately identifiable as subject to AEM. Critical equipment, whether in an AEM program or not, must also be readily identified as such.

To facilitate effective management, a well-designed equipment inventory contains the following information for all equipment included. However, hospitals have the flexibility to demonstrate how alternative means they use are effective in enabling them to manage their equipment.

- *A unique identification number;*
- *The equipment manufacturer;*
- *The equipment model number;*
- *The equipment serial number;*
- *A description of the equipment;*
- *The location of the equipment (for equipment generally kept in a fixed location);*
- *The identity of the department considered to "own" the equipment;*
- *Identification of the service provider;*
- *The acceptance date; and*
- *Any additional information the hospital believes may be useful for proper management of the equipment*

The hospital will develop and implement a Medical Equipment Plan 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.*

This shall apply to all locations of the hospital, all campuses, and all off-site facilities.

Surveyor Guidance:

Interview personnel in charge of equipment maintenance:

- *Select a sample of equipment for which the facility uses the manufacturer's*

recommendations for maintenance frequency. Sample selection should be based on:

- *Risk to patient safety from equipment failure (e.g., sample high/medium/low risk).*
- *Critical equipment (e.g., life support devices, key resuscitation devices, critical monitoring devices, equipment used for radiologic imaging etc.) with higher risk should make up the sample majority.*
- *Service Requests (e.g., sample equipment with high service requests)*
- *Failure Records (e.g., sample high failure rates)*
- *Equipment Usage (e.g., sample high use)*
- *Type of Equipment (e.g., sample medical equipment & facility components)*
- *Maintenance is being performed in accordance with manufacturer's recommendations*

For the sample selected, review maintenance records to determine if:

- *Maintenance, inspection, and testing records are complete and accurate;*
- *Maintenance records include equipment failures and down-time;*
- *Equipment failures are corrected (through repair or replacement) in a timely manner;*
- *Equipment failure patterns are investigated and addressed.*
- *Records contain the qualifications (e.g., training certificates, certifications, degrees, etc.) of hospital personnel responsible for performing maintenance and/or the hospital is able to demonstrate how they assure contracted personnel are qualified. In the case of medical equipment, qualified personnel would be clinical or biomedical technicians or engineers.*
- *Records contain documents required to support maintenance activities (e.g., manufacturer's operation and maintenance manual, standards, studies, guidance, recall information, service records, etc.)*

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

Verify that the hospital has developed and implemented a comprehensive plan to ensure that the safety and well-being 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.

Interview personnel in charge of facility, supplies and equipment maintenance to verify:

- *the hospital has identified supplies and equipment that are likely to be needed in emergency situation.*
- *the hospital has made adequate provisions to ensure the availability of those supplies and equipment when needed.*
- *Interview equipment users when surveying the various units/departments of the hospital to determine if equipment failures are occurring and causing problems for patient health or safety.*
- *Determine if there is a complete inventory of equipment required to meet patient needs, regardless of ownership.*
- *Determine if the inventory is periodically reviewed and updated.*
- *Is critical equipment readily identified?*
- *If the hospital employs an AEM program, is equipment in this program readily identified?*
- *Determine if the hospital has documentation of the qualifications (e.g., training certificates, certifications, degrees, etc.) of hospital personnel responsible for the AEM program (if one is being used by the hospital) as well as for those performing maintenance.*
- *Determine if the hospital is able to demonstrate how it assures contractors use qualified personnel.*

If the hospital is following the manufacturer-recommended equipment maintenance activities and frequencies:

In addition to reviewing maintenance records on equipment observed while inspecting various hospital locations for multiple compliance assessment purposes, select a sample of equipment from the hospital's equipment inventory to determine whether the hospital is following the manufacturer's recommendations. Critical equipment, which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc., should make up the sample majority.

For the sample selected, determine if:

- The hospital has available manufacturer's recommendations (e.g., manufacturer's operation and maintenance manual, standards, studies, guidance, recall information, service records, etc.);*
- Maintenance is being performed in accordance with manufacturer's recommendations.*

If a hospital is using an AEM for some equipment:

- Does the hospital's inventory include equipment, for example, any diagnostic imaging or therapeutic radiologic equipment, which is not eligible for AEM?*
- Determine if the hospital's development of alternate maintenance activities and frequencies for equipment in the AEM program as well as AEM activities are being performed by qualified personnel.*
- Verify the hospital has documented maintenance activities and frequencies for all equipment included in the AEM program;*
- Verify the hospital is evaluating the safety and effectiveness of the AEM program.*
- If there is equipment on the inventory the hospital has identified as having such a very low level of risk that it has determined it can use a broad interval range or departmental "sweeps," ask the hospital for the evidence used to make this determination. Does it seem reasonable?*

Select a sample of equipment in the AEM program. The majority of the sample must include critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc.

For the sample selected:

- Ask the responsible personnel to explain how the decision was made to place the equipment in an AEM program. Does the methodology used consider risk factors and make use of available evidence?*
- Ask the responsible personnel to describe the methodology for applying maintenance strategies and determining alternative maintenance activities or frequencies for the sampled equipment. Can they readily provide an explanation and point to sources of information they relied upon?*
- Determine if maintenance is being performed in accordance with the maintenance activities*

and frequencies defined in the AEM program.

- *Verify the hospital is evaluating the safety and effectiveness of the AEM maintenance activities for this equipment and taking corrective actions when needed.*
- *If there is equipment on the inventory the hospital has identified as having such a very low level of risk that it has determined it can use a broad interval range or departmental "sweeps," ask the hospital for the evidence used to make this determination. Does it seem reasonable?*

PE.8 UTILITY MANAGEMENT SYSTEM

SR.1 The organization shall require a Utility Management System that provides for a safe and efficient facility that reduces the opportunity for organization-acquired illnesses.

SR.2 The Utility Management System shall provide for a process to evaluate critical operating components.

SR.3 The Utility Management System shall develop maintenance, testing, and inspection processes for critical utilities.

SR.4 The Utility Management System shall contain a process to address medical gas systems and HVAC systems (e.g., includes areas for negative pressure).

SR.5 The Utility Management System shall provide for emergency processes for utility system failures or disruptions.

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

SR.7 The Safety Management System 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 organization (e.g., blood bank refrigerator, etc.). In all other areas not serviced by the emergency supply source, battery lamps and flashlights shall be available.

Emergency lighting standards shall comply with Section 7.9 of Life Safety Code, 101- 2012, and applicable references, such as, NFPA-99, 2012: Health Care Facilities Code, for emergency lighting and emergency power.

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

SR.10 All relevant utility systems shall be maintained, inspected, and inspected.

Interpretive Guidelines:

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

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

- *Areas using ethylene oxide, nitrous oxide, gluteraldehydes, 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);*
- *Laboratory locations: and*
- *Anesthetizing locations.*

NFPA 99, 2012 3.3.9 Anesthetizing Location. Any area of a facility that has been designated to be used for the administration of general anesthesia.*

NFPA 99, 2012 A.3.3.9 Anesthetizing Location. Areas used exclusively for sedation are not included in this definition.

(Note that this definition is applicable only for LSC purposes and does not supersede other guidance that has been given on anesthesia.)

Temperature, humidity, and airflow in the anesthetizing locations must be maintained within acceptable standards to inhibit microbial growth, reduce the risk of infection, control odor 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 Facilities Guidelines Institute (FGI) should be incorporated into hospital policy.

The hospital 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 organization (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 hospital will make provisions for battery lamps and flashlights.

The hospital must have systems for emergency gas and water needs to provide care to inpatients and other persons who may come to the hospital 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 hospital 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 hospital uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc.

The hospital 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).

Guideline for periodic testing intervals:

- Daily: once a day with a period of time that is as close as possible to 24 hours between actions*
- Weekly: once a week with a period of time that is as close as possible to 7 days between actions*
- Monthly: once a month with a period of time that is as close as possible to 30 days between actions*
- Quarterly: once every three months with a period of time that is as close as possible to 90 days between actions*
- Annually: once per year with a period of time that is as close as possible to 365 days between actions*

Surveyor Guidance:

Review and validate the hospital's Utility Management System to ensure that there is a process in place to provide for a safe and efficient facility that reduces the opportunity for hospital-acquired illnesses.

Review and validate the condition of the hospital 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 hospital'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 hospital 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 Utility Management System 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 hospital staff to determine the hospital'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 hospital 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 hospital, 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 adequate lighting is in place in all the patient care areas, and food and medication preparation areas.

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 hospital policy.

- *Review monitoring records for temperature to ensure that appropriate levels are maintained.*
- *Review humidity maintenance records for anesthetizing locations to ensure, if monitoring determined humidity levels were not within acceptable parameters, that corrective actions were performed in a timely manner to achieve acceptable levels.*