
CMS Manual System

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Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 103

Date: February 21, 2014

SUBJECT: Revised State Operations Manual (SOM) Hospital Appendix A

I. SUMMARY OF CHANGES: Clarification is provided in the SOM Appendix A for 42 CFR 482.41(c)(2), concerning the equipment maintenance requirements for hospitals.

NEW/REVISED MATERIAL - EFFECTIVE DATE: February 21, 2014
IMPLEMENTATION DATE: February 21, 2014

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/A-0724/§482.41(c)(2) - Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

III. FUNDING: No additional funding will be provided by CMS.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

State Operations Manual

Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

(Rev.103, Issued: 02-21-14)

A-0724

(Rev.103, Issued: 02-21-14, Effective: 02-21-14, Implementation: 02-21-14)

§482.41(c)(2) - Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

Interpretive Guidelines §482.41(c)(2)

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.*

Survey Procedures §482.41(c)(2)

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

- *Determine if* supplies *are* maintained in such a manner as to ensure *an acceptable level of safety and quality*.
- *Determine if* supplies *are* stored as recommended by the manufacturer.
- *Determine if* supplies *are* stored in such a manner as *not* to endanger patient safety.
- *Determine if* the hospital has identified supplies and equipment that are likely to be needed in emergency situation.
- *Determine if* the hospital has made adequate provisions to ensure the availability of those supplies and equipment when needed.

Concerning facility and medical equipment:

- *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.*