

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-07-Hospital

DATE: December 2, 2011

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clarification of Hospital Equipment Maintenance Requirements

Memorandum Summary

- **Alternate equipment maintenance schedules permitted in some instances:** Hospitals may adjust maintenance, inspection, and testing frequencies for some facility and medical equipment below those recommended by the manufacturer, based on an assessment by qualified personnel of the risk to patient and staff health and safety.
 - Manufacturer-recommended maintenance frequency is required for:
 1. All equipment critical to patient health and safety; and
 2. Any new equipment until a sufficient amount of maintenance history has been acquired.
- **Alternative equipment maintenance methods are not permitted:** Hospitals must continue to follow the manufacturer's recommended techniques for maintaining equipment, even if the hospitals alter the frequency of maintenance activities.

Section 482.41(c)(2) requires that hospital facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This memorandum updates the guidance in Appendix A of the State Operations Manual related to hospital facility and medical equipment maintenance.

Hospitals are expected to maintain equipment inventories and documentation of their maintenance activities. Federal or State laws and regulations (including Life Safety Code requirements adopted as part of Federal regulations) may require that equipment maintenance activities (i.e., maintenance, inspection and testing) be performed in accordance with the manufacturer's recommendations, or may establish other maintenance requirements. In these instances, the hospital must be in compliance with the most stringent maintenance requirements mandated. Absent such mandated requirements, it is acceptable for the hospital to follow the manufacturer's recommended maintenance schedule, to schedule more frequent maintenance than the manufacturer recommends, or, in some cases of non-critical equipment, to schedule less frequent equipment maintenance than the manufacturer calls for.

Equipment that is critical to patient health and safety is not a candidate for an alternative, less frequent maintenance activity schedule. Such equipment must be maintained at least as often as the manufacturer recommends. At a minimum such critical equipment includes, but is not limited to, life-support devices, key resuscitation devices, critical monitoring devices, equipment used for radiologic imaging, and other devices whose failure may result in serious injury to or death of patients or staff.

In addition, the manufacturer's recommended maintenance frequency must be utilized for all new equipment until a sufficient amount of maintenance history has been acquired to safely adjust the maintenance frequency below that recommended.

If a hospital is adjusting non-critical equipment maintenance frequencies to be below those recommended by the manufacturer, such adjustments must be based upon a systematic, evidence-based assessment. The hospital must document the assessment for all equipment with less frequent maintenance than what the manufacturer recommends, including the selected maintenance strategy that led to the lower adjusted frequency, and supporting evidence. The evidence must provide support that the frequency adjustment will not adversely affect patient or staff health and safety. The assessment of whether it is appropriate to use a maintenance strategy that results in less frequent maintenance than what the manufacturer recommends must be performed by qualified personnel. In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified.

Maintenance strategies are various methodologies for determining the most efficient and effective application of maintenance activities. Several maintenance strategies (e.g., Preventive, Predictive, Reactive, and Reliability-Centered) can be used to determine the appropriate frequency for maintenance, inspection, and testing of equipment, based upon acceptable risk to patient health and safety. Maintenance strategies may be applied to groups or individual pieces of equipment.

Although the hospital may elect to adjust the frequency of maintenance activities below those recommended by the manufacturer in some cases, the content of the recommended maintenance activities must not be substituted or eliminated.

Questions concerning this memorandum should be addressed to LCDR Martin Casey at martin.casey@cms.hhs.gov.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/

Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal

(Advance Copy)

Date:

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

I. SUMMARY OF CHANGES: Clarification is provided in the SOM Appendix A concerning the equipment maintenance requirements for hospitals.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

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	§482.41(c)

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2011 operating budgets.

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

A-0724

(Rev.)

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

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 well being of patients. This includes ensuring that required inspections, testing and maintenance (collectively referred to as “maintenance activities”) are performed in accordance with Federal and State laws, regulations, guidelines, standards and manufacturer’s recommendations. This is accomplished by establishing maintenance schedules and ongoing inspections and testing to identify areas in need of repair. Monitoring of maintenance activities should be incorporated into the hospital’s hospital-wide quality assessment and performance improvement program.

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

This would include that supplies are stored in such a manner to ensure the safety of the stored supplies (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.).

Additionally, “supplies must be maintained to ensure an acceptable level of safety” would include that the hospital identifies the supplies it needs to meet its patients’ needs for both day-to-day operations and 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.; and that the hospital makes adequate provisions to ensure the availability of those supplies when needed.

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

In order to ensure an acceptable level of health and safety, the hospital identifies the equipment it needs 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 its equipment needed for its operations and services. Equipment includes both facility equipment (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment (e.g., biomedical equipment, radiological equipment, patient beds, stretchers, IV infusion equipment, ventilators, laboratory equipment, etc.).

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

Equipment maintenance activities may be conducted using hospital personnel, contracts, or through a combination of hospital personnel and contracted services. Qualified individual(s) must be responsible for overseeing the development, implementation, management and performance of all equipment maintenance. In the case of medical equipment, a clinical or biomedical engineer would be considered qualified. The hospital must maintain records of hospital personnel qualifications and be able to demonstrate how they assure contracted personnel are qualified.

All policies and procedures pertaining to equipment maintenance, as well as specific equipment maintenance inventories and schedules, should be approved by the hospital's clinical maintenance and/or safety department personnel who have been assigned responsibility for equipment maintenance by hospital leadership.

The hospital must perform specific scheduled maintenance activities on the required facility and medical equipment. Federal or State laws and regulations (including Life Safety Code requirements adopted as part of Federal regulations) may require that maintenance activities be performed in accordance with the manufacturer's recommendations or may have other maintenance requirements. In these instances, the hospital must be in compliance with the most stringent maintenance requirements. An example of a specific federal regulatory requirement would be at §482.41(b)(9)(v), which requires hospitals to adhere to the manufacturer's maintenance guidelines for alcohol-based hand-rub dispensers. Absent such specified required maintenance directives in Federal and State laws, a hospital may schedule more stringent and/or frequent maintenance activities than what the manufacturer recommends, or, in some instances and under certain circumstances, may adjust equipment maintenance activity frequencies below those recommended by the manufacturer.

*If the hospital is following or exceeding the manufacturer-recommended maintenance activities, the hospital must maintain documentation of the manufacturer's recommendations and associated hospital maintenance activity records. However, if the hospital is adjusting maintenance activity frequencies below those that are recommended by the manufacturer, such adjustments must be based upon a systematic evidence-based assessment. The hospital must document this assessment procedure for all equipment with less frequent maintenance activities than the manufacturer recommends, as well as the actual maintenance strategy and frequency, and the supporting evidence. The evidence must provide support that the frequency adjustment will not adversely affect patient or staff health and safety. It is emphasized that, although the hospital may elect to adjust the **frequency** of maintenance activities below those recommended by the*

manufacturer in some cases, the content of the recommended maintenance activities must not be substituted or eliminated.

Several types of maintenance strategies can be used to determine the appropriate frequency for maintenance, inspection, and testing of hospital equipment, based upon acceptable risk to patient health and safety. Maintenance strategies are various methodologies for determining the most efficient and effective application of maintenance activities. Maintenance strategies can be based upon manufacturer recommendations, risk considerations, industry practice, and/or hospital experience. Maintenance strategies may be applied to groups of equipment or individual pieces of equipment.

- *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 performed at time intervals (e.g., annual or semi-annual), i.e., “interval-based maintenance, but may also be performed according to metered usage (e.g., hours of operation), i.e., “metered maintenance.” 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 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 tends to fall below the required threshold after this extended time interval.*
- *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 no 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. Although this approach is based upon the predictive maintenance strategy, it also recognizes that some equipment may be better served by preventive or reactive maintenance. Example: Replacing a battery in an ambulance defibrillator more frequently than the same model used*

at a nursing station as the one in the ambulance is used more frequently and is charged by an unstable power supply.

The following is a non-hospital example to illustrate different scenarios where the use of alternative maintenance strategies could result in a different maintenance schedule than that called for by the manufacturer: A car manufacturer utilizes a “Preventive Maintenance” strategy in its owners’ manual by recommending oil changes every 5,000 miles, i.e., the manufacturer provides an oil changing interval required to prevent engine failure based upon the characteristics of motor oil, the typical driver, and average miles driven.

Scenario #1 - In this case, a car owner drives only 1,000 miles a year. According to the manufacturer’s recommendation, this would suggest a five-year interval for changing the oil. Because oil may degrade over time, and not just as a result of miles driven, it may be appropriate to adjust the maintenance frequency based upon a “Predictive /Interval-based Maintenance” strategy where oil change would occur based upon an amount of time elapsed since the last oil change, e.g, once a year.

Scenario #2 - In this case, the car owner drives an older car. Upon changing the oil in accordance with the manufacturer’s recommendation, the owner finds the oil is excessively dirty. In this situation, it may be appropriate to adjust the maintenance frequency based upon a “Predictive/Metered Maintenance” strategy to decrease the number of miles driven before the oil is changed.

Scenario #3 - In this case, the car owner drives an inexpensive car, does not want to take the time for maintenance, and does not care if lack of maintenance means having to replace the car sooner rather than later. Based on this particular owner’s atypical priorities, a “Reactive Maintenance” strategy could be used, i.e., the owner would run the car without changing the oil until it breaks down.

Scenario #4 - In this case, the vehicle is an emergency vehicle, such as a fire engine or ambulance. It is imperative that the vehicle be maintained for reliable performance. Under a “Reliability-centered Maintenance” strategy, oil quality is periodically tested to ensure oil characteristics are appropriate and the frequency of oil changes is adjusted accordingly. This strategy considers factors other than the vehicle’s condition (i.e., the consequences of vehicle failure) and maintenance activities are being performed in a manner to optimize reliability.

The assessment and determination of whether it is appropriate to use an alternative maintenance strategy that results in a less frequent maintenance activity schedule than the manufacturer calls for must be performed by qualified personnel. These personnel must be intimately familiar with the operation and maintenance of the equipment and the associated risks of equipment failure to patient health and safety. In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified.

In determining alternative maintenance strategies that reduce (or increase) equipment maintenance activity frequency, factors that may be considered in determining an alternative maintenance strategy may include, but are not limited to: information, if

available, on the rationale for the manufacturer's recommendations; how the equipment is used (e.g., life support versus non-life support); the age of individual devices; the maintenance history for that model of equipment and for the individual device (e.g., number and frequency of previous failures and service requests); the availability of alternate devices or backup systems; the complexity of the equipment; its durability; the hospital's experience with that type of equipment, industry experience with that type of equipment, etc. The rationale for using an alternative maintenance strategy that results in less frequent maintenance activity than the manufacturer recommends must be documented. The hospital must also periodically re-evaluate the alternative maintenance strategy and frequency determination. The re-evaluation and subsequent modifications, if applicable, in the maintenance activities schedule must also be documented.

Equipment that is critical to patient health and safety is not a candidate for an alternative, less frequent maintenance activity schedule. Such equipment must be maintained at least as often as the manufacturer recommends. At a minimum such critical equipment includes, but is not limited to, life-support devices, key resuscitation devices, critical monitoring devices, equipment used for radiologic imaging, and other devices whose failure may result in serious injury or death of patients or staff. Manufacturer's recommendations must also be followed for all new equipment until a sufficient amount of maintenance history has been acquired to safely adjust in certain cases the maintenance frequency below what is recommended by the manufacturer.

Hospitals are expected to maintain an inventory of all facility and medical equipment required to meet its patients' needs, which includes, at a minimum:

- *Identification of critical or non-critical equipment, including associated risk criteria;*
- *Required maintenance activities (maintenance, inspection, and/or testing);*
- *The frequency of each required activity, including whether the frequency is based on or exceeds the manufacturer's recommendations or is based on an alternative, evidence-based maintenance schedule;*
- *Equipment incoming date (i.e., date new or repaired equipment is inspected and put into service);*
- *Dates of most recent maintenance activities; and*
- *Equipment incident history.*

Inventories that include maintenance strategies and maintenance activity frequencies other than those recommended by the manufacturer must also reference a documented determination that explains how the alternate maintenance frequency was determined.

Survey Procedures §482.41(c)(2)

- Interview *personnel* in charge of equipment *maintenance*:
 - *Determine if there is an equipment inventory for equipment required to meet patient needs; review it for completeness, including all required information.*

- *Determine if the inventory is periodically reviewed and updated.*
- *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)*
 - *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.)*
 - *Maintenance is being performed in accordance with manufacturer's recommendations.*
- *If a facility has elected to use maintenance activity frequencies for facility and medical equipment other than those recommended by the manufacturer:*
 - *Review the equipment inventory to ensure that critical equipment (e.g., life-support devices, key resuscitation devices, critical monitoring devices,*

equipment used for radiologic imaging, etc) or specific equipment subject to a regulatory requirement are not included under an alternative, lesser maintenance frequency.

- *Select a sample of equipment which are subjected to less frequent maintenance than what the manufacturer recommends to determine if:*
 - *The rationale for the alternative maintenance schedule is well-documented, reasonable, based on evidence on the associated risks, and approved by responsible personnel in the clinical maintenance and/or safety department.*
 - *There is evidence of periodic review to determine whether the chosen alternative schedule is still appropriate.*
 - *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;*
 - *Failure patterns are investigated, addressed, result in changes to the alternate maintenance strategy or frequency, as necessary;*
 - *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.)*
 - *Equipment is actually maintained according to the alternative schedule.*
- *Interview equipment users to determine if equipment failures are occurring and causing problems for patient safety.*
- *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 situations.
- *Determine if* the hospital has made adequate provisions to ensure the availability of those supplies and equipment when needed.