

**Office of Clinical Standards and Quality/Survey & Certification Group**

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**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**

- 1** • **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.
- 2** • **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.

3 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.

4 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](mailto: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

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# CMS Manual System

## Pub. 100-07 State Operations Provider Certification

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

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Transmittal

(Advance Copy)

Date:

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**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

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A-0724

(Rev.)

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**§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.*

6

#### **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.

# Appendix A.1

## Risk-based biomedical equipment management programme

Equipment inclusion criteria have been developed to evaluate each piece of equipment in use at a hospital or health facility. The following details a modified version of the Fennigkoh and Smith model (see reference 6) where a numerical value has been assigned to each device type by classifying its equipment function, clinical application and required maintenance. Adding the number from each subgroup and adding or subtracting a factor based on equipment failure history yields an equipment management (EM) number.

EM number equation:

$$EM \# = \text{Function \#} + \text{Application \#} + \text{Maintenance \#} + \text{History \#}$$

### Equipment function

Includes various areas in which therapeutic, diagnostic, analytical and miscellaneous equipment is used.

Category	Function description	Point score
Therapeutic	Life support	10
	Surgical and intensive care	9
	Physical therapy and treatment	8
Diagnostic	Surgical and intensive care monitoring	7
	Additional physiological monitoring and diagnostic	6
Analytical	Analytical laboratory	5
	Laboratory accessories	4
	Computers and related	3
Miscellaneous	Patient related and other	2

### Physical risk associated with clinical application

Lists the potential patient or equipment risk during use.

Description of use risk	Point score
Potential patient death	5
Potential patient or operator injury	4
Inappropriate therapy or misdiagnosis	3
Equipment damage	2
No significant identified risk	1

## Maintenance requirements

Describes the level and frequency of maintenance required as noted by the manufacturer or through experience.

Maintenance requirement	Point score
Extensive: routine calibration and part replacement required	5
Above-average	4
Average: performance verification and safety testing	3
Below-average	2
Minimal: visual inspection	1

## Equipment incident history

Any information available regarding service history that can be considered when evaluating the device type to determine an EM number.

Average equipment failures	Factor
Significant: more than one every 6 months	+2
Moderate: one every 6–9 months	+1
Average: one every 9–18 months	0
Minimal: one every 18–30 months	-1
Insignificant: less than one in the past 30 months	-2

## Included devices

All devices with a total EM number of 12 or more will be included in the programme and scheduled for inspections and preventive maintenance. During the acceptance testing, any new device will be included in the programme if the device has been previously evaluated and classified for inclusion. If the device has not been previously evaluated, a new device classification will be created. It will be evaluated according to the outlined procedure to produce an EM number and will be included in the programme if appropriate. If included, a performance assurance inspection and preventive maintenance procedure will be written for the new device.

## Maintenance interval

The maintenance requirement values are also used to determine the interval between each inspection and maintenance procedure for each device type.

- All devices classified as extensive (characteristic value of 4 or 5) are given a preventive maintenance interval of six months.
- Devices with average or minimal requirements (values of 3, 2 or 1) are scheduled for preventive maintenance annually.
- Devices with an EM number of 15 or above will be scheduled for inspection at least every six months.
- Devices with an EM number of 19 or 20 will be given an inspection interval of four months.

## Devices not included in the programme

All patient care-related equipment including therapeutic, monitoring, diagnostic or analytical equipment not included in the programme, because it did not receive an EM number of 12 or above, may still be included in the hospital's biomedical equipment inventory and be covered on a repair-only basis.



# Medical Equipment Management Strategies

Binseng Wang; Emanuel Furst; Ted Cohen; Ode R. Keil; Malcolm Ridgway; Robert Stiefel

*Clinical engineering professionals need to continually review and improve their management strategies in order to keep up with improvements in equipment technology, as well as with increasing expectations of health care organizations. In the last 20 years, management strategies have evolved from the initial obsession with electrical safety to flexible criteria that fit the individual institution's needs. Few hospitals, however, are taking full advantage of the paradigm shift offered by the evolution of Joint Commission standards. The focus should be on risks caused by equipment failure, rather than on equipment with highest maintenance demands. Furthermore, it is not enough to consider risks posed by individual pieces of equipment to individual patients. It is critical to anticipate the impact of an equipment failure on larger groups of patients, especially when dealing with one of a kind, sophisticated pieces of equipment that are required to provide timely and accurate diagnoses for immediate therapeutic decisions or surgical interventions. A strategy for incorporating multiple criteria to formulate appropriate management strategies is provided in this article.*

(Biomedical Instrumentation & Technology 2006; 40:233–237).

From the JCAHO Clinical Engineering Standards Study Group.

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The medical equipment management standards published by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have been a major driving force for the practice of clinical engineering (CE) in the United States over the last 20 years. During that time, JCAHO has continually revised and improved these standards as health care and technology have evolved. We review here some of those changes that allow us to refocus our resources on areas with the greatest potential for improving patient care and enhancing organizational success.

When JCAHO introduced the *Shared Visions-New Pathways* accreditation process in 2004, standard EC.6.10, Element of Performance-EP4 stated, “[t]he organization identifies appropriate inspection and maintenance strategies for all equipment on the inventory for achieving effective, safe, and reliable operation of all equipment in the inventory.” JCAHO also clarified in a footnote that “[h]ospitals may use different strategies for different items as appropriate...” Therefore, hospitals are allowed to *not* schedule inspection or maintenance tasks for certain pieces or types of medical equipment, if they determine that these tasks are not needed for safe and reliable operation. Furthermore, it is acceptable to establish different maintenance and/or inspection procedures or schedules for identical devices used in different areas or on different patient populations. The schedules could differ, taking into consideration factors such as the frequency of use and the severity of failure on patient safety. One example could be different strategies for defibrillators used in emergency departments and intensive care units *vs* those used in general patient care areas or clinics.

A second improvement opportunity is the use of a grace period (or *slippage*) for determining when a piece of equipment should be considered overdue for a scheduled inspection or maintenance event. This flexibility provides some leeway when a scheduled maintenance activity cannot be performed at the appropriate time due to uncontrollable factors, such as equipment that is in use on a patient or devices that cannot be located. In other

**Table 1.** An example of Medical Equipment Management Plan (MEMP) inventory inclusion criteria using patient risks and mission criticality for planning preventive maintenance (PM) and safety and performance inspection (SPI) activities.

		Patient Risks (Listed in the EP)*		
		High	Medium	Low
<b>Mission criticality</b>	Critical	Include	Include	Include
	Important	Include	Optional†	Exclude
	Necessary	Include	Exclude	Exclude

\*EP = Element of Performance, from the Joint Commission on Accreditation of Healthcare Organizations’ published accreditation standards.

†Indicates that some of the equipment may benefit from scheduled services, depending on the failure modes and effects analyses or other studies conducted by the organization.

words, a maintenance activity may be considered performed on time even if it takes place beyond the established inspection time, as long as it is consistent with the organization’s Medical Equipment Management Plan (MEMP). For example, a quarterly inspection period could have a one-month grace period, whereas an annual inspection period could have a two-month grace period.

Combined, both actions above support the primary message that each organization should analyze its equipment inventory and find the most appropriate maintenance strategies in order to have “effective, safe, and reliable operation.” In other words, CE professionals can consider in their planning the experience acquired in their daily work, such as:

1. Some high-risk (e.g. critical-care monitoring) equipment requires little maintenance, whereas some low-risk equipment (e.g. x-ray film processors) needs frequent attention.
2. Preventive maintenance often does not increase reliability and actually may introduce failures, a notion well documented in industrial maintenance.<sup>1</sup>
3. Identical pieces of equipment used in different circumstances may need different maintenance strategies.
4. The majority of sentinel events has been traced by root-cause analysis to communication, user orientation and training, and patient assessment, rather than equipment malfunction or missed maintenance actions.<sup>2</sup>

### Inventory Inclusion Criteria

In its standards, JCAHO<sup>3</sup> offers the choice of using risk criteria<sup>4</sup> to create a limited inventory, known as the MEMP inventory, or simply including all medical equip-

ment (see footnote for EP3 of EC.6.10). Although it is highly desirable to control and to document unplanned services performed on all equipment (e.g. repairs and recall upgrades), it is not possible to analyze individually every piece of equipment for scheduled maintenance needs. Even if it were possible, it would be a waste of limited resources to examine failure modes and effects of simple and low-risk devices such as otoscopes and other portable diagnostic tools. (This does not mean that hospitals cannot or should not have other inventory systems for asset management, service documentation, regulatory compliance, and so forth.)

We believe the inclusion criteria for preventive maintenance (PM) and safety and performance inspections (SPIs) should include, in addition to risk, other criteria that reflect the needs and reality of the organization, as well as technical aspects (i.e. a broader definition of risk). Some examples of other criteria that should be considered are

- Mission criticality<sup>5</sup> (also known as operational impact<sup>1</sup>)
- The detectability of failures (“hidden failures”) and their respective severities
- Equipment hazards and recall history that occur outside of the organization
- Reliability, including failure patterns and statistics
- Availability of equipment and of spares or backup.

At a minimum, mission criticality should be included in the inclusion criteria, because it addresses not only the organization’s desire to have efficient and profitable operations, but also the fact that failure of mission-critical equipment may put patients or the organization at

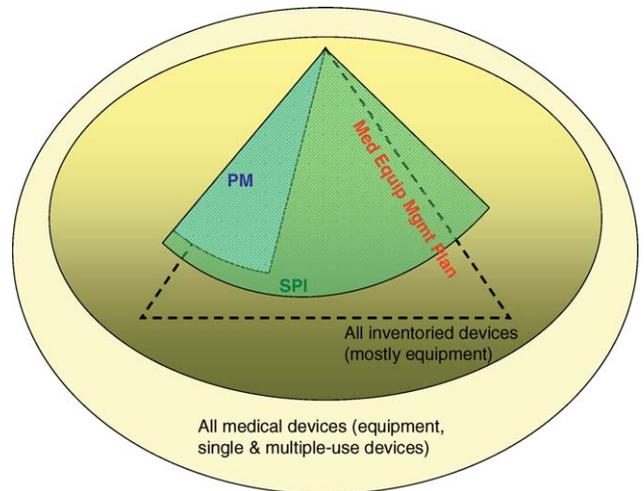
risk. For example, reliable operation of an automated clinical lab chemistry analyzer is essential for timely diagnosis, monitoring, and treatment of patients, even though it may not be considered a high-risk device when considered by itself. Table 1 shows a basic MEMP inventory approach using only mission criticality and patient risks, the latter covering the three elements mentioned in EC.6.10, EP3 (*i.e.* function, physical risk, and incident history).

Obviously, more elaborate models would need to be developed if additional criteria like those suggested above were used. Each model will have its own advantages and disadvantages. By carefully choosing the criteria and the weight factors, one can build an inclusion model that uniquely fits the nature and needs of his or her organization. One important benefit of a well-planned inclusion model is that the analysis can serve multiple, coordinated, and consistent functions. For example, mission criticality and availability of backups can be used to determine response priority for service calls. Equipment reliability, incident history, hazards, and recall history also can be important factors in considering equipment replacement.

### Maintenance Strategies

After selecting the inclusion model most appropriate to an organization, the next challenge is to determine the appropriate maintenance strategies for the included equipment. In general, planned maintenance activities can be divided into two classes: proactive and reactive.<sup>1</sup> The first class includes scheduled replacement, predictive (or *on-condition*) maintenance, and scheduled discard. The second class includes failure-finding tasks, recalibration, and redesign. In contrast, unplanned maintenance comprises repair and replacement.

To avoid ambiguity, PM will be used here solely to represent scheduled replacement of wearable parts to prevent a predictable failure (*i.e.* before their respective mean-times-between-failure [MTBFs] have been reached). As the reliability of medical equipment has improved remarkably, the need for PM has been drastically reduced. Often there are no serviceable parts or the MTBF is longer than the average useful life of the equipment.<sup>6</sup> As experience accumulated in industrial maintenance suggests,<sup>1</sup> PM should be considered only when there are clear, age-related failure patterns, and the tasks are both technically feasible (*i.e.* it is physically possible to perform the task) and “worth doing” or cost effective



**Figure 1.** Schematic diagram showing the relationship between a Medical Equipment Management Plan (MEMP) and the universe of medical equipment and devices in a healthcare organization, as well as their relationship with those pieces of equipment that need safety and performance inspections (SPIs) and/or preventive maintenance (PM).

(*i.e.* the results justify the direct and indirect cost of doing the task).

Many of the activities often called PM actually are performed to detect either hidden failures (*i.e.* failures not apparent to the user) or potential failures (*i.e.* an identifiable condition that indicates that a functional failure is either about to occur or is in the process of occurring). This group of activities should be called SPIs, defined here as scheduled actions performed to verify that a piece of equipment is performing within original specifications and that there are no obvious detectable safety hazards related to abuse or deterioration.<sup>7</sup> Thus, SPI is actually a combination of reactive, failure-finding tasks and proactive, predictive (*on-condition*) tasks.<sup>1</sup> Hopefully, this clarifies that PM and SPI tasks do not overlap and are also not mutually exclusive. To the contrary, an SPI should be performed after each PM and repair that affect either safety or performance. Furthermore, equipment that does not require PM, including some not included in MEMP, may benefit from an SPI.

One way to visualize the relationship between inclusion criteria and maintenance strategies is shown in Figure 1. The universe of medical devices, including equipment and single- or multiple-use devices, used in a

health care organization is represented by the outermost elliptical form. Within this universe, a portion, represented by the inner ellipse, is inventoried by the organization for various management purposes, such as asset management, maintenance, financial reporting, and statutory tracking (for implants and certain devices defined by the Food and Drug Administration). The challenge of defining good inclusion criteria for the MEMP can be viewed in this figure as how to draw the borders of the dashed triangle so that all the “important” equipment like CT scanners and ventilators are included and that less important equipment like portable suction pumps and patient scales are not. The challenge is significant, because one is forced to divide a continuous spectrum, represented by the gradual shading inside the inventory ellipse, into two portions.

Superimposed on the three forms mentioned above are two forms representing the two planned maintenance strategies, SPIs and PMs. The area devoted to PM is smaller than that for SPI, because of the strict definition stated earlier. Although the PM and SPI contours have not been precisely drawn in Figure 1, they have been deliberately drawn to cover only a portion of MEMP inventory, but, at the same time, to cover equipment outside of MEMP that is inventoried for a purpose other than MEMP (*e.g.* tracking and recall management). This illustrates the previously mentioned dichotomy of high risk/mission critical, no maintenance *vs* low risk, high maintenance. The lack of coincidence of the PM and SPI contours with the MEMP is the essence of the new paradigm of maintenance strategies decoupled from inventory.

Assuming that PM and SPI will be the primary planned maintenance activities, the next step is to decide for each device whether PM and/or SPI is needed, and, if needed, what tasks will be performed, who will perform them, and at what frequency. As explained above, the PM decision is straightforward, because it is justifiable only when there is an age-related failure pattern. Rationale for PM, along with proper procedure and frequency, normally can be obtained from the respective manufacturer. Their recommendations should be combined with the organization’s own use pattern and service experience. If no recommendations were provided or were provided with little justification, CE professionals will continue to use their own judgment to set initial values and will revise as they accumulate experience. They also may consult ECRI’s Inspection and Preventive Maintenance

(IPM) program,<sup>8</sup> which provides recommendations for a number of pieces of equipment.

Determining if an SPI is needed is a little more challenging, because it depends on both hidden and potential failures. Furthermore, unlike PMs, which with few exceptions must be performed by trained technicians, some SPIs can and should be performed by users. Ideally, clinical users should be trained and required to verify the safety and performance of every device in the medical equipment universe, as defined in Figure 1, just prior to use or, in the case of sterile devices, right after applying it to a patient. In practice, however, it may be unrealistic and too risky to depend solely on the users when high-risk or mission-critical equipment is used. Therefore, a systematic decision process may be necessary.

Table 2 shows an example of an SPI decision process using a simplified failure modes and effects analysis.<sup>1,7,9</sup> If the failure modes are detectable by the machine itself (self-test) or the user (*i.e.* no hidden failure) and the effects are not serious (to either patient or mission), no SPI by a technician is needed. Users should be trained and required to perform SPI themselves. However, if the effects are serious, even if the users are competent, additional (and more thorough) SPI must be performed by technicians as an added precaution. If there are hidden failures (*i.e.* not detectable by machine or users), SPI by technicians is the only alternative. Obviously, users must be included in this decision process and full endorsement must be provided by the executive management.

Like PMs, SPI rationale, procedure, and frequency should start with the respective manufacturer’s recommendations, qualified with an organization’s own use pattern and service experience, and fine-tuned periodically based on actual outcomes. The last part, the feedback loop, often is overlooked by many CE professionals. Actually, this is probably by far the best foundation for a solid maintenance program, because it provides the real-life data that many manufacturers may not have themselves.<sup>10</sup> For example, if the number of hidden failures detected during SPI is high, its frequency needs to be increased. Furthermore, review of incident, sentinel, and near-miss event reports, as well as the more common “use error” and “no problem found” service reports, can verify the effectiveness of user-performed SPIs. If the number of devices is insufficient to provide meaningful statistics, the organization should share the experience with peers that have similar devices and operational characteristics.

**Table 2.** An example for assigning safety and performance inspections (SPIs) using a simplified failure modes and effects analysis.

		Failure Modes	
		Detectable by User	Not Detectable
<b>Failure effects</b> (to either patient or mission)	Serious (i.e. mission-critical or high risk)	SPI by user and by technician*	SPI by technician
	Not serious	SPI by user	SPI by technician

\*The user SPI will consist mostly of running the machine’s self-test and visual verification of normal operation after connecting the machine to the patient; whereas the technical SPI will be the detailed, full-scale inspection.

**Discussion**

We realize it is not possible to create a single MEMP that fits all organizations. The MEMP that works well for an extremely busy, level-one, urban teaching hospital is likely more comprehensive than what is required for a small community hospital. For this reason, the discussion has been more methodological than prescriptive. Readers must use their professional judgment and experience in establishing their own maintenance strategies.

The primary goal here is to stimulate development of innovative management strategies that balance limited resources with the need to improve patient safety, clinical outcomes, patient throughput, and the organization’s mission. Time gained from eliminating unproductive scheduled maintenance is better used to improve the value of a CE service. The CE staff can participate more effectively in equipment planning and acquisition projects to ensure selection of better engineered and more appropriate equipment, and potentially reduce medical errors. CE staff can be more involved in the education and training of clinical staff, thus helping to decrease the number of “no problem found” calls and equipment abuse. Finally, the CE staff may be able to increase repair capability, thus reducing equipment downtime and costs to the organization related to vendor service and required rental of supplemental equipment.

Perhaps the most important benefit of this new approach is a shift from concentrating exclusively on medical equipment as the source of patient safety risk to

a balanced evaluation of the contribution to risk by the equipment and by the user. CE professionals will be able to shift some of their attention from equipment itself to supporting the users. This shift in focus will help health care organizations meet their commitments to achieving the goals of the JCAHO’s 10-year, intense effort of improving patient safety nationwide. ■

**References**

1. **Moubray J.** *Reliability-Center Maintenance*. 2nd ed. New York, NY: Industrial Press, Inc; 1997.
2. **Joint Commission on Accreditation of Healthcare Organizations (JCAHO).** Sentinel event statistics. Available at: <http://www.jointcommission.org/SentinelEvents/Statistics/>. Accessed March 21, 2006.
3. **Joint Commission on Accreditation of Healthcare Organizations (JCAHO).** *Comprehensive Accreditation Manual for Hospitals*. Oakbrook Terrace: JCAHO, 2006.
4. **Fennigkoh L, Smith B.** Clinical equipment management. *JCAHO PTSM Series*. 1989;2:5–14.
5. **Wang B, Levenson A.** Equipment inclusion criteria: a new interpretation of JCAHO’s medical equipment management standard. *J Clin Eng*. 2000;25:26–35.
6. **Keil OR.** Is preventive maintenance still a core element of clinical engineering? *Biomed Instrum Technol*. 1997;31:408–409.
7. **Wang B, Rice WP.** JCAHO’s equipment inclusion criteria revisited—application of statistical sampling technique. *J Clin Eng*. 2003;28:36–47.
8. **ECRI.** *Inspection and Preventive Maintenance System*. 3rd ed. Plymouth Meeting: ECRI; 1995.
9. **National Center for Patient Safety.** Healthcare failure mode and effect analysis course materials (HFMEA). Available at: <http://www.patientsafety.gov/HFMEA.html>. Accessed March 21, 2006.
10. **Ridgway M.** Analyzing planned maintenance (PM) inspection data by failure mode and effect analysis methodology. *Biomed Instrum Technol*. 2003;37:167–179.

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