

# State Operations Manual

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

### Table of Contents

*(Rev. 122, 09-26-14)*

### [Transmittals for Appendix A](#)

### Survey Protocol

#### Introduction

- Task 1 - Off-Site Survey Preparation
- Task 2 - Entrance Activities
- Task 3 - Information Gathering/Investigation
- Task 4 - Preliminary Decision Making and Analysis of Findings
- Task 5 - Exit Conference
- Task 6 – Post-Survey Activities

#### Psychiatric Hospital Survey Module

#### Psychiatric Unit Survey Module

#### Rehabilitation Hospital Survey Module

#### Inpatient Rehabilitation Unit Survey Module

#### Hospital Swing-Bed Survey Module

### Regulations and Interpretive Guidelines

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§482.41(a) Standard: Buildings

§482.41(b) Standard: Life Safety from Fire

§482.41(c) Standard: Facilities [View CMS Text](#)

§482.42 Condition of Participation: Infection Control

**A-0722 (Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)**

**§482.41(c) Standard: Facilities**

The hospital must maintain adequate facilities for its services.

*Interpretive Guidelines §482.41(c)*

Adequate facilities means the hospital has facilities that are:

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

**A-0724 (Rev. 103, Issued: 02-21-14, Effective: 02-21-14, Implementation: 02-21-14)**

**CMS §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) (Excerpts regarding Facilities)*

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.

***See following pages for more Interpretive Guidelines from CMS document***

### **Interpretive Guidelines: Key Points**

**Equipment:** Equipment includes both facility equipment, ..... 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.). [View CMS Text](#)

**Equipment Inspection:** All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. [View CMS Text](#)

**Biomed Personnel Qualifications:** Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be demonstrably qualified. [View CMS Text](#)

**Documentation:** When equipment is maintained in accordance with the manufacturer's recommendations, the facility must maintain documentation of those recommendations and the facility's associated maintenance activity for the affected equipment. [View CMS Text](#)

**Preventive Maintenance:** A facility must have a maintenance strategy for its equipment and medical devices. [View CMS Text](#)

**Equipment Inventory:** All medical facility and medical equipment, regardless of whether it is leased or owned, ..... is expected to be listed in an inventory, which includes a record of maintenance activities. [View CMS Text](#)

## Equipment (Page 362) [Return](#)

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.

*FEO Solutions' president, Roy Williams, Ph.D., is a Biomedical Engineer holding his Professional Engineering license (PE) and is therefore qualified under CMS guidelines. He performs and/or signs off on all work performed by FEO Solutions. His active PE License is kept in the facility equipment notebook. [Return](#)*

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.

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## **Background Information on Types of Maintenance Strategies (Page 367)**

**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.

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## **Maintenance Tools (Page 368)**

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.

*FEO Solutions uses the latest medical device testing equipment, which is regularly calibrated to NIST-standards. [Return](#)*

## **Equipment Inventory (Page 369) [Return](#)**

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
- Any additional information the hospital believes may be useful for proper management of the equipment.

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