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Alternate equipment management (AEM) program in healthcare delivery organizations (HDOs)

AAMI
Advancing Safety in Health Technology

Alternate equipment management (AEM) program in healthcare delivery organizations (HDOs)

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Abstract: This standard provides a framework for the development and ongoing management of an AEM program. The standard assists Healthcare Delivery Organizations (HDOs) seeking to meet the related Conditions of Participation set by the Centers for Medicare and Medicaid Services (CMS). By incorporating a quantitative, scientific, and risk-based methodology, along with input from clinical staff, this standard establishes minimum requirements for AEM programs. For devices included in an AEM program, this standard provides requirements for procedures that assure acceptable levels of safety and performance are maintained.

Keywords: AEM, alternate equipment management, alternative equipment maintenance, HTM, healthcare technology management, medical equipment maintenance, medical equipment management, PM, planned maintenance, preventive maintenance

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Committee representation

Association for the Advancement of Medical Instrumentation

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Foreword

Most healthcare delivery organizations (HDOs) in the United States receive funds from the Medicare and Medicaid programs. To receive those funds, HDOs must meet the Conditions of Participation developed by the Centers for Medicare and Medicaid Services (CMS). On December 2, 2011 (CMS Letter S&C: 12-07-Hospital), CMS published a memorandum telling hospitals that they could, in some instances, use alternate equipment maintenance schedules (i.e., schedules that were different from those recommended by the equipment manufacturer), but that they could not use alternative equipment maintenance methods. That is, only the manufacturer's recommended techniques for maintaining equipment were allowable.

After receiving feedback from healthcare technology management (HTM) professionals, CMS issued a new memorandum on December 20, 2013 (CMS Letter S&C: 14-07-Hospital). This memo allowed hospitals to adjust both the frequencies and maintenance activities associated with many types of equipment if certain criteria were met. To make those changes, a hospital must establish an alternate equipment management (AEM) program that demonstrates it can maintain an acceptable level of safety and quality.

NOTE See Annex A for CMS Letter S&C: 14-07-Hospital “Hospital Equipment Maintenance Requirements”.

This consensus standard is intended to help identify the minimum requirements for an AEM program. The document seeks to ensure that a quantitative, scientific, and risk/evidence-based methodology is used, including input from clinical and other impacted staff. It includes quality assurance requirements to ensure proper decisions are made, based on sound engineering principles, periodic review, and corrective actions to address deficiencies.

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Introduction

For certain types of equipment, the Centers for Medicare and Medicaid Services (CMS) allows HTM professionals to use their experience and expertise, along with a documented and supported analysis of equipment history, to develop maintenance strategies that modify maintenance activities and/or frequencies from those recommended by the original equipment manufacturer (OEM).

A properly implemented AEM program will not diminish the equipment's performance and safety. Furthermore, an AEM program may improve the reliability and availability of the medical equipment.

There are several reasons why HDOs may consider including medical equipment in an AEM program.

- Effectively utilize available resources in a way that maximizes patient safety.
- OEM maintenance procedures may not have anticipated all the possible utilization and environmental conditions in which the equipment may be placed.
- OEM procedures may not reference the use of equivalent alternate diagnostic or monitoring tools that are available.
- OEM instructions may be unavailable or insufficient.
- Manufacturers often develop service guidance prior to use of a product and may specify maintenance activities intended to address anticipated failures that may not occur after equipment is put into service.
- Using non-invasive methods such as condition monitoring to detect actual or potential failures and to reduce the likelihood of service-related failures.

In these cases, this standard provides a framework to assess whether medical equipment is eligible to be included in an AEM program. Once a decision is made to include a device in an AEM program, this standard provides requirements for procedures that allow service providers to assure safety and performance are maintained or enhanced.

Alternate equipment management (AEM) in healthcare delivery organizations (HDOs)

1 Scope

The scope includes the maintenance of medical equipment that is eligible for inclusion in an alternate equipment management (AEM) program. This standard addresses the potential use of AEM for medical equipment eligible for an AEM program when that equipment is used in a way that is consistent with that intended by the manufacturer. Medical equipment that is used for any other purpose is outside the scope of this standard.

2 Normative References

There are no normative references used in this document.

3 Terms and definitions

3.1
alternate equipment management (AEM) program
a program that incorporates maintenance activities, frequencies, methods and/or strategies that differ from those recommended by the manufacturer

Note 1 to entry: When OEM procedures are unavailable, refer to ANSI/AAMI EQ89, *Guidance for the use of medical equipment maintenance strategies and procedures*.

Note 2 to entry: In common usage, alternative equipment maintenance has also been called AEM. However, in this standard, AEM only refers to an alternate equipment management program.

3.2
failure
the inability of an item, product or service to perform required functions on demand due to one or more defects

3.3
healthcare delivery organization (HDO)
organization that provides medical, dental, psychiatric, nursing, obstetrical, or surgical care

Note 1 to entry: Healthcare delivery organizations include, but are not limited to, hospitals, nursing homes, limited care facilities, clinics, medical and dental offices, and ambulatory care centers, whether permanent or movable.

3.4
hidden failure
failure whose effects are not apparent to the user under normal circumstances

Note 1 to entry: Sometimes referred to as latent failure.

3.5
inspection
interaction with medical equipment designed to detect unsuspected equipment problems, or to perform planned maintenance