HTMMIXER
POWERED BY MDEXPO

Understanding AEM in HTM: Risk, Requirements, and Results

August 1st, 2025

Meet today's speaker

Joe Stockman

Director, Product Experience

22 years with FSI

30 years with Healthcare CMMS

Works with customers to solve problems and improve the CMMS experience of healthcare services professionals

Learning Objectives

- Understanding risk and regulatory requirements around AEM/OEM
- Analyzing data and justifying AEM on eligible assets
- Monitoring/documenting your AEM program for regulatory inspectors

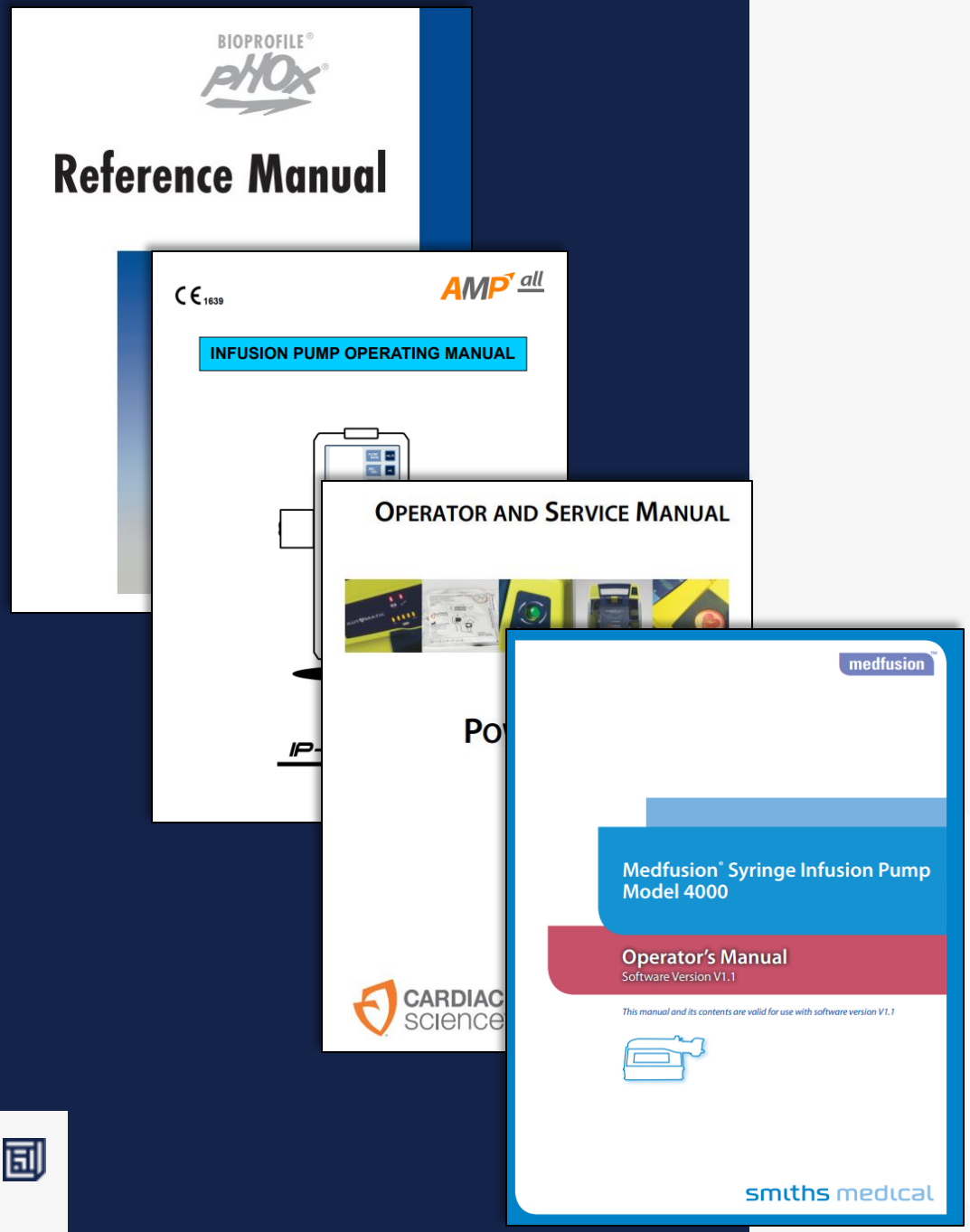
Today’s Agenda

1. What is AEM?
2. What does the code say?
3. Setting up your AEM program
4. Maintaining your AEM program
5. Summary and Q&A

What is AEM?

Preventive Maintenance Approaches

- **OEM** – Original Equipment Manufacturer
- **AEM** – Alternative Equipment Maintenance
- **RCM** – Reliability Centered Maintenance
- Predictive/Condition Based Maintenance
- Run to Fail Maintenance



Original Equipment Manufacturer

OEM maintenance involves following the guidelines and recommendations provided by the equipment's manufacturer. This approach ensures that maintenance is performed according to the specifications and standards set by the OEM, which can help in maintaining equipment warranty and performance.

Alternative Equipment Maintenance

AEM maintenance refers to using **parts and services** from manufacturers other than the original equipment manufacturer. This approach can be cost-effective and may offer more flexibility, but it's essential to ensure that alternative parts and services meet the required standards and **do not compromise the equipment's performance**.

What does the code say?

Choose Your Poison

Some of you don’t really get to choose, but know which standards to reference. And don’t forget state agencies and other authorities having jurisdiction (AHJs).

1951
TJC

1965
HFAP -> ACHC

2008
DNV

Question

Who are you using for accreditation?

- The Joint Commission
- DNV
- ACHC
- Other AHJs

Multiple Authorities Having Jurisdiction

TJC - EC 02.04.03

Inspects, tests, maintains medical equipment.

DNV - PE.7

Medical equipment management system.

CIHQ - CE-8: Q

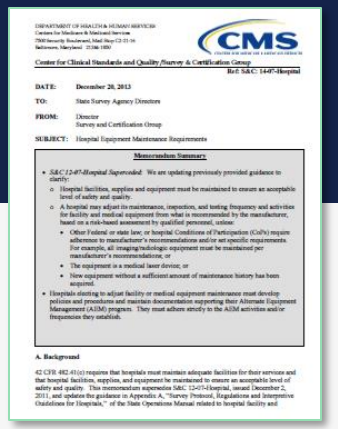
The organization must assure that medical equipment used in patient care is safe.

Other AHJs

Check local and state requirements as well.

CMS S&C: 14-07-Hospital

Link



Center for Clinical Standards and Quality/Survey & Certification Group

DATE: December 20, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Hospital Equipment Maintenance Requirements

Memorandum Summary

- *S&C 12-07-Hospital Superseded.* We are updating previously provided guidance to clarify:
  - Hospital facilities, supplies and equipment must be maintained to ensure an acceptable level of safety and quality.
  - A hospital may adjust its maintenance, inspection, and testing frequency and activities for facility and medical equipment from what is recommended by the manufacturer, based on a risk-based assessment by qualified personnel, unless:
    - Other Federal or state law, or hospital Conditions of Participation (CoPs) require adherence to manufacturer's recommendations and/or set specific requirements. For example, all imaging/radiologic equipment must be maintained per manufacturer's recommendations; or
    - The equipment is a medical laser device; or
    - New equipment without a sufficient amount of maintenance history has been acquired.
- Hospitals electing to adjust facility or medical equipment maintenance must develop policies and procedures and maintain documentation supporting their Alternate Equipment Management (AEM) program. They must adhere strictly to the AEM activities and/or frequencies they establish.

A. Background

42 CFR 482.41(c) requires that hospitals must maintain adequate facilities for their services and that hospital facilities, supplies, and equipment be maintained to ensure an acceptable level of safety and quality. This memorandum supersedes S&C 12-07-Hospital, issued December 2, 2011, and updates the guidance in Appendix A, "Survey Protocol, Regulations and Interpretive Guidelines for Hospitals," of the State Operations Manual related to hospital facility and

Hospital Equipment Maintenance Requirements

42 CFR 482.41(c) requires that hospitals must maintain adequate facilities for their services and that hospital facilities, supplies, and equipment be maintained to ensure an acceptable level of safety and quality. This memorandum supersedes S&C 12-07-Hospital, issued December 2, 2011, and updates the guidance in Appendix A, "Survey Protocol, Regulations and Interpretive Guidelines for Hospitals," of the State Operations Manual related to hospital facility and medical equipment maintenance. Facility equipment refers to devices intended to support the physical environment of the hospital. Medical equipment refers to devices intended to be used for diagnostic, therapeutic, or monitoring care provided to a patient by a hospital.

https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-14-07.pdf

TJC – EC 02.04.01 EP 4

The hospital manages medical equipment risks.

The hospital identifies the activities and associated frequencies, in writing, for maintaining, inspecting, and testing all medical equipment on the inventory. These activities and associated frequencies are in accordance with manufacturers' recommendations or with strategies of an alternative equipment maintenance (AEM) program.

Note 1: The strategies of an AEM program must not reduce the safety of equipment and must be based on accepted standards of practice, such as the American National Standards Institute/Association for the Advancement of Medical Instrumentation handbook ANSI/AAMI EQ56: 2013, Recommended Practice for a Medical Equipment Management Program.

TJC – EC 02.04.01 EP 4 (Cont'd)

Note 2: Medical equipment with activities and associated frequencies in accordance with manufacturers' recommendations must have a 100% completion rate.

Note 3: Scheduled maintenance activities for both high-risk and non-high-risk medical equipment in an alternative equipment maintenance (AEM) program inventory must have a 100% completion rate. AEM frequency is determined by the hospital's AEM program.

TJC – EC 02.04.03 EP 2

The hospital inspects, tests, and maintains medical equipment.

These activities are documented.

Note 1: High-risk equipment includes medical equipment for which there is a risk of serious injury or even death to a patient or staff member should it fail, which includes life-support equipment.

Note 2: Required activities and associated frequencies for maintaining, inspecting, and testing of medical equipment completed in accordance with manufacturers' recommendations must have a 100% completion rate.

Note 3: Scheduled maintenance activities for high-risk medical equipment in an (AEM) program inventory must have a 100% completion rate.

TJC – EC 02.04.03 EP 3

The hospital inspects, tests, and maintains medical equipment.

The hospital inspects, tests, and maintains non-high-risk equipment identified on the medical equipment inventory. These activities are documented.

Note: Scheduled maintenance activities for non-high-risk medical equipment in an alternative equipment maintenance (AEM) program inventory must have a 100% completion rate. AEM frequency is determined by the hospital's AEM program.

Code Language Takeaways

TJC and DNV Code Language is very vague.

YOU determine the frequency!

AEM frequency is determined by the hospital's AEM program.

High Risk vs. Non-High Risk

Both are 100% Completion, so don't get too into the weeds on this one.

100% Completion

Complete 100% of the Assets you find and can perform an ITM. Can you decrease the frequency to meet this goal?

What’s an AEM Program?

An Alternative Equipment Maintenance (AEM) Program is a **strategy** used primarily in healthcare settings to maintain medical equipment. Unlike traditional maintenance programs that follow a strict, calendar-based schedule, AEM programs are more flexible and data-driven.

AEM Program Key Points

Data-Driven Approach: AEM programs use historical data, equipment usage, performance history, and maintenance logs to determine when and how maintenance should be performed.

Cost Efficiency: By focusing maintenance efforts where they are most needed, AEM programs can reduce unnecessary maintenance tasks, thereby saving costs and extending the lifespan of equipment.

Risk-Based: The program assesses the risk associated with equipment failure and prioritizes maintenance tasks accordingly.

Regulatory Compliance: AEM programs must comply with specific regulations and standards, such as those set by CMS, The Joint Commission, DNV, etc.

Setting up your AEM program

Defining the Policy

- It’s YOUR policy
- What’s in it and should you change it

Anonymized Health Policy

TITLE/SUBJECT	*Alternate Equipment Management Program for Medical Equipment*

PURPOSE: To establish a standard alternate approach to the Medical Equipment maintenance process for devices where the hospital adjusts the maintenance, inspection, and testing frequencies from the manufacturer recommendations.

This policy applies to Medical Equipment that is not considered high-risk or otherwise regulated by Federal, State or Hospital Conditions of Participation [CoPs].

SCOPE All Facilities

AUTHORIZATION

DEFINITIONS

AEM Alternative Equipment Management

CMMS Computerized Maintenance Management System

CMS Centers for Medicare & Medicaid Services

EOC Environment of Care

Medical Device Section 201 (h) of the Food, Drug and Cosmetic Act defines a "device" as follows:

- Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them.
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals, and
  Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

In short, a device is any product that is used for health purposes but that is not a drug or biological substance, such as blood or its components.

Medical Equipment Fixed and portable equipment used for the diagnosis, treatment, monitoring and direct care of individuals

MEMP Medical Equipment Management Plan

OEM Original Equipment Manufacturer

POLICY

Per CMS, an AEM program allows a healthcare facility to "adjust its maintenance, inspection, and testing frequency and activities for facility and Medical Equipment from what is recommended by the manufacturer, based on a risk-based assessment by qualified personnel."[1]

- All electronic Medical Equipment within the program will be risk-scored whether under OEM or AEM requirements. Risk Scoring detail will be built into the CMMS.
- Any candidate device/system proposed by a hospital to go under AEM will be evaluated by the Biomedical Engineering Council. If the council quorum agrees, the hospital will take that recommendation to the hospital Environment of Care / Safety Committee for approval and inclusion in the hospital MEMP.
- All Medical Equipment placed in the AEM program will have supporting documentation attached to the model in the CMMS. This support documentation will include the risk scoring, and data that justifies the AEM conversion.
- As a system, Hospitals will maintain a repository of records to support the AEM selection, based on history from CMMS, and/or industry standards, accreditation agency recommendations or quality standards.
- Devices identified as under the AEM will be monitored for any reported events to that model.
- The determination of timing, testing performance, and testing frequencies for Medical Equipment maintenance must be made by qualified personnel. In the case of Medical Equipment, a clinical or biomedical technician or engineer would be considered qualified. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program.
- Devices in the AEM program will be identified in the CMMS Classification field with risk non-high and AEM.

PROCEDURE

- All Medical Devices proposed to go to an AEM will have an AEM Evaluation Form attached to the CMMS model.

[1] Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality/Survey & Certification Group Memorandum Ref: S&C: 14-07-Hospital. *Hospital Equipment Maintenance Requirements*. December 20, 2013.

- All supporting documentation including OEM recommendations, service history, and industry information (if available) supplied to support the recommendation and be attached to the model
- Documentation should include:
  - Intended equipment usage and the consequences of equipment failure or malfunction
  - Notation to the timely availability of alternate devices / backup systems in case of equipment failures.
  - Incident history of identical or remarkably similar equipment.
- Minutes from the Biomedical Engineering Council where recommendation was accepted will be attached to the model;
- Approval from the hospitals EOC committee must be obtained and documented via attachment to the model within the CMMS.

- **REFERENCES**
  CMS: Ref: S&C: 14-07-Hospital

Policy Title/Subject

- Title/Subject defines the policy document
- Defined the purpose and scope
- Try and follow same format for all hospital policies
- Align with format for Facilities Engineering for AEM policy as well

TITLE/SUBJECT	*Alternate Equipment Management Program for Medical Equipment*
PURPOSE:	To establish a standard alternate approach to the Medical Equipment maintenance process for devices where the hospital adjusts the maintenance, inspection, and testing frequencies from the manufacturer recommendations. This policy applies to Medical Equipment that is not considered high-risk or otherwise regulated by Federal, State or Hospital Conditions of Participation [CoPs].
SCOPE	All Facilities
AUTHORIZATION	

Policy Definitions

- Define any abbreviations and other relevant definitions
- Include AEM, OEM, CMMS, CMS, etc.

DEFINITIONS

AEM	Alternative Equipment Management
CMMS	Computerized Maintenance Management System
CMS	Centers for Medicare & Medicaid Services
EOC	Environment of Care
Medical Device	Section 201 (h) of the Food, Drug and Cosmetic Act defines a "device" as follows: • Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them. • Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals, and Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes. In short, a device is any product that is used for health purposes but that is not a drug or biological substance, such as blood or its components.
Medical Equipment	Fixed and portable equipment used for the diagnosis, treatment, monitoring and direct care of individuals
MEMP	Medical Equipment Management Plan
OEM	Original Equipment Manufacturer

The Policy

Don’t squint, we will go through relevant bullet points.

POLICY

Per CMS, an AEM program allows a healthcare facility to "adjust its maintenance, inspection, and testing frequency and activities for facility and Medical Equipment from what is recommended by the manufacturer, based on a risk-based assessment by qualified personnel."[1]

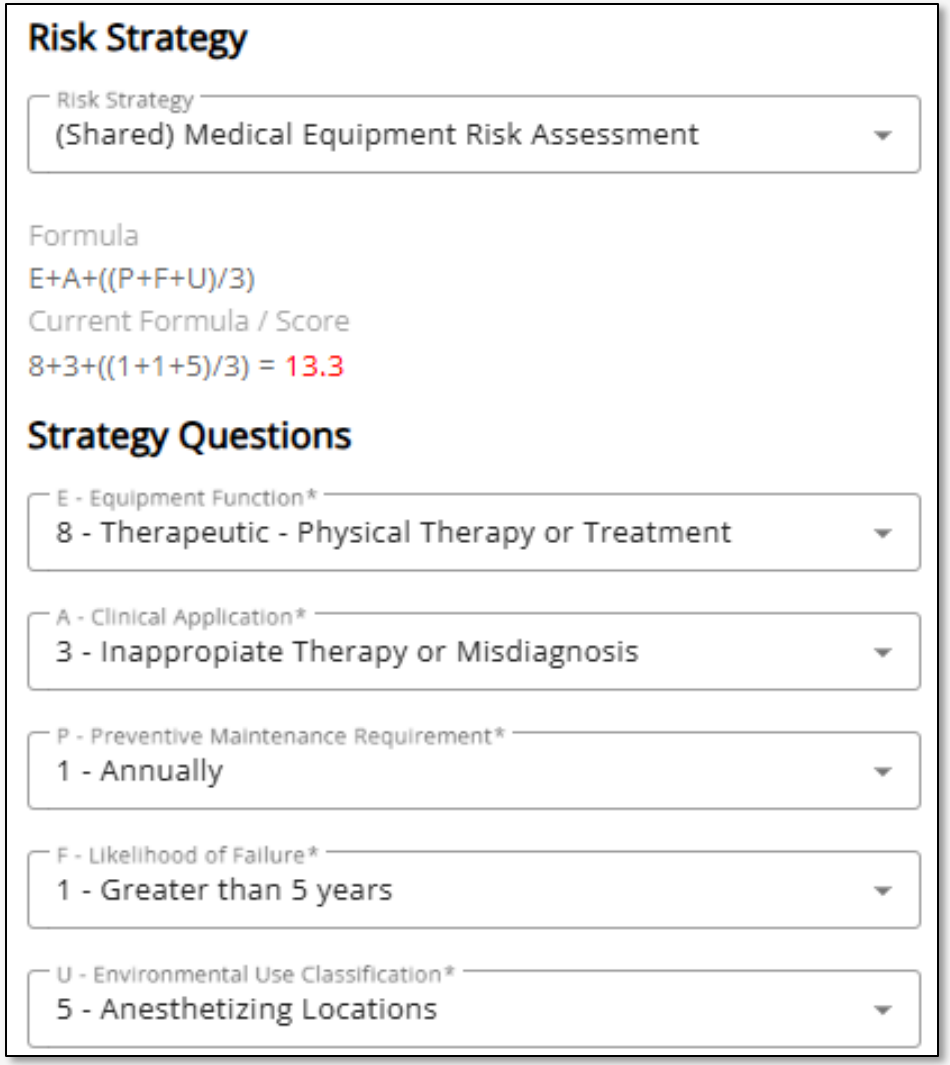
- All electronic Medical Equipment within the program will be risk-scored whether under OEM or AEM requirements. Risk Scoring detail will be built into the CMMS.
- Any candidate device/system proposed by a hospital to go under AEM will be evaluated by the Biomedical Engineering Council. If the council quorum agrees, the hospital will take that recommendation to the hospital Environment of Care / Safety Committee for approval and inclusion in the hospital MEMP.
- All Medical Equipment placed in the AEM program will have supporting documentation attached to the model in the CMMS. This support documentation will include the risk scoring, and data that justifies the AEM conversion.
- As a system, Hospitals will maintain a repository of records to support the AEM selection, based on history from CMMS, and/or industry standards, accreditation agency recommendations or quality standards.
- Devices identified as under the AEM will be monitored for any reported events to that model.
- The determination of timing, testing performance, and testing frequencies for Medical Equipment maintenance must be made by qualified personnel. In the case of Medical Equipment, a clinical or biomedical technician or engineer would be considered qualified. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program.
- Devices in the AEM program will be identified in the CMMS Classification field with risk non-high and AEM.

The Policy

All electronic medical equipment within the program will be risk-scored whether under OEM or AEM requirements. Risk scoring detail will be built into the CMMS.

Risk scored in CMMS by asset category

*Infusion pump shown



The Policy

- Any candidate device/system proposed by a hospital to go under AEM will be evaluated by the “Biomedical Engineering Council”. If the council quorum agrees, the hospital will take that recommendation to the hospital Environment of Care/Safety Committee for approval and inclusion in the hospital MEMP.
- All medical equipment placed in the AEM program will have supporting documentation attached to the model in the CMMS. This support documentation will include the risk scoring, and data that justifies the AEM conversion.
- As a system, hospitals will maintain a repository of records to support the AEM selection, based on history from CMMS, and/or industry standards, accreditation agency recommendations or quality standards.

The Policy

- Devices identified as under the AEM will be monitored for any reported events to that model.
- The determination of timing, testing performance, and testing frequencies for medical equipment maintenance must be made by qualified personnel. In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program.
- Devices in the AEM program will be identified in the CMMS Classification field with risk non-high and AEM.

PROCEDURE

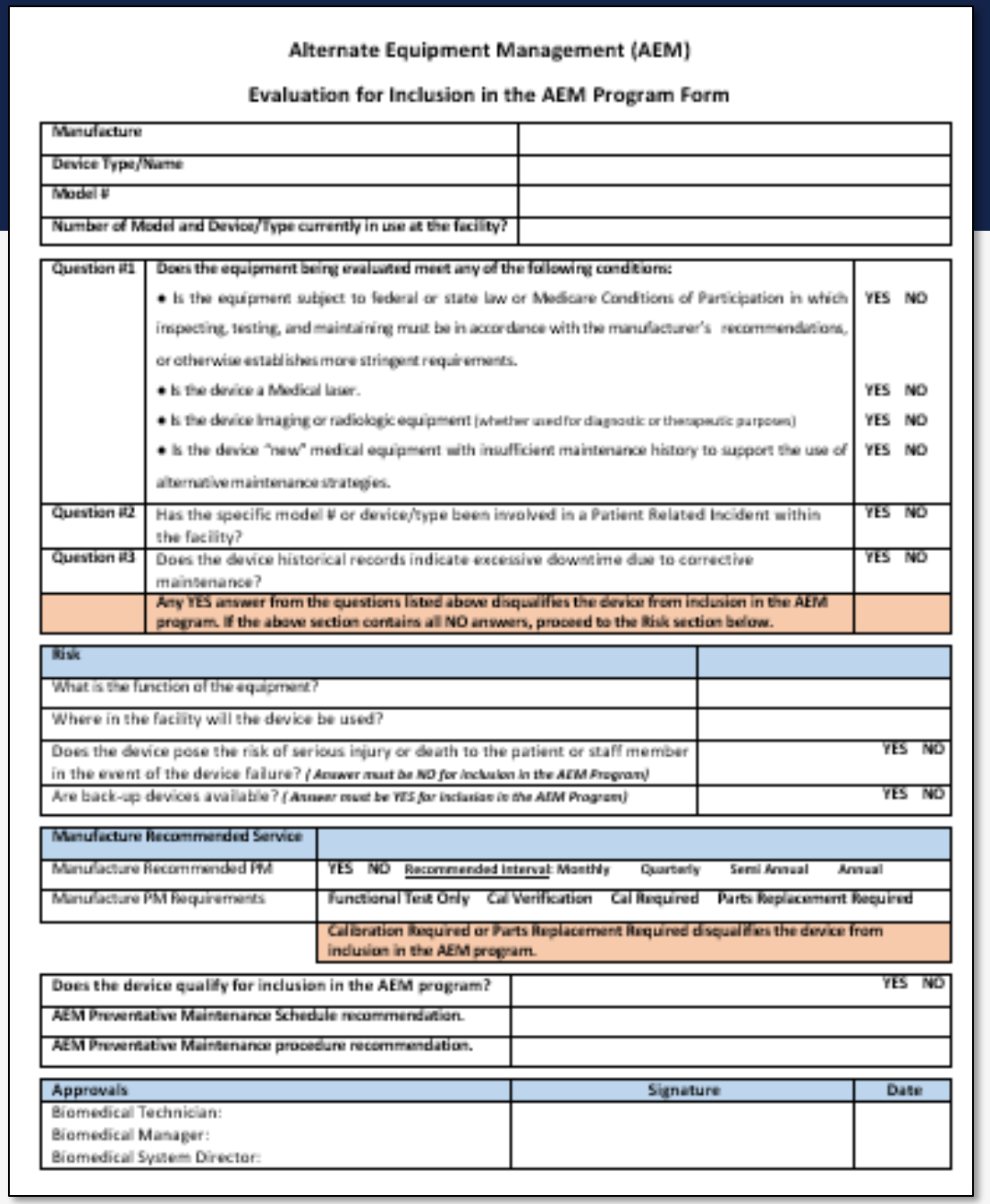
- All Medical Devices proposed to go to an AEM will have an AEM Evaluation Form attached to the CMMS model.
    - All supporting documentation including OEM recommendations, service history, and industry information (if available) supplied to support the recommendation and be attached to the model
    - Documentation should include:
        - Intended equipment usage and the consequences of equipment failure or malfunction
        - Notation to the timely availability of alternate devices / backup systems in case of equipment failures.
        - Incident history of identical or remarkably similar equipment.
    - Minutes from the Biomedical Engineering Council where recommendation was accepted will be attached to the model;
    - Approval from the hospitals EOC committee must be obtained and documented via attachment to the model within the CMMS.

- **REFERENCES**

  CMS: Ref: S&C: 14-07-Hospital

AEM Evaluation Form

- Includes device type, model, count at facility
- Incorporates “excluded” equipment
- Asks about past incidents
- Asks if it’s “new” equipment
- Uses risk and calibrated/required OEM parts in determining eligibility
- If it’s “allowed” to be AEM, document changes to procedure and schedule
- Sign off, save to CMMS!



Alternate Equipment Management (AEM)

Evaluation for Inclusion in the AEM Program Form

Manufacture	
Device Type/Name	
Model #	
Number of Model and Device/Type currently in use at the facility?	

Question #1	Does the equipment being evaluated meet any of the following conditions: • Is the equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining must be in accordance with the manufacturer's recommendations, or otherwise establishes more stringent requirements. • Is the device a Medical laser. • Is the device Imaging or radiologic equipment (whether used for diagnostic or therapeutic purposes) • Is the device "new" medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies.	YES NO YES NO YES NO YES NO
Question #2	Has the specific model # or device/type been involved in a Patient Related Incident within the facility?	YES NO
Question #3	Does the device historical records indicate excessive downtime due to corrective maintenance?	YES NO
	Any YES answer from the questions listed above disqualifies the device from inclusion in the AEM program. If the above section contains all NO answers, proceed to the Risk section below.	

Risk	
What is the function of the equipment?	
Where in the facility will the device be used?	
Does the device pose the risk of serious injury or death to the patient or staff member in the event of the device failure? *(Answer must be NO for inclusion in the AEM Program)*	YES NO
Are back-up devices available? *(Answer must be YES for inclusion in the AEM Program)*	YES NO

Manufacture Recommended Service	
Manufacture Recommended PM	YES NO Recommended Interval: Monthly Quarterly Semi Annual Annual
Manufacture PM Requirements	Functional Test Only Cal Verification Cal Required Parts Replacement Required
	Calibration Required or Parts Replacement Required disqualifies the device from inclusion in the AEM program.

Does the device qualify for inclusion in the AEM program?	YES NO
AEM Preventative Maintenance Schedule recommendation.	
AEM Preventative Maintenance procedure recommendation.	

Approvals	Signature	Date
Biomedical Technician: Biomedical Manager: Biomedical System Director:		

TJC – EC 02.04.01 EP 5

For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital's activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers' recommendations:

- Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining must be in accordance with the manufacturers' recommendations, or otherwise establishes more stringent maintenance requirements

- Medical laser devices

- Imaging and radiologic equipment (whether used for diagnostic or therapeutic purposes)

- New medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies

TJC – EC 02.04.01 EP 5 (Cont'd)

Note: Maintenance history includes any of the following documented evidence:

- Records provided by the hospital's contractors
- Information made public by nationally recognized sources
- Records of the hospital's experience over time

TJC – EC 02.04.01 EP 6

For hospitals that use Joint Commission accreditation for deemed status purposes: A qualified individual(s) uses written criteria to support the determination whether it is safe to permit medical equipment to be maintained in an alternate manner that includes the following:

- How the equipment is used, including the seriousness and prevalence of harm during normal use
- Likely consequences of equipment failure or malfunction, including seriousness of and prevalence of harm
- Availability of alternative or backup equipment in the event the equipment fails or malfunctions
- Incident history of identical or similar equipment
- Maintenance requirements of the equipment

(For more information on defining staff qualifications, refer to Standard HR.01.01.01)

H1						Total Devices	1117
Device Count	777					Total years	10
Time Frame	3 years					Total failures	4
PM's completed	2138					Total PM Preventable failures	0
Corrective WO's	76					Average failures per year	0.4
PM preventable failures	0					Annual failure rate	0.00035%
Device failures	2						
Failures due to Probes/batteries	46						
H2							
Device Count	140						
Time Frame	3 years						
PM's completed	187						
Corrective WO's	13						
PM preventable failures	0						
Device failures	1						
Failures due to Probes/batteries	9						
H3							
Device Count	54						
Time Frame	1 Year						
PM's completed	81						
Corrective WO's	8						
PM preventable failures	0						
Device failures	0						
Failures due to Probes/batteries	8						
H4							
Device Count	146?	(based on 440 PMs/3 years)					
Time Frame	3 years						
PM's completed	440						
Corrective WO's	21						
PM preventable failures	0						

Let's look at some data!

Maintaining your AEM program

Maintaining your AEM program

- **Perform and track maintenance activities**
- **Report regularly on each model in AEM**
- **Report on hospital safety concerns on AEM device models**
- **Include preventive maintenance activity, including failures**
- **Include corrective (service request) work**
- **Determine if this should remain in the AEM program**
- **Revert back to OEM if:**
  - Patient impact exception occurs
  - Risk categorization changes
  - Code changes

Learning Objective Summary

- Understanding the risk and regulatory requirements around AEM/OEM
- Analyzing data and justifying AEM on eligible assets
- Monitoring/documenting your AEM program for regulatory inspectors

FSI: A Brief Introduction

99.4%
Customer Retention

1200+
Hospitals Using CMS

10.6 Million
Work Orders Closed in 2024

Healthcare-centric CMMS, built for, and by, Healthcare professionals

- Scalable, robust platform designed to address the complex, evolving needs of independent hospitals to large nationwide IDN's.
- Industry leading tools to ensure TJC and DNV compliance.
- Direct healthcare experience in Facilities and HTM/Biomed.
- A robust community; an extension of your team
  - Monthly support and educational webinars
  - Annual on-site User Conference – free for all customers
  - FSI Neighborhood – 24/7 learning community

SSM Health · UPMC Life Changing Medicine · Encompass Health · Atrium Health · Northwell Health · University of Utah Health · Montefiore · Ballad Health

Questions?

Joe Stockman

Director, Product Experience

FSI