



CLINICAL POLICY

Medical Equipment Alternate Equipment Maintenance (AEM) Assessment

A. EFFECTIVE DATE :

July 21, 2021

B. PURPOSE :

There are many types of medical equipment failures, including spontaneous component failure, use/process related failures, utility related failure, maintenance related failure and malicious damage. Doing more maintenance or less maintenance will only affect “maintenance related failures” and has no impact on the other types of failures.

This policy/procedure defines how UConn Health (UCH) assesses the relative risks associated with maintenance-related failures of medical equipment and mitigates risks that could compromise the safety of patients, staff, or others.

C. POLICY :

UCH Clinical engineering is responsible for the medical equipment risk assessment process and works with owner/operators and other knowledgeable stakeholders as appropriate to ensure an effective risk assessment is conducted on each major medical equipment category.

D. SCOPE :

The scope of this AEM policy applies to all Medical Equipment (as defined below) intended for use in the delivery of patient care within any JDH or UMG patient care areas, excluding central sterile and dental within emergency services.

E. DEFINITIONS :

Medical Equipment – The Joint Commission defines medical equipment as equipment used for the diagnosis, treatment, monitoring, and direct care of patients.

High-Risk Medical Equipment – Medical equipment for which there is a risk of serious injury or death to patient or staff member should the equipment fail. High-risk medical equipment includes life-support equipment.

Alternative Equipment Maintenance (AEM) Program- A program that allows a healthcare facility to deviate from manufacturer-recommended maintenance activities in certain circumstances.

Major failure- Any medical equipment failure where the equipment is not operational or has a safety issue that threatens the safety or well-being of patients or staff.

Maintenance-related failure (MRF) - A failure that could have reasonably been detected or prevented before failure occurred by maintenance (testing and /or replacement of parts or materials).

Risk score - The product of the severity score and the probability score.

F. MATERIAL(S) NEEDED :

NONE

G. PROCEDURE :

Following this policy/procedure, qualified UCH Clinical Engineering staff use written criteria and a checklist/form to determine whether it is safe to maintain medical equipment using an alternate maintenance (AEM) methodology. The AEM program must not reduce the safety of medical equipment.

AEM Analysis Criteria:

Equipment reviewed under the AEM program are given a risk score to indicate the relative risk to patients and staff of a major maintenance-related failure to that medical equipment. A major failure is defined as any medical equipment failure where the equipment is not operational or has a safety issue that threatens the safety or well-being of patients or staff.

- 1) Qualified UCH Clinical Engineering staff determines if the medical equipment is a Medical Laser , Imaging Device or Medical Equipment with under three years worth of service history. All Medical Lasers, Imaging Devices and Medical Equipment with under three years worth of service history require OEM preventative maintenance and not legible for the AEM program.
- 2) UCH Clinical Engineering assigns a *severity* score to each major medical equipment category based on the organization's experience and/or the industry's experience with that category. Factor(s) addressed in determining severity include:
 - 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 back-up equipment in the event the equipment fails or malfunctions
 - Detectability by clinical staff prior to harm through timely alarms, vigilance and practice

The severity score is given to each major medical equipment category according to how the potential consequences of a major failure are classified. Those severity consequences are

classified and scored in Table 1. Note that any device (or device category) with a severity score of 3 or 4 is considered by this organization as “critical / high risk” in accordance with relevant regulations and standards (e.g., CMS, TJC).

Table 1: Severity Levels-What would happen if the device fails?

Level #	Level Description	Criteria
1	Negligible	No or negligible adverse effect (e.g., little or no health effect)
2	Marginal	Reversible adverse effect (e.g., minor injury)
3	Critical	Permanent adverse effect (e.g., serious injury)
4	Catastrophic	Loss of life

- 3) UCH Clinical Engineering assign a *probability* score to each major medical equipment category based on the organization’s experience and/or the industry’s experience with that category. Factor(s) in determining probability include:
- Incident history of identical or similar equipment
 - The *probability* score of a **maintenance-related failure** is given to each major medical equipment category according to how probable a *major maintenance-related failure* is likely to occur in the equipment lifetime.
 - Analysis of service data (from the organization’s own service data or from other credible data sources) is used to determine the type and frequency of service necessary to ensure maintenance-related failures do not pose an unacceptable risk to patients or staff.

The probability of a major maintenance-related failure is classified and scored in one of the four categories described in Table 2.

Table 2: Probability Levels of Maintenance-related Failure

Level #	Level Description	Criteria	Mean Time Between MRF
1	Improbable	very unlikely to occur	≥ 25 years
2	Remote	unlikely but possible to occur	≥ 10 and < 25 years
3	Occasional	likely to occur	≥ 5 and < 10 years
4	Probable	very likely to occur	< 5 years

- 4) UCH Clinical Engineering calculates the risk score. The *risk score* for each major equipment category is calculated by multiplying its *severity* score by its *probability* score as shown in Figure 4 below.

Figure 4: Risk Matrix

Risk Score = Severity x Probability

		Severity (Consequence)			
		1 Negligible	2 Marginal	3 Critical	4 Catastrophic
Probability	4 Probable	4	8	12	16
	3 Occasional	3	6	9	12
	2 Remote	2	4	6	8
	1 Improbable	1	2	3	4

- 5) UCH Clinical Engineering determines overall risk level: The resultant *risk* scores for major medical equipment categories are classified as either *low*, *medium* or *high* and are subject to review at an appropriate organizational level according to the description in Table 5.

Table 5: Risk Levels

Level #	Level Description	Severity x Probability =	Review Required
1	Low	1,2,3,4	acceptable risk: changes may be made in maintenance procedures & frequencies
2	Medium	6,8	requires mitigation to further reduce risk (including changes in maintenance if appropriate) or the Director of Clinical Engineering authorization to proceed at this risk level
3	High	9,12,16	requires mitigation to further reduce risk (including changes maintenance if appropriate) ... or <i>senior leadership</i> authorization to proceed at this risk level

The *Risk* score of maintenance-related failure is *LOW* (4 or below), a medical device (except for lasers, imaging, & radiologic devices that CMS has elected to exclude from consideration, and medical equipment with insufficient maintenance history) can be placed in the *alternate equipment maintenance* (AEM) program and kept in the program as long as the risk to patients or staff does not increase. Factor(s) in addition to risk addressed when considering equipment for inclusion in an AEM program include:

- maintenance requirements of the equipment

- 6) **Develop a Mitigation Plan for Elevated Risks:** Development of a *mitigation plan* should be considered for any medical equipment category whose *probability* score combined with a medical device category *severity* score **exceeds 4**. Any mitigation plan should identify what changes in maintenance activities or frequencies should be taken to reduce the risk to a more acceptable level. If changes in maintenance activities or frequencies are not possible and the equipment is to continue to be used, sign-off by appropriate parties (e.g., manager of clinical

engineering, senior leadership) should be made.

- 7) Review: High-Risk equipment placed on the AEM program are reviewed with representative equipment operators and other stakeholders prior to finalization. Medical equipment category severity, probability and risk scores along with any mitigation plans are reviewed by UCH Clinical Engineering at least annually to assure a continued level of safety and effectiveness. A report of this review is made to the EOC committee.

H. **ATTACHMENTS :**

[Appendix A: AEM Analysis](#)

I. **REFERENCES :**

TJC Standards-

HAP EC.02.04.01 EP4. 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.*
- *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.*

HAP EC.02.04.01 EP5. 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
- *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*

HAP EC.02.04.01 EP6. 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 back-up equipment in the event the equipment fails or malfunctions - Incident history of identical or similar equipment
- Maintenance requirements of the equipment

HAP EC.02.04.01 EP7. The hospital identifies medical equipment on its inventory that is included in an alternative equipment maintenance program.

HAP EC.02.04.03 EP2. The hospital inspects, tests, and maintains all high-risk equipment. These activities are documented. (See also PC.02.01.11, EP 2)

- *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 alternative equipment maintenance (AEM) program inventory must have a 100% completion rate*

HAP EC.02.04.03 EP3. 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 are to be completed at 100%. AEM frequency is determined by the hospital's AEM program.*

J. SEARCH WORDS :

NONE

K. ENFORCEMENT:

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

L. STAKEHOLDER APPROVALS :

On File

M. COMMITTEE APPROVALS :

Medical Equipment Sub Committee

N. FINAL APPROVAL :

- | | |
|---|-----------------------------------|
| <p>1. <u>Andrew Agwunobi, MD (Signed)</u>
Andrew Agwunobi, MD, MBA
UConn Health Chief Executive Officer</p> | <p><u>08/10/2021</u>
Date</p> |
| <p>2. <u>Anne D. Horbatuck, (Signed)</u>
Anne D. Horbatuck, RN, BSN, MBA
Clinical Policy Committee Co-Chair</p> | <p><u>08/12/2021</u>
Date</p> |
| <p>3. <u>Scott Allen, MD (Signed)</u>
Scott Allen, MD
Clinical Policy Committee Co-Chair</p> | <p><u>08/11/2021</u>
Date</p> |
| <p>4. <u>Caryl Ryan (Signed)</u>
Caryl Ryan, MS, BSN, RN
Interim Chief Operating Officer, JDH
VP Quality and Patient Services & Chief Nursing Officer</p> | <p><u>08/11/2021</u>
Date</p> |

O. REVISION HISTORY :

Date Issued: 7/76

Date Revised: 1/86, 11/88, 12/88, 9/91, 8/09, 10/14, 5/18, 7/21

Date Reviewed: 11/94, 5/97, 2/00, 10/03, 05/06, 9/08, 09/12, 04/16