SPECIAL SERIES

A Clinical Engineer's Approach to CMS Compliance: Part Two

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About the Author

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Editor's note: This is the second of three articles about McLaren Health Care's comprehensive effort to demonstrate compliance with various regulations, including those from the Centers for Medicare & Medicaid (CMS), dealing with medical devices and equipment. In this article, the author explains how his organization's medical equipment management program was modified to incorporate new CMS requirements.

To date, efforts to update our medical equipment management program (MEMP) policy have focused on demonstrating compliance with new language contained in the Centers for Medicare & Medicaid Services (CMS) guidance document. These efforts also will address both The Joint Commission (TJC) and Healthcare Facilities Accreditation Program (HFAP) interpretations of the CMS regulation. Below are examples of selected text contained within our revised MEMP document.

Purpose

The purpose of this policy is to 1) outline components of the MEMP administered by McLaren Clinical Engineering Services (MCES) and 2) define criteria as to how an assessment process will be used in the development and implementation of a strategy for minimizing equipment use-related risks. Program oversight, including responsibilities and authorities to make decisions on equipment maintenance types and procedures, alternate equipment management (AEM) strategies, inspection schedules, labor, and parts sources are assigned to hospital-specific managerial and/or supervisory clinical engineering staff by the author (i.e., the corporate director of clinical engineering at McLaren Health Care). These individuals, by nature of their education, training, and experience, have the necessary skills to carry out such activities, as outlined in their job descriptions and as validated during their annual performance reviews.

The MEMP is a corporate policy that references additional hospital policies specific to medical equipment use, operation, and maintenance. Multiple device-specific (maintenance) strategies will be used to maximize medical equipment safety in support of recommendations of various regulatory and/or inspection agencies, such as TJC, College of American Pathologists, American Association of Blood Banks, Healthcare Facilities Accreditation Program (HFAP; of the American Osteopathic Association), CMS, and National Fire Protection Association (NFPA).

Definitions

AEM Program

The AEM program consists of inventoried devices within the MEMP whose scheduled inspection frequency and/or maintenance procedures vary from the manufacturer recommendations (excluding diagnostic imaging devices, lasers, and devices that are

new and therefore lacking historical maintenance or risk assessment data). Maintenance strategies used to minimize equipment failures and associated risks may include equipment operational assessments performed by the device user; using the device until an operational defect is observed (i.e., run to fail); scheduled maintenance, such as battery replacement, fan/filter cleaning, or installation of a defined preventive maintenance (PM) parts kit; or equipment performance verification measurements only. Devices managed by the AEM program may have inspection procedures performed on a periodic (random) basis or performed when the device is new and after repair. The inspection frequencies or procedures for these devices may have been modified from original equipment manufacturer (OEM) recommendations based on review of historical data documenting no risk to the patient. In additon, devices on an AEM program must not involve a known risk of injury or death to the patient resulting from a relationship to scheduled inspection frequencies or procedures.

Life Support and Critical/High-Risk Equipment

Devices involving a risk of death should the equipment fail are considered life support devices. Typically, all life support equipment also is considered critical (or high-risk) equipment, but not all critical/high-risk equipment is life support equipment. Critical/high-risk equipment is considered high priority in terms of availability to meet patient care delivery needs, such as surgical robot systems, select imaging systems, or other special diagnostic devices. Examples of life support equipment include heart/lung bypass machines, anesthesia machine/circulatory assist devices, ventilators, and defibrillators.

Services Provided by MCES as Components of the MEMP

1. **Scheduled Equipment Inspections**, whereby the staff of the MCES department (or their designated service representatives) perform periodic safety and performance verification inspections and/or other planned maintenance activities on medical (clinical) direct patient care equipment. (This excludes patient implantable devices, disposables, or single-use patient care items.)
2. **Corrective Maintenance**, whereby the staff of the MCES department (or their designated service representatives) perform or otherwise manage and oversee repairs and other maintenance activities performed on equipment identified to be malfunctioning or suspected of having operational problems. This includes services provided by external vendors, where equipment is under warranty, service contract, or a time and material service arrangement.
3. **Vendor Service Management**, whereby the staff of the MCES department is responsible for selecting and approving external vendor parts and labor sources. All requests for external vendor maintenance services are coordinated through MCES, including service report documentation to be reviewed and invoice payment processing.
4. **Incident Investigations**, whereby the staff of the MCES department (or their designated service representatives) assist with evaluating proper operational conditions of medical equipment suspected to have been involved with a patient or operator incident, injury, or other reported problem. In addition, MCES shall assist with providing required information in support of compliance with the FDA Safe Medical Devices Act.
5. **New Equipment Evaluation, Acceptance Testing, and Inventory Management**, whereby the staff of the MCES department participates in the selection, evaluation, and assessment of new equipment under consideration for purchase and—if acquired for use—for inclusion in the MEMP inventory listing. In addition, MCES staff shall document acceptance of newly purchased, leased, or rented medical equipment and assign identification numbers and other relevant inventory control and inspection labels to devices to be managed within the program.
6. **Equipment Inventory Tagging, Labeling, and Reporting**, whereby the MCES department shall develop and adhere to a process in which—through the combined uses of the equipment identification numbers and periodic reporting—all users of equipment shall have a means to

Patient care devices or biomedical equipment for which there is a risk of death to a patient, should the equipment fail, are considered life support devices.

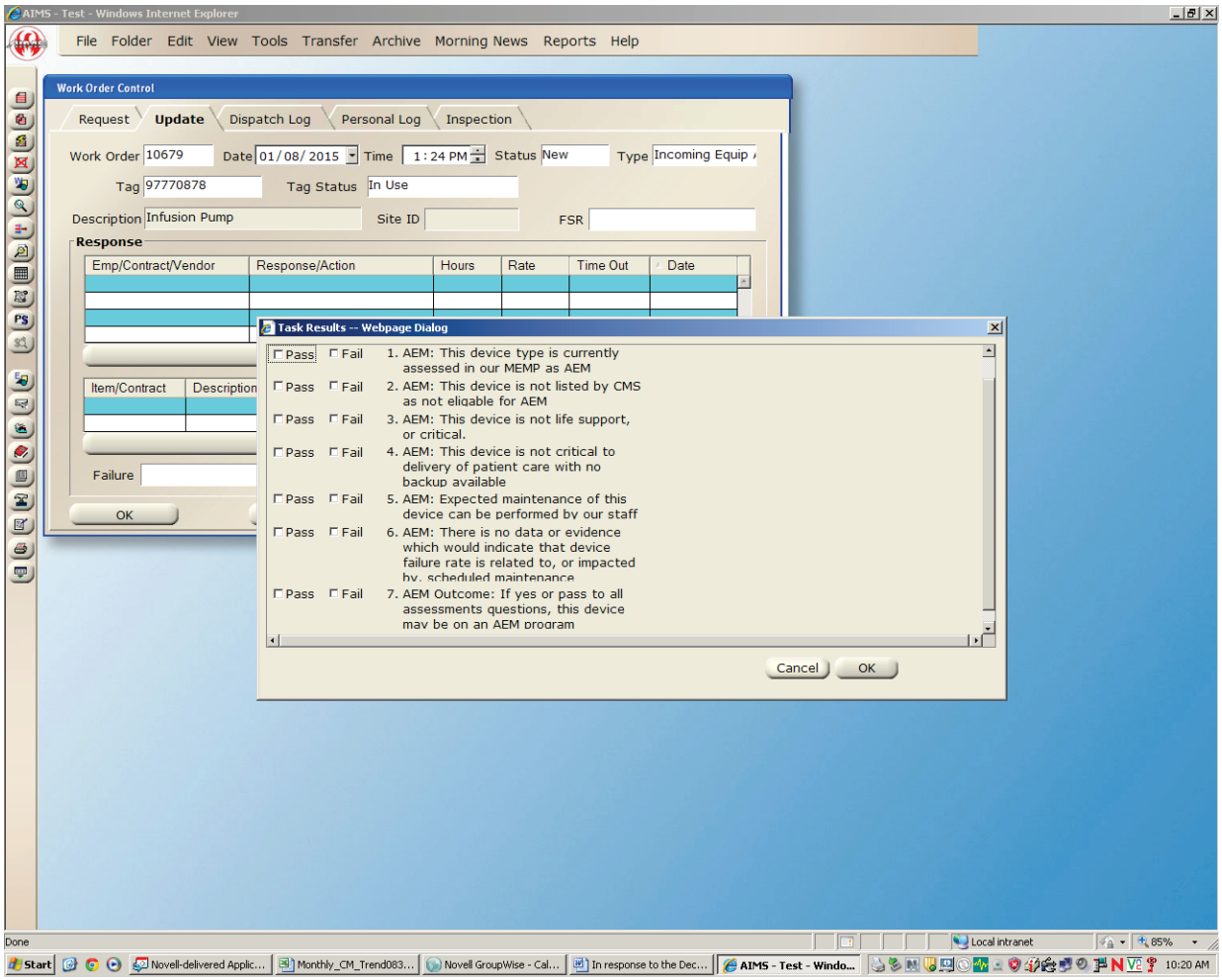
identify or otherwise obtain updated information on the status of equipment contained in the program. All equipment included in the program shall be identified in the inventory, which is a computerized database system that uniquely identifies manufacturer, model number, serial number, date of installation, user department, and other key information.

7. **Service Documentation Management**, whereby the MCES department shall maintain all records related to inventory and maintenance of medical equipment, including services performed by MCES staff and external vendors.
8. **Fiscal Management**, whereby the MCES department operates the MEMP according to an approved program by controlling expenses related to all medical equipment maintenance budgets under MCES jurisdiction.
9. **Technical Risk Management**, whereby the MCES departmental management staff reviews and takes appropriate actions on all recall and hazard notices received that outline specific or potential equipment defects, hazards, or warnings on equipment that may be contained in the hospital's active equipment inventory. Additional duties shall include periodic review of equipment failure rates, equipment alarm operation, and assessment of reported equipment operator problems.
10. **Educational and Equipment User Support**, whereby MCES staff respond to equipment user requests for technical and operational support.
11. **Equipment Related Projects, Acquisitions, Installations, and Upgrades**, whereby the staff of the MCES department participate in or manage the process of selecting new equipment being considered for purchase, plan or assist with equipment installation and/or upgrades, and assist with other equipment project activities as authorized by the appropriate clinical department.

Acquiring and Processing Newly Purchased Equipment

The following list outlines crucial components in the procurement process.

1. MCES shall participate and provide guidance regarding the evaluation, selection, procurement, and installation of new and replacement patient care equipment, in accordance with corporate policy.
2. All newly purchased patient (clinical) care equipment is to be inventoried and inspected (or validated as safe and operational) by MCES staff or their designated representative(s) prior to patient use. All newly purchased equipment should be either 1) sent to MCES for testing upon initial receipt from the vendor or 2) held for testing by the purchasing or end-user department until such time that MCES can provide, or arrange for, initial testing.
3. All newly purchased equipment (to be managed within the MEMP) shall include, as a condition of purchase, at least one copy of an operator's manual, as well as a technical service manual in hard copy or digital format, including written testing/PM inspection procedures, schematics, parts lists, theory of operation, and all other pertinent information required to maintain the equipment. Equipment suppliers that do not comply shall be noted as not being in compliance with state of Michigan NFPA 99 within a separate file maintained by the corporate MCES office.
4. Each type of equipment listed in the program shall have a written procedure with respect to inspection, testing, and maintenance, to be kept on file in the MCES hospital-specific department. If a device-specific testing and inspection procedure was not provided by the equipment manufacturer as a condition of the initial purchase, MCES may develop a generic procedure that includes procedures for testing, at a minimum, electrical safety and operational verification.
5. As part of the new equipment inspection, the device type shall be reviewed to determine inclusion within the MEMP against established criteria, including determination of scheduled inspection priority. Devices that only need an acceptance test and not requiring scheduled inspections shall be retested for electrical safety only upon repair, if suspected to be malfunctioning, or if a visual inspection indicates that problems with the power cord or casing may exist.



The CMS regulation requires all decisions on AEM program inclusions to be documented but does not provide guidance on how to do this. The CMMS program at McLaren Health Care has a feature that generates a new inspection work order for each device that is added to the inventory, which is a user-customizable document. This allows staff to document a series of assessment questions, which then becomes a part of the device master record. This screenshot shows an example of that documentation. Note: "Pass" = "yes".

6. As part of the new equipment inspection, the device shall be evaluated to determine whether it is a candidate for inclusion in the AEM program. Typically, most commonly used medical device types can be candidates for an AEM program, except for imaging devices, medical treatment lasers, and new device types for which no known historical patient risk factors are available for assessment, as outlined by CMS regulations. This evaluation shall be documented on an approved MCES AEM assessment form.
7. If an assessment currently exists for the device category, additional items added to the program within that category do not require a new assessment to be made. Items to be included within new device categories will be assessed by the MCES management staff. Results of the evaluation will be documented on the MCES device category risk assessment spreadsheet.
8. Equipment involved in an incident will be reevaluated by a MCES clinical engineer, or his/her designee (program manager).
9. On an annual basis, the listing of devices managed within the MEMP will be reviewed, taking into account historical inspection outcome data, recent incident investigations, corrective maintenance failure codes, and overall equipment failure rates, in order to validate any need

for changes to inspection frequency or procedure. This annual evaluation shall be documented.

Major Changes to the MEMP Document Based on CMS Regulation

Although the information below does not outline all elements of our revised MEMP, the sections most affected by the CMS regulation are described.

1. Definition of Critical, Life Support, and High-Risk Equipment

TJC wants your program to be able to generate a separate listing of "high-risk" equipment. CMS refers to this same subset of equipment as "critical" and requires it to be identified. HFAP still requires a separate listing of equipment that is "life support." After much internal debate, we have come to the conclusion that critical equipment is the same as high-risk equipment. A subset of this listing then could be considered life support equipment, but the opposite is not necessarily true. (In other words, not all critical/high-risk equipment is life-support equipment.)

One example that has surfaced is an infant hearing analyzer. While not life-support or high-risk equipment, it is critical to the operation of the hospital, since the patient cannot be discharged without this test being done.

The computerized maintenance management system (CMMS) we use has a separate flag for identifying, on each equipment record, that the device is critical. Using a data export function, this designation can be used to generate a separate critical equipment listing. It also has an equipment function setting, whereby we can classify equipment (by device type or by unique ID tag number) in one of the following categories: 1) life support, 2) critical/high risk, 3) miscellaneous patient care, and 4) non–patient care.

Using these options, we can track and generate listings of devices that are critical and/or life support. We also can determine which devices are both critical and on an AEM program, as we are aware that the inspection agencies will have a focused interest on such equipment.

Equipment Function (EF)	Points
Life support	8
Critical/high risk	4
Miscellaneous patient care device	2
Non–patient care device	1
Potential Risk (PR; due to typical device failure)	
Undetected failure could result in death or injury	8
Undetected failure could result in misdiagnosis	4
Equipment failure could delay patient care	2
None	1
Maintenance Requirements (MR)	
AEM not allowed, or OEM procedures being used	30
Time-based parts need or clinical alarm test required	8
User operational verification	4
No service manual available	1
Device History (DH)	
Documented previous patient incident or near miss	8
High scheduled inspection result outcomes	4
Preventable device failure findings	2
Random failures or no significant risk findings	1
Use/Environment (UE)	
Device is used unattended, no user test available	8
Device is used unattended, with user test available	4
Device is used attended, no user test available	2
Device is used attended, with user test available	1

Table 1. Five-factor equipment score (ES) for determining inclusion in medical equipment management plan.
ES = EF + PR + MR + DH + UE

2. Revised Equipment Maintenance Assessments to Define Equipment Appropriate for an AEM Program

In this time-consuming exercise, we developed a new risk-based and point assignment scheme (and formula) that takes into account all of the assessment factors that CMS requires for deciding which equipment is appropriate for an AEM program. One new assessment element, which we actually began using years ago, is the use/environment factor. It takes into account whether a device is left unattended and whether it has a user test capability. Also, we wanted to make use of the customizable mathematical formula and reporting options that our CMMS provides. Although many publications have described elaborate methods to prioritize and quantify equipment risk, our goal was to incorporate all assessment factors (i.e., use of

historical failure rate data, historical outcome findings of scheduled inspections, risk to the patient due to likely equipment failure, how and where the equipment is used, user test options) outlined within the new CMS regulations into a simple assessment process. Our end result led to the definition of three different categories of our AEM program, and one non-AEM program maintenance strategy category. All of this information has been defined in our MEMP policy document, as outlined below.

Equipment Maintenance Assessment Program

Equipment is assessed/evaluated for inclusion within the MEMP and for assignment within a service model category using a five-factor scoring system (Table 1).

Once you determine what equipment items will be on an AEM program, you need to able to uniquely identify these in your CMMS. Currently, we have two means to do so within our CMMS. The first is by assigning points. The second is by a user-definable expansion field, in which we can insert "Y" (i.e., yes) into the "On AEM?" field. Also, our CMMS vendor has released new features related to tracking and identifying devices on an AEM program that we are in the process of evaluating.

3. Strategy for Equipment Safety: Scheduled Equipment Inspections

One strategy MCES uses to minimize equipment risk is through implementing a device-specific scheduled inspection program, based on multiple factors (described above). This process incorporates a review and assessment of the impact of equipment failure on the patient, outcomes of previous inspections, and how the device is used (attended or unattended). The process also takes into account equipment self-testing capabilities and whether the device is continuously monitored (i.e., used in the presence of a clinical caregiver or via real-time connection to an alternate location) or left unattended during patient care.

Using the scoring methodology described here, clinical equipment is scheduled and prioritized for completion of periodic scheduled inspections. Of note, we do not use this point system to define inspection frequency. Instead, inspection frequencies are initially established (for new equipment types for which we have no applicable historical maintenance or patient safety risk data) per manufacturer recommendations, then potentially changed based on review of inspection outcome data and other assessments. Each year, inspection frequencies on selected devices may be modified based on recommendations made by MCES technical staff. Using our modified assessment system scoring scheme, each device will fall into one of the following inspection categories:

Category I: Equipment risk assessment scores of 33 or greater are given the highest priority for testing, calibration, and repair, following OEM recommended frequencies and procedures, where available. All (100%) life support devices defined within Category I will have inspections completed by their scheduled due date. By design, these devices are not on an AEM program.

Category II: Equipment risk assessment scores between 20 and 32 points on the criteria evaluating system shall be inspected on a scheduled basis, following appropriate testing and inspection procedures as approved by MCES. Devices within this category are on an AEM program model, where the frequency of inspection, or procedure used, varies from what may be listed in the OEM service manual.

Category III: Equipment risk assessment scores between 16 and 19 are scheduled for inspection and performance verification testing on a periodic (or random sample) basis and are on an AEM program. Electrical safety, equipment operational verification, and related performance tests (where applicable) will be performed upon initial inspection, after repairs are made, and when a suspected equipment problem is reported. Each year, a sample of at least 25% of the inventoried items defined as Category III will be tested and documented. Should periodic sampling of these devices result in equipment defects or safety-related issues that are not discoverable by the equipment user, an assessment will be made that could result in category level reassignment. If no significant device defects are discovered during periodic (or random) sampling, devices in this

category could be moved to a Category IV AEM program model. Of note, if historical data justify "no need for scheduled inspections" (even random), the devices may be moved to a Category IV service model.

Category IV: Equipment risk assessment scores of 15 or less will be listed in the MCES inventory but not scheduled for routine or periodic inspections, except for during a repair or if suspected by the user to be malfunctioning.

Points assignment, identification of equipment included in an AEM program, next inspection due date, inspection frequency and procedures to be followed all are contained in the CMMS, which is accessible from any computer on the hospital network. Many types of equipment reports can be generated, in order to identify equipment coded as life support, critical, or on an AEM program.

4. Starting Over with Equipment Risk Scoring

We asked our CMMS vendor to provide a database SQL statement that would clear out all points previously assigned to inventoried devices. Although this was a bit scary, it had to be done. To validate the effectiveness of this new equipment scoring approach, our management team shared in the task of rescoring all of the active equipment types in use at their respective hospitals. Then, we imported all equipment scores into one spreadsheet, which allowed for comparions in terms of the final maintenance category assigned to each equipment type. This was very time consuming, to say the least, as we had more than 5,000 separate makes and models of equipment in our central database (of 65,000 items) to rescore. To our surprise, a high amount of consistency was observed in the final scoring among our various hospitals, as demonstrated by the example provided in Table 2.

Pushing out the final equipment assessment scores can be done globally by equipment type to one or multiple facilities, which will make this task easier. Any outliers, by make, model, or individual ID number, can be updated individually as required. After all scores are pushed out, we can then run separate inventory and work history reports filtered by any of the point assignments, or total scores. ■

Hospital	Equipment Type	Manufacturer	Model	EF	CR	MR	DH	UE	Score
Flint	Camera, Processor	Carl Zeiss Surgical, Inc.	ZVS1470	2	2	1	1	2	8
Flint	Camera, Processor	Karl Storz Endoscopy	22200011U102	2	2	1	1	2	8
McLaren Greater Lansing	Camera, Processor	Karl Storz Endoscopy	9050B	2	2	4	1	1	10
Flint	Camera, Processor	Olympus Corporation	CV-160	2	2	1	1	2	8
McLaren Bay Region	Camera, Processor	Olympus Corporation	CV-160	2	2	1	1	2	8
Flint	Camera, Processor	Olympus Corporation	OTV-S7V	2	2	1	1	2	8
Lapeer	Camera, Processor	Smith & Nephew Inc.	460	2	2	1	1	2	8
McLaren Greater Lansing	Camera, Processor	Smith & Nephew Inc.	325Z	2	2	4	1	1	10
Flint	Camera, Processor	Stryker Corporation	1188HD	2	2	1	1	2	8
Lapeer	Camera, Processor	Stryker Corporation	1188HD	2	2	1	1	2	8
McLaren Greater Lansing	Camera, Processor	Stryker Endoscopy Inc.	1188-010-000	2	2	4	1	1	10
McLaren Bay Region	Camera, Processor	Stryker Endoscopy Inc.	1188-010-000	2	2	1	1	2	8
McLaren Greater Lansing	Camera, Processor	Stryker Endoscopy Inc.	1188HD	2	2	4	1	1	10
Flint	Camera, Processor	Stryker Endoscopy Inc.	1288HD	2	2	1	1	2	8

Table 2. Example demonstrating agreement among all McLaren Health Care hospital sites that "Camera, Processor" equipment falls into Category IV and is appropriate for an alternate equipment management strategy. See Table 1 for definition of acronyms used.

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