

# **New CMS & Joint Commission Regulations on Medical Equipment Maintenance:**

Taking the Smart Approach to Compliance

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## Taking the Smart Approach to Compliance

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### Executive Summary

The new Centers for Medicare and Medicaid Services (CMS) and the Joint Commission (TJC) regulations have substantially changed how hospitals are going to formulate and implement *medical equipment management plans* (MEMPs). It is critical that hospital leaders understand the implications of these changes since this will not only affect their compliance status, but will have a significant impact on their staffing and financial resources as well.

### History

Until the issue of these latest regulations, hospitals had been given a great deal of flexibility in how they implemented medical equipment maintenance practices. In fact, over the past 25 years CMS and TJC have allowed hospitals to use a popular risk-based approach that enabled them to streamline scheduled maintenance activities and minimize associated costs as long as patient and staff safety were not compromised.

This previously approved risk-based approach encouraged hospitals to focus scheduled maintenance activities primarily on the most critical medical equipment – those whose service histories suggested replacing worn components and scheduled testing of particular functions could likely reduce equipment failures. Many hospitals dropped several low risk categories of medical equipment from their maintenance inventories and schedules altogether (sometimes representing as much as 20 to 30 percent of their total inventory), and other non-critical medical equipment categories were receiving little more than cursory visual inspections and electrical safety tests.

This evidence-based approach toward scheduled maintenance has been at the heart of *medical equipment management programs* in the vast majority of hospitals for more than two decades. This approach generally served hospitals well in permitting them to focus their limited resources (e.g., finances and staff) on the medical equipment maintenance issues that had a real potential effect on patient safety and care.

## Summary of Key Changes

On July 1, 2014 TJC announced new standards for medical equipment maintenance. These new standards align TJC's accreditation with updated regulations from CMS issued on December 20, 2013. The CMS and TJC regulations became effective *immediately* on their publication dates.

A summary of the more significant changes includes:

- Hospitals must maintain an inventory of all medical equipment used in their facilities regardless of ownership (e.g., physician-owned, loaners, rental, etc.) and regardless of risk. *This will likely increase hospital inventories significantly, particularly as medical equipment is added that was previously considered of sufficiently low risk so as not to merit inclusion in a maintenance program.*
- Hospitals must follow medical equipment manufacturer recommendations regarding maintenance procedures and frequencies if:
  - The equipment is diagnostic or therapeutic radiologic (including any ultrasound). *Note -- this kind of equipment typically represents at least one half of a hospital's total medical equipment maintenance expenditure.*
  - The equipment is a medical laser.
  - The hospital does not have access to detailed equipment service histories and has not analyzed those histories sufficiently to demonstrate a proposed change in maintenance procedures or schedules from manufacturer recommendations would have no adverse effect on patient or staff safety.
- Hospitals must obtain actual manufacturers' maintenance recommendations for all medical equipment. *These recommendations may not be immediately available in hospitals because they often previously relied on general industry guidelines and practices for their equipment maintenance methods.*
- Hospitals must identify "critical" or "high-risk" medical equipment in their inventory (i.e., equipment where there is a risk of serious injury or death to a patient or staff person should the equipment fail). *Previously, "life-support" equipment (i.e., equipment whose failure could lead to death of a patient or staff) was a primary focus. Focusing on "critical" (aka "high-risk") equipment, the new CMS and TJC requirements considerably broadens the number of equipment categories under special consideration.*
- Hospitals must review and revise as appropriate their MEMP, all their medical equipment-related policies and procedures, and their risk assessment processes to align with these new regulations.
- Hospitals must obtain and monitor appropriateness of the credentials of all persons providing maintenance on medical equipment (including in-house staff and vendor and manufacturer staff) and for all persons (whether in-house or vendor) overseeing the hospital's *medical equipment management program*.

## Impact on Hospitals

These new regulations do represent a significant added staffing and financial burden for most hospitals as they move to achieve the additional compliance requirements.

Medical equipment that was previously considered of sufficiently low-risk, rented or loaned, or otherwise brought in by another owner now must be included in the hospital inventory. The low-risk category alone is likely to add anywhere from hundreds to thousands of additional pieces of medical equipment that the hospital must now track and ensure are serviced per manufacturer recommendations.

Most hospitals are not following manufacturer recommendations for maintenance, and doing so now to comply with the new regulations will likely require significantly more time and expense. Even when equipment is being serviced by the manufacturer, evidence suggests manufacturers often do not follow their own published recommendations. The likely reason for this is manufacturers' published recommendations are generally based on "worst-case" environments that aren't normally applicable for most hospitals. Until manufacturers provide more nuanced maintenance recommendations, hospitals will be required to comply and ensure whoever conducts the maintenance strictly abides by those recommendations.

The new regulations may permit hospitals to deviate from manufacturers' maintenance recommendations on some non-radiologic/non-laser medical equipment only after the hospital has conducted and documented a service history analysis. Unfortunately, the medical equipment service histories maintained by most hospitals do not have the requisite detail to allow for a meaningful analysis. Therefore, most hospitals will either need to revise the type and length of service histories they collect or will need to seek an authoritative source of service analysis prior to considering any deviation from manufacturers' recommendations.

The new regulations require hospitals to avail themselves of appropriate expertise to manage and revise medical equipment-related policies and procedures, conduct risk assessments, and conduct analyses of service histories prior to considering any deviation from manufacturers' recommendations. CMS and TJC suggest the best source of this expertise should be from knowledgeable members of the hospital's clinical engineering services. Hospital leaders would be advised to ensure their existing clinical engineering service (whether in-house or contracted through a vendor) has sufficient expertise and bandwidth to develop and implement an aggressive and complex compliance plan.

## Summary

Adhering to the new regulations will be challenging. Compliance is likely to require considerably more time and money than what hospitals typically spent in the past on medical equipment maintenance. However, these regulations are now the standard and must be addressed.

It is extremely important hospital leaders and compliance officers become informed of these issues and work with those responsible for medical equipment management in their organizations to ensure an appropriate plan to achieve compliance is properly implemented. That plan should be comprehensive and include elements that help lay the necessary groundwork for compliance as well as guide the organization along a fiscally prudent and timely path toward that goal.

And, if hospital leadership recognizes the necessary expertise is not available through existing resources, they should be prepared to seek out and retain that expertise because, ultimately, any gaps or missteps are likely to represent a much higher cost.

### Author Info

Stephen L Grimes, FACCE FHIMSS FAIMBE is Chief Technology Officer of ABM Healthcare Support Services. Mr. Grimes has more than 30 years of experience with hospitals, shared service organizations, and healthcare consulting firms. He is a nationally recognized authority on topics ranging from future challenges facing clinical engineering and healthcare technology integration to medical device security and risk management. Mr. Grimes is a frequent author and sought-after speaker at national and international venues. He is a Fellow of the Healthcare Information and Management Systems Society (HIMSS) and currently chairs their Medical Device and Patient Safety Task Force. He was also named a Fellow of the American Institute of Medical and Biological Engineering (AIMBE) and a Fellow of the American College of Clinical Engineering (ACCE) where he is a past President. In February 2011, he received the joint industry ACCE/HIMSS Excellence in Clinical Engineering & Information Technology Synergies Award. Mr. Grimes is a graduate of Purdue University's Biomedical Engineering Program.



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