

Medical Equipment Management: HTM Programs, Cybersecurity, and FDA Requirements

THE DIRECT ANSWER

A hospital medical equipment management program—usually led by Healthcare Technology Management (HTM) or clinical engineering—maintains an accurate inventory, performs risk-based preventive and predictive maintenance, and documents that equipment is safe for patient care. CMS Conditions of Participation and Joint Commission Accreditation 360 (2026 Physical Environment chapter) expect written processes, maintenance records, and competent operators; FDA's Quality Management System Regulation (QMSR), effective February 2, 2026, mainly governs manufacturers but changes what facilities should require at procurement and during the device lifecycle.

WHAT HTM OWNS IN THE HOSPITAL

- Healthcare Technology Management is the discipline—aligned with AAMI and clinical engineering practice—that keeps medical devices available, calibrated, and safe. Facility managers rarely run HTM day to day, but you share survey heat: broken equipment in clinical zones, missing PM stickers, and “we’ll.

INVENTORY AND RISK-BASED MAINTENANCE PLANNING

- Start with a single authoritative equipment list: location, asset tag, manufacturer, model, serial number, criticality, and maintenance owner. Criticality should reflect patient harm if the device fails—not just purchase price.

FIELD QUESTION

Who should own the hospital medical equipment management program?

Most acute care hospitals assign operational ownership to HTM or clinical engineering, with accountability shared by the chief nursing officer or chief medical officer for clinical use and by facilities or safety leadership for Environment of Care integration.

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Caution: codes, editions, and targets vary by facility and authority having jurisdiction (AHJ). Figures marked as common practice are facility targets, not code requirements. Confirm against your AHJ and the current code text before acting.

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