AAMI
Advancing Safety in Medical Technology

HTM LEVELS GUIDE

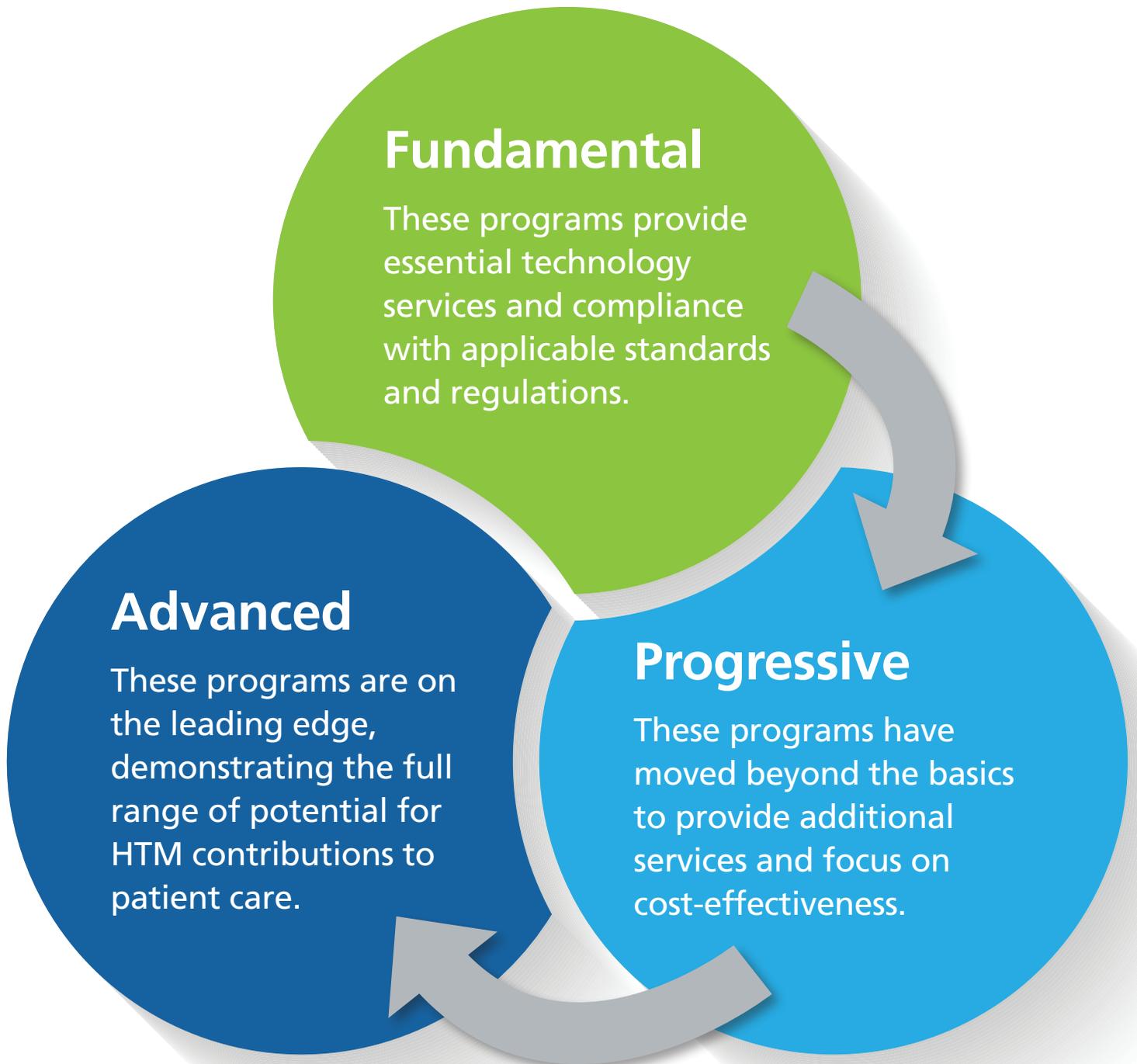*A program-planning tool for healthcare technology management departments*

About This Guide

AAMI developed this guide to help Healthcare Technology Management (HTM) departments maximize the services they provide to healthcare delivery organizations. It is part of a broader effort to standardize and elevate the HTM field.

AAMI (the Association for the Advancement of Medical Instrumentation) is a non-profit organization of nearly 7,000 healthcare technology professionals united by one important mission—supporting the healthcare community in the development, management, and use of safe and effective technology. AAMI's Technology Management Council (TMC) launched the effort in 2013 and commissioned a team of HTM experts that included Matt Baretich (Baretich Engineering), Frank Painter (University of Connecticut), and Ted Cohen (UC-Davis Medical Center) to carry out the project. The guide underwent extensive peer-review by TMC members and other experts reviewed the document and made recommendations that resulted in this guide.

The three levels of an HTM Department...

Fundamental

These programs provide essential technology services and compliance with applicable standards and regulations.

Progressive

These programs have moved beyond the basics to provide additional services and focus on cost-effectiveness.

Advanced

These programs are on the leading edge, demonstrating the full range of potential for HTM contributions to patient care.

How to Use This Guide

Healthcare Technology Management (HTM) programs are not all alike. Some programs, especially those in smaller healthcare organizations, are intended to provide basic services. Others have the resources to provide additional services with a wider scope. All have the objective of supporting safe and effective healthcare technology for patient care in their organizations.

HTM programs are available in three levels:

- **Fundamental.** These programs provide essential technology services and compliance with applicable standards and regulations.
- **Progressive.** Programs at this level have moved beyond the basics to provide additional services and focus on cost-effectiveness.
- **Advanced.** These programs are on the leading edge, demonstrating the full range of potential for HTM contributions to patient care.

Each HTM program level includes a checklist of the key characteristics defining that level. The checklist items address the following issues:

- Program scope
- Regulatory compliance
- Program management
- Equipment maintenance and technology management
- Personnel management and staff development
- Tactical and strategic planning
- Performance monitoring and performance improvement
- Patient and staff safety
- Internal and external relationships

This document can be used to review the checklist items and see which of them have been achieved by your HTM program. That process will enable you to identify the level of your program. You may find, for example, that you have Level 1 under control (except perhaps for that one issue that's been giving you trouble) and are tackling some Level 2 items. This document is not a standard, formal metric, or a rigid set of steps to follow. It's a tool to help identify opportunities to expand and improve.

What's the next logical step for your HTM program? What issues do you need to work on? What opportunities might be worth a discussion with your boss? All of the checklist items in this document are doable and are being done right now by many of our colleagues throughout the HTM profession. References are included to enable retrieval of further information. A poster version has been created to hang on the wall and maintain focus. **Go for it!**

— The AAMI Team
Matt Baretich, Baretich Engineering
Frank Painter, University of Connecticut
Ted Cohen, UC-Davis Medical Center

HTM Program Level 1
Fundamental

At the fundamental level, HTM programs focus on compliance with applicable standards and regulations and on maintenance of general biomedical equipment. After ensuring that their programs have accomplished all of the items listed below, HTM professionals should then build on this foundation.

Program Scope

✓ **The HTM program maintains most of the general biomedical equipment in the organization.**

General biomedical equipment includes medical devices that provide monitoring, diagnosis, treatment, or life support but excludes imaging equipment, therapeutic radiology equipment, clinical laboratory equipment, and other advanced technologies that are often managed by other departments.
Reference: *Medical Equipment Maintenance Manual* (AAMI, 2009).

Compliance

✓ **The HTM program achieves compliance with accreditation standards and government regulations.**

In the United States, the most prominent accreditation organization is The Joint Commission (TJC). However, the HTM program should be aware of any other equipment-related standards and regulations that apply to their organizations.
Reference: *Environment of Care Essentials for Health Care* (The Joint Commission, 2013).
Reference: *Electrical Safety Manual,* Baretich and Shepherd, AAMI, 2008.

Program Management

✓ **The HTM program has a current, written medical equipment management plan (MEMP).**

Activities of the HTM program should be based on a plan that summarizes its responsibilities and describes how it meets those responsibilities.
Reference: Joint Commission Standard EC.01.01.01 EP3.

✓ **The HTM program has an equipment control program in place with a risk-based inventory.**

The program should maintain an accurate inventory of the equipment it maintains. Inclusion in the maintenance inventory should be based on factors such as physical risk.
Reference: Joint Commission Standard EC.02.04.01 EP2.

✓ **The HTM program uses a Computerized Maintenance Management System (CMMS) for inventory, maintenance scheduling, and maintenance history.**

The maintenance inventory should be kept in a CMMS with basic capabilities for scheduling maintenance activities and recording maintenance history.

Reference: *Computerized Maintenance Management Systems for Clinical Engineering* (AAMI, 2003)

Equipment Maintenance and Technology Management

✓ **The HTM program has written procedures for safety and functional testing and for preventive maintenance.**

Procedures should include functional testing as well as electrical and other types of safety testing. These procedures should be based on manufacturer recommendations and recognized professional resources, such as those provided by the ECRI Institute.

Reference: Joint Commission Standard EC.02.04.01 EP3.

✓ **The HTM program has written schedules for inspecting and maintaining medical equipment.**

In a basic HTM program, calendar-based scheduling is most common. Schedules should be based on manufacturer recommendations and recognized professional resources, such as those provided by the ECRI Institute.

Reference: Joint Commission Standard EC.02.04.01 EP4.

✓ **The HTM program has a process for regular calibration of test equipment.**

Test equipment should be professionally calibrated at intervals recommended by the manufacturer.

Reference: "The Calibration Process: Inspection, Measuring, and Test Equipment Control," *Biomedical Instrumentation* & *Technology* (May/June 2009).

✓ **The HTM program has the ability to readily obtain repair parts.**

The program should be able to acquire parts in a timely manner as needed, especially for emergency repairs.

Reference: "Controlling Repair Part Costs Through Supply Chain Management," *Biomedical Instrumentation* & *Technology* (May/June 2003).

Personnel Management and Staff Development

✓ **HTM program personnel have appropriate education, experience, credentials, and values.**

The provision of safe and effective medical equipment depends on well-qualified personnel in the HTM program.

Reference: *Core Competencies for the Biomedical Equipment Technician* (AAMI 2013).

✓ **HTM program job descriptions and job titles conform to professional standards.**

Professional titles including the terms "technician" or "technologist" should be reserved for HTM personnel with technician-level education and credentials. Professional titles including the term "engineer" should be reserved for HTM personnel with engineering education and credentials.

Reference: *Core Competencies for the Biomedical Equipment Technician* (AAMI 2013).

Note: Throughout this document, the terms "maintains" and "manages" are used. When the word "maintains" is used, it's meant that the HTM program is responsible for maintenance (inspection, scheduled maintenance, and repair) primarily using HTM program staff. When the word "manages" is used, it's meant that the HTM program is responsible for maintenance (inspection, scheduled maintenance, and repair) and the cost of maintenance using an external service provider (by contract or by noncontract labor and materials).

Tactical and Strategic Planning

✓ **The HTM program is regularly included in the process for selection and acquisition of medical equipment.**
The experience and technical knowledge of the HTM program is essential for effective medical equipment planning for the organization.
Reference: Joint Commission Standard EC.02.04.01 EP1.

Performance Monitoring and Performance Improvement

✓ **The HTM program regularly monitors and reports compliance with the MEMP.**
At a minimum, performance monitoring should include tracking of on-time completion of scheduled maintenance, but other metrics should be considered.
Reference: Joint Commission Standard EC.02.04.03 EP2 and EP3.

✓ **The HTM program participates in the Safety/EOC Committee's annual evaluation of the MEMP.**
This evaluation should be multidisciplinary and based on data.
Reference: Joint Commission Standard EC.04.01.03 EP3.

The HTM program responds to product notifications and recalls related to medical equipment.

HTM program responsiveness allows the organization to quickly implement corrective actions.

Reference: Joint Commission Standard EC.02.01.01 EP11.

Patient and Staff Safety

✓ **The HTM program responds to product notifications and recalls related to medical equipment.**
HTM program responsiveness allows the organization to quickly implement corrective actions.
Reference: Joint Commission Standard EC.02.01.01 EP11.

✓ **The HTM program reports equipment-related problems and use errors to the Safety/EOC Committee.**
To meet its responsibilities for safety in the environment of care, the committee must have complete and timely information regarding medical equipment.
Reference: Joint Commission Standard EC.04.01.01 EP10.

Internal and External Relationships

✓ **The HTM program is represented on the Safety/EOC Committee.**
The key value of this committee is its interdisciplinary nature, which brings multiple perspectives to bear on problem identification and resolution.
Reference: Joint Commission Standard EC.04.01.01 EP1.

✓ **The HTM program participates in environmental tours in patient care areas.**
Although Joint Commission standards do not require HTM program representation for environmental tours (formerly known as hazard surveillance rounds), it promotes interdepartmental communication and supports timely resolution of identified issues.
Reference: Joint Commission Standard EC.04.01.01 EP12.

HTM Program Level 2
Progressive

A Level 2 HTM program meets all of the Level 1 requirements and provides increasing value to the healthcare organization by focusing on cost-effectiveness and performance improvement.

Program Scope

✓ **The HTM program maintains or manages almost all general biomedical equipment.**
Compared with Level 1 programs, Level 2 programs cover essentially all general biomedical equipment, either by direct maintenance or by management of services provided by others. See the Note in the green circle on page 8.
Reference: "Up and Running: Choosing the Right Equipment Service Option," *Health Devices* (August 2011).

✓ **The HTM program maintains or manages some advanced medical technology (e.g., imaging, laboratory).**
As HTM programs advance, they reduce service contracts and take on more advanced and specialized (and expensive) equipment such as imaging and/or clinical laboratory devices.
Reference: "At Your Service: The Ins and Outs of Servicing Equipment In-House," *Health Devices* (June 2010).

✓ **The HTM program has "clinical engineering" capabilities available from a qualified clinical engineer.**
Clinical engineering capabilities, which include formal risk assessment (e.g., FMEA, IEC80001), technology assessment and planning, systems analysis, and incident investigations with root cause analysis (RCA), are available from either an in-house, "corporate," or contracted staff clinical engineer. A clinical engineer is a graduate of a four-year and/or postgraduate engineering program with a bachelor's or advanced degree in biomedical, electrical, mechanical, or other engineering discipline and with clinical engineering certification (CCE) or equivalent education, experience, and qualifications.
Reference: EQ56, 9.1.2 Staff Qualifications.
Reference: "Enhancing Patient Safety: The Role of Clinical Engineering," ACCE, 2001 (accenet.org/downloads/ACCEPatientSafetyWhitePaper.pdf).
Reference: "Core Competencies for the Biomedical Equipment Technician," AAMI, 2013.
Reference: "What is A Clinical Engineer?," ACCE (www.accenet.org/downloads/reference/Whats_a_Clinical_Engineer.pdf).

Compliance

✓ **The HTM program has up-to-date knowledge of applicable codes, standards, and regulations.**

Many voluntary AAMI, IEC, ISO, and other standards exist in addition to the required accreditation standards and state laws that a progressive HTM program needs to understand and keep track of.
Reference: EQ56, Annex D Medical equipment management standards crosswalk.
Reference: AAMI Standards Monitor Online (www.aami.org/standards/smo.html).

✓ **The HTM program implements cost-effective compliance strategies.**

Appropriate scheduled maintenance strategies, consideration of the risks and benefits of using third-party parts, benchmarking, and analysis of repair history all support cost-effective compliance strategies.
Reference: AAMI HTM Benchmarking (www.aami.org/abs).

Program Management

✓ **The HTM program is a distinct organizational entity with a qualified, dedicated manager and a separate budget.**

The HTM manager needs to be qualified and focused on HTM. To effectively manage a budget, it needs to be separate and distinct from other (non-HTM) budgets.
Reference: EQ56, 9.1.2 Staff Qualifications.
Reference: EQ56, 9.2 Budgets.

✓ **The HTM program manager has access to financial information needed to carry out these responsibilities.**

The healthcare organization and the HTM program manager receive regular information summarizing all of the in-house and external costs associated with the provision of medical equipment repair and maintenance services.
Reference: EQ56, 9.2 Budgets.

✓ **The HTM program calculates the Cost of Service Ratio (COSR).**

The COSR (the ratio of all repair, maintenance, and HTM program operating expenses divided by the total equipment acquisition costs) is a recognized HTM cost metric.
Reference: AAMI HTM Benchmarking (www.aami.org/abs).
Reference: EQ56, Appendix B Benchmarking. CMMS.

✓ **The HTM program uses a CMMS with productivity and cost analysis capabilities.**

To convert CMMS data to actionable information, computer-based tools need to be used to measure productivity and analyze equipment repair and maintenance cost data.
Reference: EQ56, Appendix A. CMMS.
Reference: *Computerized Maintenance Management Systems for Clinical Engineering,* Cohen et al., AAMI, 2003.

✓ **The HTM program has adequate space, tools, and equipment.**

Although different HTM programs take different approaches, 120 square feet of space is generally the minimum required per maintenance FTE. Tools and test equipment need to be provided so technicians can complete maintenance on assigned devices.
Reference: EQ56, 9.1.3 Space.
Reference: EQ56, 9.1.4 Test Equipment and Tools.

Equipment Maintenance and Technology Management

✓ **Including all newly acquired device types in the MEMP is based on a written risk assessment process.**

As new equipment is purchased, it needs to go through a formal process (e.g., policy, flowchart) to determine which scheduled maintenance strategy (e.g., interval-based maintenance, run-to-fail, hours-based maintenance, sampling), if any, should be used for that device model.
Reference: EQ56, 5.4.3 Inventory Inclusion.

✓ **Maintenance procedures and schedules are based on recognized resources and organizational data.**

Inspection schedules and procedures are based on manufacturer's defaults or documented alternatives based on data.
Reference: EQ56, 7.1 Inspection Procedures.
Reference: 7.2 Inspection Schedules.

✓ **The HTM program includes management of stock parts (e.g., in their CMMS or other materials management system).**

Depending on local conditions (e.g. access to priority shipping), HTM departments need to determine commonly used parts that need to be kept in stock and parts that can be obtained on a "just-in-time" basis.
Reference: EQ56, Appendix A. CMMS.
Reference: *Computerized Maintenance Management Systems for Clinical Engineering,* Cohen et al., AAMI, 2003.

✓ **The MEMP inventory accuracy is verified at documented regular intervals by a sample physical inventory.**

Accurate inventory is a core requirement for an HTM program.
Reference: EQ56, 5.4.4 Inventory Accuracy.

✓ **Service contracts include provision for periodic auditing of vendor qualifications.**

HTM departments need to be able to confirm that vendor staff, particularly those of third-party vendors, are qualified on the devices they maintain.
Reference: EQ56, 9.1.2 Staff Qualifications.

Personnel Management and Staff Development

✓ **The HTM program supports certification and has at least one CBET, CLES, or CRES on staff.**

Certification demonstrates that technicians have the knowledge to ensure a safe, reliable healthcare environment. It also demonstrates a significant commitment to career and competence.
Reference: EQ56, 9.1.2 Staff Qualifications.
Reference: ICC certification website (www.aami.org/certification).
Reference: "The Value of Certification," Baretich. *Biomedical Instrumentation* & *Technology* (January/February 2012).

✓ **The HTM program has a process for orienting new staff members.**

The orientation program is documented and includes competency review for core job duties.
Reference: EQ56, 9.1.3 Orientation.

✓ **The HTM program has a budgeted continuing education program.**

Each service provider needs to participate in a documented continuing education program at a minimum of 72 hours of formal training every 3 years for each technical staff member.
Reference: EQ56, 9.1.4 Ongoing Education and Training.

✓ **The HTM program supports participation in regional or national professional associations.**

Access to ideas and information from peers is important to improving all HTM programs.
Reference: www.aami.org/communities/societies.
Reference: www.ACCEnet.org.

Tactical and Strategic Planning

✓ **The HTM program is involved in capital equipment planning and replacement equipment planning.**

HTM programs can provide healthcare organizations with a vast amount of information on equipment performance, safety, and reliability. Clinical engineering expertise is critical to cost-effective medical equipment planning for replacement and new construction.
Reference: "Technology Evaluation," Hardin and Epstein, Chapter 33 in *Clinical Engineering Handbook,* Dyro (ed.), Elsevier, 2004.
Reference: "The Dividends of an Effective Clinical Technology Management Program," *Journal of Clinical Engineering,* January/March 2014.

✓ **The HTM program is involved in equipment planning for construction and renovation projects.**

HTM programs can provide healthcare organizations with information on equipment utility (e.g., electrical power, water, communication/IT, medical gases, HVAC) and other equipment installation requirements. Clinical engineering expertise is critical to

cost-effective medical equipment planning for new construction and renovation projects. **Reference:** "How to Build your Role in Construction Projects," *Biomedical Instrumentation* & *Technology* (September/October 2005).

✓ **The HTM program is involved in all purchases of new equipment.**
Early involvement is best, and policies and procedures enforcing HTM approval of every purchase is paramount.
Reference: EQ56, 5.1 Equipment Evaluation and Selection.
Reference: EQ56, 5.2 Acquisition.

✓ **The HTM program records data for technology planning in the CMMS.**
For example:
• Warranty data
• End-of-support data
• Complete maintenance cost, including time, materials, vendor charges, and service contracts
• Acquisition cost
Modern CMMSs can store large amounts of data, and the HTM department should use key fields such as those listed.
Reference: *Computerized Maintenance Management Systems for Clinical Engineering,* Cohen et al., AAMI 2003.

✓ **The HTM program works with clinical staff to understand their needs and identify appropriate technologies.**
Communication with clinical staff (e.g., nurses, physicians, respiratory therapists, rad techs) is imperative to high-quality, multidisciplinary technology purchasing decisions.
Reference: "A Roundtable Discussion: Understanding Medical Device Users in Context," Logan et al., *Horizons* (Fall 2013).
Reference: "Basic Concepts of Needs Analysis and Technology Assessment," *Health Devices* (January 1997).

✓ **The HTM program ensures that user and servicer training is included in most new equipment purchases.**
User and servicer training is best negotiated at the time of equipment purchase. Once included on the purchase, HTM programs need to make sure that the agreed upon user and service training is indeed provided.
Reference: EQ56, 5.2 Acquisition.

Performance Monitoring and Performance Improvement

✓ **The HTM program performs internal benchmarking, monitoring multiple metrics over time. For example:**
• Maintenance cost
• Use error
• Productivity
• Customer satisfaction
Internal benchmarking allows comparison of key quantitative indicators such as those listed and the Cost of Service Ratio (COSR) year over year.
Reference: AAMI HTM Benchmarking (www.aami.org/abs).

✓ **The HTM program considers external benchmarking relative to HTM programs of similar organizations.**
External benchmarking allows comparison of key quantitative indicators such as those listed above and the COSR against peers and competitors.
Reference: AAMI HTM Benchmarking (www.aami.org/abs).

✓ **The HTM program is engaged in continuous performance improvement.**
Quantitative and qualitative indicators for scheduled maintenance (e.g., preventive maintenance compliance), repairs (e.g., downtime of critical systems), and other activities are used to identify areas where improvement is needed. Performance improvement projects then are implemented and tracked until completion.
Reference: EQ56, 4.4 Performance Improvement.

Patient and Staff Safety

✓ **The HTM program is part of the organization's patient safety program.**
HTM staff can make significant contributions to patient safety projects through technology

assessment, user education, equipment-related incident investigations, and other activities. Examples include dose error reduction systems, "smart" infusion pump log analysis, analysis of use error on work orders, and review of equipment incident trends.
Reference: "Flexing Your Muscle: How to Increase Your Value and Influence," *Biomedical Instrumentation & Technology* (May/June 2006).
Reference: "Adverse Patient Events Involving Medical Devices," *Biomedical Instrumentation & Technology* (March/April 2013).

✓ **The HTM program conducts "no problem found" (NPF) and equipment failure analyses.**
Chronic NPF problems indicate user training opportunities and/or human factors design issues with the equipment involved. Periodic equipment failure analysis is needed to identify equipment replacement funding priorities.
Reference: EQ56, Annex A. CMMS.

✓ **The HTM program manages the organization's process for handling equipment-related alerts and recalls.**
The HTM program not only participates in equipment alerts and recalls for medical equipment but also manages them for the organization.
Reference: EQ56, 6.2 Recalls and Alerts.

✓ **The HTM program routinely participates in medical equipment-related incident investigations.**
The HTM program needs to be involved in every serious medical device-related accident, incident, or near miss.
Reference: EQ56, 6.3 Incidents.

Internal and External Relationships

✓ **The HTM program has effective working relationships with clinical departments.**
HTM management should meet routinely with key clinical staff.
Reference: "Building Relationships between Biomedical Engineering and Clinical Staff to Improve Medical Device Safety and Event Reporting" (www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/ucm371354).

Reference: "Communication Tips for Clinical Engineering: Keeping Hospital Staff in the Loop," *Health Devices* (June 2013).

✓ **The HTM program has collaborative relationships with Information Technology (IT) and Facilities.**
As medical devices have become computerized and networked, HTM and IT must have a collaborative relationship. The IT network has become a critical utility and needs to be managed as such.
Reference: "Clinical Engineering and Information Technology" (www.accenet.org/downloads/reference/clinical_engineering_and_information_technology.pdf).
Reference; "Clinical Engineering and Information Technology: Working Together to Implement Device Integration," *Biomedical Instrumentation & Technology* (November/December 2011).
Reference: "Engineering the Clinical Environment," Section X in *Clinical Engineering Handbook,* Dyro (ed.), Elsevier, 2004.

✓ **The HTM program is represented on one or more of the following groups or committees:**
• Capital Acquisition
• Facility Design and Construction
• Patient Safety
• Strategic Planning
• Nursing Education
• Laser Safety
• Radiation Safety
• Product Evaluation
• Quality Assurance
• Performance Improvement
HTM involvement in organizational decisions is key, and although different organizations have different names and structures for patient safety, technology planning, construction, and performance improvement committees and ad hoc groups, HTM needs to be involved in these activities.
Reference: "Flexing Your Muscle: How to Increase Your Value and Influence," *Biomedical Instrumentation & Technology* (May/June 2006).

HTM Program Level 3
Advanced

A level 3 program meets all Level 2 requirements and works at highest levels of the organization to bring the benefits of medical technology to support the mission and vision. The department also provides comprehensive technology management and focuses on strategic planning and technological leadership within the organization. As noted below, some checklist items are examples of advanced HTM practice rather than requirements for all Level 3 HTM programs.

Program Scope

✓ **The HTM program manages all HTM-related costs for the organization.**
All service costs related to medical technology are managed by the HTM program. This includes services provided by both internal and external service providers, as well as all healthcare technologies throughout the organization.
An examples of an advanced HTM practice:
• All service contracts and outside vendor costs related to technology management are centralized in the HTM budget.
Reference: "Breaking out of the Biomed Box: An Audit Assessment and Recommendations for an In-house Biomedical Engineering Program," *Biomedical Instrumentation* & *Technology* (September/October 2003).

Compliance

✓ **HTM program leadership works proactively with regulatory agencies and standards organizations to develop and update medical technology–related regulations, codes, and standards.**
The leadership of the HTM program does more than know mandatory and other requirements; it also is involved in shaping future HTM standards.
Examples of advanced HTM practice:
• Establishes lines of communication with regulators and accrediting organizations.
• Supports advocacy efforts by professional associations regarding codes, standards, and regulations.
Reference: MedSun Medical Product Safety Network (www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork).
Reference: FDA committees (www.aami.org/news/2013/091813_FDA_Review_Puts_Focus_on_Patients.html).
Reference: AAMI technical committees (www.aami.org/standards/TechnicalCommittees.pdf).

Program Management

✓ **The HTM program operates like a business.**
Whether internal or external, profit on not-for-profit, the HTM program functions as a

business unit and should be managed as such. Examples of advanced HTM practice:

- The HTM program prepares a comprehensive annual report.
- The HTM program makes cost-effective long-term business decisions.
- The HTM program is aware of practices and costs of competing organizations.

Reference: "Developing a Five Year Business Plan for Your Department," *Biomedical Instrumentation* & *Technology* (March/April 2010).

Reference: "Create Your Own Business and Marketing Plan," *Biomedical Instrumentation* & *Technology* (January/February 2008).

Reference: "Dashboards: A Required Business Management Tool," *Biomedical Instrumentation* & *Technology* (May/June 2010).

✓ **The HTM program monitors productivity.**

People are the key to a successful HTM program, and labor costs are the majority of HTM support costs. Therefore, efficient labor management is required for HTM program success. One measure of labor efficiency is staff productivity.

Examples of advanced HTM practice:

- Performance improvement activities include productivity measures.
- Staffing models are based on workload and productivity metrics.

Reference: "Carefully Measuring Productivity Proves Key to Managing Resources," *Biomedical Instrumentation* & *Technology* (January/February 2010).

Reference: "Clinical Engineering Productivity and Staffing Revisited: How Should It Be Measured and Used?" *Journal of Clinical Engineering* (October/December 2012).

✓ **The HTM program's CMMS has extensive analytical and technology management features.**

The HTM program uses a comprehensive CMMS with robust reporting tools that allow access to, and detailed analysis of, HTM-related data.

Examples of advanced HTM practice:

- RTLS/RFID system with CMMS location interface.
- IT fields (e.g., IP addresses, wireless frequencies, device software version information).

- Downtime measurements for mission-critical systems.
- Internal customers are allowed to enter work orders, review work order status, and view reports.
- Advanced graphical presentations, HTM dashboard, clinical effectiveness, outcomes measurement.

Reference: *Using Your CMMS to Help Manage Network Connected Medical Systems,* Fourth Annual Medical Device Connectivity Conference and Exhibition, November 2012 (www.thehtf.org/documents/2012%20 Connectivity%20Conference%20Boston%20 Cohen.pdf).

Reference: "Selecting a Computerized Maintenance Management System," Kuloli, *Biomedical Instrumentation* & *Technology* (July/August 2008).

Equipment Maintenance and Technology Management

✓ **The HTM program manages medical technologies throughout the entire equipment life cycle.**

Medical technology must be managed through all life cycle stages: assessment, prepurchase evaluation, purchase, installation, acceptance, repair and maintenance, decommissioning, and disposal.

Examples of advanced HTM practice:

- Sustainability is a factor that is included in technology assessment and evaluation.
- Interface capability is included in technology assessment and evaluation.

Reference: "Life Cycle of Medical Equipment," World Health Organization (www.euro.who.int/en/health-topics/Health-systems/health-technologies/ life-cycle-of-medical-equipment).

Reference: "Sustainability, A Responsible Product Life Cycle," AAMI, 2013 (www.aami. org/hottopics/sustainability).

Reference: "Achieving Interoperability, What's Happening Out There?," AAMI 2013 (www. aami.org/hottopics/interoperability/BIT/2012_ BIT_Achieving_Interoperability.pdf).

✓ **The HTM program uses evidence-based maintenance strategies.**

Maintenance strategies, which include the specific, unique benefits and challenges of the organization, are determined by conducting device failure analysis and analyzing internal data to adjust maintenance procedures and frequencies.

Examples of advanced HTM practice:

- Document the success of certain evidence-based maintenance strategies (e.g., sampling, run-to-failure) using CMMS failure data.
- Analyze periodically failure rates of equipment and assessment of maintenance procedures and frequencies.
- Analyze periodically specific equipment failures are performed to determine if changes in maintenance strategies could affect future reliability.
- Contribute to efforts to standardize service data documentation to allow it to be aggregated across different healthcare organizations.

Reference: HTM Community Database Project (www.htmcommunitydb.org).
Reference: "Optimizing our PM Programs," *Biomedical Instrumentation* & *Technology* (May/June 2009).
Reference: "Medical Equipment Management Strategies," *Biomedical Instrumentation* & *Technology* (May/June 2006).
Reference: "Evidence-Based Maintenance: Part IV-Comparison of Scheduled Inspection Procedures," *Journal of Clinical Engineering* (July/August 2013).

✓ **The HTM program integrates RM (risk management) and QA (quality assurance) into HTM.**

Formal risk analyses (e.g., FMEA) and formal quality improvement tools (e.g., Six Sigma, LEAN) are used by the HTM program to improve equipment management.

Examples of advanced HTM practice:

- FMEA study of nuisance alarms.
- Quality assurance projects (e.g., improving data management and service data integrity).

Reference: "Equipment Selection Criteria," *Journal of Clinical Engineering* (April/June 2010).
Reference: "How to Manage Your HTM Data," *Biomedical Instrumentation* & *Technology* (March/April 2014).

Personnel Management and Staff Development

✓ **The HTM program reports directly to the vice president or C-suite level.**

To have broad organization-wide perspective and visibility, the HTM program needs to report to senior leadership.

Example of an advanced HTM practice:

- Routine access to senior leadership provides opportunity to maximize contribution to organization objectives such as strategic technology planning.

Reference: "How to Become a High-Performing HTM Department," *Biomedical Instrumentation* & *Technology* (November/December 2013).

✓ **The HTM program has a qualified clinical engineer on staff.**

Every healthcare organization needs the services and skill sets of a clinical engineer, and this person needs to have the organization as his or her primary focus. For this clinical engineer to be knowledgeable of and fit well into the organization, he or she needs to be a staff member.

Examples of advanced HTM practice:

- A clinical engineer on staff has the organization's best interests as their primary focus by being more knowledgeable of the technical and cultural aspects of the organization.
- A clinical engineer on staff can have a wide scope of involvement assessing technology problems and projects in a proactive manner with a broad organization-wide view rather than a contracted project or maintenance-restricted focus.

Reference: "Enhancing Patient Safety: The Role of Clinical Engineering," ACCE, 2001 (accenet.org/downloads/ACCEPatientSafetyWhitePaper.pdf).
Reference: *Core Competencies for the Biomedical Equipment Technician,* AAMI, 2013.
Reference: "What is A Clinical Engineer?," ACCE (www.accenet.org/downloads/reference/Whats_a_Clinical_Engineer.pdf).

✓ **At least 30% of HTM program technical staff holds a professional certification.**

Important professional certifications include CCE, CBET, CRES, and CLES. Also relevant

are IT-related and other certifications that recognize skills applicable to HTM. Examples of advanced HTM practice:

- The HTM program provides support to staff who are pursuing certification.
- Certification is promoted by subsidizing certification exam costs, preparation course costs, pay increases for those who achieve certification, and prominent recognition of certified individuals.

Reference: "Certification Preparation 101: How to Get Ready for Your Exam," *Biomedical Instrumentation* & *Technology* (July/August 2010).

Reference: Clinical Engineering Certification (www.thehtf.org/certification).

Reference: BMET Certification (www.aami. org/certification)

Reference: CABMET Study Group (www. cabmet.org/study-group).

Strategic Technology Planning

✓ **The HTM program has a leadership role in important clinical technology decisions.**

With regard to healthcare technology decisions, the Level 3 HTM program should move beyond participation in the process and adopt a leadership role.

An example of an advanced HTM practice:

- Serving as Chair, or Co-chair with an IT professional, of technology acquisition committees.

Reference: "Dividends of an Effective Clinical Technology Management Program," *Journal of Clinical Engineering* (January/March 2014).

✓ **The HTM program actively participates in strategic (long-term) technology planning and assessment.**

While certainly being involved in the process to decide which technology will be purchased for each need, the HTM program participates in the strategic planning process, helping the organization become prepared for the future.

An example of an advanced HTM practice:

- Participates in the organization's technology planning committees, which decide future directions with regard to healthcare technology, and assists in developing the 5- and 10-year strategic plans for technology.

Reference: "Technology Review Committee Plans Ahead on Construction Projects," *Biomedical Instrumentation* & *Technology* (May/June 2007).

✓ **The HTM program provides guidance on healthcare technology integration in all construction and renovation.**

The HTM program supports the construction review process to ensure that infrastructure and utility systems will support the healthcare technologies in each project.

An example of an advanced HTM practice:

- The HTM program reviews all construction and renovation plans for medical equipment installation and use, including utility and IT requirements.

Reference: "Risk and Use of Medical Equipment, Where Does Patient Safety Fit In?" *Journal of Clinical Engineering* (April/June 2008).

✓ **The HTM program collaborates on the selection of all medical device-related technologies.**

HTM plays a key role in all technology selection decision in the organization, including peripherals and disposables.

Examples of advanced HTM practice:

- The HTM program uses technology assessment reports, utilization forecasts (e.g., procedure volumes, case mix), and other analytical data for strategic and tactical decision making.
- The HTM program has the authority to withhold full or partial payment for new equipment until it is accepted and approved.
- The HTM program understands clinical workflow implications in technology planning.
- The HTM program has access to a laboratory for technology evaluation, human factors assessments (including usability testing), and clinical simulation.

Reference: "The Business End of Equipment Purchasing," *Journal of Clinical Engineering* (October/December 2012).

✓ **The HTM Program takes leadership and active participant roles in CE-IT convergence issues.**

HTM leaders and staff are actively

participating in projects and support for networked medical devices and their interoperability with various IT systems (e.g., PACS, EMR).

Examples of advanced HTM practice:

- Leadership in medical device interoperability for the organization.
- Leadership in frequency spectrum management.
- Involvement in planning and support for healthcare services in homes and other external venues.
- Involvement in planning and support for telemedicine services.
  - Formalized role in IT-related activities, including:
  - IEC 80001 or similar network risk processes implemented.
  - MDS2 or similar document for IT-related acquisitions.
  - HTM management and/or staff on IT Change Management Board.
  - HTM part of IT organization or regular meetings/formal relationship with IT Management/CIO.
  - HTM participates in IT Security audits/reviews.

Reference: ANSI/AAMI/IEC 80001. "Application of Risk Management for IT Networks Incorporating Medical Devices" (www.aami.org/publications/standards/80001.html).

Reference: MDS2 form (www.himss.org/files/HIMSSorg/Content/files/MDS2FormInstructions.pdf).

Reference: "FDA Safety Communication: Cybersecurity for Medical Devices and Hospital Networks" (www.fda.gov/medicaldevices/safety/alertsandnotices/ucm356423.htm).

Reference: "Networked Medical Devices: Security and Privacy Threats," Symantec (www.symantec.com/en/au/content/en/us/enterprise/white_papers/b-networked_medical_devices_WP_21177186.en-us.pdf).

Reference: "Neglecting Change Management for Networked Devices and Systems" (Top 10 Technology Hazards for 2014), *Health Devices,* November 2013 (members2.ecri.org/Components/HDJournal/Pages/Top10TechnologyHazards_SurgicalFires.aspx).

Performance Monitoring and Performance Improvement

✓ **The HTM program benchmarks externally, identifies best practices, and implements performance improvement.**

Benchmarking externally provides comparison data from comparable Level 2 and Level 3 organizations that can be used for performance improvement planning.

An example of an advanced HTM practice:

- Participates actively in external benchmarking by providing comprehensive data to a national database.

Reference: "Benchmarking That Matters: A Proposed New Direction for Clinical Engineering," *Biomedical Instrumentation* & *Technology* (March/April 2011).

Reference: "Designing and Developing a CE Department," *Biomedical Instrumentation* & *Technology* (November/December 2011).

Reference: "How to Use Financial Benchmarks," *Biomedical Instrumentation* & *Technology* (September/October 2011).

Reference: "Staffing Metrics: A Case Study," *Biomedical Instrumentation* & *Technology* (July/August 2011).

Patient and Staff Safety

✓ **The HTM program participates in RCA, FMEA, and other Risk Management activities within the organization.**

HTM works closely with the Risk Management program and across the organization to evaluate the risks associated with all aspects of the technology life cycle.

Examples of advanced HTM practice:

- Maintains a proactive, collaborative relationship with Risk Management.
- Collaborates with others in the organization to have The Joint Commission–mandated proactive FMEA be a technology-related exercise (e.g., clinical alarms management).
- Works with Risk Management to implement organizational changes based on RCA findings.

Reference: "A Systems Approach to Patient Safety at the VA," *Biomedical Instrumentation* & *Technology* (January/February 2014).

✓ **The HTM program takes a leadership role in acquiring and distributing up-to-date knowledge on technology-related issues relevant to the organization's patient safety process.**

The HTM program obtains available sources of technology-related information and related literature, reviews them for applicability, and distributes to key individuals across the organization to improve organizational awareness and preparedness for upcoming decision making.

Examples of advanced HTM practice:
- Leadership in management of clinical alarms for the organization.
- Leadership in the organization's response to technology-related Joint Commission NPSGs (National Patient Safety Goals).

Reference: "An Estimate of Patient Incidents Caused by Medical Equipment Maintenance Omissions," *Biomedical Instrumentation* & *Technology* (January/February 2013).

Reference: "Patient Safety Trilogy: Perspectives from Clinical Engineering," *Biomedical Instrumentation* & *Technology* (March/April 2013).

Internal and External Relationships

✓ **The HTM program has a website for intra-organizational communications and reference.**

Modern organizations use Internet and intranet tools such as websites to communicate.

An examples of an advanced HTM practice:
- The internal HTM program website communicates technology-related information to HTM program "customers" and highlights "hot topics" and other timely information.

Reference: Duke University Health System's Department of Clinical Engineering website (clinicalengineering.duhs.duke.edu).

✓ **The HTM program is an active contributor to key technical and management groups in the organization.**

Capital Acquisition, Facility Design and Construction, Patient Safety, Strategic Planning, Nursing Education, Laser Safety, Radiation Safety, Product Evaluation, Quality Assurance, and Performance Improvement.

Examples of advanced HTM practice:
- Leadership in the management of technology-related training for clinicians.
- Participation in technology-related credentialing for clinicians.
- HTM-related public service (e.g., professional association active membership).
- HTM-related teaching. Includes serving as CE/BMET instructor, mentor, and/or internship sponsor.
- HTM-related writing (e.g., journal articles, books chapters).

Reference: "A Guaranteed Way to Succeed in Your Career," *Biomedical Instrumentation* & *Technology* (July/August 2013).

Reference: "Changing Faces," *Biomedical Instrumentation* & *Technology* (September/October 2013).

✓ **HTM program personnel provide leadership in national and regional professional associations.**

Moving beyond supporting and participating in regional and national professional organizations, HTM program leaders can take leadership roles.

Examples of advanced HTM practice:
- Leadership roles in AAMI, ACCE, META, and FDA committees and other activities.
- Leadership roles in related organizations (e.g., HIMSS, ASHE, ACHE, HFES).

Reference: "Association Roundtable," *Biomedical Instrumentation* & *Technology* (May/June 2013).