



THE MEDPRO GROUP DIFFERENCE

— GUIDELINE —

Medical Equipment Management



This document should not be construed as medical or legal advice. Because the facts applicable to your situation may vary, or the laws applicable in your jurisdiction may differ, please contact your attorney or other professional advisors if you have any questions related to your legal or medical obligations or rights, state or federal laws, contract interpretation, or other legal questions.

MedPro Group is the marketing name used to refer to the insurance operations of The Medical Protective Company, Princeton Insurance Company, PLICO, Inc. and MedPro RRG Risk Retention Group. All insurance products are underwritten and administered by these and other Berkshire Hathaway affiliates, including National Fire & Marine Insurance Company. Product availability is based upon business and regulatory approval and may differ among companies.

© 2019 MedPro Group Inc. All rights reserved.

Contents

Introduction	1
Objectives	1
Equipment Selection and Purchase/Acquisition	1
Equipment Management	3
Inventory Management and Documentation.....	4
Evaluation of Equipment	5
Testing.....	5
Maintenance and Usage	6
Education and Training	7
Incident Response Procedure	7
Equipment Recalls	8
Documentation	9
Onsite Laboratory, Anesthesia, Sterilization, Dialysis or Radiology Services.....	10
Patient-Supplied Medical Equipment.....	11
Conclusion.....	12
Resources.....	13
Endnotes	13
Appendix A. Sample Equipment Inventory/Tracking Log	14
Appendix B. Sample Log of Preventive Maintenance and Repairs..	15

Introduction

Medical equipment plays a vital role in healthcare; however, when equipment is not properly used or maintained, it also can cause harm. In many instances, patient injuries occur because of assumptions about who may use, calibrate, modify, or repair equipment.

Injuries from medical equipment also might arise from training gaps that don't address pre-use testing, preventive maintenance, malfunction reports (and incident reports), and repair procedures.

A commitment to safety is an essential element of any process related to the use of medical equipment – whether the medical equipment is purchased, rented, borrowed, or leased.

Objectives

The objectives of this guideline are to:

- Review due diligence considerations for selecting and acquiring medical devices and equipment
- Define key aspects of an equipment management program and offer risk strategies to consider when developing such a program
- Discuss the necessary components of a well-defined incident response procedure
- Offer guidance related to responding to equipment recalls and documenting essential information about medical devices and equipment
- Provide general recommendations for managing risks associated with the operation of onsite laboratory and radiology equipment
- Review proactive strategies for addressing patient-supplied medical equipment.

Equipment Selection and Acquisition

The selection of medical equipment should not be based on hasty or insufficient decision-making. Each healthcare organization (e.g., practices, hospitals, clinics, and large health systems) should formally establish a team that is responsible for researching and recommending medical equipment.

Once recommendations are made, prospective equipment should be thoroughly reviewed in a collaborative effort by end users – especially if it will be used in the direct diagnosis, treatment, or care of patients. Due diligence when selecting medical equipment might include:

- A literature review
- Consultation with experts
- Consideration of whether to contract the services of a biomedical engineering company
- Requests for data and research results from clinical trials
- Discussions with other healthcare providers who use the same equipment (follow-up of references)
- A review of the history and fiscal standing of potential vendors

The medical equipment selection process also should include a formal assessment of the anticipated risks and benefits associated with the equipment. For example, consider the following questions:

- Is the use of the equipment consistent with your healthcare organization’s mission and ethical policies and procedures?
- Does the equipment or new technology reduce the risk of injury to patients or staff members who may be required to use it (e.g., exposure to lower levels of radiation, latex, or mercury)?
- Do health benefits and/or time-savings for patients, healthcare providers, and staff outweigh the cost associated with the equipment?
- Will the equipment require any costly software upgrades? Can the manufacturer supply a schedule of upgrades?
- Will charges to the patient that are associated with this equipment remain consistent with similar community pricing?

- Are the procedures for which the equipment is used billable? Does your electronic health record (EHR) system or billing system need to be modified to bill for these services?
- What is the community standard? Are market pressures influencing the decision to purchase new equipment (e.g., “our competition offers it” or “we don’t want to be left behind”)?
- Do staff and providers need to be aware of any regulatory requirements related to the equipment (e.g., only licensed independent practitioners can operate the equipment, environmental safety requirements, etc.)?
- Are you able to integrate direct patient care equipment (e.g., blood pressure monitors and laboratory equipment) with your EHR (if appropriate)? If not, what additional resources would be required to do so?
- Does the new equipment require additional supplies or materials to use or maintain it? If so, what are the availability and costs of these items?
- Is vendor support or other technical support for maintenance available?
- Have you considered the purchase/lease requirements and options (e.g., warranties, volume purchasing, trade-in programs, upgrades, indemnification for injuries/failures, contract terms, new versus used/refurbished equipment, etc.)?
- What are the training and ongoing competency considerations?

The answers to these questions and the rationale for purchasing the equipment should be documented and saved for future reference.

Equipment Management

A patient injury caused by a medical device or piece of medical equipment may trigger a claim against a practitioner, healthcare organization, and/or an equipment manufacturer. To reduce patient safety and liability risks associated with medical devices and equipment, healthcare organizations should have effective programs for managing equipment used in patient care.

Considerations when developing an equipment management program include inventory management and documentation; evaluation of equipment; testing; maintenance and usage; and education and training.

Inventory Management and Documentation

A first step in designing an effective equipment management program is documenting what equipment you have. Each healthcare organization should:

- Maintain an inventory of all medical equipment, whether it is leased or owned and whether it is maintained according to manufacturer recommendations or an alternative equipment maintenance (AEM) program.¹
- Include as part of the inventory a record of maintenance activities. (See Appendix A and Appendix B for sample tracking and maintenance/repair logs.)
- Ensure that equipment managed through an AEM program is clearly identifiable as subject to AEM. Further, critical equipment, whether subject to AEM or not, must be readily identified as such.
- Document the following information for all equipment included in the inventory:
 - Unique identification number
 - Equipment manufacturer
 - Model number and serial number
 - Description of the equipment
 - Location of the equipment (for equipment generally kept in a fixed location)
 - Identity of the department considered to “own” the equipment

Risk Tip

If an organization opts to use a biomedical engineering contractor’s equipment management plan, designated personnel at the facility should review and adopt that plan. Language in the plan should specifically refer to the organization; it should not be a boilerplate plan that fails to integrate services and responsibilities between the organization and the contractor.

Evaluation of Equipment

In addition to having a written inventory of medical equipment, healthcare providers and staff should understand the purpose of each piece of equipment. As part of the equipment management program, each organization should:

- Evaluate each piece of equipment to determine:
 - Function and clinical application
 - Preventive maintenance requirements and expected lifespan
 - Likelihood of equipment failure; check [U.S. Food and Drug Administration \(FDA\) reports](#), consumer reviews, and literature reviews.
 - Compatibility with other equipment used at the facility
 - Space allocation for equipment and supplies
- Once the equipment has been evaluated, assign each item a tier level (1, 2, or 3) based on how critical its function is to the practice or patient.
 - Tier 1 is for the most critical equipment, such as life support and emergency devices (e.g., an automatic external defibrillator).
 - Tier 2 is for common use equipment, such as blood pressure monitors and heat therapy units.
 - Tier 3 is for equipment that has little to no risk, such as a patient scale.

Testing

Testing medical equipment is an essential element of an equipment management program and vital for patient and staff safety. Each organization should:

- Test equipment based on manufacturer recommendations or the tier level assigned (whichever is most frequent):
 - Equipment in Tier 1 should be tested on at least a semi-annual basis.
 - Equipment in Tier 2 should be tested on at least an annual basis.
 - Equipment in Tier 3 may only need to be visually inspected on an annual basis.

- Ensure that qualified personnel inspect, test, and maintain all medical equipment (diagnostic, therapeutic, life support, and monitoring).
- Consider contracting the services of an approved biomedical engineering company to assist with equipment testing and maintenance.

Maintenance and Usage

Each organization's equipment management program should include guidance related to maintaining and using medical equipment. For example:

- Maintain and use all equipment according to manufacturers' recommendations or a specified AEM program. Document all inspections, testing, preventive maintenance, and repairs – and include telephone numbers for the equipment vendors.
- Ensure maintenance processes include specific accountability and schedules for preventive maintenance and testing.
- As part of maintenance guidance, include specific information about (a) disinfecting all reusable equipment according to [FDA guidelines](#) and [CDC guidelines](#), and (b) documenting equipment disinfection processes.
- Develop a plan for monitoring and updating software on medical devices. Work closely with the organization's information technology team to research updates and implement appropriate strategies.
- Develop a competency process for using equipment. Make sure the process takes into account job descriptions and training (external and in-service).
- Determine the healthcare organization's point of contact for reporting any equipment malfunctions or incidents that could cause patient injuries.
- Ensure staff members who are responsible for addressing reports of equipment malfunctions or incidents know their responsibilities and timeframes for taking action.
- Never use a piece of medical equipment that shows signs of damage or has been partially repaired or otherwise altered from its original condition by nonqualified staff members.

Education and Training

Healthcare providers and staff cannot be expected to properly use and maintain medical equipment unless they receive appropriate education and training. Each organization should:

- Provide all staff members (including temporary staff) with initial training and ongoing annual training on medical equipment procedures. Training should address:
 - How to report a piece of medical equipment that is not functioning properly, which can include visual clues like smoking, sparking, or display errors.
 - How to remove the piece of medical equipment from service, tag-out the device, and notify the appropriate repair service or biomedical engineering contractor for repairs.
- Train appropriate staff on how to properly set up, use, calibrate, and clean equipment. If a staff person has not been trained, or is not appropriately licensed/certified, he or she should not be allowed to use the equipment.
- Educate staff about back-up plans for when a piece of equipment needs to be serviced or repaired.
- Provide timely training and education for any new or updated equipment prior to putting the equipment into use.
- Document all equipment training and competency for both providers and staff in each individual's personnel file.

Incident Response Procedure

In the event that a piece of equipment or medical device causes patient injury or harm, each healthcare organization should have a well-defined incident response procedure. As part of this procedure, appropriate staff members should:

- Stabilize the patient.
- Remove from service and secure any equipment involved in the incident.
- Complete an incident report per organizational policy.

- Report the incident as required by the Safe Medical Devices Act (SMDA).
 - A designated staff member should complete the required form and forward it (or an electronic equivalent) to the appropriate party as required by law.
 - If an incident results in death, it should be [reported to the FDA](#) and the equipment/device manufacturer.
 - Serious injuries/illnesses should be reported directly to the manufacturer. If the manufacturer is not known, the user organization should report directly to the FDA.
- Notify the organization's professional liability claims specialist immediately (he/she will advise you if/when you should release the equipment).

Risk Tip

Equipment that has caused an injury should never be returned to the manufacturer. Additionally, a manufacturer's representative should not be allowed to examine or attempt to repair the equipment. The equipment should be sequestered, rendered inoperable (locked, etc.), and examined by a company that specializes in independent testing of equipment.

Equipment Recalls

If a healthcare organization or a biomedical engineering contractor receives a recall or hazard notice from a manufacturer or distributor, the organization is responsible for taking appropriate action, as outlined in the notification.

If the notification does not clearly state what steps to take, a designated staff member should contact the entity that issued the recall/hazard notification for guidance. Until the process is clarified, cease use of the equipment.

Risk Tip

To ensure accountability, healthcare organizations should consider assigning one person within the organization the responsibility of receiving and managing equipment recalls and alerts.

If the organization fails to take appropriate action in the face of such notice and the defective device injures a patient, the organization might be found negligent. Additionally,

the organization might bear legal responsibility for improper revisions or modifications made to medical devices as a result of a recall notice.

Manufacturers may specify how they will conduct a recall of equipment. Some contracts, especially those addressing the purchase of equipment with high potential for patient or user injury, may specify how and within what timeframe a manufacturer will notify users of possible risks that have precipitated a recall.

Documentation

Documentation related to medical equipment use and management should include written policies and procedures for:

- Procurement of equipment (purchase, acquire, lease, borrow)
- Disposal of equipment (sale, recycle, destroy)
- Pre-use testing, calibration, and use
- Development and implementation of training programs, as well as periodic training updates
- Responses to, and reporting of, equipment-related incidents

Additional documentation might be required and should be considered with the purchase of new equipment. For example, contracts related to the lease of equipment or maintenance agreements should be kept in a central location. The appropriate individuals should assume responsibility for reviewing and asking questions about the agreements before they are signed (including legal counsel as needed). Vendors may not be accountable for “assumptions” that weren’t included in a contract.

Preventive maintenance and repair records should be available for all procured equipment (leased, borrowed, used, etc.). Further, documentation related to who insures the equipment should be maintained.

If necessary for proper pre-use testing or calibration, information from the manufacturer should be used to develop training and in-service staff updates. These materials should also

be available for reference, and originals of these documents should be filed with contractual arrangements.

Manufacturers' specifications, schematics, testing, and calibration directions – and any other user instructions – should be retained in a master file. Copies should be available, as needed, for equipment users. Manufacturers' warranties (and information about actions that might void warranties) also should be retained.

Codes or stickers placed on equipment for the purposes of identification, inventory management, and preventive maintenance should be consistently color-coded throughout the organization and should comply with state regulations.

All communications regarding damaged or nonfunctional equipment should be maintained, including logs of telephone conversations. When disposing of equipment, all protected health information should be wiped from the equipment memory.

Onsite Laboratory, Anesthesia, Sterilization, Dialysis or Radiology Services

If your healthcare organization performs laboratory, anesthesia, sterilization, dialysis or radiology services, constant vigilance to ensure the safety and accuracy of equipment is necessary.

All radiological testing and services must be in compliance with Nuclear Regulatory Commission (NRC) rules and regulations, as well as state and private licensing and certification requirements. Similarly, all laboratory, anesthesia, sterilization, and dialysis equipment must be maintained based on federal, state, and private licensing and certifications requirements.

Therefore, each organization's personnel should be knowledgeable about the laws and ensure that onsite equipment operates in compliance with all of the applicable rules and regulations.

The following general recommendations are intended to help manage risks associated with the operation of onsite diagnostics:

- Retain licensing documents within your organization's permanent files.
- Train, supervise, and periodically test the proficiency of all personnel performing laboratory or radiology services.
- Maintain an inventory log of all diagnostic equipment and use it to monitor equipment maintenance, recalibration, and servicing (as recommended by the manufacturer).
- Maintain and revise written instructions and procedures, including maintenance and reporting results, on an annual basis.

Patient-Supplied Medical Equipment

Patients might bring their own medical equipment to use during inpatient stays, such as canes, heating pads, insulin pumps, home dialysis machines, continuous positive airway pressure (CPAP) units, and CPAP masks. Their comfort level with the equipment or desire to avoid fees related to using the facility's equipment might motivate these decisions.

However, patient-supplied medical equipment comes with risks. The ECRI Institute notes that "Healthcare organizations have a duty to ensure the safety of equipment and devices used in their institutions. When they allow the use of patient-supplied equipment, they may also assume responsibility for the equipment's performance and safety."²

Healthcare organizations can proactively address patient-supplied medical equipment by developing and following a policy for how to manage these situations. When developing a policy, consider these questions:³

- Has your organization conducted an assessment to determine what types of medical equipment patients are mostly likely to bring with them? Have you considered the risks versus benefits associated with the identified types of equipment and the steps required to evaluate and maintain the equipment?

- Has your organization developed a written policy that clearly states which types of patient-supplied medical equipment are allowed (if any) and which types are prohibited?
- Are healthcare providers, staff members, patients, and families educated about the organization's policy on patient-supplied equipment? Are patients made aware of their responsibility for any equipment that is permitted and they choose to bring?
- Is physician approval required for all patient-supplied medical equipment?
- Is a requirement in place that biomedical or engineering staff inspect all patient-supplied medical equipment to make sure it is in good working condition? Is the equipment tagged following inspection, and is the inspection documented?
- In urgent or time-sensitive cases, do nurses or other frontline staff members inspect the equipment for obvious defects or problems until biomedical or engineering staff can fully evaluate the equipment?
- Do staff members who will be caring for the patient know how to operate the equipment?
- Does your organization plan to use waivers to address liability associated with patient-supplied medical equipment? Has legal counsel reviewed these forms?

Once your healthcare organization has developed a policy for patient-supplied medical equipment, make sure that healthcare providers and staff members are aware of the policy and procedures for handling these types of requests.

Conclusion

Medical equipment provides many valuable services to support and enhance patient care, but its use is never without risk. While appreciating the benefits that medical equipment can provide, healthcare providers and staff also should remain cognizant of potential safety issues. Risk management strategies can help healthcare personnel proactively manage medical equipment. When equipment is properly tested, used, and maintained, it is more likely to work properly, which can help avoid delays in care, reduce the risk of patient and staff injuries, and optimize patient outcomes.

Resources

- Centers for Disease Control and Prevention: Guide to Infection Prevention for Outpatient Settings
- Centers for Disease Control and Prevention: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
- Centers for Medicare & Medicaid Services: Clinical Laboratory Improvement Amendments (CLIA)
- Nuclear Regulatory Commission
- U.S. Food and Drug Administration: Enforcement Reports (information about product recalls and other enforcement actions)
- U.S. Food and Drug Administration: Medical Device Reporting
- U.S. Food and Drug Administration: Recalls, Market Withdrawals, & Safety Alerts
- U.S. Food and Drug Administration: Reprocessing of Reusable Medical Devices

Endnotes

¹ Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality/Survey & Certification Group. (2013, December 20). Hospital equipment maintenance requirements [Memorandum, CMS S&C 14-07]. Retrieved from www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-and-Cert-Letter-14-07.html

² ECRI Institute. (2008, May). Patient-supplied equipment. *Healthcare Risk Control*. Retrieved from www.ecri.org/components/HRC/Pages/MedTech8.aspx

³ Ibid; Relias Media. (2004, November). Liability begins as patients bring their own equipment. Retrieved from www.reliasmedia.com/articles/3332-liability-begins-as-patients-bring-their-own-equipment

Appendix A. Sample Equipment Inventory/Tracking Log

Name/Type of Equipment:		
Model #:	Serial #:	Tier Level: <input type="checkbox"/> Tier 1 – Critical Equipment <input type="checkbox"/> Tier 2 – Moderate Risk Equipment <input type="checkbox"/> Tier 3 – Low Risk Equipment
<input type="checkbox"/> Own		<input type="checkbox"/> Lease
Rationale for Choosing Equipment:		
Location of Equipment Within Office:		
Warranty (Length of Time and What Is Included):		
Names of Staff/Users Trained on Equipment and Date Trained:		
Preventive Maintenance Requirements:		
Person/Vendor Responsible for Preventive Maintenance:		
Address:		Phone Number:

Appendix B. Sample Log of Preventive Maintenance and Repairs

Date	PM/Repair	Description

medpro.com

PATIENT SAFETY & RISK SOLUTIONS