EQUIPMENT MANAGEMENT:
PURCHASE, USE, MAINTENANCE, REPAIR,
AND OTHER RISK CONSIDERATIONS

Medical Protective
Clinical Risk Management Department

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INTRODUCTION

Technology is a boon to healthcare; but when 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 may also 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 equipment — whether the equipment is purchased, rented, or leased.

OBJECTIVES

The objectives of this guideline are to:

- Discuss due diligence considerations for selecting and purchasing/acquiring medical devices and equipment;
- Define key aspects of an equipment management program and offer risk strategies to consider when developing such a program;
- Offer guidance related to equipment use, maintenance, and repair; equipment recalls; and documentation related to medical devices and equipment; and
- Provide general recommendations for managing risks associated with the operation of onsite laboratory and radiology equipment.

EQUIPMENT SELECTION AND PURCHASE/ACQUISITION

When it comes to equipment selection, the office/facility should first determine whether one person or a group of people is formally assigned the responsibility to research and recommend equipment.

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

- A literature review;
- Consultation with experts;
- Requests for data and research results from clinical trials;
- Discussions with other healthcare providers who use the same equipment (follow-up of references); and
- Review of the history and fiscal standing of potential vendors.
The 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:

- Will charges to the patient that are associated with this equipment remain consistent with similar community pricing?
- Do health benefits and/or time savings for patients, healthcare providers, and staff outweigh the cost associated with the equipment?
- Are the procedures for which the equipment is used billable? Does the electronic health record (EHR) system or billing system need to be modified to bill for this service?
- 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)?
- What is the community standard? Are market pressures influencing the decision to purchase new equipment (e.g., “our competition offers it; we don’t want to be left behind”)?
- Are there regulatory requirements that need to be in place?
- Are you able to integrate direct patient care equipment (e.g., blood pressure monitors, laboratory equipment, etc.) with the 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/failure, contract terms, new versus used/refurbished equipment, etc.)?
- Is the use of the equipment consistent with the organization’s mission and ethical policies and procedures?
- 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 from a medical device or piece of equipment may trigger a claim against both the practitioner and the equipment manufacturer. To reduce patient safety and liability risks associated with medical devices and equipment, your office/facility should have an effective program for managing equipment used in patient care.
Equipment Management Strategies

Below are some suggested risk strategies for managing equipment:

- Select equipment based on appropriateness for the office/facility and desired use.
- Inventory all equipment using an equipment tracking log. (See Appendix A for a sample log.)
- When developing an equipment management program, evaluate each piece of equipment to determine:
  - Function;
  - Clinical application;
  - Preventive maintenance requirements and expected lifespan;
  - Likelihood of equipment failure (check U.S. Food and Drug Administration [FDA] reports, consumer reviews, literature reviews, etc.);
  - Compatibility with other equipment used at the practice; and
  - Space allocation for equipment and supplies.
- Assign the equipment a tier level (1, 2, or 3) based on how critical its function is to the practice and/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.
- Test the equipment based upon the tier level assigned:
  - 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.
- Train staff on how to properly use all equipment, as well as any backup plans for when a piece of equipment needs to be serviced or repaired. If a staff person has not been trained, he or she should not be allowed to use the equipment.
- Maintain and use all equipment according to manufacturers’ recommendations. Use equipment logs to document all inspections, testing, preventive maintenance, and repairs, and include telephone numbers for the equipment vendors. (See Appendixes A and B for sample tracking and maintenance/repair logs.)
Disinfect all reusable equipment according to FDA guidelines, and document accordingly.

Determine the office/facility point of contact for reporting any equipment malfunctions or incidents that could cause patient injury.

Remove any defective equipment from the patient care area immediately, and identify it as such, so it is not used until it is repaired.

**Incident Response Procedure**

In the event that a piece of equipment or medical device causes patient injury or harm, the office/facility 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.
  - Deaths 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 facility should report directly to the FDA.
- Notify the practice’s claims specialist immediately (he or she will advise you if/when you should release the equipment).

**Note:** 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 USE, MAINTENANCE, AND REPAIR**

As part of an equipment management program, the office/facility should consider establishing guidance for the use, maintenance, and repair of equipment. When developing this guidance, consider whether:

- A competency process is in place for using equipment. Does the process take into account job description, training (external and in-service), etc.?
  - Is training and ongoing competency completed and documented for all users?
  - Are equipment upgrades/changes communicated to staff? Is reeducation conducted as appropriate?
  - Is equipment use part of training for new employees and temporary staff?
- Specific training processes exist for equipment setup, use, calibration, and cleaning, as well as handling equipment failures.
- Maintenance processes include specific accountability, preventive maintenance, and testing.
- Providers and staff are aware of organizational and SMDA requirements and obligations.

**EQUIPMENT RECALLS**

If a healthcare facility receives a recall or hazard notice from a manufacturer or distributor, the facility 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.

If the facility fails to take appropriate action in the face of such notice and the defective device injures a patient, the facility might be found negligent. Additionally, the facility may bear legal responsibility for improper revisions or modifications made to medical devices as a result of a recall notice.
**DOCUMENTATION**

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

- Pre-use testing, calibration, and use;
- Development and implementation of training programs, as well as periodic training updates; and
- 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. Vendors may not be accountable for “assumptions” that weren’t included in a contract.

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 users of the equipment.

Manufacturers’ warranties (and information about actions that might void warranties) should be retained.

Codes or stickers placed on equipment should be consistently color-coded throughout the practice and should comply with state regulations.

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.

All communications regarding damaged or nonfunctional equipment should be maintained, including logs of telephone conversations.
ONSITE LABORATORY OR RADILOGY SERVICES

If your office/facility performs laboratory 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 equipment must be maintained based on federal, state, and private licensing and certifications requirements.

Therefore, it is important that you are knowledgeable of the laws and ensure that your onsite equipment operates in compliance with all of the applicable rules and regulations.

The following are some general recommendations for managing risks associated with the operation of onsite diagnostics:

- Retain licensing documents within your practice’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/procedures, including maintenance and reporting results, on an annual basis.

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 technology provides, healthcare professionals should never take the risks for granted.

Risk management strategies can help providers and their staffs maximize their use of technology. 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**

- FDA: Medical Device Reporting — [http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm](http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm)
# Appendix A. Sample Equipment Tracking Log

<table>
<thead>
<tr>
<th>Name/Type of Equipment:</th>
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<tbody>
<tr>
<td>Model #:</td>
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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:

Preventative Maintenance Requirements:

Person/Vendor Responsible for Preventative Maintenance:

Address:                       | Phone Number:
## Appendix B. Sample Preventative Maintenance and Repairs

<table>
<thead>
<tr>
<th>Date</th>
<th>PM/Repair</th>
<th>Description</th>
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