

Purpose

The Medical Equipment Management Plan governs the process for the purchasing and maintenance of medical equipment and promotes safe and effective use throughout the hospital. This plan is designed to objectively monitor, evaluate, and improve the services for equipment used in the diagnosis, treatment, and/or care of patients at Spring Grove Hospital Center.

Objectives

- A. Provide a systematic process for acquiring medical equipment.
- B. Ensure that equipment used at Spring Grove Hospital Center is safe, effective, and meets the manufacturer's specifications of performance.
- C. Provide for training of staff in the use of medical equipment.
- D. Provide a process for managing medical equipment failure and recalls.
- E. Meet standards of accreditation as defined by the Joint Commission.

Scope

This plan covers all electrical medical equipment and medical equipment for diagnosis, treatment, and/or care of our patients at Spring Grove Hospital Center, whether owned or leased, as determined.

Responsibilities

Overview: Since there are no medical equipment maintenance or repair services directly available at Spring Grove Hospital Center, all maintenance will be performed under contract and all equipment in need of repair will be sent to qualified repair contractors. Medical equipment will be operated under four departments within the hospital: Nursing, Specimen Collection and Processing and Dental. Accountable Officers have been identified in each of these departments for accountability of all property, to include medical equipment.

User Department Directors: User Department Directors will be responsible for assessing the need for medical equipment within the department and for implementation of this plan at the department level through their Accountable Officers. They will be responsible for assuring that testing, evaluation, preventive maintenance, and documentation of medical equipment used by department staff, as well as reporting and recall procedures are done in accordance with this plan.

Accountable Officer(s): There are Accountable Officers in the Nursing, Dental and the Specimens Collection & Processing Areas. These officers represent the Director of the Department for all medical equipment functions in their department. They report directly to the Director of the Department for all medical related issues. They keep the Department Director informed of all issues related to medical equipment management and are responsible for all records related to medical equipment repair, purchase, and maintenance for their department.

Purchasing Department: Processes all requests for purchase of medical equipment.

Property Department: Includes all medical equipment in its inventory program using a code unique for these items. Inventories and bar codes all equipment brought into the hospital whether purchased, leased, loaned, rented and/or for demonstration. The Property Department ensures that all medical equipment is released to the appropriate department.

Safety Committee: Determines which items meet the definition of medical equipment and reviews all Management Variance Reports of medical equipment misuse or failure. Monitors and evaluates the Medical Equipment Management Program to determine the program's efficiency and effectiveness.

Fire & Safety Department: Forwards all MVRs related to medical equipment misuse or failure to the Safety Committee for review. Notifies appropriate department Accountable Officer of the incident. Reviews all incidents for the possibility that a medical device caused or contributed to the serious injury/illness or adverse experience of patients and reports positive findings to executive hospital administration and FDA per policy.

Hospital Administration: Enforces implementation of this plan and related policies and procedures.

All Hospital Staff: Responsible for being familiar with this plan, and with the safe and proper use of equipment assigned/used in providing patient care.

I.

Selecting and Acquiring Medical Equipment

- A. Medical equipment needs will be determined by each department director in collaboration with the Accountable Officer and the clinical staff involved in the equipment use.
- B. Requests for purchase will be sent to the Purchasing Department, which will solicit

bids through standard state procedures and maintain an inventory of all medical equipment purchased and/or leased.

- C. All medical equipment will be assigned a Spring Grove Hospital Center identification number and a bar code by the Property Department.

II.

Criteria for Evaluating, Identifying and Taking Inventory of Medical Equipment to be Included in this Program Before Equipment is Used

- A. All medical equipment will be included in the Medical Equipment Management Program.
- B. Medical equipment includes all electrical and battery-operated medical equipment used for diagnosis, treatment, and/or care of our patients at Spring Grove Hospital Center, whether owned or leased, as determined by the Safety Committee.
- C. The Safety Committee will determine which items meet the definition of medical equipment and notify the user departments.
- D. This plan does not cover wheelchairs, furniture, non-electric patient beds, and computers. The Safety Committee may recommend that certain other categories of items do not constitute medical equipment.
- E. If equipment is not owned by the hospital (i.e., it is leased, rented, loaned, or demonstrated in patient care area), the using Accountable Officer will assure that it is covered by a Preventive Maintenance (PM) contract.
- F. All medical equipment will be included in the inventory program used by the Property Department to track all equipment.
- B. The Accountable Officer will assure that all medical equipment is added to the service contract for annual preventive maintenance, if indicated (PM). This maintenance will be scheduled by the Accountable Officer.
- C. All medical equipment will have a preventive maintenance frequency of yearly, unless frequent equipment failures, manufacturer's maintenance recommendations or other factors warrant additional maintenance. These determinations will be made by the department Accountable Officer based on records for the previous year.
- D. The preventive maintenance contracts will be designed to ensure optimum performance, safe operation, minimum downtime, and maximum of shelf life of each item of medical equipment.
- E. The scheduled annual maintenance will include servicing, verification of performance and safety, calibration, and detection of worn or failing parts.
- F. Vendors will provide a report of all inspection and PM data to the Accountable Officer. Vendors will also affix stickers with inspection date and equipment status to each piece of equipment.
- G. A master list of the preventive maintenance schedule of all equipment in the department will be maintained by the Accountable Officer.
- H. The Accountable Officer will arrange for the vendor or a qualified hospital employee to provide initial education of the users and will determine the need for additional education.

III.

Assessing and Minimizing Clinical and Physical Risks Associated with Medical Equipment through Inspection, Testing, and Maintenance of Equipment and Education of Users

- A. All new medical equipment included in this plan will be visually inspected for damage and missing parts (including manuals) by the Accountable Officer prior to use. The Accountable Officer will assure that all equipment is checked for proper operation and safety prior to use.

IV.

Medical Equipment Hazard Recall

- A. Any staff member who receives a recall notice, equipment notices, user warning, manufacturer's action notice or any other notice of product or equipment malfunction or potential problem will receipt-date the notice and send it to the Fire & Safety Department immediately.
- B. The Fire & Safety Department will address the issue with the appropriate Department Director through the Accountable Officer, take the necessary actions, document actions taken and forward this information

to the Safety Committee for their review and further action as appropriate.

- C. The Fire & Safety Department will maintain documentation of all notices and subsequent actions taken. (See hospital policy #SGHC 070395 "Product Recall/Warning Notices")
- D. The Accountable Officer will maintain information about all recalls in the department medical equipment records.

V.

Monitoring and Reporting According to the Safe Medical Device Act

- A. Any Spring Grove Hospital Center staff who witnesses, discovers, or becomes aware of information that reasonably suggests that a medical device may have caused or contributed to the death of, serious injury to, or serious illness of a patient and/or employee will be responsible for immediately reporting the incident to the Fire & Safety Department via the established MVR reporting system.
- B. The Fire & Safety Department will address the issue with the appropriate Department Director through the Accountable Officer and review this information for the probability that a medical device caused or contributed to the death, serious injury/illness, or other adverse experience of a patient.
- C. If the findings indicate that a device probably did contribute to an adverse outcome, the Fire & Safety Department will alert executive hospital administration and file the required report with the Food and Drug Administration. (See hospital policy #SGHC 120991-Medical Device Reporting.)

VI.

Medical Equipment Failure and User Errors

- A. When medical equipment malfunctions or does not perform as specified or whenever any device fails to operate to the manufacturer's specifications, whether due to technical or user problems, the user will discontinue its use, remove the equipment immediately from the location of use, and tag the equipment with a "Broken Medical Equipment—Do Not Use" tag. If the equipment is on a patient unit, the equipment is sent to the Clinic in Smith Building as soon as possible.

- B. Any/all broken or damaged parts must remain with the equipment.

- C. For any nursing department equipment, the clinic will:

1.

- a. Receive the broken/malfunctioning medical equipment
- b. Tag the broken/malfunctioning medical equipment with a "Broken Medical Equipment—Do Not Use" tag, if not already done
- c. Isolate the broken/malfunctioning medical equipment to the designated area
- d. Complete an MVR if the broken/malfunctioning medical actually or was suspected to be related to a patient and/or employee injury
- e. Forwarded the MVR to the hospital Fire & Safety Department
- f. Replace the broken/malfunctioning medical equipment with operable equipment if available
- g. Send a completed Request for Purchase to repair the broken/malfunctioning medical equipment to the Purchasing Department, noting the vendor of preference/history.
- h. After the broken/malfunctioning medical equipment is repaired, re-test the equipment to demonstrate the repair was sufficient before it is reissued.

- 2. For any broken/malfunctioning medical equipment from the Dental, or the Specimens Collection & Processing Department, these department staff will:

- a. Tag the broken/malfunctioning medical equipment with a "Broken Medical Equipment—Do Not Use" tag
 - b. Isolate the broken/malfunctioning medical equipment to the designated area
 - c. Complete an MVR if the broken/malfunctioning medical actually or was suspected to be related to a patient and/or employee injury
 - d. Forwarded the MVR to the hospital Fire & Safety Department.
 - e. Replace the broken/malfunctioning medical equipment with operable equipment if available.
 - f. Send a completed Request for Purchase form to repair the broken/malfunctioning medical equipment to the Purchasing Department, noting the vendor of preference.
 - g. After the broken/malfunctioning medical equipment is repaired, re-test the equipment to demonstrate the repair was sufficient before it is reused.
- D. The hospital Fire & Safety Department will notify the department Accountable Officer immediately upon receipt of any broken/malfunctioning medical equipment MVR and forward the MVR through the normal routing system and to the Safety Committee for review.
 - E. The Purchasing Department will arrange for the repair through the appropriate vendor, using approved state practices.
 - F. The Accountable Officer will replace the malfunctioning equipment with operable equipment if available.
 - G. All MVRs related to medical equipment failure and user errors will be reviewed by the Safety Committee.
 - H. The Accountable Officer will maintain information about all medical equipment repairs in the department medical equipment records.

VII. Education

- A. When a new type of equipment is received within the department, the Accountable Officer will arrange for initial training by the vendor or by a qualified hospital employee.
- B. Education will include:
 1. Capabilities, limitations, and special applications of equipment.
 2. Basic operating and safety procedures for equipment use.
 3. Emergency procedures in the event of equipment failure.
 4. Information and skills necessary to perform assigned maintenance responsibilities.
 5. Processes for reporting medical equipment management problems, failures, and user errors.
- C. After the initial training, the Accountable Officer will determine the need for additional training based on the following factors:
 1. Equipment which has changed significantly during past year.
 2. Equipment which has malfunctioned during the past year due to mechanical problems.
 3. Equipment which has malfunctioned due to operator errors.
- D. Each department will be responsible for determining which, if any, equipment will require regular training to maintain competency of clinical staff.
- E. Annual competency evaluation will be required for equipment involved in "waived testing". Documentation must be maintained on this training.
- F. Documentation of training:
 1. Documentation of training, along with the in-service sign in sheets, will be maintained by the Accountable Officer for each department.
 2. Copies of the certificates of training will be maintained by the individual and in the unit or department personnel files
 3. All training must be reflected on the Education Record which will be maintained in the hospital personnel

files as part of the employee's end of cycle PEP.

VIII.

Ongoing Monitoring of Performance Measures

Quality controls for managing broken medical equipment and contracts will be reviewed as an indicator of performance. The information from the indicator of performance will be tracked, trended, and reported to the Hospital Quality Assurance Performance Improvement Department and the Safety Committee by the Accountable Officer of the clinic.

Contract service reports — Accountable Officers will annually review and assure that all annual servicing has been done according to the contract.

IX.

Department under the Medical Equipment Plan

- A. **Nursing Department:** The Department of Nursing has medical equipment which is used in the direct care of patients.
 1. When normal equipment services are not available to report and respond to medical equipment disruption and/or failures (weekends, holidays, evenings, and night shifts), the immediate needs of the patient will take precedence.
 2. The function of the device will be determined, and appropriate substitutions made, or the patient moved if appropriate.
 3. The Nursing Administration Office supervisor will be notified to assist in locating substitutions.
 4. After the needs and safety of the patient have been met, action to resolve the problem will be taken by the Charge Nurse and/or designee.
 5. If substitute equipment is not available on the unit, the user will contact the Nursing Administration Office to obtain back up equipment, if available
- B. **Dental Department:** The Department of Dentistry also has medical equipment which is used in the direct care of patients.
 1. If dental equipment is not available for care of patients and the procedure is an emergency, then the patient will be sent to another dental facility for care.
 2. If the procedure is not an emergency, then the appointment will be

rescheduled after the equipment is repaired or replaced.

D. Specimen Processing & Collection (Lab):

1. This department only has medical equipment which is used indirectly for patient care (i.e., Centrifuge Machine).
2. In the event of an emergency or equipment failure of the main centrifuge, a spare centrifuge machine is readily available in the area while the main one is repaired. The centrifuge machines are connected to the emergency power source should a power failure occur.

X.

Reporting and Investigation

The Safety Committee will review each Management Variance Report related to user errors, equipment failures, and possible injury related to equipment use as it occurs. Each year, the committee will compile this information, examine it for trends and patterns and make recommendations for future actions. This information and recommendations will be included in the Fire & Safety Department annual report.

XI.

Annual Evaluation

- A. The Safety Committee will evaluate:
 1. The performance and effectiveness of each aspect of the plan,
 2. Whether the objectives of the program have been met, and
 3. The scope of the plan and submit this evaluation in the form of an Annual Report to Hospital Administration.
- B. The Safety Committee will evaluate policies and procedures related to this plan at least every three years and submit recommendations for revisions to the Chief Executive Officer.

XII.

Responsibility for Enforcement

This Plan and related policies and procedures will be enforced by Hospital Administration.

References

Hospital Policy #SGHC 070395 "Product Recall/Warning Notices"

Hospital Policy #SGHC 120991 "Medical Device Reporting"

Hospital Policy #SGHC 031891 "Management Variance Report (MVR) Process"

Approved by

<u>Signature on File</u>	<u>2/26/2026</u>
Monica Chawla, M.D., FAPA, Chief Medical Officer	Date

<u>Signature on File</u>	<u>2/26/2026</u>
Marie Rose Alam, M.D., FAPA, Chief Executive Officer	Date

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