POLICY AND PROCEDURE MANUAL

Clinical Engineering Policy CE-004

Initial Testing and Evaluation

PURPOSE:

To assure that all clinical equipment is inspected prior to its initial use and identified for inclusion/exclusion in the equipment management program.

POLICY:

All Clinical (*Diagnostic and/or Therapeutic)* Equipment coming into the Health System that is included in the Medical Equipment Management program is tested before initial use and appropriately inventoried. These tests, evaluations, and inventories are documented.

All clinical equipment, regardless of ownership, falling under the responsibility of Clinical Engineering is covered by this policy. The following categories of equipment provide examples of equipment covered under this policy:

- Rental/Leased Equipment
- Physician-Owned Equipment
- Donated/Loaned Equipment
- Health System-Owned Equipment
- Non-hospital-Owned Equipment

Equipment purchased, leased, on-loan, here for trial evaluation, or equipment donated, must pass the incoming inspection before it will be allowed into the Health System.

PROCEDURES (Health System Owned Equipment)

A. When notified that new clinical equipment is received in the Health System, Clinical Engineering will initiate a work order.
B. The Clinical Engineering Department will ensure that the new equipment is inspected for:
    1. Presence of all accessories required for proper operation.
    2. Presence of Operators Manuals and Technical Service Manuals, and Schematics.
    3. Proper operation of the equipment as specified in the performance specifications in the manufacturer's service literature.
    4. Clinical alarm functionality and audibility.
    5. Passage of electrical safety requirements as specified by NFPA, and other applicable agencies.
    6. Inclusion into, or exclusion from, the Equipment Management Program.
    7. Compliance on labeling of equipment, to ensure that the equipment has been "evaluated for safety and suitability for intended use" by a nationally recognized testing laboratory as required, Acceptable Listings as to the Safety of Goods. (e.g. UL, CSA, etc.)
C. If equipment passes all required inspections the Technician will affix a Clinical Equipment Maintenance inspection sticker in a visible location on the device.

The Clinical Engineering technical staff (biomed) who performs the inspection is responsible for ensuring the completion of the initial inspection documentation. If the biomed determines that an in-service education would be beneficial, the technician will make a recommendation to the Health System Education Department or the department Manager. Should a manufacturer in-service be required, the biomed will assist in coordinating this effort with Health System Education.

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D. Testing of devices brought in for demonstration or trial evaluation:
Health System is responsible for the safety of all patients, staff, and visitors: When notified that clinical equipment is coming into the Health System for loan, evaluation, or demonstration, Clinical Engineering will evaluate the equipment to ensure that it is safe.

1. All electrical equipment which passes the Clinical Engineering safety inspection will have a Clinical Equipment Maintenance sticker affixed in a visible location, indicating that it has been inspected, and is safe for use in the Health System. (Certain battery-operated devices may be excluded from the PM program, and will not have a sticker affixed. Device included in the program, but that do not require regular preventive maintenance will also receive a "PM Exempt" sticker)
2. Any equipment that fails the Clinical Engineering safety inspection will be returned to its originating source with a description of the failure. This unit will be prohibited from being used in the facility until it has been repaired and satisfactorily passes the Clinical Engineering safety inspection.

E. Equipment on loan or trial to the facility.
Loaned or trialed equipment is tested prior to its use in the Health System, unless an emergency dictates otherwise. In this instance, the user should ensure with reasonable certainty that the equipment is in safe working condition before operating. If the equipment is to remain in the Health System subsequent to its emergency use, it must be safety tested by the Clinical Engineering Department.

F. Equipment intended for use in a clinical laboratory application.
Equipment intended for use in a clinical laboratory application, for the analysis of body fluids, cells or tissues, must be approved by the office of the Executive Director, Clinical Laboratories, Department of Pathology, and safety tested as required by CAP prior to being placed into service.

G. Non-hospital medical equipment.
Follow above Inspection of Patient Care Equipment Procedure or Non-hospital Owned Medical Equipment Policy

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