

Medical Equipment Standards:

POLICY:

All electromechanical patient care equipment will be evaluated prior to use based on function, physical risks associated with clinical use, maintenance requirements and equipment incidents.

All incoming and existing equipment meeting the evaluation criteria are included in the medical equipment management program. An inventory of equipment included in the program and equipment maintenance records documenting all maintenance on equipment is kept in the TMS

PROCEDURE:

- All biomedical equipment is evaluated on function, risk, maintenance requirements and equipment history. Each piece of equipment is assigned an equipment management number.
- Equipment Function shall be divided into four (4) groups:
 - Therapeutic
 - Diagnostic
 - Analytical
 - Miscellaneous
- Physical Risk associated with application is evaluated on the following criteria:
 - Patient death
 - Patient or operator injury
 - Inappropriate therapy or misdiagnosis

- No significant risks
- Maintenance Requirements are evaluated on the following criteria:
 - Extensive:
 - Includes equipment that requires routine alignment, calibration or extensive parts replacement.
 - Above Average:
 - Includes equipment requiring preventive maintenance a minimum of every six (6) months.
 - Average:
 - Includes equipment that needs only performance verification and Electrical Safety Inspection (ESI).
 - Below Average:
 - Includes equipment that receives only a visual inspection, basic performance test and safety testing is minimal.

Minimal

Includes equipment that does not require preventive maintenance.

- Equipment history and incidents involving injuries or deaths will be used to assist in evaluating equipment.
- All equipment not included in the inventory will be inspected every time it requires corrective maintenance.
- The Clinical Engineering Department will maintain an inventory of all equipment included in the medical equipment management program. The inventory will include function value, risk value, maintenance value, equipment management number and preventive maintenance interval.
- All incoming equipment will be compared to an included device list.
- Summary Reports are available upon request to all department managers/directors in which equipment is used.
- Equipment evaluation results shall be reported for review by the Institutional Safety Committee (ISC). Any changes to the medical equipment management program must be approved by the ISC.