

CENTRAL STATE HOSPITAL
POLICY

SUBJECT: **BIOMEDICAL EQUIPMENT MANAGEMENT**

ANNUAL REVIEW MONTH: October

RESPONSIBLE FOR REVIEW: Director of Safety/Environmental Health

LAST REVISION DATE: July 2009

I. General

The quality of client care depends in part on the uninterrupted provision of essential services. Therefore, it is necessary that biomedical equipment, both clinical and non-clinical, be maintained at optimum levels of performance and that the equipment be functionally and environmentally safe. Biomedical equipment management is a vital part of the Environment of Care Safety Program.

II. OBJECTIVE

1. To create and maintain a safe environment for clients, visitors and staff through the establishment of a Biomedical Equipment Management Program that includes inspection, testing and scheduled, preventive and emergency maintenance. The plan sets forth guidelines for each phase through procedural documentation.
2. To establish procedures for selecting and acquiring biomedical equipment.
3. To describe/determine risk based criteria that all biomedical equipment must meet to be included in the program.
4. To prescribe guidelines for the safe operation of biomedical equipment.
5. To establish guidelines for the safe operation of client-owned medical equipment.
6. To establish guidelines for the safe operation of client-owned electrical appliances, i.e. radios, CD players, televisions, electric razors, heating pads.
7. To establish guidelines for the proper use of biomedical equipment in anesthetizing locations.

8. To establish guidelines for the proper use of biomedical equipment in an oxygen enriched atmosphere.

III. CRITERIA FOR INCLUSION

Medical devices that are used for therapeutic, diagnostic, analytical and monitoring functions where the malfunction, failure or improper use of such equipment could adversely affect client outcomes shall be assessed in accordance with the Risk Assessment Criteria listed in paragraph X. These include devices used for life support, surgical and intensive care treatment, surgical and intensive care monitoring, physiological monitoring and diagnosis, laboratory equipment and accessories and other monitoring and diagnostic equipment.

IV. DEFINITIONS

1. Clinical Equipment: This includes therapeutic, diagnostic, and monitoring devices that are directly involved in client care, to include client-owned medical equipment. Some examples are defibrillators, respirators, bedside monitors, personal monitors, fall-alert monitors, and electrosurgical devices and laboratory blood bank equipment. Clinical equipment requires extensive testing to ensure reliability and safe, efficient operations.
2. Non-clinical Equipment: Refers to analytical and other miscellaneous equipment that is not used in direct client care treatment. Some examples are electric beds and some laboratory analytical equipment.
3. Preventive Maintenance: This is the systematic care, servicing and inspection for the purpose of maintaining equipment in a serviceable condition and detecting and correcting defects before they result in equipment failure.

V. RESPONSIBILITY

1. DIRECTOR OF SAFETY/ENVIRONMENTAL HEALTH SHALL:
 - A. Develop and maintain an equipment management program for biomedical equipment, which includes State-owned, leased, and privately owned equipment, with the primary emphasis on inspection and preventive maintenance.
 - B. Develop and maintain a current inventory of all equipment included in the program by item description, location, model and serial number, and

CSH inventory control number.

- C. Develop and maintain equipment check lists and documents for performing scheduled and unscheduled maintenance.
- D. Ensure that all biomedical equipment included in the program is inspected/tested at required intervals in accordance with manufacturer's recommendations and other appropriate guidelines. All equipment shall be inspected at least annually, unless otherwise approved by the CSH Environment of Care Function Team and the Medical Product Evaluation Committee. All inspections, tests, maintenance, repair, adjustment or modification shall be documented, and records of such actions shall be maintained by Biomedical Engineering.
- E. Ensure that all equipment included in the program meets the risk-based criteria as listed under the RISK-BASED ASSESSMENT CRITERIA section of this plan, and as set forth under NEW EQUIPMENT PREPARATION.
- F. Report quarterly to the CSH Environment of Care Team.

2. OPERATORS/USERS:

- A. Prior to utilizing the equipment with a client, Operators/users of biomedical equipment shall be trained in the safe use and operator maintenance of all biomedical equipment they are required to use. Such training shall provide for, but not be limited to, operational check-out procedures, startup and shutdown procedures, minor troubleshooting, equipment capabilities and limitations, operator replacement or repair procedures for failed equipment. All training shall be documented and coordinated with the Staff Development and Training Department prior to operating the equipment with/on a client. Training shall be included in the employee competency file.
- B. Client-owned medical equipment shall meet these same criteria. Competency shall be documented in the client medical chart.
- C. The department/service using the biomedical equipment/device has the responsibility of providing trained operators and providing a safe environment for the operator and the client. This responsibility includes restricting the use of cell phones, two-way radios, and other transmitting

devices within three feet of medical devices.

- D. Operators/users shall report all malfunctions, failures and deficiencies such as frayed cords, and broken or missing knobs immediately to Biomedical Engineering. Defective equipment shall be taken out of service immediately, and the Director of Biomedical Engineering shall be notified.
- E. Training on all new equipment shall be provided at the time equipment is received and prior to placing the equipment in use. Additional training shall be scheduled as dictated by history and experience.
- F. The Biomedical Equipment Technician shall be notified immediately whenever listed equipment is transferred to a location different from that listed in the current inventory. The biomedical Equipment Technician shall be notified whenever a client presents with a personally owned medical device.
- G. The business manager for each division shall maintain a division equipment inventory and report any changes (additions or removal from inventory) to the inventory to the Biomedical Equipment Technician.
- H. Users shall be familiar with and implement all requirements of the JCAHO National Patient Safety Goals and Sentinel Event Alerts related to medical equipment.

VI. NEW EQUIPMENT PREPARATION - INCLUSION IN BIOMEDICAL EQUIPMENT PROGRAM

- 1. Equipment meeting the criteria described under "RISK ASSESSMENT CRITERIA" section of this plan shall be included in the Biomedical Equipment Program.
- 2. All biomedical equipment shall be inspected, tested and maintained in accordance with manufacturer's recommendations and shall be in compliance with the National Electric Code and the applicable National Fire Codes. No modification shall be made to the equipment without the manufacturer's approval.
- 3. 95 percent of scheduled preventive maintenance shall be completed on time.

VII. Engineering or Biomedical Department may be used.

SPECIAL USE AREAS

1. ELECTRONIC INTERFERENCE:

No electronic emitting devices such as two-way radios, cell phones shall be permitted in the vicinity of sensitive medical equipment. Signs shall be posted in all such sensitive areas.

VIII. SAFE MEDICAL DEVICES ACT OF 1990

Biomedical Equipment maintainers and users shall be familiar with the Safe Medical Devices Act of 1990 including current amendments and CSH policy 5.17, Safe Medical Devices and Laboratory Product Reporting, which describes requirements for compliance.

IX. MONITORING AND EVALUATION

The effectiveness of the Biomedical Equipment Management Plan shall be monitored by the CSH Safety Director through the CSH Environment of Café Team. The plan shall be reviewed annually, with revisions to the plan dictated by periodic review of Equipment Service Reports, Incident Reports, Equipment Failure Reports, trend variations, user error reports, and analyses from hazard surveillance reports.

X. RISK ASSESSMENT CRITERIA

Therapeutic, diagnostic, analytical, and miscellaneous equipment used in direct client care or in support of client care shall be evaluated according to the degree of risk, to determine inclusion or non-inclusion in the Biomedical Equipment Management program. Equipment assigned an aggregate degree of risk of 12 or more shall be included in the program. Equipment with an aggregate degree of risk of 11 or below shall not be included in the program. The degree of risk shall also be utilized to determine preventive maintenance intervals.

Criteria for this assessment is as follows:

<u>1. EQUIPMENT FUNCTION</u>	<u>DEGREE OF RISK</u>
Life Support	10
Physical Therapy and Treatment	8
Critical Laboratory (Blood Bank)	8
Physiological monitoring and diagnosis	6

	Analytical Laboratory	5
	Laboratory Accessories	4
	Computer, medical information	3
	Other Client-related	2
2.	<u>CLINICAL APPLICATION:</u>	<u>PHYSICAL RISKS</u>
	Client Death	5
	Client or Operator Injury	4
	Inappropriate Therapy or Misdiagnosis	3
	Other Physical Risks	2
	No Significant Risks	1
3.	<u>MAINTENANCE REQUIREMENTS</u>	<u>Degree of risk</u>
	<u>EXTENSIVE:</u> Highly mechanical, pneumatic or fluidic failure/damage <u>WILL</u> occur to device without periodic maintenance, or equipment history on device indicates a high failure rate, recall activity, or high incident rate.	5
	<u>ABOVE AVERAGE:</u> Some mechanical, pneumatic or fluidic failure/damage is <u>PROBABLE</u> to device without periodic maintenance.	4
	<u>AVERAGE:</u> Equipment may not be equipped with automated self diagnostics and requires periodic operation verification beyond the capability of the operator. Equipment needs safety testing.	3
	<u>BELOW AVERAGE:</u> Item equipped with automated self diagnostics and operation <u>CAN</u> be verified by the operator. Equipment history does not indicate the need for safety testing.	2
	<u>MINIMAL:</u> Visual inspection and basic operation may be performed by the operator. No analytical devices or diagnostics required to verify proper operation. Few or no mechanical components. Equipment history or design does not indicate the need for safety inspection.	1

EXAMPLE OF EQUIPMENT ASSESSMENT

<u>DEVICE</u>	<u>FUNCTION</u>	<u>RISK</u>	<u>MAINTENANCE</u>	<u>A/R#</u>	<u>CLASS</u>	<u>PM INTERVAL</u>
BALLOON PUMP	10	5	5	20	I	6 MOS
CENTRIFUGE	5	3	5	13	I	6 MOS
BED, ELECTRIC	2	3	3	8	N	12 MOS
DEFIBRILLATOR	10	5	4	19	I	6 MOS

*** A/R # IS THE AGGREGATE RISK FACTOR.

Approved:

This policy has been approved by the CEO and CMO on 12/09.