

<b>BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY</b>	CRC POLICY: 6.8	PAGE 1 OF 2
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SUBJECT: Preventive Maintenance Program	REVIEWED BY: W. GUNTHER	
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### 1.0 **PURPOSE**

Preventive Maintenance (PM) is done to maintain essential standards of safety and performance for equipment used in conjunction with an approved clinical research protocol within the Clinical Research Center.

### 2.0 **POLICIES**

2.1 All subject care equipment used in conjunction with an approved clinical protocol shall be in good working condition. To insure that such equipment is in good working condition, it shall be inspected/tested on a semi-annual basis by the CRC Equipment Technician or other qualified individual.

2.2 All electrical equipment that is in direct contact with a subject shall be inspected by the CRC Equipment Technician or other qualified individual no less than semi-annually to insure it is in proper working condition and is safe.

2.3 The semiannual testing of all equipment described in Sections 2.1 and 2.2 shall be documented and maintained by the CRC Equipment Technician.

### 3.0 **PROCEDURES-INSPECTION AND PREVENTATIVE MAINTENANCE**

3.1 Inspection tags, indicating inclusion in the CRC PM program, will be attached to each item noting the following:

- a) date of last inspection
- b) next inspection due date
- c) Type of inspection (e.g., calibration, safety, performance, PM)
- d) Name of technician who conducted the inspection/testing

3.2 The computerized database program shall have, for each item of medical equipment, the following information:

- a) Control number (BNL bar code is primary source)
- b) Device type (classification)
- c) Department (location and room number)
- d) Manufacturer and vendor (if different from mfr.) information
- e) Model number
- f) Serial number
- g) Acquisition date (where possible)
- h) Warranty expiration date (if applicable)
- i) Maintenance and repair data
- j) Device specific checks used in performance assurance testing and preventive maintenance
- h) Name of person performing the inspection/testing

3.3 The CRC Equipment Technician shall maintain a file of service and operating manuals, schematic drawings and service related product literature including the ECRI Health Device Alerts subscription.

3.4 All electrical equipment intended for use in the subject vicinity, where subject contact is likely, shall have chassis leakage currents that comply with NFPA99 (1993 edition) standards for Health Care Facilities. Intentionally applied equipment, such as ECG electrodes, shall meet manufacturer's recommended test criteria. These checks shall be done no less than twice yearly.

3.5 Performance assurance and calibration checks shall be performed twice yearly to ensure that medical instrumentation operates safely, accurately and reliably for patients and CRC personnel.

3.6 The electrical resistance between equipment chassis, or any exposed conductive surface, and the ground pin of the power cord shall measure less than, or equal to, 0.50 ohms.

3.7 Preventative maintenance shall be done annually to minimize the risk of equipment failure and to ensure proper operation. This may include lubricating, cleaning, adjusting, aligning, parts replacement (e.g., motor brushes, power cords, batteries) and electronic or mechanical adjustments required due to wear.

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#### 4.0 **HAZARDS/MITIGATION**

4.1 Risks that may be encountered during Preventive Maintenance procedures are:

- radiation exposure;
- electrical problems; or
- contaminated equipment (blood, body fluids, chemicals, etc).

4.2 To mitigate the hazards listed at Section 4.1, the CRC Technician or other qualified individual performing preventative maintenance and/or semi-annual inspections shall have appropriate BNL training. If there is a question regarding proper training, the CRC staff member's Department Training Coordinator shall be consulted.

4.3 The CRC Technician shall coordinate equipment inspections and PM procedures with the facility Clinical Head, or his delegate, in order to minimize the likelihood that hazards be encountered.

4.4 To further mitigate hazards associated with equipment inspection and preventative maintenance, the CRC Equipment Technician or other individuals performing such inspections or PM procedures shall wear protective eyewear, gloves and labcoat.

4.5 In the event that the CRC Equipment Technician encounters a situation wherein he/she does not feel equipment testing or PM procedures should be performed because the equipment or local area does not appear hazard-free, the CRC Technician shall postpone his/her scheduled procedures and report the situation to the Clinical Head of the facility and to the CRC Manager.

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