

Name: Inspection of Patient Care Equipment Procedure

Effective Date: 7/07

Review / Revision: 11/97; 11/99; 1/00; 11/02; 1/04; 12/04, 1/06, 7/07
History

Definitions:

Patient Care Equipment (Medical Equipment): Equipment intended to be used for diagnostic, therapeutic, or monitoring purposes in a patient care environment regardless of ownership.

Appliances: Devices intended for staff use or personal care and not intended for therapeutic or diagnostic purposes. Appliances are not intended to contact the patient. Included are, but not limited to, hairdryers, coffee pots, curling irons, electric heaters, fans and computer equipment.

Preventive Maintenance Program: Regularly scheduled inspections and testing, including clinical alarms, of patient care equipment determined and performed by Clinical Engineering.

Procedure:

- Duke Owned Equipment
 - Clinical Engineering works with Procurement Services in the scheduling of equipment deliveries.
 - Clinical Engineering will perform an incoming inspection and evaluate the device for inclusion in the Equipment Management Program.
 - Clinical Engineering will ensure that the new equipment is inspected for:
 - Presence of all accessories required for proper operation
 - Presence of Operator's and Technical Service Manuals
 - Proper operation of equipment as specified in the performance specifications in the manufacturer's service literature
 - Clinical alarm functionality and audibility
 - Passage of electrical safety requirements as specified by NFPA, JCAHO, and other applicable agencies
 - Compliance with labeling of equipment to ensure that equipment has been evaluated for safety and suitability for intended use by a nationally recognized testing laboratory
 - Determination of inclusion in the Equipment Management Program
 - Upon satisfactory completion of the inspection, a Clinical Engineering number tag and a Clinical Equipment Maintenance sticker will be affixed in a visible location on the device.
 - User departments are responsible for reporting to Clinical Engineering any equipment delivered directly to their department.
 - Should equipment fail to pass inspection, Clinical Engineering will inform the user department of the failure and provide the necessary documentation.
 - Clinical Engineering will work with Hospital Education Services and the end users to determine the need for in-service education and make appropriate

recommendations for training. It is the user department's responsibility to schedule any required training prior to the device being placed in service.

- Duke Owned Non-Medical Appliances

- These appliances will be inspected at regular intervals if they are used in the patient care vicinity and when in normal use contact patients.

- Patient Owned Medical Equipment

- Use of patient owned medical equipment is discouraged. However, patients are permitted to use their own equipment if a suitable Duke-owned or rented equivalent is not available. (NOTE- Patient owned life support equipment, i.e. ventilators, may not be used. Only Duke-owned or approved rental devices may be used for life support.)
- The patient's caregiver will be responsible for performing an inspection of the device for safety prior to the device being used on the patient. Inspection will consist of a visual inspection of the electrical cord and housing as well as all patient cables to ascertain integrity.
- If the device does not pass this visual inspection, it should not be placed in service and the Clinical Operations Director or designee should be notified.
- Should the caregiver need assistance with the inspection or if the device has three prongs, the caregiver will contact Clinical Engineering during normal business hours 7:30 a.m. – 4:30 p.m. (DHRH 7:00 –3:30)

DUH/ DUAP's/ PDC's/ Clinical Labs - 681-2525

DRH - 470-8184

DHRH - 954-3583

- Patient is responsible for the operation of their equipment. The patient's condition must be considered when determining if equipment can be safely operated.

- Patient Owned Non-Medical Appliances

- Use of personal non-medical appliances by patients is discouraged. However, if such an appliance is brought in to the hospital the patient's caregiver will inspect the appliance for safety.
- Inspection of the appliance will consist of a visual inspection of the electrical cord and housing to ascertain integrity.
- If the appliance does not pass this visual inspection, it should not be placed in service.
- Should the caregiver need assistance with the inspection, Engineering & Operations may be contacted.

DUH - 684-3232

DRH – 470-4159

DHRH – 954-3390

- Patient is responsible for the operation of their appliance. The patient's condition must be considered when determining if appliance can be operated safely.

- Rental Equipment

- Rental equipment obtained from Duke Hospital approved vendors may be taken directly to the patient care area for use. Procurement Services and Respiratory Care Services have a list of the current approved vendors. Clinical Engineering has evaluated these vendors. These approved vendors have shown that they have adequate programs in place to ensure that their equipment has received all necessary safety inspection and maintenance and is safe for use. The list of vendors is evaluated and updated on a regular basis and is approved by the applicable Safety/ EOC Committee.
- Life support equipment rented from an unapproved vendor is allowed only if appropriate maintenance documentation is provided to Clinical Engineering before the equipment is placed into use.
- The vendor will appropriately label the device with the current inspection date.
- The caregiver will perform a visual inspection of the electrical cord, housing, and all accessories prior to use to ascertain integrity prior to the device being used on the patient. If the device does not pass this inspection, the device should not be placed in service and the Clinical Operations Director or designee should be notified.
- If assistance is needed with the inspection, Clinical Engineering may be contacted during normal business hours, 7:30 a.m. - 4:30 p.m. (DHRH 7:00 –3:30)

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DHRH - 954-3583

- The caregiver should be competent in the use of the device. The Rental Company or Hospital Education Services may provide training.

- Equipment on Loan or Trial or Brought in for Demonstration

- Procurement Services must authorize prior to shipment, any equipment to be used on loan or trial. A no charge purchase order must be completed prior to receipt of the equipment. A change order will be issued to purchase the equipment at the end of the loan or trial period and must have all necessary approvals.
- Clinical Engineering should be notified in advance of the receipt of the equipment so that an inspection may be scheduled and performed.

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DRH - 470-8184

DHRH - 954-3583

This will ensure that necessary personnel are available to perform the inspection. (Exception- During an emergency situation the caregiver and physician may make the decision to use the equipment prior to inspection by Clinical Engineering. In this case, the caregiver would be responsible for performing a visual inspection of the device prior to use and then contacting Clinical Engineering to perform an inspection.)

- Life support equipment brought in as a loaner, on trial, or for demonstration must have appropriate maintenance documentation submitted to Clinical Engineering during its inspection.
- Clinical Engineering will inspect the equipment, including clinical alarms and will affix a Clinical Equipment maintenance sticker in a visible location on the device. The device will also be evaluated for inclusion into the Equipment Management Program.
- Equipment failing inspection cannot be used in the facility until the deficiencies identified have been corrected and appropriate safety tests completed. Equipment failing inspection should be reported to the manager or their designee.
- Equipment brought in for a specific procedure and removed from the premises must be re-inspected each time it re-enters the facility.
- It is the responsibility of the using department to coordinate any necessary training for staff on equipment brought in on loan, for trial, or for demonstration.

- Physician Owned Equipment

- Use of physician owned medical equipment is discouraged. However, physicians are permitted to use their own FDA approved equipment if a suitable Duke-owned or rented equivalent is not available. (NOTE- Physician owned life support equipment, i.e. ventilators, may not be used. Only Duke-owned or approved rental devices may be used for life support.)
- Clinical Engineering should be notified in advance of the receipt of the equipment so that an inspection may be scheduled and performed.

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 - It is the responsibility of the using department to coordinate any necessary training for staff on equipment brought in on loan, for trial, or for demonstration.
- Equipment intended for use in a Clinical Laboratory application
 - Equipment for the analysis of body fluids, cells or tissues must be approved by the Office of the Executive Director, Clinical Laboratories, prior to being placed in service.

Cross Reference:

Applicable Standards	CAMH EC 6.10 CAMH EC 6.20 NFPA99 NCGS 66-23, Sale of Electrical Goods Regulated NCGS 66-24, Identification Marks Required NCGS 66-25, Acceptable Listings as to the Safety of Goods (e.g. UL, CSA, etc)
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Developed by:

Policy Primary: Senior Director, Clinical Engineering

Scheduled Review Date: 7/2010