

CODE NO: CE-001
SECTION: SAFETY
SUBJECT: MEDICAL DEVICE INCOMING
INSPECTION PROCEDURE
DATE: July 2010
REVISED: Sept 2011

UMass Memorial Health Care

Clinical Engineering Policy Manual

- I. **PURPOSE:** To provide guidelines for every employee/intern/volunteer within the department.
- II. **SCOPE:** This policy is applicable to all incoming medical devices within the hospital system.
- III. **RESPONSIBILITY:** Compliance with this policy is the responsibility of all departments using clinical device as well as employees within the Clinical Engineering Department. Reference toward the Medical Device Management Plan should be made for all employees outside of the Clinical Engineering Department.
- IV. **TOOLS:**
- Equipment Management Database
 - Work Order
 - Electrical Safety Analyzer
 - Wireless handheld device, laptop,
 - Any other related test device needed to check function of incoming device
- V. **PROCEDURE:**
1. Contact manufacturer's representative if the device requires manufacturer's authorized personnel to perform the inspection.
 2. Unpack the device carefully. Contact the manufacturer if the device is physically defective or damaged during delivery.
 3. Obtain the following information, and complete the incoming inspection work order on the equipment management database:

Device Name	Department
Model Number	Manufacturer
Serial Number	Address and Phone Number
Purchase Order Number	Vendor and Person to Contact
Device Cost	Address and Phone Number
 4. Perform Functional test according to manufacturer's specifications.
 5. Perform electrical safety inspection, and document all measurements. See Electrical Safety Inspection Protocol. (Proc#: CE-003)
 6. If the device does not pass any of the tests in Proc# CE-003, contact Materials Management department to arrange manufacturer's repair or replacement of the unit.
 7.
 - a. If the device is owned, loaned, leased, rented to UMMMC and passes all the above tests, assign a Clinical Device Control Number, and affix the number tag, neatly, onto the front panel of the device.
 - b. If the device is a medical device, owned by a patient, and passes the Electrical Safety Inspection Protocol (CE-003), assign a "Not Hospital Owned Equipment (NHOE)" control number to the device, then ensure that patient signs release form indicating that the device has been appropriately maintained.

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- c. If the device is a medical device, rented/loaned/evaluation unit, and passes the Electrical Safety Inspection Protocol (CE003), assign a "Not Hospital Owned Equipment (NHOE)" control number to the device.
8. With reference to 7a/c, assign PM frequency and PM due date based on device type and it's location, and mark them on the Service Slip/Work Order.
 9. Affix a safety sticker according to the Safety Sticker Procedure. (Proc#: CE-008)
 10. Technician performing the service should enter all related documentation into database.

VI. RECESSSION:

This policy becomes effective upon issuance.

Theresa K. Crofts Date
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