

Johns Hopkins Safety Manual	<i>Policy Number</i>	HSE 009
<i>Subject:</i> Clinical Equipment	<i>Last Review Date</i>	09/01/09
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POLICY

It is the policy of Johns Hopkins to assure that all clinical systems and devices are safe and effective for their intended purpose.

All clinical systems and devices, all accessories to such equipment, and all equipment used to calibrate, repair, or otherwise assure the proper performance and safety of clinical equipment shall be tested for safety and performance prior to initial use and periodically thereafter. Recalibration or repair shall be performed as required.

Clinical Engineering Services shall be notified immediately whenever there is an incident involving a medical device.

The FDA defines a medical device as "... an article that is:

- recognized in the National Formulary, or the United States Pharmacopeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes."

This includes not only durable medical equipment, (e.g., X-ray machines, ventilators), but disposable products including but not limited to catheters, needles, administration sets, breathing circuits, etc.

PROCEDURE

Incident involving patient care equipment:

1. Call 4-SAFE (4-7233).
2. Remove equipment from service.
3. Hold all involved equipment and any ancillary devices (including disposables) for evaluation. The date, time and person most familiar with the incident should be noted and attached to the equipment.
4. Complete a Report of Occurrence form in its entirety, listing the manufacturer, model, serial number and JHH registration number on the yellow metal plate. If the device is a disposable product, list the manufacturer, catalog or stock number, lot number and expiration date.

REFERENCE

US Food and Drug Administration, The Safe Medical Devices Act of 1990.

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RESPONSIBILITIES

Director of the Functional Unit

Assure that the equipment is not used for patient care prior to acceptance testing, and that the equipment is made available for scheduled services.

Assure that all clinical equipment is entered into the JHH medical equipment inventory database.

Assure that training in the use of clinical equipment shall be provided and documented.

Clinical Engineering Services and/or
Radiology Physics Engineering

Perform acceptance testing, scheduled service, and repair; and certify that it has been performed in accordance with applicable safety and performance standards, and manufacture's criteria.

Establish written procedures for performance verification and testing intervals.

Authorize and/or perform modifications to clinical equipment when such action is required to correct significant safety hazards and/or improve performance. All such modifications shall be properly documented.

Document acceptance testing procedures and results for all scheduled maintenance and repairs on clinical systems and devices.

Perform an investigation of suspected or reported malperformance of a medical device when requested to do so by the Clinical Staff or Legal Department, or when a Report of Occurrence has been forwarded to Clinical Engineering Services.

SPONSOR

Director, Clinical Engineering Service

REVIEW CYCLE

Annually