UNIVERSITY of VIRGINIA HEALTH SYSTEM

Clinical Staff Executive Committee

MEDICAL CENTER POLICY NO. 0076

A. SUBJECT: Management of Medical Devices Used in Patient Care

B. EFFECTIVE DATE: October 1, 2011 (R)

C. POLICY:

Any Medical Device, whether purchased, contracted, donated, loaned or for trial or research, that is to be used in the Medical Center for inpatient or outpatient care purposes shall be registered with Clinical Engineering. A Medical Device (also referred to in this Policy as "Device") is defined as any technology, supply, implant, tissue (excluding solid organs), software or equipment used for inpatient or outpatient care, diagnosis or treatment at the Medical Center. Only properly trained and appropriately credentialed personnel shall be allowed to operate medical equipment.

D. PROCEDURE:

1. A New Medical Device Monitoring Form shall be completed prior to the procurement or use of any new Medical Device[1] at the Medical Center. The completed form shall be sent to the Director of Clinical Engineering.

2. The Director of Clinical Engineering shall oversee a registration process for new Medical Devices that shall include the following components (see Exhibit 1: Process Roles and Responsibilities and Exhibit 2: New Medical Device Process):

   a. Validation of the financial impact of the use of the Device;

   b. Assessment of compatibility with other Medical Devices or appropriateness for use by other departments in the Medical Center ;

   c. Verification that appropriate purchasing documents, including a purchase order, are on file before a new Device is put into use in the Medical Center;

   d. Verification that appropriate parties (medical directors, administrators, leadership, etc.) have reviewed and approved the introduction of the Device/procedure into the appropriate patient care environment;

[1] New Medical Device: Any Medical Device not previously utilized by clinicians to be introduced into any care environment for the purpose of diagnosis, treatment, analysis or care of patients.

e. Assurance that appropriate acceptance and safety inspections are conducted prior to the Device being used for patient care and that preventative maintenance, where appropriate, has been scheduled;

f. Coordination of all facets of equipment deployment, including replacement of Devices and supplies, testing, competency-based training and proficiency evaluations and process audits;

g. Notification of the Clinical Staff Office, GME, Nursing Governance, Supply Chain and, as required, Administrators and Medical Directors;

h. Maintenance of medical equipment inventory records.

3. A Qualified Inspector[2] shall survey radiation producing equipment within 30 days of installation for compliance with state regulations. A Qualified Inspector shall perform routine inspections at the frequencies required by state and federal regulations. Each location in the Medical Center where radiation producing equipment is utilized shall review such usage and establish appropriate safety and health procedures per University Policy SEC-009: Utilization of Radioactive Materials (https://policy.itc.virginia.edu/policy/policydisplay?id=SEC-009) and follow guidelines of the Environmental Health and Safety (EHS) Radiation Safety Program (http://ehs.virginia.edu/rad/home.html). Such procedures shall address usage and condition of the equipment and the health exposure of those involved.

4. Each location in the Medical Center where non-ionizing radiation in the form of lasers is utilized shall review such usage and establish appropriate safety and health procedures. Such procedures shall address usage and condition of the equipment and the health exposures of those involved. See Medical Center Policy 0188, "Laser Safety" for additional guidance.

5. There shall be documentation that training and education has been provided to potential users of new Medical Devices based on the "Clinical Staff Equipment and Supply Training Assessment Tool" (part of the New Medical Device form referenced in 1 above). Procedures or competencies shall be written and approved, when appropriate.

   a. Training shall be specific to the equipment being used, shall be commensurate with the responsibility of the individual, and shall be documented, with the documentation kept in departmental files.

   b. Training shall be tracked centrally for any Devices which are used in multiple disciplines and/or multiple settings.

   c. Training syllabi shall be on file for all Devices.

   d. Vendor training is audited to ensure adherence to vendor-provided syllabi.

6. In addition to new Medical Devices meeting the criteria listed above, all supplies labeled for single use that are being reprocessed or under consideration for reprocessing for patient reuse must also have a New Medical Device Monitoring request form on file; refer to Medical Center Policy 0222, "Reprocessing and Reuse of Single Use Devices".

[2] Qualified Inspector: Individual qualified by training and experience to perform surveys or calibrations according to the criteria in Part VII, Appendix D of the Virginia Radiation Protection regulations

7. New implantables and tissue introduction must comply with specific department policies regarding FDA and other regulatory requirements before use.

8. At the conclusion of evaluations and research projects, all equipment, accessories, and/or supplies must be returned to the manufacturer or otherwise be removed from use unless the Device is accepted for continued use within the Medical Center. Notification must be made to Clinical Engineering if evaluation or research Devices are to be purchased, used in any way varying from the original request or moved to other clinical areas.

9. The introduction of a new Medical Device may be halted at any point in the process by any party if any risk is detected in any step in the process.

10. Any variance in the use of Medical Devices shall be documented in the automated quality reporting system (QR Track) as defined by Medical Center Policy 0132, "The Quality Reporting Process". Any Medical Device variance that involves a patient and results in serious illness, injury, or death to a patient shall also be reported directly to the Office of Patient Safety and Risk Management for immediate investigation and determination of external reporting requirements under the Federal Safe Medical Devices Act, per Medical Center Policy 0165, " Safe Medical Devices Act Reporting".

11. The Director of Clinical Engineering shall provide regular reports regarding Medical Device registration and training to the Medical Center's Safety and Security Subcommittee *via* its Equipment Management Work Group.

12. All managers, administrators and medical directors are responsible for ensuring adherence to this policy for any Medical Device used in their respective areas.

13. Questions regarding this policy shall be directed to the Director of Clinical Engineering.

SIGNATURE:

Robert S. Gibson, MD, President, Clinical Staff

R. Edward Howell, CEO, UVA Medical Center

9/20/11

DATE

Medical Center Policy No. 0076 (R)
Approved August 1990
Revised May 1993, March 1996, July 1998, May 2000, April 2001, May 2004, July 2004, September 2007, September 2009, September 2011
Approved by Quality Committee
Approved by the Clinical Staff Executive Committee

Exhibit 1:

Process Roles and Responsibilities

ROLE	RESPONSIBILITY	ASSIGNMENT
Oversight Committee	• Reviews and facilitates process outcomes. • Ensures integrity of the processes. • Insures systems design meets the needs of the redesigned processes. • Oversees outcomes.	Sub-Workgroup of the Equipment Management Workgroup
New Medical Device Office/Gatekeeper	• Controls the day-to-day aspects of process and is accountable for program outcomes. • Utilizes decision criteria to move patient safety sensitive Devices through correct process. • Tracks review and approval of process steps. • Manages and resolves issues. • Tracks progress of each Device introduction and evaluation, and manages change control process. • Maintains on-going communications with requestors. • Documents and reports request and implementation status. • Coordinates efforts with other UVAHS departments, including Value Analysis, Technology Assessment, Education, Medical Directors, Administrators, Supply Chain, HSCS, Clinical Staff Office, Nursing Governance and GME. • Develops and coordinates implementation and education of Devices. • Manages tracking database.	Clinical Engineering Clinical Liaison
Secondary Process Check	• Develops processes to ensure that Devices are not purchased without proper approvals consistent with this process.	Medical Center Procurement
Value Analysis	• Conducts financial analyses of budgetary impact of Device. • Assesses overall operational impact.	Director, Supply Chain Analytics
Service Specific Assessment	• Conducts formal risk assessments. • Reviews technical assessment and value analysis data. • Executes review and approval process	SCOPE Action Teams
Technology Assessment	• Conducts documentation review of Device, competitive products, regulatory status, recalls and alerts, Device incidents, process impact, patient safety impact, training needs, infrastructure needs, life cycle costs, economic impact. • Assists with formal risk assessments. • Generates technology white paper.	Clinical Engineering

ROLE	RESPONSIBILITY	ASSIGNMENT
Nurse Educator	• Assesses needs for clinical procedure changes related to Device introduction in collaboration with established clinical practice governance structures. • Coordinates practice change process as indicated. • Oversees training development and deployment. • Uses decision matrix to determine training delivery and competency assessment methods. • Manages and resolves training issues. • Creates and approves training curriculum and materials. • Audits clinical classroom sessions to ensure adherence to training syllabus. • Develops on-going training process post implementation. • Audits compliance of educational requirements to meet regulatory standards and follows up with managers.	Nursing Governance
Training Scheduling Coordination	• Schedules training with support of the New Medical Device Office.	Clinical Engineering
Physician/Clinical Liaison	• Assesses needs for clinical procedure changes related to Device introduction in collaboration with credentialing where appropriate. • Determines the need for credentialing. • Uses decision matrix to determine training delivery and competency assessment methods. • Schedules, documents and audits training with support of the New Medical Device Office.	GME Clinical Staff Office
Vendor Management	• Enforces UVAMC vendor rules and regulations. • Establish and enforce UVAMC Vendor Code of Conduct. • Reviews expectation agreements within procurement contracts. • Validates vendor presence.	Supply Chain Management

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Exhibit 2: New Medical Device Process