

February 9, 2009

USE AND REPROCESSING OF REUSABLE MEDICAL EQUIPMENT (RME) IN VETERANS HEALTH ADMINISTRATION FACILITIES

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides procedures for the design and implementation of a systematic approach for the set up, proper use, reprocessing, and maintenance of all reusable medical equipment (RME) used in VHA facilities.

2. BACKGROUND

a. The safe performance of procedures involving RME requires a systematic process including, but not limited to: initial training of personnel, proper setup, use, and reprocessing for each occurrence; an annual validation of the competency of the staff involved; and quality oversight. The details for each of these steps can effectively be documented in a locally-established standard operating procedure (SOP).

b. Multiple professional disciplines and many different types of RME used across a spectrum of clinical services are involved. For this reason, clear lines of responsibility and accountability must be established to ensure proper outcomes of the identified procedures, SOPs, competency requirements, quality monitoring processes, and clear identification of oversight and accountability for every step and handoff in the process.

c. Definitions

(1) **Reusable Medical Equipment (RME).** RME is any medical equipment designed by the manufacturer to be reused for multiple patients. All RME must be accompanied by reprocessing instructions provided by the manufacturer.

(2) **Standard Operating Procedure (SOP).** An SOP is a document detailing all steps and activities of a process or procedure that is dated and signed by an approving official.

(3) **Reprocessing.** Reprocessing is the cleaning, disinfection, sterilization, and preparation of equipment to full readiness for its subsequent use. This can occur in part or in whole, either inside or outside of Supply, Processing, and Distribution (SPD).

(4) **Set-up.** Set-up is the process of assembling the RME in preparation for a procedure in accordance with manufacturer's instructions.

(5) **Competency.** Competency is the assurance that an individual has received the appropriate training and has demonstrated an achieved skill level required to independently and appropriately perform an assigned task or responsibility.

(6) **Quality Assurance.** Quality assurance is the process for continuously monitoring the processes and outcomes of a pre-determined procedure to ensure safe patient care.

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(7) **Maintenance.** Maintenance includes the actions taken, in accordance with manufacturer's instructions, to preserve the optimal and safe usefulness of medical equipment and its associated accessories.

3. POLICY: It is VHA policy that systematic and local standard processes are developed in compliance with manufacturer's instruction, infection prevention and control principles, and effectively communicated and deployed to staff wherever procedures using RME are performed.

4. ACTION

a. **Infectious Diseases Program of the Office of Patient Care Services.** The National Director of the Infectious Diseases Program, Office of Patient Care Services, is responsible for:

- (1) The development of national policy pertaining to the reprocessing of RME, and
- (2) Liaising with the Networks and the Office of the Deputy Under Secretary for Health for Operations and Management.

b. **Network Director.** The Network Director is responsible for:

- (1) Establishing a continuing oversight function, coordinated by the Network Chief Medical Officer, using subject matter experts.
- (2) Conducting, at least annually, unannounced site audits of each facility in their Network, that must include.
 - (a) Ensuring that RME systematic processes are fully implemented and executed at all facilities.
 - (b) Ensuring that appropriate training is provided and completed for all users of RME prior to initial use.
 - (c) Ensuring competencies are documented and SOPs exist for each RME and are current and correct based upon manufacturer's written instructions.
 - (d) Ensuring identification of accountability, responsibility and documented performance at each step in the process.
 - (e) Ensuring a quality assurance process is established.
 - (f) Ensuring assigned staff are collecting data, conducting an analyses, and taking required actions to ensure safe and effective use of RME.

(3) Ensuring that local standards and systematic RME processes are established and documented in a SOP within any medical facilities under the purview of VHA that perform procedures utilizing RME.

c. **Facility Director.** The Facility Director is responsible for ensuring:

(1) All personnel that are in any way involved in the use and reprocessing of RME have documented training on the setup, use, reprocessing, and maintenance of the specific equipment leading to initial competency and validation of that competency on an annual basis.

(a) The duties and expected outcomes must be clearly evident in the staff's position description and functional statements and must be identified as a critical element in their annual performance standards.

(b) The language and process for validation is a collaborative effort with the standards being established by the highest level of authority within the medical center on each of the following elements: reprocessing, disinfection, sterilization, maintenance and incorporation of manufacturer's instructions.

(2) That device-specific standards and systematic RME processes are established and documented in a SOP that includes at least the following elements:

(a) Defined process and accountability for performing and documenting initial competency for staff, including required training to be accomplished prior to initial use.

(b) Process and accountability for validating continued staff competency at least annually.

(c) Process and accountability for setup of RME equipment based on manufacturer's instructions.

(d) Process and accountability for reprocessing and maintenance of equipment and supplies utilized in RME procedures.

(e) Organizational structure that includes an interdisciplinary approach to monitoring the compliance with the established process(es) and documents outcomes related to the defined process(es).

(f) Interdisciplinary approach requires participation by Chief, SPD; a representative of Quality and Risk Management; a Nursing Service representative; an Infection Control Professional; a Patient Safety manager; and a representative of Bio-Medical Engineering.

(g) Reporting required to the Executive Committee of the Medical Staff, including, but not limited to: validation of initial and on-going competency of staff, results of compliance with established SOPs, results of infection prevention and control monitoring, and risk management related activities.

(3) That device-specific SOPs for set up and reprocessing of RME are posted in any area where these devices are reprocessed.

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d. **Associate Medical Center Director, Nurse Executive, or Chief of Staff.** The Associate Medical Center Director, Nurse Executive, or Chief of Staff is responsible for execution of the defined process(es), including, but not limited to:

(1) Ensuring that all staff involved in RME processes have clearly defined responsibilities within their position descriptions or functional statements.

(2) Ensuring that all staff involved in RME processes have clearly-defined performance standards that are identified as critical elements in performance appraisals.

(3) Ensuring implementation of a systematic approach to the performance of procedures involving RME throughout the facility and associated sites.

(4) Ensuring collaboration of all organizational structures within the facility to achieve a comprehensive monitoring system that supports safety and quality in the performance of procedures involving RME.

e. **Chief, SPD.** The Chief, SPD, is responsible for:

(1) Technical oversight of all reprocessing of RME and equipment used in reprocessing wherever such reprocessing occurs within the facility, regardless of organizational alignment.

(2) Development, administration, and validation of initial and annual competencies for staff performing reprocessing of RME and for all personnel involved in using the reprocessing equipment.

(3) Ensuring all functions of SPD, regardless of organizational alignment, are functioning effectively; this includes: decontamination, preparation, case cart and distribution, etc.

5. REFERENCE

a. Centers for Disease Control and Prevention, Rutala, William A., Weber, David J. and the Healthcare Infection Control Practices Advisory Committee. Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008.

b. VA Handbook 7176, Supply, Processing, and Distribution (SPD), Operational Requirements.

6. FOLLOW UP RESPONSIBILITY: The Office of Patient Care Services (11) is responsible for the contents of this Directive. Questions regarding the administrative components may be referred to the Chief Consultant Medical Surgical Services (111) at (202) 461-7120. Questions related to the technical components of this Directive may be referred to the Infectious Diseases Program Office at (513) 475-6398.

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7. RECISIONS: None. This VHA Directive expires February 28, 2014.

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