Department of Veterans Affairs **VHA DIRECTIVE 2009-031**
Veterans Health Administration
Washington, DC 20420 **June 26, 2009**

IMPROVING SAFETY IN THE USE OF REUSABLE MEDICAL EQUIPMENT THROUGH STANDARDIZATION OF ORGANIZATIONAL STRUCTURE AND REPROCESSING REQUIREMENTS

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides specific requirements for the organizational structure charged with oversight responsibilities for reprocessing specified reusable medical equipment (RME) at the Veterans Integrated Service Network (VISN) and Facility levels, and includes specific guidance for standardization of equipment types and for ensuring that reprocessing requirements are met. This Directive applies to RME, which requires High Level Disinfection or Sterilization in order to be reused on another patient. ***NOTE:*** *This Directive augments previous Department of Veterans Affairs (VA) Central Office policies issued to assure quality in the setup, use and reprocessing of reusable medical equipment.*

2. BACKGROUND: The safe use of RME depends on good manufacturing practices, including the uniform implementation of current manufacturers' instructions for cleaning and disinfection and sterilization (reprocessing).

b. Endoscopic procedures are inherently safe with infection rates in the range of 1 in 1.8 million procedures; virtually every case of pathogen transmission related to an endoscopic procedure has ultimately been attributed to failure to follow established reprocessing guidelines or to the use of defective equipment. Proper reprocessing of RME is a key component to ensuring patient and staff safety, and therefore must be performed to exacting standards.

c. Consistency and high reliability in the reprocessing of RME across unit, facility, VISN, and national levels requires a uniform chain of command and accountability over all such processes.

3. POLICY: It is VHA policy that each VHA facility must have a systematic standardization and oversight plan for reprocessing RME according to current manufacturers' instructions and systematically retire and replace older equipment in place, and that each VISN must have a Supply, Processing, and Distribution (SPD) Management Board established and functioning no later than September 1, 2009.

4. ACTION

a. **Chief, Patient Care Services (11).** The Chief, Patient Care Services (11), is responsible for:

(1) Continued development and oversight of national policy pertaining to the standardization and reprocessing of RME.

(2) Development, in collaboration with the Office of Quality and Safety, national Quality Management, metrics to ensure expected actions and outcomes are met.

b. **Office of the Deputy Under Secretary for Health for Operations and Management.** Office of the Deputy Under Secretary for Health for Operations and Management, in cooperation with Chief Consultant Medical Surgical Service, is responsible for ensuring this policy is effectively deployed and implemented by the VISNs and facilities.

c. **VISN Director.** Each VISN Director is responsible for:

(1) Appointing a VISN SPD Management Board, no later than September 1, 2009, charged with the oversight of SPD at the VISN level to specifically include all reprocessing of RME occurring within the VISN.

(a) Members of the VISN SPD Management Board must have specialized knowledge of the reprocessing of RME.

(b) Board membership must include, at a minimum, an:

1. Nurse Executive,

2. Associate Director,

3. Safety Officer,

4. Chief Medical Officer or Quality Management Officer,

5. Practitioner of Infection Control,

6. Chief of Staff, and

7. Chief, SPD.

(c) The SPD Management Board has the authority and accountability for ensuring reprocessing (and other SPD functions) occurs to exacting standards, i.e., current manufacturer's instructions, across the VISN facilities as described in this Directive and in VHA Directive 2009-004, dated February 9, 2009, “Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities.”

(2) Ensuring that facility Directors comply with the actions contained within this Directive and they are actively engaged with the oversight of all RME reprocessing.

(3) Verifying that Infection Control, Training, and Quality Management programs at each facility within the VISN are in place

d. **Facility Director.** The Facility Director is responsible for:

(1) Ensuring the Chief of SPD (or equivalent, e.g., a Director of Sterile Processing), is delegated responsibility for reprocessing of RME wherever reprocessing occurs throughout the facility and affiliated sites (e.g., Community-based Outpatient Clinics).

(2) Standardization of RME is effected in order to facilitate consistency and efficiency in setup, use, and reprocessing, whether through facility-owned equipment or through a leasing agreement. ***NOTE:*** *Exceptions must have the written concurrence of the Chief Consultant, Medical Surgical Services (111).*

(3) Equipment is replaced uniformly throughout the facility, when needed. This is a key component to the standardization process.

(4) Ensuring there is a plan in place, no later than September 1, 2009, to systematically retire and replace older equipment, as well as that from different manufacturers, in order to maintain uniformity in the equipment used for any given procedure.

(5) Initial and ongoing training programs for the Infection Control Program, Quality Management Program, Competency Management Program, Equipment Maintenance Program, and Repair for Medical Equipment Program are in place. ***NOTE:*** *These need to be considered as integral components to any purchase or lease arrangements*.

(a) These training programs must include the initial implementation of standard operating procedures (SOP) governing the setup, use, reprocessing, a method for periodic review (at a minimum annually), and a plan for implementing any changes to a given SOP.

(b) Independent repair maintenance contracts or in-house service agreements need to be executed in order to ensure adherence with current manufacturers' maintenance and repair guidelines.

(6) Processes for determining which equipment is to be utilized involve all the stakeholders and include the needs and training of the operator, infection control, logistics, SPD, and Biomedical Engineering.

(7) SPD has input into any:

(a) Decisions that impact or require SPD-related functions or support, specifically including the purchase and lease of any medical equipment requiring reprocessing or consumable supplies.

(b) Facility construction projects where medical equipment is used or reprocessed, or where supplies are to be stored.

(8) The following is verified:

(a) All requirements for training and documentation of competencies are in place,

(b) SOPs are available and are being followed, and

(c) Quality systems are in place, being appropriately reported, and when necessary, corrective action(s) is taken.

(9) There is, for all quality control programs, documentation of testing procedure(s), (including locations, the serial number or unique identifier for scopes, solution lot numbers, identification of automated washer or disinfectors, etc.), the results of the testing, and any actions taken. This information must be maintained and reviewed by the Infection Prevention and Control Committee, or equivalent oversight group, at least on a quarterly basis.

(10) Biomedical Engineering reviews all requests for independent repair maintenance contracts or in-house service agreements.

e. **Nurse Executive.** The Nurse Executive is responsible for the day-to-day supervision of local SPD operations and ensures the Chief of SPD, or equivalent, implements all provisions of subparagraph 4f.

f. **Chief of SPD.** The Chief of SPD, or equivalent, is responsible for ensuring:

(1) The facility's reprocessing of all RME is performed with high reliability according to current manufacturers' instruction wherever these processes are performed and regardless of who is performing them.

(2) Any and all individuals charged with reprocessing duties are appropriately trained and competent in performing the assigned tasks, and when SOPs are changed all designated staff are retrained and competency is again established. Personnel reprocessing RME must be continually evaluated to ensure that they are demonstrating proficiency in all reprocessing activities and meeting all critical elements in their performance standards relating to RME. Appropriate training must be done whenever new or different equipment is used; new critical elements related to reprocessing must be added to performance standards, as necessary. Temporary personnel must not be permitted to reprocess RME until training has been completed and proficiency has been demonstrated.

(3) Specific processes and procedures are in place for any given RME. This includes, but is not limited to following specific guidance regarding the use and reprocessing of endoscopes:

(a) All clinical and technical personnel involved in endoscope use and reprocessing are to be trained in standard infection control methods, including those to protect both patients and themselves.

(b) SOPs reflecting current manufacturers' instructions must be available in each area where reprocessing occurs for each type of endoscopic equipment used. Personnel assigned to reprocess endoscopes must be trained according to device-specific SOPs in order to ensure proper cleaning and high-level disinfections and sterilization.

(c) All SOPs must be kept up-to-date, and methods in place to sequester outdated versions and to disseminate revised SOPs, as well as to ensure compliance and competence in the execution of any revised procedure.

(d) A method is in place to identify that a given RME has been reprocessed; if not clearly identified as having been done, it must be reprocessed before use. A system or log is in place to record, for each instance of use, the:

1. Serial number, or other unique identifier, of the endoscopic equipment used for each patient procedure.

2. Specific procedure, operator(s), date and time, and patient identifier.

(e) A quality management program must be in place to ensure appropriate and safe reprocessing is being performed. While this is required for all RME, the following examples related to endoscopes are all highly recommended:

1. Testing to ensure bio-burden has been removed after reprocessing endoscopes that have been used for biopsy, (both the biopsy and suction channels).

2. Routine testing of liquid disinfectant and sterilization solutions to ensure minimal effective concentrations of the active ingredients, and that these solutions are discarded at the end of their prescribed reuse life, regardless of effective concentration.

3. Site inspections to ensure personnel are using appropriate protective equipment to protect against exposure to chemicals, blood, or potentially infectious materials.

4. Testing adequacy of ventilation systems in cleaning areas to ensure that vapor concentrations of sterilizing solutions do not exceed allowable standards.

5. REFERENCES

a. Guidelines for use of high level disinfectants and sterilants for reprocessing flexible gastrointestinal endoscopes, Society of Gastroenterology Nurses and Associates, Inc. pages 1-24, 2007.

b. Multi-society Guidelines for Reprocessing Flexible Gastrointestinal Endoscopes, Gastrointestinal Endoscopy, Volume 58, No. 1, 2003.

c. VHA Directive 2009-004, Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities, dated February 9, 2009.

NOTE: *Facilities need to be aware that current manufacturer's instructions and guidance needs to be followed.*

6. FOLLOW-UP RESPONSIBILITY: The Office of Patient Care Services (11) is responsible for the content of this Directive. Questions may be addressed to National Director, Infectious Diseases, through the Office of Medical Surgical Services at (202) 461-7120.

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

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DISTRIBUTION: E-mailed to the VHA Publications Distribution List 6/26/2009