MANAGEMENT OF CRITICAL AND SEMI-CRITICAL REUSABLE MEDICAL DEVICES

1. SUMMARY OF MAJOR CHANGES: This Veterans Health Administration (VHA) directive:

a. **Amendment dated September 9, 2024:** Adds clarification that critical and semi-critical single use devices can be recycled only for the purpose of collecting raw materials but not for reuse. See paragraph 7.f.

b. **Amendment dated June 13, 2024:**

(1) Adds the Department of Veterans Affairs (VA) medical facility Patient Safety representative to the VA medical facility Reusable Medical Devices (RMD) Committee membership. The VA medical facility Patient Safety representative was inadvertently omitted from the required VA medical facility RMD Committee membership. This change reflects baseline membership for the VA medical facility RMD Committee. See paragraph 2.n.

(2) Adds a VA medical facility Infection Prevention or Infectious Disease representative to the Veterans Integrated Services Network (VISN) RMD Management Board membership. The VA medical facility Infection Prevention or Infectious Disease representative was inadvertently omitted from required member of the VISN RMD Management Board. This change reflects baseline membership for the VISN RMD Management Board. See paragraphs 2.i.(2).

(3) Updates the link to the Office of Sterile Processing Staffing Tool. See paragraphs 2.i.(2)(b) and 2.j.(5).

(4) Assigns oversight responsibility to the VA medical facility Associate Director of Patient Care Services to ensure the VA medical facility Sterile Processing Services (SPS) Chief obtains a VA recognized sterile processing certification no later than 1 year after appointment. See paragraph 2.l.(2).

(5) Assigns oversight responsibility to the VA medical facility SPS Chief to ensure the VA medical facility SPS Assistant Chief and SPS supervisory positions obtain a VA recognized sterile processing certification no later than 1 year after appointment. See paragraph 2.m.(2).

(6) Removes requirement that reusable medical devices stored on crash carts must not be stored in a monitored environment. See paragraph 5.e.(3).

(7) Removes requirement that non-high risk RMD must have competency validation completed prior to assigned task performance and clarifies that competency renewal must follow VA accrediting agency guidance. See paragraph 6.b.(5)(c).

(8) Clarifies that RMD used in human research must follow VHA Directive 1761, Supply Chain Management Operations, dated December 30, 2020. See paragraph 7.c.

(9) Updates paragraph 7.f. to state that VHA must not knowingly use critical or semi-critical reprocessed single-use devices from third party vendors.

c. **As published on July 17, 2023,** this directive:

(1) Updated program office name from the National Program Office of Sterile Processing to the Office of Sterile Processing (OSP).

(2) Updated the term reusable medical equipment (RME) to reusable medical devices (RMD), to align with verbiage used by the Food and Drug Administration (FDA) and the Association for the Advancement of Medical Instrumentation (AAMI).

(3) Removed duplicate language already contained in AAMI standards and technical guidance, as well as other VHA directives.

(4) Appointed the Executive Director as the lead of OSP, reflecting changes to the OSP organizational chart.

(5) Updated title of the Veterans Integrated Service Network (VISN) Lead to VISN Chief Sterile Processing Officer (CSPO), included responsibilities and required each VISN to have a dedicated CSPO with no collateral duties within 6 months of publication date of this directive.

(6) Eliminated the requirement for a standard operating procedure (SOP) for tasks related to RMD, if the task already has accompanying manufacturer’s instructions for use (MIFU). MIFU must provide all requisite information to define how the task will be accomplished.

(7) Changed the requirement of conducting a minimum SOP review every 3 years to every 5 years, which aligns with VHA Directive 0999, VHA Policy Management, dated March 29, 2022. Updates are required with any change in MIFU, policy or standard.

(8) Incorporated language regarding the Competency Assessment Tool (CAT), the record of competency validation. For processes that require an SOP, a combined SOP and CAT document is acceptable.

(9) Specified restrictions related to 3D-printed devices.

(10) Required Department of Veterans Affairs (VA) medical facilities to initiate procurement and utilize the approved instrument tracking system (ITS) within 6 months of publication of this directive.

(11) Included a written requirement for 400 hours of hands-on reprocessing experience for the VHA Sterile Processing Services (SPS) certification exam by VA medical facility SPS leadership or have a nationally recognized certification, completed within 1 year of appointment.

(12) Required development of VA medical facility SOP to manage fluctuations in required parameters for temperature and humidity monitoring and hazard communication and automated monitoring for environmental parameters. See paragraph 3.e.

2. RELATED ISSUES: VHA Directive 0999, VHA Policy Management, dated March 29, 2022; VHA Directive 1061(1), Prevention of Health Care-Associated Legionella Disease and Scald Injury from Water Systems, dated February 16, 2021; VHA Directive 1081.02, Management of Biological and Non-Biological Implants, dated October 29, 2020; VHA Directive 1131(5), Management of Infectious Diseases and Infection Prevention and Control Programs, dated November 7, 2017; VHA Directive 1220(1), Facility Procedure Complexity Designation Requirements to Perform Invasive Procedures In Any Clinical Setting, dated May 13, 2019; VHA Directive 1761, Supply Chain Management Operations, dated December 30, 2020; VHA Directive 1850.03, Textile Management, dated June 13, 2023; VHA Directive 7713, Safe Use of Ethylene Oxide, dated April 6, 2017.

3. POLICY OWNER: The Office of Sterile Processing (12OSP) under the Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer is responsible for the content of this directive. Questions may be addressed to vha12spssterileprocessingaction@va.gov.

4. RESCISSIONS: VHA Directive 1116(2), Sterile Processing Services (SPS), dated March 23, 2016, is rescinded.

5. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working July 2028. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

6. IMPLEMENTATION SCHEDULE: This directive is effective within 6 months of publication.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ M. Christopher Saslo
DNS, ARNP-BC, FAANP
Assistant Under Secretary for Health
for Patient Care Services/CNO

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

DISTRIBUTION: Emailed to the VHA Publications Distribution Lists on July 18, 2023.

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1. POLICY

It is Veterans Health Administration (VHA) policy that Department of Veterans Affairs (VA) medical facilities exercise appropriate care and management of critical and semi-critical reusable medical devices (RMDs), including establishing Sterile Processing Services (SPS). SPS is a distinct service line and is not subordinate to any other service line. It is also VHA policy that Veterans receiving medical care at VA medical facilities are provided with appropriately reprocessed RMD. ***NOTE:*** *Some VA medical facilities utilize the United States Department of Defense SPS through a memorandum of understanding and therefore do not need their own SPS service line.* **AUTHORITY:** 38 U.S.C. § 7301(b).

2. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer.** The Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer (CNO) is responsible for supporting the Office of Sterile Processing (OSP) with implementation and oversight of this directive regarding reprocessing, storage and maintenance of specified RMD. SPS is a distinct service line and is not subordinate to another service line.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **Executive Director, Office of Sterile Processing.** The Executive Director, OSP is responsible for:

(1) Providing oversight for VISN and VA medical facility compliance with this directive and ensuring corrective action is taken when non-compliance is identified.

(2) Developing metrics annually to ensure outcomes are met as defined by OSP.

(3) Developing and implementing an RMD assessment plan that provides consultative oversight and guidance to VISN and VA medical facilities and communicating the plan through an emailed memorandum to VISN Directors.

e. **Director, Office of Sterile Processing.** The Director, OSP is responsible for:

(1) Supporting the Executive Director, OSP, in ensuring all designated responsibilities listed above are met.

(2) Providing technical and clinical oversight and guidance to VA medical facilities on all matters related to the reprocessing of RMD.

(3) Addressing RMD issues raised by VISNs and VA medical facilities (e.g., through SharePoint, email, Microsoft Teams) that have significant national impact on patient care.

(4) Serving as the SPS subject matter expert (SME) to the Executive Director, OSP; the Assistant Under Secretary for Health for Patient Care Services/CNO; VISNs; VA medical facilities; and other program offices for all VHA SPS programs and initiatives.

f. **Deputy Director for Operations, Office of Sterile Processing.** The Deputy Director for Operations, OSP is responsible for ensuring OSP Health System Specialists (HSS) fulfill all responsibilities related to this directive. See paragraph 2.g. for more information.

g. **Office of Sterile Processing Health System Specialist.** The OSP HSS is responsible for:

(1) Responding to questions and providing guidance related to critical and semi-critical RMD.

(2) Reviewing and approving RMD reprocessing and storage room construction and renovation plans submitted by the VA medical facility Chief, Healthcare Engineering Service on the Healthcare Environment and Facilities Program (HEFP) SharePoint site. ***NOTE:*** *All plan updates must be tracked and approved on the HEFP SharePoint site https://dvagov.sharepoint.com/sites/VHA10NA5E/SitePages/Home.aspx. This is an internal VA website that is not available to the public.*

(3) Collaborating with the VISN Chief Sterile Processing Officer (CSPO) to perform either virtual or on-site VA medical facility RMD assessments, as determined by Director, OSP and track action plans until all items are resolved and sustained.

(4) Scheduling routine meetings with VISN CSPOs at least quarterly.

(5) Ensuring VISN CSPOs have access to OSP communications on SharePoint at: https://dvagov.sharepoint.com/sites/NPOSP/SitePages/Supplemental-Guidance.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(6) Meeting with VISN and VA medical facility RMD staff, as requested by OSP or VISN CSPOs.

(7) Serving as an SPS SME on interview panels for prospective SPS leadership positions (i.e., VISN CSPO, VA medical facility SPS Chief and VA medical facility SPS Assistant Chief), as requested.

h. **Veterans Integrated Services Network Director.** The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barrier to compliance are identified.

(2) Appointing a dedicated 1.0 Full-Time Equivalent (FTE) VISN CSPO that is not to be a collateral role with other VISN-level positions or responsibilities. ***NOTE:*** *The VISN CSPO was previously titled VISN Lead. This is title change, not a new position.*

(3) Ensuring a VISN RMD Management Board is established and maintained for oversight of VISN SPS related to RMD.

(4) Attending meetings with the OSP HSS regarding RMD and SPS issues.

(5) Ensuring VISN RMD program assessments are conducted in accordance with the OSP memorandum.

(6) Collaborating with VA medical facility Directors to ensure:

(a) There is a dedicated SPS Chief at all VA medical facilities.

(b) There is a dedicated SPS Assistant Chief in addition to a VA medical facility SPS Chief at all complexity-level 1 and 2 VA medical facilities.

(7) Ensuring the VA medical facility SPS Chief reports directly to the VA medical facility Associate Director of Patient Care Services (ADPCS).

(8) Forwarding all RMD reprocessing and storage room construction and renovation plans to the VISN CSPO for review.

i. **Veterans Integrated Services Network Chief Sterile Processing Officer.** ***NOTE:*** *This position is a dedicated, 1.0 FTE who possesses foundational knowledge of SPS, as outlined by OSP, and reports to the VISN CNO. This is not a collateral role.* The VISN CSPO is responsible for:

(1) Serving as the VISN SPS SME responsible for collaboration with VA medical facilities in achieving the highest quality RMD outcomes.

(2) Serving as the Chair to the VISN RMD Management Board. ***NOTE:*** *The VISN RMD Management Board consists of chartered members who assist the Chair with their*

responsibilities. *Chartered members are VISN CSPO, as Board Chair; VISN CNO; VISN Patient Safety Officer; VISN Engineering, Capital Asset Manager; VISN Dental Service Line Chief; VA medical facility ADPCS; VA medical facility Gastroenterologist; VA medical facility Patient Safety, Infection Prevention or Infectious Disease representative; VA medical facility Operating Room (OR) or Surgical Services representative; a VA medical facility Chief, Healthcare Engineering/Facility Maintenance Service; VA medical facility SPS Chief; Chief, Healthcare Technology Management (HTM); VA medical facility RMD Coordinator; VA medical facility RMD Educator; and VA medical facility Chief, Environmental Management Service (EMS).* This includes:

(a) Providing oversight of reprocessing and management of RMD within the VISN.

(b) Providing support to VA medical facilities in recruiting and maintaining SPS staffing levels per the OSP Staffing Tool, available athttps://dvagov.sharepoint.com/:x:/r/sites/NPOSP/_layouts/15/doc2.aspx?sourcedoc=%7BCC69E3F6-4A8B-4419-9E09-A9800C5D1A0C%7D&file=OSP%20SPS%20Staffing%20Tool%20%20v5.6.xlsm&action=default&mobileredirect=true&DefaultItemOpen=1&clickparams=eyAiWC1BcHBOYW1lIiA6ICJNaWNyb3NvZnQgT3V0bG9vayIsICJYLUFwcFZlcnNpb24iIDogIjE2LjAuMTY3MzEuMjA2MzYiLCAiT1MiIDogIldpbmRvd3MiIH0%3D&CID=1771E2FA-2BAD-4AF6-BA18-7193EED08FBF&wdLOR=c31EDB87E-056C-4EF2-AB20-8882453F344F.
NOTE: *This is an internal VA website that is not available to the public*.

(c) Reviewing quality indicators reported by VA medical facilities throughout the VISN to support the development of sustainable corrective actions related to identified RMD management vulnerabilities.

(d) Collaborating with VISN support services to ensure proper care and management of RMD.

(3) Collecting, analyzing and reporting on SPS quality assurance and process improvement data to the VISN Director and OSP and collaborating with the VA medical facility ADPCS, VA medical facility Director and VA medical facility SPS Chief to identify and mitigate associated risks.

(4) Participating in the selection and orientation of VA medical facility SPS Chiefs within the VISN.

(5) Conducting meetings with VA medical SPS Chiefs at least once a month.

(6) Collaborating with the OSP HSS to perform VA medical facility RMD assessments virtually, on-site or a combination of both.

(7) Attending meetings with the OSP HSS regarding RMD and SPS issues.

(8) Providing input on VA medical facility SPS Chief performance, as appropriate.

(9) Supporting the VA medical facility SPS Chief to ensure oversight of RMD.

(10) Providing guidance to SPS programs, in accordance with paragraph 10.c. of this directive and American National Standards Institute/Association for the Advancement of Medical Instruments (ANSI/AAMI) which can be found at: https://dvagov.sharepoint.com/sites/NPOSP/Shared%20Documents/Forms/AAMI.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(11) Approving action plans developed by the VA medical facility SPS Chief in response to reprocessing non-conformities identified by OSP, the Office of Inspector General, Office of the Medical Inspector or The Joint Commission.

(12) Providing final approval for closure of action plans with sustainment processes in place.

(13) Reviewing and providing concurrence for reprocessing and RMD Storage Room construction and renovation plans in collaboration with the OSP HSS and HEFP Compliance Engineer.

(14) Providing oversight to all VA medical facilities that perform RMD reprocessing.

(15) Ensuring VA medical facility RMD program assessments are completed as specified by the OSP requirements.

(16) Providing oversight of the request and utilization of SPS Specific Purpose Funds for appropriate planning and procurement of RMD and reprocessing equipment needed to support operations.

j. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring overall VA medical facility compliance with this directive and appropriate corrective action is taken if non-compliance is identified.

(2) Establishing a VA medical facility RMD Committee that reports to the executive leadership team and follows an interdisciplinary approach to ensure compliance with this directive.

(3) Ensuring the VA medical facility SPS Chief is a dedicated position with no collateral duties and reports directly to the VA medical facility ADPCS.

(4) Collaborating with the VISN Director to ensure:

(a) There is a dedicated VA medical facility SPS Chief at all VA medical facilities.

(b) There is a dedicated SPS Assistant Chief in addition to a VA medical facility SPS Chief at all complexity-level 1 and 2 VA medical facilities.

(5) Using data submitted by the VA medical facility SPS Chief to evaluate SPS staffing levels to determine requirements to support SPS management, administrative and technical workloads at a minimum of once every 2 years. ***NOTE:*** *The OSP SPS*

Staffing Tool assists with assessing staffing levels and can be accessed via the following link:https://dvagov.sharepoint.com/:x:/r/sites/NPOSP/_layouts/15/doc2.aspx?sourcedoc=%7BCC69E3F6-4A8B-4419-9E09-A9800C5D1A0C%7D&file=OSP%20SPS%20Staffing%20Tool%20%20v5.6.xlsm&action=default&mobileredirect=true&DefaultItemOpen=1&clickparams=eyAiWC1BcHBOYW1lIiA6ICJNaWNyb3NvZnQgT3V0bG9vayIsICJYLUFwcFZlcnNpb24iIDogIjE2LjAuMTY3MzEuMjA2MzYiLCAiT1MiIDogIldpbmRvd3MiIH0%3D&CID=1771E2FA-2BAD-4AF6-BA18-7193EED08FBF&wdLOR=c31EDB87E-056C-4EF2-AB20-8882453F344F. This is an internal VA website that is not available to the public.

(6) Ensuring an SPS representative, appointed by the VA medical facility SPS Chief, is included on the VA medical facility Water Safety Committee (in accordance with VHA Directive 1061(1), Prevention of Health Care-Associated Legionella Disease and Scald Injury from Water Systems, dated February 16, 2021) to facilitate compliance with utility water, steam and critical water standards for all RMD reprocessing. ***NOTE:*** *Critical water standards are taken from AAMI, available at https://dvagov.sharepoint.com/sites/NPOSP/Shared Documents/Forms/AAMI.aspx. This is an internal VA website that is not available to the public.*

(7) Ensuring RMD reprocessing and storage room construction and renovation plans comply with current VHA design guides and have been reviewed and approved by the VA medical facility SPS Chief, VISN CSPO, OSP HSS and HEFP Compliance Engineer.

(8) Ensuring VA medical facilities purchase the nationally designated instrument tracking system (ITS) and utilizes it to document all RMD processing activity.

(9) Maintaining a clear record of continuing education units (CEUs) for all employees that perform RMD reprocessing. For more information, see paragraph 8.a.(3).

(10) Forwarding SPS quality assurance and process improvement data to the VISN RMD Management Board and collaborating with the VISN CSPO, VA medical facility ADPCS and VA medical facility SPS Chief to identify and mitigate associated risks.

(11) Ensuring the following services support sterile processing operations related to RMD reprocessing and storage: Supply Chain Management, Environmental Management Services, Facilities Management/Healthcare Engineering Program, Biomedical Engineering and other services, as required. ***NOTE:*** *The VISN CSPO, VA medical facility SPS Chief, OSP and HEFP must be included in the review of the design plans at the 30%, 60% and 90% design phase of any construction or renovation projects where critical or semi-critical RMD is reprocessed or stored.*

k. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff (CoS) is responsible for:

(1) Collaborating with the VA medical facility ADPCS and VA medical facility SPS Chief to ensure the proper RMD processes (e.g., RMD reprocessing, high-level

disinfection (HLD), sterilization and transportation) are in place in all clinical areas and in compliance with this directive.

(2) Facilitating collaboration and coordination between VA medical facility surgical services, end user services and SPS to ensure RMD availability.

(3) Collaborating with the VA medical facility SPS Chief and VA medical facility ADPCS to ensure all RMD end-users are compliant with this directive.

l. **VA Medical Facility Associate Director of Patient Care Services.** The VA medical facility ADPCS is responsible for:

(1) Providing oversight and leadership for SPS operations, retaining organizational responsibility for SPS and ensuring compliance with this directive.

(2) Ensuring the VA medical facility SPS Chief obtains a VA recognized sterile processing certification no later than 1 year after appointment, as defined in paragraph 8.

(3) Providing direct supervision to the VA medical facility SPS Chief.

(4) Collaborating with the VA medical facility CoS and VA medical facility SPS Chief to ensure the proper RMD processes (e.g., RMD reprocessing, HLD, sterilization and transportation) are in place for end-users and are in compliance with this directive.

(5) Ensuring all RMD reprocessing is only completed by personnel that have validated competency.

(6) Ensuring that an SPS representative is involved in all discussions and decisions impacting RMD management or operations.

(7) Providing executive-level support to the VA medical facility Director and VA medical facility SPS Chief in recruiting and retaining staff to support the workload demands for reprocessing of RMD.

(8) Analyzing, validating and reporting on SPS quality assurance and process improvement data to the VISN Management Board in collaboration with VA medical facility Director and VISN CSPO and VA medical facility SPS Chief to identify and mitigate associated risks.

m. **VA Medical Facility Sterile Processing Services Chief.** ***NOTE:*** *The VA medical facility SPS Chief reports directly to the VA medical facility ADPCS.* The VA medical facility SPS Chief is responsible for:

(1) Obtaining a VA recognized sterile processing certification no later than 1 year after appointment, as defined in paragraph 8.

(2) Ensuring the VA medical facility SPS Assistant Chief and SPS supervisory positions obtain a VA recognized sterile processing certification no later than 1 year after appointment, as defined in paragraph 8.

(3) Managing SPS as a service line within the VA medical facility using a planned, implemented and evaluated Quality Management System (QMS) Program. ***NOTE:*** *For more information on the QMS Program, see paragraph 6.*

(4) Serving as the VA medical facility RMD Committee Chair.

(5) Serving as the VA medical facility SME for RMD reprocessing.

(6) Collaborating with VA medical facility service lines that provide support to SPS to ensure compliance with this directive.

(7) Overseeing the reprocessing of VA medical facility RMD.

(8) Collaborating with the VA medical facility ADPCS and VA medical facility CoS to ensure the proper RMD processes (e.g., RMD reprocessing, HLD, sterilization and transportation) are in place in all clinical areas and are in compliance with this directive.

(9) Ensuring all VA medical facility staff that are responsible for point-of-use cleaning, transport and storage of RMD have the required education, training and competence validation.

(10) Developing, implementing, documenting and tracking education and training programs, including initial orientation for new employees, competence validation, continuing education and staff development for all VA medical facility staff performing RMD reprocessing.

(11) Ensuring manufacturer's instructions for use (MIFU) is available for all RMD, including consigned and loaned devices, reprocessing equipment and expendable products used in reprocessing.

(12) Evaluating VA medical facility SPS staffing levels annually to determine requirements to support SPS management, administrative and technical workloads and reporting findings to the VA medical facility Director. ***NOTE:*** *The OSP SPS Staffing Tool assists with assessing staffing levels and can be accessed via the following link: https://dvagov.sharepoint.com/:x:/r/sites/NPOSP/_layouts/15/doc2.aspx?sourcedoc=%7BCC69E3F6-4A8B-4419-9E09-A9800C5D1A0C%7D&file=OSP%20SPS%20Staffing%20Tool%20%20v5.6.xlsm&action=default&mobileredirect=true&DefaultItemOpen=1&clickparams=eyAiWC1BcHBOYW1lIiA6ICJNaWNyb3NvZnQgT3V0bG9vayIsICJYLUFwcFZlcnNpb24iIDogIjE2LjAuMTY3MzEuMjA2MzYiLCAiT1MiIDogIldpbmRvd3MiIH0%3D&CID=1771E2FA-2BAD-4AF6-BA18-7193EED08FBF&wdLOR=c31EDB87E-056C-4EF2-AB20-8882453F344F. This is an internal VA website that is not available to the public.*

(13) Providing input to the VA medical facility Chief, Healthcare Engineering/Facility Maintenance Service during the designing process to ensure RMD processing and storage room construction and renovation plans submitted are in compliance with current VHA design guides (refer to the Sterile Processing Service and Logistics Service Design Guide available at https://www.cfm.va.gov/til/dGuide/dgSPS-Log.pdf) and the heating, ventilation and air conditioning (HVAC) Design Manual (https://www.cfm.va.gov/til/dManual/dmHVAC.pdf). ***NOTE:*** *All plans must be reviewed and approved by the VISN CSPO, OSP and HEFP at the 30%, 60% and 90% design phase. For other environmental parameters see paragraphs 3 through 7.*

(14) Collaborating with RMD users and VA medical facility Chief, Healthcare Engineering/Facility Maintenance Service to develop a plan to systematically retire RMD and reprocessing equipment, prior to expected end-of-life.

(15) Overseeing the RMD management program, including programmed or preventive maintenance, sharpening, repair or replacement, service plans and contract monitoring.

(16) Collecting, analyzing and reporting on SPS quality assurance and process improvement data to the VA medical facility ADPCS and collaborating with the VISN CSPO, VA medical facility Director and VA medical facility ADPCS to identify and mitigate associated risks.

(17) Appointing an SPS representative to participate on the VA medical facility Water Safety Committee (in accordance with VHA Directive 1061(1)) to facilitate compliance with utility water, steam and critical water standards for all RMD reprocessing. ***NOTE:*** *Critical water standards are taken from AAMI, available at https://dvagov.sharepoint.com/sites/NPOSP/Shared Documents/Forms/AAMI.aspx. This is an internal VA website that is not available to the public.*

(18) Collaborating with the VA medical facility CoS and VA medical facility ADPCS to ensure all RMD end-users are compliant with this directive.

(19) Meeting with the VISN CSPO at least once a month to communicate program status.

(20) Developing action plans in response to identified reprocessing non-conformities identified by OSP, the VISN CSPO, the Office of Inspector General, Office of the Medical Inspector or The Joint Commission; forwarding action plans to the VISN CSPO for approval; and overseeing implementation of action plans after approval received.

n. **VA Medical Facility Reusable Medical Devices Committee Chair.** ***NOTE:*** *The VA medical facility RMD Committee membership must include, at minimum, the defined role or representation of VA medical facility ADPCS; VA medical facility SPS Chief; RMD Coordinator; RMD Educator; Patient Safety, Infection Prevention or Infectious Disease representative; Quality Management representative; Surgical Services representative; GI Service representative; Dental Service representative; Biomedical Engineering representative; Healthcare Engineering representative; EMS*

representative; Logistics representative; and additional end-user representation, as appropriate. The VA medical facility RMD Committee Chair is responsible for:

(1) Designating a charter that prescribes regular meeting intervals and quorum level and state-of-affairs report to an executive-level committee.

(2) Creating, implementing, monitoring and managing the QMS Program and developing, implementing and tracking sustainable corrective actions related to vulnerabilities identified. ***NOTE:*** *For more information on the QMS Program, see paragraph 6.*

(3) Reviewing quality indicators and measures developed by the VA medical facility RMD committee and supporting the development of sustainable action plans related to RMD management vulnerabilities.

(4) Collaborating with VA medical facility support services to ensure proper care and management of RMD, in accordance with MIFU, paragraph 10.c. of this directive and ANSI/AAMI.

(5) Ensuring RMD assessments and corresponding action plans are followed until closed by the VISN CSPO.

(6) Developing a contingency plan to support safe patient care and avoid case cancellation when RMD availability or sterility is compromised.

(7) Performing a RMD competency risk analysis in accordance with the VA medical facility RMD Committee's schedule for each device. For more information see paragraph 6.b.(5).

(8) Evaluating immediate-use steam sterilization (IUSS) reports from the VA medical facility Surgery Service to determine root cause and appropriate corrective action. For more information, see paragraph 7.a.(3).

o. **VA Medical Facility Chief, Healthcare Technology Management Service.** The VA medical facility Chief, Healthcare Technology Management (HTM) Service is responsible for:

(1) Collaborating with RMD users and the VA medical facility SPS Chief to develop a plan to systematically retire RMD and reprocessing equipment, prior to expected end-of-life.

(2) Ensuring required RMD preventive maintenance and calibration in accordance with MIFU.

p. **VA Medical Facility Chief, Healthcare Engineering/Facility Maintenance Service.** The VA medical facility Chief, Healthcare Engineering/Facility Maintenance Service is responsible for:

(1) Designing RMD processing and storage room construction and renovation plans with input from the VA medical facility SPS Chief to ensure compliance with current VHA design guides (refer to the Sterile Processing Service and Logistics Service Design Guide available at https://www.cfm.va.gov/til/dGuide/dgSPS-Log.pdf) and the HVAC Design Manual (https://www.cfm.va.gov/til/dManual/dmHVAC.pdf). ***NOTE:*** *All plans must be reviewed and approved by the VISN CSPO, OSP and HEFP at the 30%, 60% and 90% design phase. For other environmental parameters see paragraphs 3 through 7.*

(2) Submitting RMD reprocessing and storage room construction and renovation plans on the HEFP SharePoint site for approval from the OSP HSS.

(3) Developing a VA medical facility SOP to manage occurrence of variance fluctuations in performance parameters. See paragraph 3.e.

q. **VA Medical Facility Reusable Medical Devices Reprocessing Staff.** VA medical facility RMD reprocessing staff are responsible for:

(1) Using instrument count sheets for surgical instrument sets assembly. For more information see paragraph 4.d.(5).

(2) Following attire specifications as specified in paragraph 5.a.

(3) Completing appropriate training as specified in paragraph 8.

(4) For loaned RMD, obtaining inventory sheets for trays, sets and implants from the vendor. For more information, see paragraph 6.e.

3. ENVIRONMENTAL PARAMETERS AND AIR QUALITY

The following requirements apply to all sterile processing areas (decontamination, preparation and packaging and sterile storage) along with all Primary and Secondary RMD Storage Rooms:

a. Automated, continuous monitoring devices for temperature, humidity and differential pressure must be utilized to verify parameters referenced in the HVAC Design Manual, available at https://www.cfm.va.gov/til/dManual/dmHVAC.pdf. Devices must be installed and calibrated once a year by a representative from the manufacturer or the VA medical facility healthcare engineering department in accordance with MIFU. ***NOTE:*** *Monitoring devices must be present to monitor pressure differences between adjoining spaces.*

b. VA medical facility healthcare engineering services must consult with the HEFP Compliance Engineer to address HVAC compliance deficiencies. Stand-alone systems (i.e., portable dehumidifier, portable air-conditioning (AC) unit, split system AC units) must not be used without prior HEFP and OSP notification and approval.

c. There must be systematic processes for monitoring HVAC performance parameters and a mechanism for identifying and resolving variances within the rooms throughout the VA medical facility where sterile processing occurs and RMD is stored.

d. If variance in HVAC environmental parameters occurs, sterile processing personnel and affiliated representatives from the VA medical facility RMD Committee must evaluate the variance to determine if a risk assessment is necessary.

e. A VA medical facility SOP must be developed by the VA Medical Facility Chief, Healthcare Engineer/Facility Maintenance Service to manage occurrence of variance fluctuations in performance parameters and must:

(1) Define who will respond and what actions will be performed for environmental ranges out of compliance (i.e., temperature, humidity and air exchanges per hour).

(2) State that any temperature, humidity or pressure differential variances must be reported to the VA medical facility Comprehensive Environment of Care and RMD Committees. For more information on the VA medical facility Comprehensive Environment of Care Committee, see VHA Directive 1608, Comprehensive Environment of Care Program, dated June 21, 2021.

4. REPROCESSING CORE AREAS

a. **Attire and Personal Protective Equipment.** All VA health care providers must follow regulations, standards and professional practice guidelines regarding attire and personal protective equipment (PPE) in the employee's work area or job assignment. Visitors are required to follow the same requirements for attire as SPS employees. Appropriate attire and PPE in restricted areas of SPS are required to mitigate all risk of device, environmental and cross-contamination.

b. **Decontamination Room.**

(1) A decontamination room (Decon) is anywhere within a VA medical facility designated for decontamination (i.e., manual and mechanical cleaning) of soiled or contaminated RMD. This room must meet requirements defined in the Sterile Processing Service and Logistics Service Design Guide, available at https://www.cfm.va.gov/til/dGuide/dgSPS-Log.pdf, and HVAC Design Manual, available at https://www.cfm.va.gov/til/dManual/dmHVAC.pdf.

(2) MIFU for decontamination activities must be available in Decon.

(3) Magnifying lights must be available in Decon to aid in device inspections.

(4) Manual cleaning must be completed on all RMD.

(5) Automated handpiece cleaner or lubrication stations must be placed and used in Decon.

c. **Automated Endoscope Reprocessor/High Level Decontamination Room.**

(1) An automated endoscope reprocessor (AER)/HLD room is a designated space within a VA medical facility for HLD of semi-critical RMD. This room must meet requirements defined in the Sterile Processing Service and Logistics Service Design Guide, available at https://www.cfm.va.gov/til/dGuide/dgSPS-Log.pdf, and HVAC Design Manual, available at https://www.cfm.va.gov/til/dManual/dmHVAC.pdf.

(2) MIFU for HLD activities must be available in this room.

d. **Preparation and Packaging Room/Sterilization Room.**

(1) The Preparation and Packaging/Sterilization Room (Prep) must be physically separated from Decon. This room is a designated place for inspecting, assembling and packaging devices prior to sterilization and may also include the sterilization processes. This room must meet requirements defined in the Sterile Processing Service and Logistics Service Design Guide, available at https://www.cfm.va.gov/til/dGuide/dgSPS-Log.pdf, and HVAC Design Manual, available at https://www.cfm.va.gov/til/dManual/dmHVAC.pdf.

(2) Prep must not be used as a distribution area or case cart staging area.

(3) MIFU for all aspects of preparing, packaging and sterilization activities must be available in Prep.

(4) Magnifying lights must be available in Prep to aid in RMD inspections.

(5) RMD reprocessing staff must use instrument count sheets for surgical instrument sets assembly, with detail of each device name, size, quantity and type. This includes individual parts of disassembled instruments placed in the set separately.

5. PRIMARY AND SECONDARY REUSABLE MEDICAL DEVICES STORAGE ROOM

a. **Attire Specific to Preparation and Packaging/Sterilization Room and Primary Reusable Medical Devices Sterile Storage Rooms.**

(1) A jacket with cuffs down to the wrists must be worn, if short-sleeved scrub suits are provided. The jacket must be kept closed. Jackets may be reusable and laundered by the VA medical facility or disposable.

(2) Shoe covers are not required when dedicated hospital shoes are worn. Dedicated hospital shoes must not be worn outside the VA medical facility. If dedicated hospital shoes are not worn, shoe covers are required and must be removed and discarded prior to exiting the restricted area.

b. Primary and Secondary RMD Storage Rooms are designated places for the storage of RMD until needed for use, mitigating the risk of cross contamination. This room must meet requirements defined in the Sterile Processing Service and Logistics

Service Design Guide, available at https://www.cfm.va.gov/til/dGuide/dgSPS-Log.pdf, and HVAC Design Manual, available at https://www.cfm.va.gov/til/dManual/dmHVAC.pdf.

(1) **Primary Reusable Medical Device Storage Room.** The Primary RMD Storage Room is the main storage room of a VA medical facility and designed to store RMD. This is a restricted room that requires appropriate attire. For attire restrictions, see paragraph 5.a. Clean and sterile expendable products may be stored in the Primary RMD Storage Room. Non-critical RMD must not be stored in this room.

(2) **Secondary Reusable Medical Device Storage Room.** The Secondary RMD Storage Room is a traffic-controlled room in which RMD is stored and is located in the clinic, OR, emergency department or procedure area. Appropriately cleaned and disinfected non-critical RMD can be stored in the Secondary RMD Storage Room, which must be stored in a manor to mitigate all risk of cross-contamination with sterile products.

c. Event-related sterility guidelines must be used in all VA medical facilities. The shelf life of a packaged, sterile item is event-related and depends on the quality of the packaging material, storage conditions, handling amount and conditions during transport.

d. Stored RMD must be rotated on a “first in, first out” basis (i.e., use oldest stored RMD first). Packages or containers must be visibly inspected for package integrity prior to distribution and use.

e. **Management of Reprocessed, Issued Reusable Medical Device that was Not Used.**

(1) Unused HLD or sterilized devices issued and maintained in a secured environment must be returned to either Primary or Secondary RMD Storage Rooms if the devices are protected from contamination with no evidence of compromise and returned within the same business day.

(2) Reusable items that have been opened, damaged or have been in an uncontrolled environment must be unwrapped and reprocessed beginning in decontamination.

(3) RMD stored on crash carts must be included in quality assurance (QA) audits to ensure package integrity.

6. REUSABLE MEDICAL DEVICES PROGRAM REQUIREMENTS

a. **Quality Management System.** A QMS Program must be in place to ensure appropriate and safe point-of-use cleaning, reprocessing, transport, storage and maintenance to identify process vulnerabilities before an adverse event occurs. RMD vulnerabilities must be reported to and reviewed by the VA medical facility RMD Committee and executive leadership team.

(1) The QMS Program must emphasize managing processes effectively, continuous improvement and using data and evidence to drive decisions.

(2) As part of a comprehensive QMS Program, quality assurance, control and performance measures must be documented and recorded in the Sterile Processing Accountability Tool (SPAT), maintained and reported to the VISN RMD Management Board for review. Use AAMI as a guide; however, minimally required VA medical facility processes are:

(a) Monitoring biological, mechanical and chemical indicators.

(b) Assessing HLD minimum effective concentrations.

(c) Preventing early release of implants.

(d) Verification testing for mechanical cleaning processes.

(e) Tracking RMD limited life cycles.

(f) Ensuring traceability of RMD.

(g) Monitoring preventative maintenance of all RMD and reprocessing equipment used in the service (e.g., sterilizers, washers, heat sealers).

(h) Monitoring expiration dates of all chemicals and expendables.

(i) Cleaning verification testing of every flexible, channeled endoscope.

(j) Avoiding and mitigating IUSS events.

(k) Monitoring chemical exposure (e.g., Ethylene Oxide).

(l) Validating case cart assembly, if applicable.

(m) Verifying instrument assembly and packaging.

(n) Monitoring temperature, humidity, airflow and air pressure in all SPS areas and RMD Storage Rooms. ***NOTE:*** *AAMI is available at https://dvagov.sharepoint.com/sites/NPOSP/SitePages/Supplemental-Guidance.aspx. This is an internal VA website that is not available to the public.*

b. **Standard Operating Procedures for Reusable Medical Device Reprocessing and Competency Validation.**

SOPs are not required for device performance or reprocessing when there is MIFU that provides clear guidance to SPS staff. The VA medical facility SPS Chief must develop SOPs when MIFU does not outline complete reprocessing steps. If no SOP exists, the competency is to be created from MIFU. Competency validation is required for all tasks before being performed independently.

(1) The frequency of SOP review is at least once every 5 years, as defined by VHA Directive 0999, VHA Policy Management, dated March 29, 2022.

(2) Each SOP must have a corresponding Competency Assessment Tool (CAT). In addition, any RMD that provides specific reprocessing MIFU must have a CAT (excluding MIFU for general stainless steel RMD). The CAT must be developed based on MIFU and can be combined with the SOP into one document.

(3) A variety of competency validation methods are used to measure the proficiency of an individual for a specific task. At least two of the following validation methods must be used to adequately assess competence: test, return demonstration, simulation, interview or observation. For RMD reprocessing tasks at least one validation method must be direct observation.

(4) The validator must have current competency for the task the employee is being validated for and must provide full signatures for a handwritten CAT. Electronic signatures (within an ITS or other electronic format) are acceptable when Personal Identity Verification card technology is utilized to verify authenticity of all signatures.

(5) The frequency of competency validation is defined by a RMD competency risk analysis.

(a) The VA medical facility RMD Committee performs risk analysis on all RMD in order to determine high-risk competencies that must be evaluated annually. All flexible, channeled endoscope competencies must be validated once a year at minimum.

(b) The analysis is based on, but not limited to, complexity of the device, reprocessing frequency and bioburden exposure during use.

(c) Validation is required for new employees; new devices; changes in any policies, standards or procedures; or when the employee demonstrates a need for additional education, training and competency validation. Competency renewal must follow VA accrediting agency guidance.

c. **Water Quality.**

(1) Water quality requirements within SPS are defined in AAMI. (https://dvagov.sharepoint.com/sites/NPOSP/Shared%20Documents/Forms/AAMI.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*). This guidance defines the parameters that must be monitored, outlines the frequency of quality testing and provides limits for the noted contaminants in utility water and critical water. All VA medical facilities must comply with this guidance for water quality limits.

(2) All critical water testing results for RMD reprocessing activities must be reported to the VA medical facility RMD Committee.

d. **Transport of Reusable Medical Devices.**

(1) VA medical facilities must ensure a process that is in alignment with regulations, standards and professional practice guidelines, as referenced in paragraph 10.d., for pickup and distribution of RMD.

(2) Pneumatic tube systems must not to be used to transport any RMD.

(3) Manufacturer carrying cases must not be used to store or transport HLD RMD (i.e., endoscopes, probes or dilators) within the VA medical facility and must not be used to transport any contaminated RMD.

e. **Loaned Reusable Medical Devices Reprocessing Management.**

(1) The service line intending to use the loaned RMD must place the order once the procedure is scheduled.

(2) All loaned RMD is considered non-sterile upon arrival to the VA medical facility; therefore, all loaned RMD must be delivered to SPS for reprocessing, with inventory sheets and MIFU provided by the vendor.

(3) Prior to reprocessing, all loaned RMD must be inventoried, inspected and recorded upon receipt and departure. SPS must obtain inventory sheets for trays, sets and implants from the vendor.

(4) Loaned RMD must be delivered to SPS a minimum of 2 business days prior to planned use for reprocessing. ***NOTE:*** *Exceptions exist for emergency procedures as determined by VA medical facility CoS and VA medical facility SPS Chief.*

f. **Biological Sterilization Monitoring.**

(1) A biological indicator (BI) must be run with every sterilizer load.

(2) An Early Implant Release Form (an example can be found in ANSI/AAMI) must be initiated by the using service representative if an implant must be released before the BI is read. The form must be approved with a signature by the VA medical facility CoS and received in SPS prior to the release. All early releases and load failures must be reported to the VA medical facility RMD Committee and reviewed for sustainable correction. A recall, as outlined by VA medical facility SOP, will be initiated if biological growth is evidenced.

g. **Reprocessing of Flexible Endoscopes and Reusable Accessories.** The maximum storage time for channeled endoscopes and dilators is 12 calendar days.

h. **Reprocessing of Intraocular Reusable Medical Devices.** Enzymatic detergents and products must not be used in any step when reprocessing intraocular RMD, per VHA Memorandum 2020-11-13, Review of Proposal for Enzymatic Cleansing of Intraocular Instruments, dated November 13, 2020, from the National Program Directors of VHA National Ophthalmology Service and the National Surgery Office.

i. **Sharing Agreements and Joint Ventures.**

(1) Reprocessing RMD is permitted at non-VA medical facilities that have executed contracts or a memorandum of understanding (MOU) for such services, to include QA measures.

(2) The contract or MOU must state the explicit understanding of the appropriate State laws, VHA policies, MIFU and standards outlined in paragraph 10.c.

7. RESTRICTIONS AND PROHIBITIONS

a. **Immediate-Use Steam Sterilization.**

(1) IUSS must only be performed by trained and competent SPS or OR staff.

(2) The VA medical facility RMD Committee must develop a contingency plan to support safe patient care and avoid case cancellation when instrument availability or sterility is compromised.

(3) IUSS measures must be reported once a month by the VA medical facility Surgery Service representative to the VA medical facility RMD Committee and the VA medical facility Infection Control Committee (see AAMI). The VA medical facility RMD Committee evaluates the IUSS report to determine the root cause and appropriate corrective action.

b. **Reusable Laparoscopic Devices.** Reusable laparoscopic devices must be designed to be fully disassembled in accordance with MIFU.

c. **Instruments Used in Research, Morgue and Laboratory.** Instruments used in non-human or cadaver research, morgue and laboratory must not be reprocessed by SPS. RMD used in human research must follow the clinical product review requirements in VHA Directive 1761, Supply Chain Management Operations, dated December 30, 2020. RMD intended for use in human research must be submitted through the to the Clinical Product Review Committee for approval as part of the research approval process.

d. **Home Health Equipment.** Home health equipment or other health equipment used outside the VA medical facility must not be reprocessed in SPS core areas.

e. **3D-Printed Devices.** Manufacturers are required to validate the complete RMD reprocessing cycle to ensure that a safe, quality, sterile or HLD device is produced. When VHA prints a 3D device that requires disinfection or sterilization, VHA becomes the manufacturer and must comply with 21 C.F.R. subchapter H. Sterilization process validation must be done by a third party in accordance with 21 C.F.R. subchapter H. Under no circumstances is VHA to be the validating entity of manufactured devices for reprocessing activities.

f. **Single Use Devices.** Single-use devices must not be reprocessed in VA medical facilities. ***NOTE:*** *VHA must not knowingly use critical or semi-critical reprocessed single use devices from third party vendors. Critical and semi-critical single use devices can be recycled only for the purpose of collecting raw materials but not for reuse.*

8. TRAINING

a. The following training is ***required***:

(1) **VHA Level 1 Training.** All VHA employees that perform decontamination, HLD or sterilization of RMD must complete VHA Level 1 Training through modules in the VHA Talent Management System (TMS) (VHA-174) prior to the employee finishing orientation.

(2) All OR staff that perform IUSS must complete TMS course VA34354: Immediate Use of Steam Sterilization for Staff Use.

(3) **VHA Sterile Processing Services Certification.** The VA medical facility SPS Chief, VA medical facility SPS Assistant Chief and SPS supervisory positions must obtain VHA SPS Certification within 1 year of appointment and annually maintain VHA SPS Certification by completing CEUs or obtain annual certification through a nationally recognized sterilization organization such as HSPA's Certified Registered Central Service Technician certification program or CBSPD. To be eligible for the VHA SPS Certification exam, 400 hours of hands-on reprocessing experience must be completed with an attestation by the employee's supervisor. The VHA SPS Certification is maintained with 12 CEUs annually. Preparation materials include but are not limited to the OSP SharePoint (https://dvagov.sharepoint.com/sites/NPOSP. ***NOTE:*** *This is an internal VA website that is not available to the public)* and Healthcare Sterile Processing Association available at https://myhspa.org/education/publications/.

(4) **Continuing Education.** All employees that perform RMD reprocessing must participate in a continuing education program with a minimum of 12 CEUs per year. A clear record of CEUs for each employee must be maintained by the VA medical facility Chief SPS.

b. The following training is ***recommended***: It is recommended that non-supervisory SPS staff obtain VHA SPS Certification.

9. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

10. BACKGROUND

a. Multiple professional disciplines use RMD across a spectrum of clinical services within VA medical facilities. For this reason, clear lines of responsibility and accountability must be established to ensure a standardized process for proper reprocessing and maintenance of RMD.

b. OSP is an organizational element within VHA under the Office of the Assistant Under Secretary for Health for Patient Care Services/CNO that establishes the authority for the operation of SPS within VA medical facilities and outlying clinics at VHA Central Office. Proper care and management of RMD within VA medical facilities is the responsibility of all employees. This necessitates accessibility, understanding and implementation of regulations, MIFU, standards and professional practice guidelines, as defined by VHA and this directive.

c. This VHA directive establishes oversight responsibilities to ensure proper point-of-use cleaning, reprocessing, transport, storage and maintenance of critical and semi-critical reusable medical devices. This directive also provides specific requirements for the organizational structure charged with oversight responsibilities for reprocessing specified RMD at VISN and VA medical facility levels to ensure requirements are met. SPS is a service line at every level within the organization. The primary responsibility of SPS is to provide oversight and reprocessing of critical and semi-critical RMD. SPS is not responsible for cleaning or disinfecting non-critical RMD.

d. RMD management practices are based on MIFU and standards set by ANSI/AAMI. Additional guidance that supports and enhances ANSI/AAMI standards is considered from other organizations, including the Association of Perioperative Registered Nurses (AORN), HSPA and Association for Professionals in Infection Control and Epidemiology (APIC).

11. DEFINITIONS

a. **Competency Assessment Tool.** A CAT is a document that generates a record of competency validation and is specific to each RMD. CAT is in a step-by-step format which allows the evaluator to follow the actions of the staff member when assessing competency. When MIFU offers appropriate but multiple steps in the process, CAT will delineate the appropriate steps for completing the task.

b. **Inventory Sheets.** Inventory sheets are a complete list of medical devices and are included in an RMD set.

c. **Limited Life Cycles.** Limited life cycles are defined by the device manufacturer and provide limitation to the reuse longevity of the device. This can be defined as a time frame, number of uses or number of reprocessing events until the device cannot be used any longer.

d. **Point-of-Use Cleaning.** Point-of-use cleaning is the process where RMDs receive initial decontamination and cleaning and steps are taken to prevent drying of blood, tissue, other biological debris and contaminants on the device.

e. **Reprocessing.** Reprocessing refers to all MIFU-compliant steps performed to make a contaminated item safe for patient care, including decontamination and HLD, or decontamination and sterilization.

f. **Reusable Medical Devices.** RMDs are devices that can be reprocessed and reused on multiple patients. RMDs can fall under one of three categories based on degree of risk of infection associated with the use of the device: critical, semi-critical or non-critical. For the purposes of this directive, RMD refers to critical and semi-critical RMD. Non-critical RMD will be specifically identified as such.

g. **Reusable Medical Device Management.** RMD management is all processes related to handling RMDs including point-of-use cleaning, reprocessing, maintenance, transportation and storage of all RMD, according to MIFU.

12. REFERENCES

a. 38 U.S.C. § 7301(b).

b. VHA Directive 0999, VHA Policy Management, dated March 29, 2022.

c. VHA Directive 1061(1), Prevention of Health Care-Associated Legionella Disease and Scald Injury from Water Systems, dated February 16, 2021.

d. VHA Directive 1608, Comprehensive Environment of Care Program, dated June 21, 2021

e. VHA Directive 1761, Supply Chain Management Operations, dated December 30, 2020.

f. VHA Memorandum 2020-11-13, Review of Proposal for Enzymatic Cleansing of Intraocular Instruments, dated November 13, 2020.

g. AAMI. https://dvagov.sharepoint.com/sites/NPOSP/Shared%20Documents/Forms/AAMI.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

h. HEFP SharePoint. https://dvagov.sharepoint.com/sites/VHA10NA5E/SitePages/Home.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

i. SPS. OSP SPS Staffing Tool.https://dvagov.sharepoint.com/:x:/r/sites/NPOSP/_layouts/15/doc2.aspx?sourcedoc=%7BCC69E3F6-4A8B-4419-9E09-A9800C5D1A0C%7D&file=OSP%20SPS%20Staffing%20Tool%20%20v5.6.xlsm&actio

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NOTE: *This is an internal VA website that is not available to the public.*

j. OSP. Supplemental Guidance. https://dvagov.sharepoint.com/sites/NPOSP/SitePages/Supplemental-Guidance.aspx.
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k. VA. HVAC Design Manual. https://www.cfm.va.gov/til/dManual/dmHVAC.pdf.

l. VA. Sterile Processing Service and Logistics Service Design Guide. 2015. https://www.cfm.va.gov/til/dGuide/dgSPS-Log.pdf.

m. International Association of Healthcare Central Service Material Management (IAHCSMM). Central Service Leadership Manual. https://myhspa.org/education/publications/.

n. IAHCSMM. Central Service Technical Manual. https://myhspa.org/education/publications/.