Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1108.12
Transmittal Sheet
November 5, 2018

MANAGEMENT AND MONITORING OF PHARMACEUTICAL COMPOUNDED STERILE PREPARATIONS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes national policy regarding outsourcing and in-house preparation of pharmaceutical compounded sterile preparations (CSPs) at Veterans Affairs (VA) medical facilities and establishes requirements for compliance with the standards of the United States Pharmacopeia Chapters 797 and 800 (USP <797> and USP <800>) on "Pharmaceutical Compounding – Sterile Preparations" and "Hazardous Drugs – Handling in Healthcare Settings" respectively. Since 2004, published standards and best practices have evolved and become more complex, with increased involvement of regulatory agencies such as the Food and Drug Administration (FDA) and accrediting organizations such as The Joint Commission.

2. SUMMARY OF CONTENT: This new directive outlines management and oversight requirements and organizational responsibilities for USP <797> and USP <800> cleanroom design and engineering controls, environmental monitoring and cleaning, policy/procedures/requirements and core competencies for personnel involved in hazardous and non-hazardous CSPs. This directive establishes robust oversight provisions at the Veterans Integrated Service Network (VISN) and VA medical facility levels that support monitoring programs, advisory committees, safety and quality assurance programs, occupational hazards assessment, and medical surveillance programs.

3. RELATED ISSUES: VHA Directive 1108.06, Inpatient Pharmacy Services, dated February 8, 2017, and VHA Directive 7702, Industrial Hygiene Exposure Assessment Program, dated April 29, 2016.

4. RESPONSIBLE OFFICE: The Chief Consultant, Pharmacy Benefits Management (PBM) Services (10P4P) in the Office of Patient Care Services, is responsible for the content of this directive. Questions may be referred to PBM Action group at: VHA10P4PAction@va.gov.

5. RESCISSIONS: None.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of November 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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Executive in Charge

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 Publication Distribution List on November 8, 2018.

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MANAGEMENT AND MONITORING OF PHARMACEUTICAL COMPOUNDED STERILE PREPARATIONS

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1. PURPOSE

This Veterans Health Administration (VHA) directive establishes a national policy for the preparation of compounded sterile preparations (CSPs) in Veterans Affairs (VA) medical facilities. In addition, it provides policy to ensure VA medical facilities follow a decision-making hierarchy when outsourcing the compounding of sterile preparations, including a risk versus benefit analysis and a careful assessment of any outsourced vendor selected to compound CSPs (see Appendix B). **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b).

2. BACKGROUND

a. The process of compounding sterile preparations consists of combining or manipulating commercially-available sterile drug products to make a final sterile drug formulation to meet customized patient needs and minimizing the risk of adverse events. In addition, the compounding process includes safe storage, handling, and transportation of the CSPs to meet patient-specific needs, as well as the process for ensuring a safe and clean environment exists for the preparation of CSPs.

b. VHA Directive 1108.06, Inpatient Pharmacy Services, dated February 8, 2017, requires VA facilities to comply with federal laws and regulations pertaining to compounded sterile preparations (e.g., Drug Quality and Security Act), as well as the Standards of United States Pharmacopeia (USP) <797> and USP <800>. Pursuant to the Federal Food, Drug, and Cosmetic Act (FD&C) (21 USC 353a, Section 503A, Pharmacy Compounding) VA pharmacies are classified as 503A facilities.

c. USP <797> standards apply to all persons who prepare CSPs and to all locations where CSPs are prepared, stored and transported. USP <800> standards describe practice and quality specifications for the handling of sterile and non-sterile hazardous drugs (HDs) to promote patient safety, worker safety, and environmental protection. Handling HDs includes, but is not limited to, the receipt, storage, compounding, dispensing, administration and disposal of sterile and nonsterile products and preparations. USP standards also detail the requirements for cleanroom environments and related primary engineering controls (PECs) used to prepare CSPs where CSPs (both hazardous and non-hazardous) are prepared, personnel competency, as well as ensuring that CSPs meet standards of purity, quality, potency, stability, sterility and strength. Only pharmacy personnel that meet CSP core competencies are to compound/prepare CSPs.

d. This directive defines organizational responsibility for USP <797> and USP <800> standards for cleanroom design and engineering controls, environmental monitoring and cleaning of primary and secondary engineering controls, and the core competencies for personnel involved in the processes of compounding sterile preparations including HDs (both sterile and nonsterile dosage form preparations).

3. DEFINITIONS

a. **Ante Area.** An ante area is an International Organization for Standardization (ISO) Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate-generating activities are performed. It is also a transition area that (1) provides assurance that air pressure relationships are constantly maintained so that air flows from clean to dirty areas and (2) reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.

b. **Assessment of Risk.** An Assessment of Risk is the evaluation of risk to determine alternative containment strategies and or work practices.

c. **Buffer Area.** A buffer area is an ISO Class 7 or cleaner area where the Primary Engineering Control (PEC) that generates and maintains an ISO Class 5 environment is physically located.

d. **Biological Safety Cabinet.** A Biological Safety Cabinet (BSC) is a ventilated cabinet used for preparation of hazardous CSPs for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. A BSC is an example of a Containment Primary Engineering Control (C-PEC).

e. **Cleanroom.** A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

f. **Compounding Aseptic Isolator.** A Compounding Aseptic Isolator (CAI) is a form of isolator referred to as a Primary Engineering Control (PEC) specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes by maintaining positive air pressure inside the CAI relative to the outside ("positive pressure") during the compounding process. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum). CAIs cannot be used for the preparation of hazardous drugs. ***NOTE:*** *CAIs are categorically known as Restricted-access barrier systems (RABS) and are not isolators. Please see definition for RABS*.

g. **Compounding Aseptic Containment Isolator.** A Compounding Aseptic Containment Isolator (CACI) is a form of isolator referred to as a Containment Primary Engineering Control (C-PEC) designed to provide worker protection from exposure to undesirable levels of airborne drugs throughout the compounding and material transfer processes and to provide an aseptic environment for sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through

a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly-designed external building ventilation. ***NOTE:*** *CAIs are categorically known as RABS and are not isolators. Please see definition for RABS.*

h. **Compounded Sterile Preparation.** A Compounded Sterile Preparation (CSP) is a preparation intended to be sterile that is created by combining, diluting, pooling, or otherwise altering a drug product or bulk drug substance. A product produced by reconstituting a conventionally manufactured product for an individual patient strictly in accordance with the directions contained in the approved labeling provided by the product manufacturer is not considered a CSP within the standards of USP <797>.

i. **Containment Primary Engineering Control.** A Containment Primary Engineering Control (C-PEC) is a type of Primary Engineering Control (PEC) that is a ventilated device designed and operated to minimize worker environmental exposures to hazardous drugs by controlling emissions of airborne contamination. Also refer to the definitions on Biological Safety Cabinet, Compounding Aseptic Containment Isolator and Primary Engineering Control.

j. **Controlled Environment Testing Association Application Guide.** Controlled Environment Testing Association (CETA) Controlled Application Guide (CAG) standards define certification procedures to assess the primary engineering control (PEC) if it is performing and operating as designed to maintain a sterile environment for the preparation of CSPs. USP <797> and USP <800> standards make specified CETA CAG guidelines enforceable by inclusion.

k. **Critical Site.** A critical site is a location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g. opened ampules, needle hubs) exposed and at risk of direct contact with air (e.g. ambient room or HEPA filtered), moisture (e.g. oral and mucosal secretions), or touch contamination. The risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time. As such PECs and C-PECs provide unidirectional (laminar) HEPA-filtered air at a velocity sufficient to prevent airborne particles from contacting critical sites.

l. **Hazardous Drug.** A hazardous drug (HD) is any drug identified by at least one of the following six-criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or newly approved drugs that mimic existing hazardous drugs in structure or toxicity.

m. **High-efficiency Particulate Air (HEPA) Filtration.** An extended-medium, dry-type filter in a rigid frame, having a minimum particle collection efficiency of 99.97% for particles with a mass median diameter of 0.3 micrometers when tested at a rated airflow in accordance with Military Standard (MIL STD) 282 using Institute of Environmental Sciences and Technology (IEST) Recommended Standard RP-CC0001.5.

n. **International Organization for Standardization Class.** An ISO class is an air quality classification of the ISO.

o. **Isolator.** An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. ***NOTE:*** *CAIs and CACIs are not categorically isolators*.

p. **Microbial Contamination.** Microbial contamination is the presence of microorganisms in or on an item.

q. **Laminar Airflow Workstation.** A Laminar Airflow Workstation (LAFW), also known as a Laminar Air Flow Hood or Laminar Flow Clean Bench, is a device that is a type of Laminar Airflow System (LAFS) that provides an ISO Class 5 or better environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow. A LAFW may be either horizontal or vertically oriented. Use of these devices is recommended for the non-hazardous cleanrooms. These devices can be 100 percent re-circulatory type.

r. **Primary Engineering Control.** A Primary Engineering Control (PEC) is a device that provides an ISO Class 5 environment for the exposure of critical sites when compounding hazardous and non-hazardous CSPs. Such devices include C-PECs (Class II BSCs and CACIs) for hazardous CSPs and PECs (LAFWs and CAIs) for non-hazardous CSPs.

s. **Quality Assurance.** Quality Assurance (QA) is a system of procedures, activities, and oversight that ensures that operational and quality standards are consistently met.

t. **Restricted-access Barrier System.** Restricted-access Barrier System (RABS) is an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.

u. **Secondary Engineering Control.** A Secondary Engineering Control (SEC) is an area such as a buffer area and ante area which generally serve as a core for the location of the PEC.

v. **Standard Operating Procedure.** A Standard Operating Procedure (SOP) is a written procedure describing operations, testing, sampling and interpretation of results, and corrective actions that relates to the operations that are taking place.

w. **Unidirectional Air.** Unidirectional air is an airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical site.

***NOTE*:** *For definitions of other relevant terms please see USP <797> and <800>.*

4. POLICY

It is VHA policy that each VA medical facility that provides CSPs have a pharmaceutical CSP program in place that conforms to the standards in USP Chapter <797> "Pharmaceutical Compounding-Sterile Compounding" and USP <800> "Hazardous Drugs – Handling in Healthcare Settings."

5. RESPONSIBILITIES

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

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management (DUSHOM) is responsible for:

(1) Ensuring each Veterans Integrated Service Network (VISN) has a process in place to assess and monitor VA facilities' compliance with USP <797> and USP <800> standards for the handling of CSPs.

(2) Ensuring a process is in place for each VISN to report when VA facilities experience issues that impact the ability to be compliant with USP <797> and USP <800> cleanroom design, environmental controls and monitoring, core competencies of the personnel involved in the handling of CSPs and any other issues pertinent to CSPs.

(3) Establishing a multidisciplinary National CSP Advisory Committee comprised of USP <797> and USP <800> subject matter experts. This Committee will provide consultative services to VISN and VA facility leadership in cleanroom design, environmental controls and monitoring, and core competencies. The committee membership shall by chaired by the VHA Office of Quality, Safety, and Value and at a minimum include representatives from Pharmacy Benefits Management (PBM) Services, Office of Capital Asset Management, Engineering and Support (OCAMES), Occupational Safety, Health, and Green Environmental Management Systems (GEMS), and Infection and Prevention Control Services. The National CSP Advisory Committee will review and provide consultative recommendations based on VISN Advisory Committee reports.

c. **Chief Consultant, Pharmacy Benefits Management Services.** The Chief Consultant, Pharmacy Benefits Management Services (PBM) is responsible for:

(1) Providing policy and guidance on USP <797> and USP <800> standards for the management and monitoring of pharmaceutical CSPs to VA medical facilities.

(2) Ensuring PBM subject matter experts with a focus on cleanroom operations participate in the National CSP Advisory Committee.

d. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Ensuring the VISN has a process in place to bi-annually assess and monitor VA facilities compliance with USP <797> and USP <800> standards for the handling of CSPs.

(2) Establishing a multidisciplinary VISN CSP Advisory Committee that includes USP <797> and USP <800> subject matter experts capable of providing consultative services to VISN and VA facility leadership in cleanroom design, environmental controls and monitoring, and core competencies. The committee membership shall be chaired by a member of the VISN executive leadership team and co-chaired by the VISN Pharmacist Executive and at a minimum include: the VISN Quality Manager, Biomedical/Engineering/Facilities Management Services, Occupational Safety, Health, and Green Environmental Management Systems (GEMS) and Infection Prevention and Control Services.

(3) Ensuring that the VISN CSP Advisory Committee reports issues impacting CSP processes at the VA facilities using the process established by the DUSHOM. The VISN CSP Advisory Committee is responsible for ensuring the VA facility corrective action plan is consistent with USP <797> and USP <800> standards with appropriate milestones and target dates.

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

(1) Ensuring the VA facility has a policy and processes in place to assess and monitor compliance with USP <797> and USP<800> standards for the handling of CSPs including cleanroom design, environmental controls and monitors, and core competencies of personnel involved in CSP processes.

(2) Establishing a multidisciplinary VA Facility CSP Advisory Committee. The committee shall be chaired by a member of the VA facility executive leadership team (i.e., Quadrad) and at a minimum include the Chief of Pharmacy, Quality Manager, Biomedical/Engineering/Facilities Management Services, Occupational Safety, Health, and Green Environmental Management Systems (GEMS), and Infection Prevention and Control Services or equivalent positions. The committee shall meet on a quarterly basis with an emphasis on environmental controls and monitoring results and to ensure all staff has the core competencies necessary for handling CSPs.

(3) Ensuring that the VA Facility CSP Advisory Committee reports issues impacting CSP processes at the VA facilities to the VISN using processes established by the VISN. The VA Facility CSP Advisory Committee is responsible for ensuring compliance with all VHA Directives and TJC standards. Any VA facility corrective action plans needed will be consistent with USP <797> and USP <800> standards with appropriate milestones and target dates.

(4) Ensuring that the VA Facility CSP Advisory Committee provides a quarterly report on USP <797> and USP <800> compliance to the facility medical executive

committee (MEC) and Quadrad. The quarterly report must identify, and facilitate formal investigations for, any substandard environments that may prohibit the preparation of CSPs or warrant corrective actions due to failures in microbial monitoring parameters.

(5) Ensuring the Pharmacy Department has a designated CSP Pharmacist as required in USP <800> to provide oversight of the Pharmacy Department's cleanroom compliance with USP <797> and USP <800> standards.

f. **Facility Chief of Pharmacy Service.** The facility Chief of Pharmacy Service is responsible for:

(1) Designating a full-time CSP pharmacist who is responsible for oversight of USP compliance in the Pharmacy Department with USP <797>, USP <800>, The Joint Commission Standards, FDA requirements and VHA policies related to CSPs. ***NOTE:*** *The CSP pharmacist duties cannot be assigned as collateral duties.*

(2) Ensuring that appropriate policies and procedures are in place to support full compliance with all USP <797>, USP <800>, The Joint Commission standards, and VHA policies related to CSPs.

(3) Developing a written contingency plan that may be activated to obtain CSPs from an alternative source in situations where CSP preparations at the facility need to be suspended because of non-compliance with relevant standards.

(4) Collaborating with the facility Chief of FMS, Engineering and/or Biomedical Engineering Staff to ensure the contingency plan includes the assessment of an alternative site in the VA medical facility for the preparation of CSPs, if the cleanroom is not compliant with USP <797> and USP <800> standards.

(5) Ensuring HDs that are transported, stored, and handled by other health care professionals are appropriately labeled to alert staff to handle the HDs as required by USP <800>.

(6) Considering the feasibility of employing a CSP pharmacist with a Board of Pharmacy Specialties (BPS) CSP certification as a preferred specialty qualification.

(7) Considering the feasibility of employing pharmacy technicians with a Pharmacy Technician Certification Board (PTCB) certification in Compounded Sterile Preparation Technician (CSPT) or equivalent as a preferred specialty qualification.

g. **Compounded Sterile Preparations Pharmacist.** A Clinical Pharmacist (CP), Clinical Pharmacist Specialist (CPS), Pharmacy Program Manager or Supervisory Pharmacist assigned by the facility Chief of Pharmacy Service is responsible for:

(1) Ensuring that the decision to outsource CSP prescriptions or to prepare CSPs in the medical facility pharmacy follows the VHA PBM decision-making hierarchy and associated guidance. ***NOTE:*** *See Appendix B for a list of available guidance documents.*

(2) Ensuring the pharmacy service has written procedures for compliance with the USP <797> and USP <800> standards.

(3) Ensuring the competency of Pharmacy personnel in the preparation and handling of CSPs as required by USP <797> and USP <800>. ***NOTE:*** *Please see tools provided in Appendix A.*

(4) Maintaining environmental control of the sterile compounding areas, including:

(a) Collaborating with Biomedical/Engineering/Facilities Management Services to ensure that Primary Engineering Controls (PEC) and Secondary Engineering Controls (SEC) are certified in accordance with USP <797> and USP <800> standards. The VA medical facility CSP Advisory Committee will review the results of the certification report to determine a corrective action plan if needed. ***NOTE:*** Please see Appendix B "*Guidance for Defining, Certifying and Procuring Primary Engineering Controls for Compounded Sterile Preparations*."

(b) Collaborating with the facility Quality Manager and the Chief, Infection Prevention and Control to develop a formal written CSP Safety and Quality Assurance (QA) Plan in accordance with USP <797> standards.

(c) Ensuring the VA medical facility's hazardous drug list is reviewed and updated annually.

h. **Facility Nurse Executive.** The facility Nurse Executive is responsible for:

(1) Ensuring that policy and procedures are in place and that nursing personnel adhere to appropriate preparation, handling, administration, storage and disposal requirements for CSPs including hazardous drugs, in accordance with USP <797> and USP <800> standards.

(2) Ensuring the competency of nursing personnel in the handling and administration of CSPs.

i. **Facility Quality Management Coordinator.** The facility Quality Management Coordinator is responsible for:

(1) Providing facility oversight to ensure policies and procedures are in place to support full compliance with all regulations and policies relating to CSPs.

(2) Ensuring the facility has a written contingency plan, developed by the Chief of Pharmacy Service that can be activated to obtain CSPs from an alternative source in situations where facility CSP preparations need to be suspended due to non-compliance with relevant standards.

(3) Consulting with the Chief of Pharmacy Service to establish and maintain a formal written QA plan that defines a process for monitoring, evaluating, correcting and improving CSP activities and processes as described in USP <797> and USP <800>.

j. **Manager, Occupational Safety and Health Service.** The facility Manager, Occupational Safety and Health Service is responsible for:

(1) Anticipating, evaluating exposures, and recommending controls for occupational safety and health exposures in accordance with VHA Directive 7702, Industrial Hygiene Exposure Assessment Program, dated April 29, 2016.

(2) Collaborating with the CSP Pharmacist, and/or appropriate workplace supervisor(s) for alternative containment strategies, personal protective equipment, and/or work practices and alternative dosage forms.

(3) Collaborating with the CSP Pharmacist if an Assessment of Risk approach is taken and an alternative containment strategy or work practice to minimize exposure is employed. If an Assessment of Risk approach or an alternative containment strategy is utilized, they must be reviewed and documented every 12 months.

k. **Employee Occupational Health Manager.** The facility Employee Occupational Health (EOH) Manager is responsible for:

(1) Enrolling employees having potential exposure to hazardous drugs and identified by the Assessment of Risk, exposure and containment assessments into the VA medical facility's Medical Surveillance Program. The enrollment and monitoring of employees in the Medical Surveillance Program shall be done in collaboration with the supervisors of the employees.

(2) Providing occupational health and medical management advice, when appropriate, to identify and recommend intervention strategies for assessed or potential exposures to HDs.

(3) Acting as a consultant to the Pharmacy Service and Occupational Safety and Health Service in the development of employee competency on the clinical aspects of potential exposure to HDs.

(4) Providing analysis of aggregate data (individual and population based), in coordination with Occupational Safety and Health, from the Medical Surveillance Program to assess the effectiveness of workplace controls.

l. **Facility Chief of Facility Management Service, Engineering and/or Biomedical Engineering Staff.** The facility Chief of Facility Management Service (FMS), Engineering and/or Biomedical Engineering Staff is responsible for:

(1) Ensuring that USP <797> and USP <800>standards are incorporated in pharmacy cleanroom design, installation, renovation, or other construction projects and that the ISO-certified areas are installed in accordance with manufacturer specifications and Federal, and state regulations.

(2) Ensuring that cleanroom primary and secondary engineering controls are installed and maintained in compliance with USP <797> and USP <800> standards

through third party testing and certification. ***NOTE:*** *USP <797> implies Controlled Environment Testing Association (CETA) Controlled Applications Guides (CAGs) "or equivalent" may be used. CETA CAGs define certification procedures to assess the PEC is performing and operating as designed to maintain a sterile environment for the preparation of CSPs. Via this Directive, VA is adopting CETA CAGs as the mandatory standard;* ***no "equivalent" standards may be used.*** *All vendors used to conduct primary and secondary engineering controls certifications/assessments must be registered with CETA. See Appendix B "Guidance for Defining, Certifying and Procuring Primary Engineering Controls for Compounded Sterile Preparations."*

(3) Coordinating with the CSP Pharmacist to ensure engineering related corrective actions associated with cleanroom environmental controls are taken.

(4) Establishing and maintaining a preventive maintenance program for engineering control systems to ensure the systems and controls operate as designed.

m. **Facility Green Environmental Management Systems Manager.** The facility Green Environmental Management Systems (GEMS) Manager is responsible for:

(1) Ensuring that Pharmacy CSP waste processes are in compliance with applicable Federal requirements (Environmental Protection Agency, VA or other Federal agencies) and, if applicable, state standards.

(2) Consulting with Pharmacy on regulatory changes to waste regulations and facility permit requirements and how they affect the processes in the pharmacy.

n. **Facility Chief of Environmental Management Services.** The facility Chief of Environmental Management Services (EMS) is responsible for:

(1) Ensuring appropriate cleaning and management of the physical infrastructure in the pharmacy service cleanrooms and CSP preparation areas is performed no less frequently than once per day, at a time of day that does not interrupt pharmacy operations, that Standard Operating Procedures are developed and communicated to EMS staff, and that compliance is regularly and continuously monitored.

(2) Ensuring that EMS personnel have the proper competencies on cleanroom sterilization and disinfection standards and, that they are documented in the personnel folder in a readily retrievable manner for auditing purposes. ***NOTE:*** *See Appendix C "Assessment Tools on Environmental Protection Services (EPS) Competency and Cleaning Log for Compounding Sterile Preparations Pharmacy and EPS Staff."*

(3) Ensuring that EMS personnel complete daily logs documenting the cleaning products used for cleaning floors, walls and ceilings in the pharmacy cleanrooms and the time of day cleaning was performed.

(4) Ensuring that EMS has a contingency plan to provide back-up cleaning personnel in cases where regularly scheduled personnel are not available.

6. TRAINING

It is expected and required that individuals identified under section 5 of this directive (Responsibilities) will ensure appropriate education and training is conducted to carry out the full range of their responsibilities.

7. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created in response to this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule (RCS) 101. If you have any question to the regarding any aspect of records management, you should contact your facility Records Manager or your Records Liaison. See also VHA Directive 6300, Records Management, dated October 22, 2018.

8. REFERENCES

a. VHA Directive 1108.06, Inpatient Pharmacy Services, dated February 8, 2017.

b. VHA Directive 6300, Records Management, dated October 22, 2018.

c. VHA Directive 7701, Comprehensive Occupational Safety and Health (OSH), dated May 5, 2017.

d. VHA Directive, 7702, Industrial Hygiene Exposure Assessment Program, dated April 29, 2016.

e. Employee Occupational Health Guidebook, VHA Center for Engineering & Occupational Safety and Health (CEOSH), available at: http://vaww.ceosh.med.va.gov/01HP/02HP_Guidebooks/03_Collections/04HP_OccupationalHealth/EOH.pdf. ***NOTE:*** *This is an internal VA Web site and is not available to the public.*

f. General Safety Guidebook, VHA Center for Engineering & Occupational Safety and Health (CEOSH), available at: http://vaww.ceosh.med.va.gov/01IH/Pages/SIH_Pharmacy_Safety.shtml. ***NOTE:*** *This is an internal VA Web site and is not available to the public.*

g. Industrial Hygiene Guidebook, Chapter 11.1 Hazardous Drugs, VHA Center for Engineering & Occupational Safety and Health (CEOSH), available at: http://vaww.ceosh.med.va.gov/01HP/02HP_Guidebooks/03_Collections/04HP_Industrialhygiene/2012IHPF.pdf. ***NOTE:*** *This is an internal VA Web site and is not available to the public.*

h. VHA Pharmacy Benefits Management Services, Pharmacy Staff Core Competency: Preparation and Handling of Compounded Sterile Preparations, 2015, available at: https://vaww.cmopnational.va.gov/cmop/PBM/USP%20797%20PBM%20Compounded

%20Sterile%20Preparations%20Workgr/USP%20797%20References/PBM%20ALL%20Pharmacy%20Staff%20Compounded%20Sterile%20Preparations%20Competency%20March%202015.pdf. ***NOTE:*** *This is an internal VA Web site and is not available to the public.*

i. American Society of Health-System Pharmacists. ASHP Guidelines on Compounding Sterile Preparations, *American Journal of Health System Pharmacists* 2014; 71: 145 – 66.

j. Buchanan EC, Schneider PJ, Forrey RA, eds. Compounding Sterile Preparations. 4th ed. Bethesda, MD: *American Society of Health-System Pharmacists*; 2017.

k. Controlled Environment Testing Association (CETA). CETA Certification Guide for sterile compounding facilities (CAG-003-2006). Raleigh, NC: CETA; 2015 available at: https://vaww.cmopnational.va.gov/cmop/PBM/USP%20797%20PBM%20Compounded%20Sterile%20Preparations%20Workgr/VHA%20PBM%20CSP%20GUIDANCE%20DOCUMENTS/CETA-CAG-003-2006v13May2015.pdf. ***NOTE:*** *This is an internal VA Web site and is not available to the public.*

l. Subramaniam V, Coggins P, Dang C, Vargas J. USP 797 Monitoring Guidelines: Standards for Pharmacy Practice; *Pharmacy Practice News*, 2011:38(4).

m. Subramaniam V, Coggins P, Wilkes V, Sehgal S, Dhokai M. Design Alert - Pharmacy Design Guidance – Update on compliance with USP <797> Standards. VHA Pharmacy Benefits Management Services and VA Office of Construction and Facilities Management: May 2008.

n. United States Pharmacopoeia Convention. Hazardous Drugs – Handling in Healthcare Settings, (General Information Chapter <800>). In the United States Pharmacopoeia, 39th rev., and the National Formulary, 34th ed. Rockville, MD: 2016.

o. United States Pharmacopoeia Convention. Pharmaceutical Compounding - Sterile Preparations, (General Information Chapter <797>). In the United States Pharmacopoeia, 36th rev., and the National Formulary, 31st ed. Rockville, MD: 2013.

PHARMACY STAFF COMPETENCY ASSESSMENT TOOLS FOR COMPOUNDING STERILE PREPARATIONS

VHA Pharmacy Benefits Management (PBM) Services Intranet has a Document Library of tools for assessing pharmacy staff competency in the preparation and handling of compounded sterile preparations (CSPs) in compliance with USP <797> requirements, available at: https://vaww.cmopnational.va.gov/cmop/PBM/USP%20797%20PBM%20Compounded%20Sterile%20Preparations%20Workgr/Forms/AllItems.aspx?RootFolder=%2Fcmop%2FPBM%2FUSP%20797%20PBM%20Compounded%20Sterile%20Preparations%20Workgr%2FCompetency%20Assessment%20Tools%5FCompounded%20Sterile%20Preparations&FolderCTID=0x012000A1FFDA56FB56014C846F3D75E71A41CE&View=%7b4B777D91-AEA7-490F-A389-5A1B7716DA69%7d. ***NOTE:*** *This is an internal VA Web site and is not available to the public.*

GUIDANCE DOCUMENTS FOR OUTSOURCING OF COMPOUNDED STERILE PRODUCTS

a. Veterans Health Administration (VHA) Pharmacy Benefits Management (PBM) Services Intranet has a Document Library of guidance document for compounded sterile preparations (CSPs) available at: https://vaww.cmopnational.va.gov/cmop/PBM/USP%20797%20PBM%20Compounded%20Sterile%20Preparations%20Workgr/Forms/AllItems.aspx?RootFolder=%2Fcmop%2FPBM%2FUSP%20797%20PBM%20Compounded%20Sterile%20Preparations%20Workgr%2FVHA%20PBM%20CSP%20GUIDANCE%20DOCUMENTS&FolderCTID=0x012000A1FFDA56FB56014C846F3D75E71A41CE&View=%7b4B777D91-AEA7-490F-A389-5A1B7716DA69%7d&InitialTabId=Ribbon%2EDocument&VisibilityContext=WSSTabPersistence. ***NOTE:*** *This is an internal VA Web site and is not available to the public.*

b. The following guidance documents may be accessed via the link provided above:

(1) **Compounded Sterile Preparations Guidance Flow Chart Diagram.** Hierarchy flow chart for making decisions on Compounded Sterile Preparations (CSPs) outsourcing vs. production at VA medical facilities.

(2) **VHA PBM Assessment Guide for Compounded Sterile Preparations within VA Medical Facilities and Outsourced Compounding Pharmacies.** This tool lists standards for outsourced compounding pharmacies versus VA medical facility compounding pharmacies, including: regulatory requirements; CSP pharmaceutical quality standards; CSP microbial contamination risk levels for compliance with USP <797> Standards; personnel competencies; and environmental quality and controls.

(3) **VHA Pharmacy Benefits Management Services Guidance for Compounded Sterile Preparations.** This is a detailed guidance document with background, designated responsibilities and references.

(4) **Guidance for Defining, Certifying and Procuring Primary Engineering Controls for Compounded Sterile Preparations.** Primary Engineering Controls (PECs) create a “state of control” that ensures a sterile International Organization for Standardization Class 5 (ISO Class 5) environment with unidirectional airflow for VA Pharmacy staff to prepare CSPs. This document provides guidance for defining, certifying and procuring PECs.

ASSESSMENT TOOLS ON ENVIRONMENTAL PROTECTION SERVICES (EPS) COMPETENCY AND CLEANING LOG FOR COMPOUNDING STERILE PREPARATIONS PHARMACY AND EPS STAFF

To ensure Environmental Management Services (EMS) personnel have the proper competencies on cleanroom sterilization and disinfection standards the following assessment tools on Environmental Protection Services (EPS) competency and cleaning log for Compounding Sterile Preparations Pharmacy and EPS Staff can be found within the internal '*USP 800: Safe Handling of Hazardous Drugs'* SharePoint site, under the '*USP 800 Training Library,' available at:* https://vaww.vashare.vha.va.gov/sites/CEOSH/HazardousDrugs/USP%20800%20Training%20Library/Forms/AllItems.aspx. ***NOTE:*** *This is an internal VA Web site and is not available to the public.*