

## MANAGEMENT AND MONITORING OF PHARMACEUTICAL COMPOUNDED PREPARATIONS

### 1. SUMMARY OF MAJOR CHANGES: Major changes include:

a. Updates the policy statement to include language that specifies the conditions under which compounding processes should be completed in paragraph 1.

b. Updates responsibilities in paragraph 2 for the Assistant Under Secretary for Patient Care Services/Chief Nursing Officer, the Assistant Under Secretary for Health for Operations, the Chair of the VHA National Pharmacy Compounding Advisory committee, Veterans Integrated Service Network Director, Chair of the VISN Pharmacy Compounding Advisory Committee, VA medical facility Director, the Facility Compounding Advisory Committee Chair, the VA medical facility Chief of Pharmacy Service, the VA medical facility Designated Compounding Pharmacist, the VA medical facility Nurse Executive, the VA medical facility Chief of Engineering and the VA medical facility Chief of Environmental Management Services (EMS).

c. Includes responsibilities for the Assistant Under Secretary for Health for Support Services, Assistant Undersecretary for Health for Quality and Patient Safety and Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer.

d. Updates the roles for committee leadership and committee names in paragraphs 2.h., 2.k. and 2.m.

e. Clarifies and reinforces the conditions under which compounding can take place at VA pharmacies in paragraph 1, paragraph 2.n.9., and paragraph 3.

f. Updates the background in paragraph 8.

g. Includes definitions for classified area, release inspection and testing and unclassified space in paragraph 9.f., 9.r. and 9.x.

h. Includes Appendix B, Additional Resources.

**2. RELATED ISSUES:** VHA Directive 1148, Allergen Therapy and Allergen Immunotherapy Clinics, dated June 28, 2022; VHA Directive 1850.05 Interior Design Operations and Management Program, dated September 22, 2017; VHA Directive 7702, Industrial Hygiene Exposure Assessment Program, dated July 29, 2021; and VHA Directive 7707, VHA Green Environmental Management System (GEMS) & Governing Environmental Policy Statement, dated April 1, 2021.

**3. POLICY OWNER:** The Executive Director, Pharmacy Benefits Management (12PBM) Services in the Office of Patient Care Services, is responsible for the content of this directive. Questions may be referred to VHA Pharmacy Benefit Management National Compounding Advisory Committee at: [VHAPBMUSP797Committee@va.gov](mailto:VHAPBMUSP797Committee@va.gov).

**FEBRUARY 14, 2024**

**VHA DIRECTIVE 1108.12**

**4. RESCISSIONS:** VHA Directive 1108.12, Management and Monitoring of Pharmaceutical Compounded Preparations, November 5, 2018.

**5. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of February 2029. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**6. IMPLEMENTATION SCHEDULE:** This directive is effective upon publication.

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

/s/ M. Christopher Saslo,  
DNS, APRN-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 Publication Distribution List on February 14, 2024.

**CONTENTS**

**MANAGEMENT AND MONITORING OF PHARMACEUTICAL COMPOUNDED PREPARATIONS**

1. POLICY .....1

2. RESPONSIBILITIES .....1

3. STERILE COMPOUNDING .....12

4. NON-STERILE COMPOUNDING.....15

5. OUTSOURCING COMPOUNDED PREPARATIONS.....15

6. TRAINING .....16

7. RECORDS MANAGEMENT .....16

8. BACKGROUND.....16

9. DEFINITIONS .....17

10. REFERENCES .....19

APPENDIX A

DEFINING, CERTIFYING AND PROCURING PRIMARY ENGINEERING CONTROLS FOR COMPOUNDED STERILE PREPARATIONS .....A-1

APPENDIX B

ADDITIONAL RESOURCES.....B-1

## MANAGEMENT AND MONITORING OF PHARMACEUTICAL COMPOUNDED PREPARATION

### 1. POLICY

It is Veterans Health Administration (VHA) policy that each Department of Veterans Affairs (VA) medical facility providing compounded preparations have a pharmaceutical compounding program in place for compounding sterile and non-sterile preparations and handling hazardous drugs in health care and clinical research settings established in the United States Pharmacopeia (USP). **NOTE:** VHA does not prepare compounded preparations that require sterility and stability testing. **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 is responsible for:

(1) Supporting Pharmacy Benefits Management (PBM) with implementation and oversight of this directive.

(2) Ensuring that PBM is appropriately resourced to perform duties and responsibilities assigned in this directive.

(3) Ensuring collaboration across the patient care and operational programs to achieve success in the goals and intent of this directive.

(4) Providing governance leadership and management of compounding programs.

(5) Providing leadership for proactive, recurring compounding reviews.

(6) Communicating enterprise-wide initiatives that may impact quality and patient safety programs, processes and practices associated with compounding and compounded preparations.

(7) Ensuring distribution of relevant compounding program procedural requirements, correspondence and guidance.

(8) Establishing a multidisciplinary VHA National Compounding Advisory Committee comprised of the United States Pharmacopeia (USP) <795>, <797> and <800> subject matter experts (SMEs).

(9) Collaborating with other Assistant Under Secretaries for Health in supporting the recommendations and actions of the National Compounding Advisory Committee.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations (AUSH 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. **Assistant Under Secretary for Health for Support Services.** The Assistant Under Secretary for Health for Support Services is responsible for collaborating with other Assistant Under Secretaries for Health in supporting the recommendations and actions of the National Compounding Advisory Committee.

e. **Assistant Under Secretary for Health for Quality and Patient Safety.** The Assistant Undersecretary for Health for Quality and Patient Safety is responsible for collaborating with other Assistant Under Secretaries for Health in supporting the recommendations and actions of the National Compounding Advisory Committee.

f. **Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer.** The Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer is responsible collaborating with other VHA Assistant Under Secretaries for Health in supporting the recommendations and actions of the National Compounding Advisory Committee.

g. **Executive Director, Pharmacy Benefits Management Services.** The Executive Director of Pharmacy Benefits Management (PBM) is responsible for:

(1) Ensuring Pharmacy SMEs provide policy and guidance related to all aspects of compounding and outsourcing practices, including interpretation of USP compounding chapters and understanding and application of Federal law.

(2) Ensuring Pharmacy compounding SMEs participate and serve as co-chairs for the VHA National Compounding Advisory Committee.

(3) Ensuring Pharmacy SMEs represent VHA as points of contact to outside regulatory and accreditation organizations for topics related to compounding.

h. **Chair, VHA National Pharmacy Compounding Advisory Committee.** The Chair of the VHA National Pharmacy Compounding Advisory Committee is responsible for:

(1) Providing consultative services to VISN and VA facility leadership in cleanroom design, environmental controls and monitoring, and core competencies. The committee membership must at a minimum include SME representatives from the VHA Office of Quality and Patient Safety, Pharmacy Benefits Management (PBM) Services, Healthcare Environment and Facilities (Engineering, Industrial Hygienist and Environmental Management Services), Occupational Safety and Health (OS&H), National Infectious Diseases Service (NIDS), Nursing, Biomedical Engineering, Green Environmental Management Systems (GEMS), and other representatives will be included on an ad hoc

basis as appropriate.

(2) Reviewing VA medical facility compounding space design, construction and remodel plans at 30%, 60% and 90% design stages and prior to execution to ensure each space meets the requirements for compounding spaces.

(3) Developing national procedural requirements for VISN and VA medical facilities on issues related to pharmaceutical compounding.

**i. Director, National Allergy and Immunology Program in the Specialty Care Program Office.** The Director National Allergy and Immunology Program in the Specialty Care Program Office is responsible for ensuring compliance with all USP <797> standards associated with the provision of compounded allergenic extracts as required by VHA Directive 1148, Allergen Therapy and Allergen Immunotherapy Clinics, dated June 28, 2022.

**j. Veterans Integrated Service 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 barriers to compliance are identified.

(2) Establishing a multidisciplinary VISN Pharmacy Compounding Advisory Committee that includes USP compounding subject matter experts capable of providing consultative services to VISN and VA medical facility leadership in cleanroom design environmental controls and monitoring and core competencies. The committee membership must be chaired by a member of the VISN executive leadership team and co-chaired by the VISN Pharmacist Executive and at a minimum include: VISN Quality Manager, Executive Engineering Service, Industrial Hygienist, Environmental Management Services, Occupational Safety and Health (OS&H) and Infection Prevention and Control. Nursing, Biomedical Engineering, GEMS, and other representatives will be included on an ad hoc basis as appropriate.

(3) Ensuring that the VISN Pharmacist Executive co-chair actively participates in setting the agenda and provides content to ensure the committee addresses topics relevant and necessary for facility end-users.

(4) Informing the VHA National Pharmacy Compounding Advisory Committee of incidents with impact to Pharmacy Compounding Operations as defined in the Issue Brief Tracker Guidance: Curtailment Reporting Requirements, available at [https://vssc.med.va.gov/IBTracker/Docs/Guide%20to%20Issue%20Briefs%20\(Updated%2004-6-22\).pdf](https://vssc.med.va.gov/IBTracker/Docs/Guide%20to%20Issue%20Briefs%20(Updated%2004-6-22).pdf). **NOTE:** *This is an internal VA website that is not available to the public.*

(5) Ensuring that each facility reports any change in a VA medical facility's compounding program using the Issue Brief process established by VHA Central Office. The VISN Compounding Advisory Committee will ensure the VA medical facility corrective action plan(s) is consistent with requirements and identifies appropriate milestones and target dates.

k. **Chair, VISN Compounding Advisory Committee.** The Chair of the VISN Pharmacy Compounding Advisory Committee is responsible for:

(1) Reviewing facility reports (e.g. CAPAs, IBs, certification reports) related to compounding compliance that adversely impact or may impact Veteran care or employee safety for the purposes of confirming compliance and advising on the resolution of noncompliance issues.

(2) Reviewing on an annual basis VA medical facility compounding contingency plans to ensure they are readily retrievable, can be operationalized and have been simulated to meet the needs of the facility.

(3) Reviewing the results of the certification reports to identify whether there were any environmental or engineering failures in the compounding spaces. Assist facilities with resolution of any identified failures

(4) Ensuring that VA medical facility corrective action plans created in response to Issue Briefs presented to the VISN Director pursuant to paragraph 2.j.(5) are consistent with requirements and identify appropriate milestones and target dates.

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

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

(2) Ensuring that the VA medical facility has the appropriate infrastructure for compounding programs.

(3) Ensuring that the VA medical facility complies with all elements associated with compounding programs.

(4) Establishing a multidisciplinary VA medical facility Compounding Advisory Committee. The committee must be chaired by a member of the VA medical facility executive leadership team (i.e., Quadrad) and, at a minimum, include the Chief of Pharmacy (or designee), Designated Compounding Pharmacist, Quality Manager, Biomedical Engineering (ad hoc), Healthcare Environment and Facilities (Engineering, Industrial Hygienist [or alternate Occupational Safety and Health Service Manager] and Environmental Management Services), GEMS (ad hoc), and Infection Prevention and Control.

(5) Assisting the VA medical facility Compounding Advisory Committee Chair with development of a charter.

(6) Ensuring that the VA medical facility Compounding Advisory Committee meets no less frequently than quarterly and provides updates (e.g., minutes) or concerns as defined by the charter.

(7) Ensuring the Pharmacy Department has the necessary resources to employ a Designated Compounding Pharmacist(s) to provide oversight of the Pharmacy Department's compliance with compounding requirements in accordance with all USP

compounding standards (Chapters <797>, <800>, <795>).

(8) Ensuring that the VA medical facility Chief of Engineering Service uploads designs for any new construction or renovation of compounding spaces at 30%, 60%, and 90% completion on the SharePoint link (Design Review Requests) for review by the National Compounding Advisory Committee prior to execution. Modular and mobile unit procurements and leases must also be submitted for review by the National Compounding Advisory Committee prior to execution. See the Design Review Requests link here, <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdvagov.sharepoint.com%2Fsites%2FVACOVHADUSHOM%2F10NA%2F10NA5%2FHealthcareEngineering%2FPages%2FDesign%2520Review%2520Requests.aspx&data=05%7C01%7C%7C1870e96920914d52e13b08da9295fe2b%7Ce95f1b23abaf45ee821db7ab251ab3bf%7C0%7C0%7C637983470150034868%7CUnknown%7CTWFpbGZsb3d8eyJWljiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTil6Ik1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sdata=HEWFU5xRNrbV08nW8kGGK0BN8DJaC7IOXPJ%2F6pnblx0%3D&reserved=0>. **NOTE:** *This is an internal VA website that is not available to the public.*

(9) Notifying the VISN Director of issues impacting compounding processes at the VA medical facility, using the Issue Brief process.

(10) Ensuring the VA medical facility compounding contingency plan is assessed annually, is operational, is retrievable, and has been simulated to meet the needs of the facility. **NOTE:** *“Real life” events with documented after-action reviews may be utilized as documentation of simulation.*

(11) Ensuring Primary Engineering Control (PEC) and Secondary Engineering Control (SEC) certification meets the requirements of USP standards and Controlled Environment Testing Association (CETA) controlled application guide (CAG) at least every 6 months. **NOTE:** *Contracts for such services may be maintained at the VISN or facility level.*

m. **Chair, VA Medical Facility Compounding Advisory Committee.** The VA medical facility Compounding Advisory Committee Chair is responsible for:

(1) Collaborating with the VA medical facility Director to develop of a charter.

(2) Convening Committee meetings no less frequently than quarterly.

(3) Providing updates (e.g., minutes) or concerns as defined by the charter to the VA medical facility Director.

(4) Ensuring review of the CSP Safety and Quality Assurance (QA) plan by the VA medical facility Compounding Advisory Committee annually.

(5) Holding committee meetings on a minimum quarterly basis to review environmental controls and monitoring results, to ensure all appropriate staff has the core competencies necessary for handling CSPs and CNSPs, and for compliance with this Directive.

(6) Reporting issues impacting compounding processes at the VA medical facilities to the VA medical facility director and VISN Director using processes established by the VHA



issue brief process.

(7) Ensuring that corrective action plans comply with applicable USP chapters, VHA requirements and applicable Federal law.

(8) Reviewing the VA medical facility compounding contingency plan and ensuring that it can be operationalized and has been simulated to meet the needs of the facility and submitting the plan to the VA facility director for review annually. **NOTE:** *“Real life” events with documented after-action reviews may be utilized as documentation of simulation.*

(9) Reviewing the results of environmental and engineering (state of control) certification reports (provided to the Pharmacy and Engineering Services by the contracted external CETA certified vendor) to determine if a corrective action plan is needed.

(10) Ensuring the situations that adversely impact or may impact Veteran care or employee safety are communicated to the VA medical facility Director to begin the issue brief process and VISN Compounding Advisory Committee for awareness.

(11) Reviewing plans for new construction or renovation of compounding spaces and modular and mobile unit procurements and ensuring that leases are submitted by the VA medical facility Director to the VISN Compounding Advisory Committee. **NOTE:** *These plans must be reviewed by the National Compounding Advisory Committee at 30%, 60% and 90% design stages and prior to execution.*

(12) Collaborate with the compounding advisory committee to evaluate certification failures, environmental control failures, or identification or exceedance of microbiological action levels as defined in the USP standards.

(13) Collaborate with the compounding advisory committee to develop and document corrective action and preventive action plans (CAPA).

(14) Ensure a quarterly report at a minimum is created and presented to the facility executive leadership team summarizing the activities of the Facility Compounding Advisory Committee.

n. **Chief, VA Medical Facility Pharmacy Service.** The VA medical facility Chief of Pharmacy Service is responsible for:

(1) Appointing full-time Designated Compounding Pharmacist(s). **NOTE:** *The Designated Compounding Pharmacist duties cannot be assigned as collateral duties.*

(2) Working with the Designated Pharmacist to develop a VA medical facility compounding contingency plan that may be activated to obtain compounded preparations through alternative means in situations where compounding preparations at the facility are suspended because the facility is unable to maintain a state of control is documented and communicated to necessary staff. VA medical facility compounding contingency plans must be tested annually to ensure the plan meets the operational needs of the facility. VA medical facility compounding contingency plans must take all precautions to not affect

patient care. **NOTE:** *“Real life” events with documented after-action reviews may be utilized as documentation of simulation.*

(3) Collaborating with the VA medical facility Chief of Engineering Services to ensure appropriate selection and development of the statement of work (SOW) for contracted certification and environmental testing services and ensuring there is no lapse in services for this critical requirement.

(4) Prior to compounding a preparation, assessing the VA medical facility Pharmacy Service’s capability to compound CSPs and CNSPs that are not commercially available based on an evaluation of equipment, resources, environment, and competencies to prepare the compounded product.

(5) Collaborating with the VA medical facility Chief of Engineering Service to ensure USP and VA standards are incorporated in pharmacy compounding spaces including unclassified segregated compounding areas (SCAs) and containment segregated compounding areas (C-SCAs), cleanroom design, installation, renovation or other construction projects.

(6) Ensuring that Hazardous Drugs (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>.

(7) Ensuring that the pharmacy uses commercially available sterile admixtures and drug products or, when unavailable, commercially available therapeutic alternative drug products.

(8) Ensuring that the VA medical facility does not prepare compounded sterile products from any non-sterile components that require sterility performing procedures.

(9) Ensuring that all decisions for outsourcing compounded preparations are in alignment with VHA procedural requirements for outsourcing. For more information on pharmaceutical compounding management standards, see [https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy\\_Operations/SitePages/Pharmaceutical-Compounding-and-Management-Standards.aspx](https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/SitePages/Pharmaceutical-Compounding-and-Management-Standards.aspx). **NOTE:** *This is an internal VA website that is not available to the public.*

(10) Collaborating with the Chief of Environmental Management Services (EMS) through a formal Memorandum of Understanding (MOU) or departmental SOP that delineates the assignment of duties for the cleaning of pharmacy spaces. **NOTE:** *For an MOU template, see <http://vaww.hefp.va.gov/resources/eps-sanitation-procedure-guide>. This is an internal VA website that is not available to the public.*

(11) Collaborating with the Chief of Environmental Management Services to review and approve non-VA contracts for cleaning services.

(12) Ensuring that training and competency processes are in place for any staff personnel involved in cleaning the primary and secondary engineering controls. **NOTE:** *This responsibility will be shared with the Chief of Environmental Management Services.*

o. **VA Medical Facility Designated Compounding Pharmacist.** A VA medical facility Designated Compounding Pharmacist assigned by the facility Chief of Pharmacy Service is responsible for:

(1) Collaborating with the VA medical facility Chief of Pharmacy Service to ensure a VA medical facility compounding contingency plan is in place that may be activated to obtain compounded preparations from alternative sources in situations where compounding services at the facility must be suspended.

(2) Collaborating with the VA medical facility Chief of Environmental Management Services, Chief of Engineering Service, Chief of Pharmacy Service and other relevant services to develop and implement a VA medical facility compounding contingency plan if primary compounding spaces are unable to be used.

(3) Collaborating with the VA medical facility Chief of Engineering Service to ensure engineering-related corrective actions associated with cleanroom environmental controls are completed and documented with records maintained based on VHA and USP requirements.

(4) Ensuring all outsourced compounded preparations meet the VHA procedural requirements for outsourcing compounded preparations. For more information on pharmaceutical compounding management standards, see [https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy\\_Operations/SitePages/Pharmaceutical-Compounding-and-Management-Standards.aspx](https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/SitePages/Pharmaceutical-Compounding-and-Management-Standards.aspx). **NOTE:** *This is an internal VA website that is not available to the public.*

(5) Ensuring the pharmacy service has written procedures for compliance with USP compounding standards, Federal law, VHA design requirements and the Joint Commission.

(6) Ensuring the training and competency of pharmacy personnel in accordance with USP compounding requirements and any facility SOPs related to compounding.

(7) Ensuring there is a process and an assigned individual who has training and documented competencies in place to review and interpret staff testing results related to Gloved Fingertip Tests(GFTs) and Media Fill Tests(MFTs). **NOTE:** *Gloved Fingertip (GFT) and Media Fill Testing (MFT) VA clinical laboratories may interpret GFT and MFT samples if authorized by the VA medical facility Director or VISN Director and they meet all required elements for demonstration of quality and competency as defined in VHA National Laboratory guidance. However, advanced/specialized training (i.e., Pathologist/Microbiologist) is not required for staff to interpret the results of the GFT and MFT. The facility may designate an individual(s) for this responsibility (as an example, Industrial Hygienist (IH) staff may be considered to interpret GFTs and MFTs). For more guidance, see <https://dvagov.sharepoint.com/:b:r/sites/VHADiagnosticServices/PLMS/edcen/Document%20Library/Directive%20Guidance/Memos%20or%20Communications/Requirements%20for%20VA%20Clinical%20Labs%20to%20Perform%20Pharmacy%20Quality%20Testing%2007-19-23-Final.pdf?csf=1&web=1&e=D5OQ46>. This is an internal VA website that is not available to the public.*

(8) Collaborating with the Chief of Environmental Management Services to develop a formal Memorandum of Understanding (MOU) for the delineation of duties related to the pharmacy compounding area's cleaning and disinfecting protocol. Please refer to <http://vaww.hefp.va.gov/resources/eps-sanitation-procedure-guide> for MOU template.

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

(9) Collaborating with the Chief of Environmental Management Services to ensure competency documentation is available for any contracted cleaning services and to randomly observe the individuals performing these tasks.

(10) Collaborating with the Chief of Environmental Management Services to ensure training and competency assessment of specific elements for any staff personnel involved in cleaning the primary and secondary engineering controls, pursuant to USP <797>.

(11) Ensuring that pharmacy personnel complete appropriate cleaning documentation (including the cleaning products) used for pharmacy compounding rooms.

(12) Collaborating with the VA medical facility Chief of Engineering Services to ensure that PEC and SEC are certified in accordance with VHA procedural requirements, CETA CAG and USP compounding standards.

(13) Ensuring the VA medical facility Compounding Advisory Committee is provided all certification and environmental assessment reports and participating in reviews and corrective action plans.

(14) Collaborating with the VA medical facility Chief of Engineering Services to ensure appropriate selection and development of the statement of work for contracted certification and environmental testing services. Ensure there is no lapse in services for this critical requirement.

(15) Collaborating with the VA medical facility Chief of Engineering Service to ensure USP and VA design standards are incorporated in pharmacy compounding spaces including SCA's and C-SCAs, cleanroom design, installation, renovation, or other construction projects.

(16) Collaborating with the VA medical facility Quality Manager, OS&H and Infection Prevention and Control to develop a formal written CSP Safety and Quality Assurance (QA) Plan to be established and implemented in accordance with VHA design requirements and USP compounding standards.

(17) Reviewing all certification and recertification records to ensure the compounding spaces meet the minimum USP standards and VA design requirements in addition to all required air quality standards in each classified area.

(18) Ensuring any personnel entering a compounding area observe all hygiene and garbing requirements and bring only necessary items or equipment related to their work to maintain the quality of the environment.

p. **VA Medical Facility Nurse Executive.** The VA medical facility Nurse Executive is

responsible for:

(1) Specifying nursing staff requirements and competences for the preparation, handling, administration, and disposal of any compound preparations including hazardous drugs in accordance with VHA requirements, National Institute for Occupational Safety and Health (NIOSH), USP standards and any facility-approved HD AoR.

(2) Providing consultation and assistance to the VA medical facility Compounding Advisory Committee as needed.

q. **VA Medical Facility Manager, Occupational Safety and Health Service.** The VA medical facility Manager, Occupational Safety and Health Service is responsible for:

(1) Collaborating with the Designated Compounding Pharmacist or appropriate workplace supervisor(s) for alternative containment strategies, personal protective equipment and work practices.

(2) Ensuring personnel of reproductive capability who handle HDs confirm in writing that they understand the risks of handling HDs, pursuant to USP <800>.

r. **VA Medical Facility Employee Occupational Health Service Manager.** The VA medical facility Employee Occupational Health (EOH) Service Manager is responsible for:

(1) Enrolling employees who may be exposed to or handle HDs and requesting monitoring by the facility's Medical Surveillance Program. Employees' enrollment and monitoring in the Medical Surveillance Program must be done in coordination with their supervisors and Occupational Safety and Health Services.

(2) Providing, in collaboration with the Occupational Safety and Health Service, occupational health and medical management advice and recommending interventional strategies for actual or potential exposures to HDs.

s. **Chief, VA Medical Facility Engineering Service.** *NOTE: This position's title may vary depending on the facility and may be delegated to service staff as appropriate (i.e., VA Medical Facility Chief Facilities Management Services, VA medical facility Chief Facilities Management Services or another facility-specific title).* The VA medical facility Chief of Engineering Service is responsible for:

(1) Ensuring that USP and VA design standards are incorporated in pharmacy compounding spaces including SCA's and C-SCAs, cleanroom design, installation, renovation, or other construction projects. **NOTE:** *A pharmacy designee familiar with the requirements of USP should be involved in the design and construction process for pharmacy spaces; the facility advisory committees should review plans. VA medical facilities must comply with the VHA heating, ventilating and air-conditioning (HVAC) Design Manual (<https://www.cfm.va.gov/til/dManual/dmHVAC.pdf>), VA Technical Information Library (<https://www.cfm.va.gov/til/>) and the VHA Pharmacy Design Guide (<https://www.cfm.va.gov/til/dGuide/dgPharm.pdf>) when remodeling or constructing new cleanroom suites. These are internal VA websites that are not available to the public.*

(2) Ensuring that PECs and SECs are installed and maintained in compliance with USP compounding chapters and VA design standards including third party testing and certification. **NOTE:** *VA uses the CETA CAGs to define certification procedures for assessing if the Primary and Secondary Engineering Controls are operating as designed to maintain a sterile environment for the preparation of CSPs.*

(3) Ensuring all vendors conducting primary and secondary engineering control certifications:

(a) Employ at least one CETA National Board Testing (CNBT) Registered Certified Professional (RCP) for Sterile Compounding Facility (SCF) individual on staff who will review and sign the final certification report.

(b) Have required CETA competencies and training related to the certification of primary and secondary engineering controls. **NOTE:** *it is preferred that the on-site certification individuals have received NSF accreditation for the field certification of Class II Biosafety Cabinets and are accredited through CNBT as a registered certification professional in the sterile compounding facility (RCP-SCF).*

(4) Collaborating with the Designated Compounding Pharmacist to ensure engineering-related corrective actions associated with cleanroom environmental controls are completed.

(5) Collaborating with the VA medical facility Director, Designated Compounding Pharmacist, and Chief of Environmental Management Services to ensure the VA medical facility compounding contingency plan includes an assessment of an alternative site within the VA medical facility for the preparation of compounding, if compounding areas are unable to be used.

(6) Collaborating with the Pharmacy Service and Engineering Service in the design, selection and construction of all pharmacy compounding spaces including temporary systems and equipment selection.

(7) Submitting all pharmacy compounding space construction and renovation documents to the VHA Office of Healthcare Environmental and Facilities Programs (HEFP) Design Review Requests SharePoint site at 30%, 60% and 90% completion stages. The VA medical facility director is responsible for ensuring plans are submitted in a timely manner. The National HEFP Design Review Requests SharePoint can be found at

[https://dvagov.sharepoint.com/sites/VHA10NA5E/Pages/Design%20Review%20Requests.aspx#InplviewHash0d5612ed-3919-497f-a460-495aa09dab34=Paged%3DTRUE-p\\_VISN%3D19-p\\_Title%3D666%252dSheridan%2520VA%2520Medical%2520Center-p\\_ID%3D436-PageFirstRow%3D31#InplviewHashb7149a94-4b93-434b-9f9c-d1a798369b49=Paged%3DTRUE-p\\_VISN%3D22-p\\_Title%3D649%252dBob%2520Stump%2520VA%2520Medical%2520Center-p\\_ID%3D162-PageFirstRow%3D91-FilterFields1%3DVISN-FilterValues1%3D22%253B%252321%253B%252320%253B%252319-FilterOp1%3DIn](https://dvagov.sharepoint.com/sites/VHA10NA5E/Pages/Design%20Review%20Requests.aspx#InplviewHash0d5612ed-3919-497f-a460-495aa09dab34=Paged%3DTRUE-p_VISN%3D19-p_Title%3D666%252dSheridan%2520VA%2520Medical%2520Center-p_ID%3D436-PageFirstRow%3D31#InplviewHashb7149a94-4b93-434b-9f9c-d1a798369b49=Paged%3DTRUE-p_VISN%3D22-p_Title%3D649%252dBob%2520Stump%2520VA%2520Medical%2520Center-p_ID%3D162-PageFirstRow%3D91-FilterFields1%3DVISN-FilterValues1%3D22%253B%252321%253B%252320%253B%252319-FilterOp1%3DIn)

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



(8) Ensure that the Engineering Service reviews and responds to comments from the National Compounding Advisory Committee about construction and design of pharmacy compounding spaces.

t. **Chief, VA Medical Facility Environmental Management Services.** The Chief of VA medical facility Environmental Management Services (EMS) is responsible for:

(2) Collaborating with the Chief of Pharmacy Service through formal Memorandum of Understanding (MOU) or departmental SOPs to establish the delineation of duties related to the pharmacy compounding area's cleaning and disinfecting protocol. Please refer to <http://vaww.hefp.va.gov/resources/eps-sanitation-procedure-guide> for MOU template.

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

(3) Collaborating with the Chief of Pharmacy Service to review and approve non-VA contracted cleaning services for pharmacy compounding spaces. Obtaining documentation of competency training and assessment of staff conducting the cleaning from the contracted services vendor.

(4) Working with the Designated Compounding Pharmacist to oversee and randomly observe the staff conducting cleaning services in compounding areas.

(5) Ensuring pharmacy compounding areas are cleaned pursuant to VHA requirements and USP standards; standard operating procedures (SOPs) are implemented and communicated to any staff personnel involved with cleaning the spaces; compliance is consistent and continuously monitored and documentation is maintained. Please refer to <http://vaww.hefp.va.gov/resources/eps-sanitation-procedure-guide> for standardized SOP and processes. **NOTE:** *This is an internal VA website that is not available to the public.*

(5) Collaborating with the Chief of Pharmacy Service to ensure that personnel responsible for cleaning compounding spaces have proper training and documented annual competencies for cleaning and disinfection of the pharmacy compounding spaces. Please refer to <http://vaww.hefp.va.gov/resources/eps-sanitation-procedure-guide> for EMS competency information. **NOTE:** *This is an internal VA website that is not available to the public.*

(6) Ensuring that EMS personnel complete appropriate cleaning documentation indicating the cleaning products used and tasks performed for pharmacy compounding rooms.

(7) Collaborate with the Chief of Pharmacy Service to ensure all cleaning, sanitizing, decontaminating and rinsing agents used to clean pharmacy compounding areas and equipment have been evaluated, are on the VHA Medical Surgical Prime Vendor (MSPV) product list and are approved for utilization within the VHA.

(8) Ensuring that EMS has a contingency plan to provide alternative cleaning personnel that have been appropriately trained and have signed competencies in cases where regularly scheduled personnel are not available.

### 3. STERILE COMPOUNDING

a. VA pharmacies are required to use commercially available sterile admixtures and drug products or, when unavailable, commercially available therapeutic alternative drug products. VA medical facilities will not prepare compounded sterile products from any non-sterile components that require sterility performing and testing procedures. If commercially prepared products are unavailable, VA medical facility pharmacies must compound or may outsource sterile drug preparations as needed in accordance with this directive.

b. VA pharmacies must ensure that all compounded sterile preparations (CSPs) are accurately identified, measured, diluted, mixed, prepared, packaged, sealed, labeled, stored, dispensed, procured, and distributed in accordance with:

(1) United States Pharmacopeia (USP) Compounding standards

(2) VHA Pharmacy Benefits Management (PBM) Guidance and Procedural Requirements for CSPs which can be found at

[https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy Operations/VHA PBM Compounding Guidance Documents/Forms/AllItems.aspx?viewid=6a64c982%2Dc912%2D4cba%2D89a1%2Dab976a7e8851&id=%2Fsites%2FVHAPBM%2FPharmacy%5FOperations%2FVHA%20PBM%20Compounding%20Guidance%20Documents%2FVHA%20PBM%20CSP%20GUIDANCE%20DOCUMENTS](https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy%20Operations/VHA%20PBM%20Compounding%20Guidance%20Documents/Forms/AllItems.aspx?viewid=6a64c982%2Dc912%2D4cba%2D89a1%2Dab976a7e8851&id=%2Fsites%2FVHAPBM%2FPharmacy%5FOperations%2FVHA%20PBM%20Compounding%20Guidance%20Documents%2FVHA%20PBM%20CSP%20GUIDANCE%20DOCUMENTS). **NOTE:** *This is an internal VA website that is not available to the public.*

c. All hazardous (e.g., cancer chemotherapy) CSPs must be prepared in an appropriate area separated from routine non-hazardous sterile product preparations. They must be prepared in a manner compliant with USP <800> standards and NIOSH requirements.

d. All antineoplastic hazardous drugs requiring further manipulation must be stored separately from other inventory in a manner to prevent contamination and personnel exposure that conform with USP <800> standards. **NOTE:** *Antineoplastic drugs only refer to those included in the most current Table 1 NIOSH list and any deemed as similar per facility review.*

e. CSPs may be prepared in limited anticipatory quantities before receipt of a medication order and labeled in accordance with USP <797>. Medications orders may be in the form of chart orders, inpatient or outpatient orders.

f. A pharmacist must inspect outsourced CSPs for quality prior to dispensing or administration within the medical facility.

g. CSPs compounded by the pharmacy after receipt of a medication order must have a label placed directly to the compounded preparation and delivered to the patient care area.

(1) These labels must comply with USP <797> and contain [at a minimum] the following:

(a) The patient's name (excludes those CSPs prepared for anticipatory compounding



need and stored in patient care areas).

(b) Identifier number (e.g., barcode, prescription, lot number).

(c) Ward or medical center location excluding those prepared as anticipatory compounds that may be stored in patient care areas.

(d) The date prepared.

(e) Identity strength or volume of each additive and diluent(s) as applicable.

(f) Total volume, flow rate (if specified) and route of administration.

(g) Special handling instructions.

(h) Appropriate auxiliary labeling (including precautions) attached.

(i) The beyond-use-date (BUD) and time as defined by USP <797>.

(j) Storage requirements if other than controlled room temperature.

(k) Identification of pharmacy personnel that prepared and checked the CSP, one of which must be a pharmacist. **NOTE:** *A check of the final product is required except in cases where only one person is staffing (e.g., on the off tour, when only a pharmacist is staffing).*

(2) When a light protective outer bag is required, a duplicate label must be affixed directly to the intravenous (IV) product, in addition to the outer bag.

h. Release physical and visual inspection for all CSPs prepared on-site and any CSP procured from an outsourced vendor for use on-site must be checked by a pharmacist prior to dispensing the product for patient administration. The release inspection must include an evaluation for:

(1) Container leaks.

(2) Container integrity.

(3) Solution cloudiness or phase separation.

(4) Particulates in the solution.

(5) Appropriate solution color.

(6) Solution volume.

i. Identity of the drug and additives (e.g., drugs, diluents, solutions) with the quantity of each additive evidenced by the empty vials, ampoules, syringes used, or by verification noted within an automated compounding workflow system. **NOTE:** *This item pertains to those products compounded in-house.*

j. Unless otherwise specified on the IV label, all unused CSPs must be returned to the pharmacy when discontinued or the following morning if not administered. CSPs may be re-cycled for use provided their BUD has not been exceeded and their storage requirements have been maintained. Release physical and visual inspection must be conducted for all re-cycled CSPs as noted above in section i.

#### **4. NON-STERILE COMPOUNDING**

a. VA pharmacies must ensure that all compounded non-sterile preparations (CNSPs) are prepared and stored in accordance with the standards established within USP <795> Pharmaceutical Compounding-Nonsterile Preparations. Handling of non-sterile hazardous drugs must additionally comply with USP <800>.

b. The requested CNSPs intended for use must be within the scope of practice or specialty of the prescriber to justify its medical necessity and should be approved for use by the local facility P&T Committee.

c. The CNSP must be prepared by trained and competent pharmacy staff in accordance with USP <795> standards and labeled and packaged accordingly.

d. CNSPs may be prepared in limited anticipatory quantities before receipt of a medication order (and labeled in accordance with USP <795>). Medication orders may be in the form of chart orders, inpatient or outpatient orders (prescription).

e. The requested CNSP must not present demonstrable difficulties in compounding (e.g., require a sophisticated drug delivery system, present concerns regarding dosage uniformity in bioavailability, a complex compounding process, sophisticated facilities or equipment).

f. When CNSPs are dispensed on site to patients directly, the pharmacist must provide patient counseling including, at a minimum: the beyond-use-date (BUD), appropriate administration, storage requirements and methods of detecting evidence of instability (e.g., visual changes, odor).

#### **5. OUTSOURCING COMPOUNDED PREPARATIONS**

(1) Outsourced CNSPs and CSPs must be approved through the facility P&T Committee process (approval must be documented within the P&T Committee minutes) and procured from 503A pharmacies or 503B FDA registered facilities that VA medical facilities have reviewed and deemed acceptable quality. The FDA has designated 503A compounding pharmacies as those that compound according to prescriptions specific to particular patients and are required by state boards of pharmacy to comply with USP and other guidelines. The FDA has designated 503B compounding pharmacies as those with outsourcing facilities that may manufacture large batches with or without prescriptions to be sold to healthcare facilities for office use only. 503B compounding pharmacies that provide patient specific medications are held to higher regulatory standards. These facilities are required to maintain full compliance with current good manufacturing practices. See compounding procedural guidance/requirements for Outsourcing and tools at:

[https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy\\_Operations/SitePages/Pharmaceutical-Compounding-and-Management-Standards.aspx](https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/SitePages/Pharmaceutical-Compounding-and-Management-Standards.aspx). **NOTE:** This is an internal VA website that is not available to the public.

(2) If not sent directly to the patient from the outsourced pharmacy, a pharmacist must conduct visual inspection of the CNSP (checking for particulate matter, discoloration, or visual contaminants) for all compounded preparations procured from an outsourced facility or pharmacy. The Pharmacist also needs to make sure the labeled CNSP matches the medication ordered along with the patient's name.

## 6. TRAINING

There are no formal training requirements associated with this directive.

## 7. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created in response to this directive must be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule (RCS) 101. All compounding records must be maintained in accordance with USP standards. Questions related to any aspect of records management contact the facility Records Manager or your Records Liaison.

## 8. 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. USP <795> and <797> standards apply to all persons who prepare CSPs and CNSPs to all locations where they 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 non-sterile products and preparations. USP standards also detail the requirements for cleanroom environments (including Buffer and Anterooms) 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 USP compounding standards core competencies are to compound/prepare CNSPs and CSPs.

c. VA facilities must 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) Chapter 795 "Pharmaceutical Compounding - Nonsterile Preparations" (<795>), USP Chapter 797 "Pharmaceutical

Compounding - Sterile Preparations” (<797>) and USP Chapter 800 “Hazardous Drugs Handling in Healthcare Settings” (USP <800>). Pursuant to 21 USC § 353a, Section 503A, Pharmacy Compounding, VA pharmacies are classified as 503A facilities. In addition, VA medical facilities must comply with the VHA heating, ventilating and air-conditioning (HVAC) Design Manual and the VHA Pharmacy Design Guide when remodeling or constructing of new cleanroom suites. Where there is a conflict between USP and the VHA design manuals and VHA design guide, the VHA documents take precedence.

d. This directive defines organizational responsibility for USP <795>, <797> and USP <800> standards for compounding space 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 non-sterile dosage form preparations).

e. USP compounding chapters provide minimum practice, quality, design, operation and maintenance standards and do not prohibit other procedures providing they are equivalent or superior to those described.

## 9. DEFINITIONS

a. **Anteroom.** An anteroom is an International Organization for Standardization (ISO) Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the facility and the buffer room. **NOTE:** *An ISO Class 7 anteroom is required when compounding hazardous drugs in compliance with USP <800>.*

b. **Anticipatory Compounding.** Anticipatory compounding is preparing compounded medications in limited quantities before the actual receipt of a prescription or practitioner’s order. This allows pharmacies with a history of filling certain prescriptions to prepare limited quantities in anticipation of need for administration at the point of care thus reducing delays patients may otherwise experience in receiving medications. Anticipatory compounding is based on the history and an established relationship between the pharmacy and facility physician (s) or other licensed practitioner (s) where a valid order for the compounded preparation will be provided prior to administration to the patient.

c. **Assessment of Risk.** An Assessment of Risk (AoR) is the evaluation of risk to determine alternative containment strategies and or work practices for handling Hazardous Drugs (HD).

d. **Beyond Use Date.** The beyond use date (BUD) is the date and time after which a CSP must not be used, stored or transported. The date is determined from the date and time the preparation is compounded.

e. **Buffer Room.** A Buffer room is an ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.

f. **Classified area.** A classified area is one that maintains an air quality classification based on the ISO standards (also known as ISO class).

g. **Cleanroom Suite.** A cleanroom suite is a room with a classified buffer and anteroom 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 and surface are not exceeded for a specified cleanliness class.

h. **Compounded Sterile Preparation.** A compounded sterile preparation (CSP) is a formulation 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. **Controlled Environment Testing Association Controlled Application Guide.** Controlled Environment Testing Association (CETA) Controlled Application Guide (CAG) standards define certification procedures to assess the PEC and SEC are 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.

j. **Compounded Non-sterile Preparation.** A compounded non-sterile preparation is the combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug or bulk substance to create a non-sterile medication.

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 Filtration.** A high-efficiency particulate air filtration is an extended-medium, dry- type filter in a rigid frame, having a minimum particle collection efficiency of 99.97% as defined with the American Society of heating, Refrigeration and Airconditioning Engineering (ASHRAE).

n. **International Organization for Standardization Class.** An international organization for standardization class is an internationally agreed upon air quality

classification standard defined by the International Organization for Standardization (ISO).

o. **Primary Engineering Control/Containment-Primary Engineering Control (PEC/C-PEC)**. Primary Engineering Control/Containment-Primary Engineering Control 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 provide unidirectional airflow and include Class II Biological Safety Cabinets and Compounding Aseptic Containment Isolators (CACI) for hazardous CSPs and Laminar Airflow Workbench (LAFW) and Containment Aseptic Isolators (CAI) for non-hazardous CSPs.

p. **Quality Assurance**. Quality Assurance (QA) is a system of procedures, activities and oversight that ensures that operational and quality standards are consistently met. A quality assurance program for compounded preparations must be established and maintained at the facility level. All records, certifications, evaluations and documents are created as part of the compounding quality-assurance program and are confidential and privileged and may not be disclosed except under limited circumstances as authorized by 38 U.S.C. § 5705 and its implementing regulations.

q. **Release inspection and testing**. Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.

r. **Secondary Engineering Control**. Secondary Engineering Control (SEC) is a space such as a buffer area which generally serves as the core for the location of the PEC and an ante area for hand hygiene and garbing.

s. **Segregated Compounding Area**. A segregated compounding area (SCA) is a designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of low risk or Category 1 CSPs only.

t. **Containment Segregated Compounding Area**. A containment segregated compounding area (C-SCA) is a type of containment secondary engineering control with nominal requirements for airflow and room pressurization as they pertain to HD compounding.

u. **State of Control**. A state of control is a condition in which the set of controls consistently provides assurance of continued process performance and product quality.

v. **Unclassified space**. A space not required to meet any air cleanliness classification based on the ISO.

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 <795>, <797> and <800>.**

## 10. REFERENCES

a. 38 U.S.C. § 7301(b).

b. VHA Directive 1148, Allergen Therapy and Allergen Immunotherapy Clinics, dated

June 28, 2022.

c. Environmental Program Services (EPS) Sanitation Procedure Guide, available at <http://vaww.hefp.va.gov/resources/eps-sanitation-procedure-guide>.

d. Guide to VHA Issue Briefs: Curtailment Reporting Requirements, available at [https://vssc.med.va.gov/IBTracker/Docs/Guide%20to%20Issue%20Briefs%20\(Updated%204-6-22\).pdf](https://vssc.med.va.gov/IBTracker/Docs/Guide%20to%20Issue%20Briefs%20(Updated%204-6-22).pdf). **NOTE:** *This is an internal VA website that is not available to the public.*

e. National HEFP Design Review Requests SharePoint, available at: [https://dvagov.sharepoint.com/sites/VHA10NA5E/Pages/Design%20Review%20Requests.aspx#InplviewHash0d5612ed-3919-497f-a460-495aa09dab34=Paged%3DTRUE-p\\_VISN%3D19-p\\_Title%3D666%252dSheridan%2520VA%2520Medical%2520Center-p\\_ID%3D436-PageFirstRow%3D31#InplviewHashb7149a94-4b93-434b-9f9c-d1a798369b49=Paged%3DTRUE-p\\_VISN%3D22-p\\_Title%3D649%252dBob%2520Stump%2520VA%2520Medical%2520Center-p\\_ID%3D162-PageFirstRow%3D91-FilterFields1%3DVISN-FilterValues1%3D22%253B%252321%253B%252320%253B%252319-FilterOp1%3DIn](https://dvagov.sharepoint.com/sites/VHA10NA5E/Pages/Design%20Review%20Requests.aspx#InplviewHash0d5612ed-3919-497f-a460-495aa09dab34=Paged%3DTRUE-p_VISN%3D19-p_Title%3D666%252dSheridan%2520VA%2520Medical%2520Center-p_ID%3D436-PageFirstRow%3D31#InplviewHashb7149a94-4b93-434b-9f9c-d1a798369b49=Paged%3DTRUE-p_VISN%3D22-p_Title%3D649%252dBob%2520Stump%2520VA%2520Medical%2520Center-p_ID%3D162-PageFirstRow%3D91-FilterFields1%3DVISN-FilterValues1%3D22%253B%252321%253B%252320%253B%252319-FilterOp1%3DIn). **NOTE:** *This is an internal VA website that is not available to the public.*

f. Pharmaceutical Compounding and Management Standards SharePoint, available at: [https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy\\_Operations/SitePages/Pharmaceutical-Compounding-and-Management-Standards.aspx](https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/SitePages/Pharmaceutical-Compounding-and-Management-Standards.aspx). **NOTE:** *This is an internal VA website that is not available to the public.*

g. Requirements for VA Clinical Laboratories to Perform Pharmacy Quality Testing (Media Fill-MFT and Glove Tip-GFT), available at: <https://dvagov.sharepoint.com/:b:/r/sites/VHADiagnosticservices/PLMS/edcen/Document%20Library/Directive%20Guidance/Memos%20or%20Communications/Requirements%20for%20VA%20Clinical%20Labs%20to%20Perform%20Pharmacy%20Quality%20Testing%202007-19-23-Final.pdf?csf=1&web=1&e=D5OQ46>. **NOTE:** *This is an internal VA website that is not available to the public.*

h. USP General Chapter <795>: Pharmaceutical Compounding – Nonsterile Preparations. United States Pharmacopeia, Rockville, MD, US. Available at: <https://www.usp.org/compounding/general-chapter-795>.

i. USP General Chapter <797>: Pharmaceutical Compounding - Sterile Preparations. United States Pharmacopeia, Rockville, MD, US. Available at <https://www.usp.org/compounding/general-chapter-797>.

j. USP General Chapter <800>: Hazardous Drugs - Handling in Healthcare Settings (2019). United States Pharmacopeia, Rockville, MD, US. Available at: <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>.

k. VA HVAC Design Manual, available at: <https://www.cfm.va.gov/til/dManual/dmHVAC.pdf>. **NOTE:** *This is an internal VA website that is not available to the public.*

l. VA Pharmacy Service Design Guide <https://www.cfm.va.gov/til/dGuide/dgPharm.pdf>.

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

m. VA Technical Information Library, available at: <https://www.cfm.va.gov/til/>. **NOTE:**

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

n. VHA Pharmacy Benefits Management Guidance and Procedural Requirements for CSPs, available at:

[https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy\\_Operations/VHA\\_PBM\\_Compounding\\_Guidance](https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/VHA_PBM_Compounding_Guidance)

[Documents/Forms/AllItems.aspx?viewid=6a64c982%2Dc912%2D4c9a%2D89a1%2Dab976a7e8851&id=%2Fsites%2FVHAPBM%2FPharmacy%5FOperations%2FVHA%20PBM%20Compounding%20Guidance%20Documents%2FVHA%20PBM%20CSP%20GUIDANCE%20DOCUMENTS](https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/VHA_PBM_Compounding_Guidance/Documents/Forms/AllItems.aspx?viewid=6a64c982%2Dc912%2D4c9a%2D89a1%2Dab976a7e8851&id=%2Fsites%2FVHAPBM%2FPharmacy%5FOperations%2FVHA%20PBM%20Compounding%20Guidance%20Documents%2FVHA%20PBM%20CSP%20GUIDANCE%20DOCUMENTS). **NOTE:** This is an internal VA website that is not available to the public.

o. VHA Space Planning Criteria (Pharmacy 268) <https://www.cfm.va.gov/til/space.asp>.

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



**DEFINING, CERTIFYING AND PROCURING PRIMARY ENGINEERING CONTROLS  
FOR COMPOUNDED STERILE PREPARATIONS****1. PROCUREMENT**

Primary Engineering Control (PEC) procurement requests must include detailed, specific requirements for acceptance requirements for the performance, testing and documentation of the equipment as part of commissioning at the completion of installation per the applicable Controlled Environment Testing Association (CETA) standards.

**2. PEC PERFORMANCE EVALUATIONS AND CERTIFICATION PROCEDURES**

a. All Department of Veterans Affairs (VA) medical facilities must establish a separate and dedicated contract for all applicable United States Pharmacopeia (USP) <797> and USP <800> PEC certifications requirements.

b. Certification procedures defined in applicable CETA Application Guides must be performed by a CETA National Board Testing (CNBT) Registered Certified Professional (RCP) for Sterile Compounding Facility (SCF) individual or a vendor that employs at least one of these individuals initially and no less than every 6 months. Areas additionally must be recertified if there are any changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.

(1) Contracts with CETA certified individuals or vendors must require that viable and non-viable testing results be provided to the Chief of Pharmacy Service and other designated VA medical facility staff (as indicated by the medical facility) no later than 2 weeks after the testing is performed. Certification must also include video of the airflow smoke pattern test documenting unidirectional flow at critical sites in the PEC.

(2) Answers to frequently asked questions may be found on the Pharmacy Benefits Management (PBM) Compliance Share Point site: [https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy\\_Operations/SitePages/Pharmaceutical-Compounding-and-Management-Standards.aspx](https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/SitePages/Pharmaceutical-Compounding-and-Management-Standards.aspx). **NOTE:** This is an internal VA website that is not available to the public.

## ADDITIONAL RESOURCES

- a. VHA Handbook 1108.04, Investigational Drugs and Supplies, dated February 29, 2012.
- b. VHA Directive 1108.08, Formulary Management Process, dated July 29, 2022.
- c. VHA Directive 1850, Environmental Programs Service, dated March 31, 2017.
- d. VHA Directive 6300, Records Management, dated October 22, 2018.
- e. VHA Directive 7701, Comprehensive Occupational Safety and Health (OSH), dated May 5, 2017.
- f. VHA Directive, 7702, Industrial Hygiene Exposure Assessment Program, dated April 29, 2016.
- g. VHA Directive 7707, Green Environmental Management System and Governing Environmental Policy, dated April 1, 2020.
- h. Controlled Environment Testing Association (CETA). CETA Certification Guide for sterile compounding facilities (CAG-003-2006). Raleigh, NC: CETA; 2015, available at: <https://coeta.memberclicks.net/login#/login>. **NOTE:** *This website requires membership to CETA to access.*
- i. Employee Occupational Health Guidebook, VHA Center for Engineering & Occupational Safety and Health (CEOSH), available at: <http://vaww.hefp.va.gov/occupational-safety-health/employee-occupational-health>. **NOTE:** *This is an internal VA website that is not available to the public.*
- j. Guidance Document for Managing Pharmaceutical Waste <http://vaww.hefp.va.gov/resources/pharmaceutical-waste>. **NOTE:** *This is an internal VA website that is not available to the public.*
- k. 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](http://vaww.ceosh.med.va.gov/01HP/02HP_Guidebooks/03_Collections/04HP_IndustrialHygiene/2012IHPF.pdf). **NOTE:** *This is an internal VA website that is not available to the public.*
- l. ISO 14644-1: Cleanrooms and associated environments - Part 1: Classification of air cleanliness by particle concentration (2015). International Organization for Standardization (ISO), Geneva, Switzerland.
- m. National Institute for Occupational Safety and Health “Managing Hazardous Drug Exposures: *Information for Healthcare Settings*”, available at

<https://www.cdc.gov/niosh/docs/2023-130/default.html>. **NOTE:** This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.

n. National Institute for Occupational Safety and Health “Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings”; available at: <https://www.cdc.gov/niosh/docs/2004-165>. **NOTE:** This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.

o. National Institute for Occupational Safety and Health “Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings”, available at <https://www.cdc.gov/niosh/docs/2023-129/>. **NOTE:** This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.

p. National Institute for Occupational Safety and Health “NIOSH List of Antineoplastic and Other Hazardous Drugs In Healthcare Settings, 2016,” available at <https://www.cdc.gov/niosh/docs/2016-161/default.html>. **NOTE:** This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.

q. NSF/ANSI 49 Biosafety Cabinetry: Design, Construction, Performance and Field Certification. NSF International (NSF), Ann Arbor, MI, US.

r. United States Pharmacopeia National Formulary (USP-NF), available at: <https://www.uspnf.com/>. **NOTE:** This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.

s. VHA PBM Compliance/Compounding SharePoint, available at: [https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy\\_Operations/SitePages/Pharmacy-Operations.aspx](https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/SitePages/Pharmacy-Operations.aspx). **NOTE:** This is an internal VA website that is not available to the public.

t. VHA Safe Handling of hazardous Drugs Guidance, Policies and Guidelines, available at: <http://vaww.hefp.va.gov/topics/usp-797-and-800>. **NOTE:** This is an internal VA website that is not available to the public.

u. VHA Space Planning Criteria (Pharmacy 268) <https://www.cfm.va.gov/til/space.asp>. **NOTE:** This is an internal VA website that is not available to the public.