Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 16-03807-223

Evaluation of Compounded Sterile Product Practices in Veterans Health Administration Facilities

May 10, 2017

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General completed a healthcare inspection of the management of compounded sterile products (CSP) in Veterans Health Administration facilities. The evaluation determined whether facilities complied with selected requirements for the safe preparation of CSPs. CSPs are pharmaceutical preparations made or modified in a controlled sterile environment.

Clear guidance for and regulatory oversight of sterile product preparation improves patient safety and protects public health. United States Pharmacopeial Convention standards provide strict requirements for preparing sterile products, including those related to the preparation area, equipment certification, and sterile technique. Despite these requirements, there have been several reports of patient deaths and harm related to unsafe CSP preparation. Further, in fiscal year 2011, the VA Office of Inspector General identified multiple opportunities for improvement related to chemotherapy drug handling.

We performed this evaluation in conjunction with 25 Combined Assessment Program reviews conducted from October 1, 2015 through March 31, 2016.

We noted high compliance in several areas, including that facilities had adequate policies and provided safe conditions for CSP preparation; that staff documented sampling for contamination in required areas and took actions when they identified positive cultures; and that when facilities used non-VA sources for CSPs, the sources were appropriately registered.

To improve operations, we recommended that the Acting Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that:

- For employees who prepare CSPs, facilities include in their competency assessment requirements gloved fingertip sampling and the required number of gloved fingertip samplings for initial competency assessment.
- Facilities include in the competency assessment checklists of employees who prepare CSPs donning of personal protective equipment in the required order and performance of appropriate hand hygiene after personal protective equipment removal.
- Competency assessments for employees who prepare CSPs include gloved fingertip sampling, written tests, and visual observation or “hands-on” skill assessment of aseptic technique at the required risk level frequency.
- Sterile chemotherapy-type gloves are available in areas where hazardous CSPs are prepared.
- Employees clean sterile compounding area floors daily and storage shelving monthly and document the cleaning.

Comments

The Acting Under Secretary for Health concurred with the report. (See Appendix B, pages 11–14, for the full text of the comments.) The implementation plans are acceptable, and we will follow up until all actions are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection of the management of compounded sterile products (CSP)[1] in Veterans Health Administration (VHA) facilities. The evaluation determined whether facilities complied with selected requirements for the safe preparation of CSPs in accordance with applicable VHA policy and industry standards.

Background

Clear guidance for and regulatory oversight of sterile product preparation improves patient safety and protects public health. United States Pharmacopeial Convention (USP) standards in chapter <797>[2] (USP <797>) provide strict requirements for preparing sterile products, including those related to the preparation area, equipment certification, and aseptic technique. Despite these requirements, there have been several reports of patient deaths and harm related to unsafe CSP preparation.[3] Further, in fiscal year 2011, OIG completed a review of chemotherapy drug handling at 44 facilities that identified multiple opportunities for improvement.

Scope and Methodology

We performed this evaluation in conjunction with 25 Combined Assessment Program reviews conducted from October 1, 2015 through March 31, 2016. OIG generated an individual Combined Assessment Program report for each facility. For this report, we summarized the data collected from the individual facility Combined Assessment Program reviews.

We reviewed facilities' policies and other relevant documents and 267 employee competency assessment records. Additionally, we inspected 38 areas used for CSP preparation and within those areas inspected 73 biological safety cabinets, laminar airflow hoods, and isolators.

Sampling. We randomly selected the 28 VHA facilities scheduled for Combined Assessment Program visits, which we had stratified by the 12 catchment areas of the OIG's Office of Healthcare Inspections' regional offices. We excluded three facilities from the review because they did not prepare CSPs.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

[1] A CSP is a pharmaceutical preparation made or modified using manufacturer labeled instructions in a controlled sterile environment.
[2] USP. *General Chapter <797> Pharmaceutical Compounding—Sterile Preparations.* 2008.
[3] CDC Responds to Multistate Outbreak of Fungal Meningitis and Other Infections. CDC website. https://www.cdc.gov/hai/outbreaks/currentsituation/. Accessed July 5, 2016.

Inspection Results

We noted high compliance in several areas, including that facilities had adequate policies and provided safe conditions for CSP preparation; that staff documented sampling for contamination in required areas and took actions when they identified positive cultures; and that when facilities used non-VA sources for CSPs, the sources were appropriately registered.

Issue 1: Competency Assessment Requirements

Compounding personnel are responsible for ensuring that CSPs are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed. USP <797> defines requirements for the competency assessment of employees who compound CSPs.[4] Compounding employees must successfully complete initial competency evaluation and at least three gloved fingertip sampling[5] procedures before being allowed to compound CSPs. After completing initial competency evaluations, re-evaluation must occur annually for employees who compound low- and medium-risk level CSPs and semi-annually for employees who compound high-risk level CSPs. Further, competency evaluation for compounding employees must include instructional training, written assessments, and skill assessment using observational audit tools. Visual observation of aseptic technique must be documented and must include the donning of personal protective equipment (PPE) in the required order and performance of appropriate hand hygiene before and after PPE removal.

Competency Assessment Requirements and Checklists. Twenty percent of facilities' competency assessment requirements did not include gloved fingertip sampling or did not include the required number of samplings for initial competency evaluation. Sixteen percent of facilities' competency assessment checklists did not include donning of PPE in the required order, and 24 percent of facilities' competency assessment checklists did not include performance of appropriate hand hygiene after PPE removal. Reasons pharmacy managers provided for noncompliance with competency assessment requirements included lack of allocated time to observe and complete assessments for each employee who prepares CSPs and not understanding requirements.

We recommended that for employees who prepare CSPs, facilities include in their competency assessment requirements gloved fingertip sampling and the required number of gloved fingertip samplings for initial competency evaluation. We also recommended that facilities include in the competency assessment checklists of

[4] USP. General Chapter <797>.

[5] Gloved fingertip sampling is performed because contamination through direct touch is the most likely source of introducing microorganisms into CSPs. The process involves the employee completing hand hygiene and personal protective equipment garbing and immediately lightly pressing each gloved fingertip of each hand onto an agar plate that will allow microorganisms (if present on a gloved fingertip) to grow. The agar plate is then incubated and assessed for growth.

employees who prepare CSPs donning of PPE in the required order and performance of appropriate hand hygiene after PPE removal.

Employee Competency Assessments. We reviewed 267 pharmacy and nursing employees' competency assessments and tests completed within the past 12 months. Eighteen percent of employee assessments did not include gloved fingertip sampling, 20 percent did not include written tests, and 15 percent did not include visual observation or "hands-on" skill assessment of aseptic technique at the required risk-level frequency. Reasons employees provided for noncompliance with competency assessment requirements included lack of allocated time to complete all required assessments and not knowing the required risk-level frequency for competency assessment.

We recommended that competency assessments for employees who prepare CSPs include gloved fingertip sampling, written tests, and visual observation or "hands-on" skill assessment of aseptic technique at the required risk-level frequency.

Issue 2: Availability of Chemotherapy-Type Gloves for Hazardous CSP Preparation

Hazardous drugs have a potential for causing cancer, developmental or reproductive toxicity, or harm to organs. Therefore, hazardous CSPs require safeguards to not only maintain the integrity of the CSPs but also to minimize the potential for exposure to employees who may come into contact with them. Chemotherapy-type gloves allow for the safe handling of hazardous drugs; they are thicker and more resistant to permeation. USP <797> requires compounding employees to use appropriate PPE when compounding hazardous drugs, including double gloving with sterile chemotherapy-type gloves.[6] We inspected 24 hazardous CSP preparation areas. Sterile chemotherapy-type gloves were not available in 17 percent of the areas. Reasons pharmacy managers provided for noncompliance included continuing the practice of using non-sterile gloves disinfected with alcohol rather than sterile chemotherapy-type gloves and the cost of sterile chemotherapy-type gloves.

We recommended that sterile chemotherapy-type gloves are available in areas where hazardous CSPs are prepared.

Issue 3: Cleaning of Floors and Storage Shelving

CSP sterility and overall freedom from contamination are dependent, in part, upon the environmental conditions under which CSPs are prepared. USP <797> requires the daily cleaning of floors and monthly cleaning of storage shelving in sterile compounding areas.[7] We inspected 38 CSP preparation areas. Facilities did not provide evidence of routine cleaning for floors in 11 percent of the areas and for storage shelving in

[6] USP. General Chapter <797>.
[7] USP. General Chapter <797>.

26 percent of the areas. Reasons pharmacy managers provided for noncompliance included not informing Environmental Management Service employees when they missed cleaning and forgetting to document completed cleanings.

We recommended that employees clean sterile compounding area floors daily and storage shelving monthly and document the cleaning.

Conclusions

We noted high compliance in several areas, including that facilities had adequate policies and provided safe conditions for CSP preparation; that facilities documented sampling for contamination in required areas and took actions when they identified positive cultures; and that when facilities used non-VA sources for CSPs, the sources were appropriately registered. We also noted high compliance for facilities reporting having processes to track and report CSP-related medication errors, including near misses. However, because of the possible variation in interpretation of what constitutes a near miss, we suggest that VHA provide guidance on the reporting of CSP-related medication errors, including near misses.

We identified system weaknesses in three main areas. First, facilities' competency assessment requirements and checklists and employees' completed competency assessments did not include all required competency assessment elements. Additionally, sterile chemotherapy-type gloves were not available in all areas where hazardous CSP were prepared. Finally, facilities did not provide evidence of consistent cleaning of sterile compounding area floors and storage shelving.

Recommendations

1. We recommended that the Acting Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that for employees who prepare compounded sterile products, facilities include in their competency assessment requirements gloved fingertip sampling and the required number of gloved fingertip samplings for initial competency assessment.

2. We recommended that the Acting Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that facilities include in the competency assessment checklists of employees who prepare compounded sterile products donning of personal protective equipment in the required order and performance of appropriate hand hygiene after personal protective equipment removal.

3. We recommended that the Acting Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, require that facility managers ensure competency assessments for employees who prepare compounded sterile products include gloved fingertip sampling, written tests, and visual observation or "hands-on" skill assessment of aseptic technique at the required risk level frequency.

4. We recommended that the Acting Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, require that facility managers ensure sterile chemotherapy-type gloves are available in areas where hazardous compounded sterile products are prepared.

5. We recommended that the Acting Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, require that facility managers ensure employees clean sterile compounding area floors daily and storage shelving monthly and document the cleaning.

Project Questions and Data

Table 1. Facility Self-Assessment Data

Project Questions	Yes	Percent Yes	No	Percent No	NA	Total
Does the facility perform sterile product compounding onsite?	25	89.3%	3	10.7%		28
Does the facility have a policy on preparation of CSPs?	25	100.0%	0	0.0%		25
Does the policy require that a pharmacist, or pharmacy techs under the supervision of a pharmacist, compounds or admixes all sterile preparations except in urgent situations?	25	100.0%	0	0.0%		25
Does the policy require that all hazardous CSPs must be prepared in an appropriate area separate from routine sterile product preparation? (NA if the facility does not compound hazardous medications.)	20	100.0%	0	0.0%	5	25
Does the policy require Environmental Quality and Control in ante and buffer areas? (NA if the facility uses compounding aseptic containment isolators.)	22	100.0%	0	0.0%	3	25
Does the policy require hood recertification every 6 months?	25	100.0%	0	0.0%		25
Does the policy require procedures for cleaning all surfaces in the ante and buffer areas? (NA if the facility uses compounding aseptic containment isolators.)	21	95.5%	1	4.5%	3	25
Has the facility established competency assessment requirements for pharmacy employees who prepare CSPs?	25	100.0%	0	0.0%		25
Do competency assessment requirements include a written test related to compounding requirements?	24	96.0%	1	4.0%		25
Do competency assessment requirements include visual observation/“hands-on” skill assessment of aseptic technique?	24	96.0%	1	4.0%		25
Do competency assessment requirements include media fill testing?	24	96.0%	1	4.0%		25
Do competency assessment requirements include gloved fingertip sampling?	20	80.0%	5	20.0%		25
If facilities use one or more outsourcing 503B facilities, does facility policy/guideline require that the compounding facility is registered with the U.S. Food and Drug Administration?	12	100.0%	0	0.0%		12
Does facility policy/guideline require that the compounding facility have a current Drug Enforcement Agency registration if compounding controlled substances? (NA if the outsourcer does not compound controlled substances for the facility.)	12	100.0%	0	0.0%	0	12

Source: VA OIG Review Guide Data from October 2015–March 2016

NA=Not applicable

Table 2. Safety Checklist and Surface Sampling Data

Project Questions	Yes	Percent Yes	No	Percent No	NA	Total
Does the pharmacy have a Quality Assurance Policy and/or safety assessment checklist/document?	25	100.0%	0	0.0%		25
Does the facility policy and/or checklist address the physical presentation of employee?	24	96.0%	1	4.0%		25
Does the facility policy and/or checklist address donning of PPE in a required order?	21	84.0%	4	16.0%		25
Does the facility policy and/or checklist address buffer area safety steps?	24	96.0%	1	4.0%		25
Does the facility policy and/or checklist address verification of all finished CSPs by a pharmacist?	23	92.0%	2	8.0%		25
Does the facility policy and/or checklist address performance of appropriate hand hygiene in the ante room after PPE removal?	19	76.0%	6	24.0%		25
Is there documented evidence of periodic surface sampling in all International Organization for Standardization classified areas?	23	92.0%	2	8.0%		25
If positive cultures were identified, did the facility complete required actions? (NA if no positive cultures were identified.)	9	100.0%	0	0.0%	16	25

Source: VA OIG Review Guide Data from October 2015–March 2016

NA=Not applicable

Table 3. Medication Error Reporting Process Data

Project Questions	Yes	Percent Yes	No	Percent No	Total
Does the facility have a process to track and report CSP-related medication errors, including near misses?	25	100.0%	0	0.0%	25
Did the facility have any CSP-related medication errors, including near misses, reported during the past 12 months?	16	64.0%	9	36.0%	25

Source: VA OIG Review Guide Data from October 2015–March 2016

Table 4. Verification of Hood Certification Data

Project Questions	Yes	Percent Yes	No	Percent No	Total
Is there documentation of initial certification if a new hood or recertification every 6 months within the past 12 months?	69	94.5%	4	5.5%	73

Source: VA OIG Review Guide Data from October 2015–March 2016

Table 5. Onsite CSP Preparation Area Physical Inspection Data

Project Questions	Yes	Percent Yes	No	Percent No	NA	Total
Does the compounding area have a separate area to store sterile products and supplies?	36	94.7%	2	5.3%		38
Does the compounding area have an ante area?	31	100.0%	0	0.0%	7	38
If the compounding area has an ante area, is hand washing performed in the ante area?	31	100.0%	0	0.0%		31
If the compounding area has an ante area, is garbing PPE performed in the ante area?	29	93.5%	2	6.5%		31
If the compounding area has an ante area, is product decontamination performed in the ante area?	29	93.5%	2	6.5%		31
Does the compounding area have a buffer area? (NA if the facility uses a compounding aseptic isolator or compounding aseptic containment isolators.)	27	96.4%	1	3.6%	10	38
If non-hazardous CSPs are prepared in this area, is there a laminar airflow hood or compounding aseptic isolator for CSP preparation? (NA if the CSP preparation area only is for hazardous compounding.)	32	100.0%	0	0.0%	6	38
If hazardous CSPs are prepared in the area, are hazardous drug spill kits available in the compounding area?	24	100.0%	0	0.0%		24
If hazardous CSPs are prepared in the area, are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?	23	95.8%	1	4.2%		24
If hazardous CSPs are prepared in the area, are all hazardous drugs prepared in a biological safety cabinet in a negative pressure area or a compounding aseptic containment isolator?	24	100.0%	0	0.0%		24
If hazardous CSPs are prepared in the area, are sterile chemo-type gloves available?	20	83.3%	4	16.7%		24

Source: VA OIG Review Guide Data from October 2015–March 2016

NA=Not applicable

Table 6. Onsite CSP Preparation Area Physical Inspection Data

Project Questions	Yes	Percent Yes	No	Percent No	NA	Total
If hazardous CSPs are prepared in the area, is a hazardous drug spill kit available for use during transport of chemotherapy medications from the pharmacy to the patient care area?	24	100.0%	0	0.0%		24
If hazardous CSPs are prepared in the area, is there an eyewash station in the area?	24	100.0%	0	0.0%		24
If there is an eyewash station in the area, is there documented evidence the eyewash station is tested weekly?	23	95.8%	1	4.2%		24
If there is an eyewash station in the area, is the eyewash station readily accessible (reachable within 10 seconds)?	22	91.7%	2	8.3%		24
Is the buffer room in good condition?	31	96.9%	1	3.1%		32
Is the buffer room free of sinks?	32	100.0%	0	0.0%		32
Is the buffer room free from doors that connect to the outdoors or high-traffic flow areas?	31	100.0%	0	0.0%		31
Is temperature inside the buffer room being monitored?	28	90.3%	3	9.7%		31
Is there documented evidence each shift of cleaning the laminar airflow workbench? (NA if no laminar airflow workbench/compounding aseptic isolator.)	30	96.8%	1	3.2%	7	38
Is there documented evidence each shift of cleaning the biological safety cabinet? (NA if no biological safety cabinet/compounding aseptic containment isolator.)	33	91.7%	3	8.3%	2	38
Is there documented evidence of daily cleaning of counters and easily cleanable work surfaces?	37	97.4%	1	2.6%		38
Is there documented evidence of daily cleaning of floors?	34	89.5%	4	10.5%		38
Is there documented evidence of monthly cleaning of storage shelving?	28	73.7%	10	26.3%		38
Do prepared CSPs have an appropriate label containing the patient identifier?	38	100.0%	0	0.0%		38
Do prepared CSPs have an appropriate label containing the date prepared?	38	100.0%	0	0.0%		38
Do prepared CSPs have an appropriate label containing the admixture components?	38	100.0%	0	0.0%		38
Do prepared CSPs have an appropriate label containing the identifier of the preparer?	37	97.4%	1	2.6%		38
Do prepared CSPs have an appropriate label containing the identifier of the checker?	37	97.4%	1	2.6%		38
Do prepared CSPs have an appropriate label containing the beyond use date?	37	97.4%	1	2.6%		38

Source: VA OIG Review Guide Data from October 2015–March 2016

NA=Not applicable

Table 7. Employee Competency Assessment/Testing Review Data

Project Questions	Yes	Percent Yes	No	Percent No	Total
Does the employee have documentation of a written test at the required risk level frequency?	213	79.8%	54	20.2%	267
Does the employee have documentation of visual observation/"hands-on" skill assessment of aseptic technique at the required risk level frequency?	228	85.4%	39	14.6%	267
Does the employee have documentation of media-fill testing and assessment at the required risk level frequency?	242	90.6%	25	9.4%	267
Does the employee have documentation of gloved fingertip sampling and assessment at the required risk level frequency?	220	82.4%	47	17.6%	267

Source: VA OIG Review Guide Data from October 2015–March 2016

Appendix B

Acting Under Secretary for Health Comments

Department of Veterans Affairs

Memorandum

Date: March 28, 2017

From: Acting Under Secretary for Health (10)

Subject: **Office of Inspector General (OIG) Draft Report, Combined Assessment Program (CAP) Summary Report – Evaluation of Compounded Sterile Product Practices in Veterans Health Administration Facilities (Project No. 2016-03807-HI-0681) (VAIQ 7773529)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on the draft report, Evaluation of Compounded Sterile Product Practices in Veterans Health Administration Facilities. The Veterans Health Administration (VHA) is strongly committed to developing long-term solutions that mitigate risks to the timeliness, cost-effectiveness, quality and safety of the Department of Veterans Affairs (VA) health care system. VHA is using the input from VA's Office of Inspector General, and other advisory groups to identify root causes and to develop critical actions. As VHA implements corrective measures, we will ensure our actions are meeting the intent of the recommendations. VHA is dedicated to sustained improvement in the high risk areas.

2. The recommendations in this report apply to GAO high risk areas 1, 2 and 4. VHA's actions will serve to address ambiguous policies and inconsistent processes, inadequate oversight and accountability, and inadequate training for VA staff.

3. I have reviewed the draft report, and provide the attached action plan to address the report's five recommendations.

4. If you have any questions, please email Karen M. Rasmussen, M.D., Director, Management Review Service at VHA10E1DMRSAction@va.gov.

Poonam Alaigh, M.D.

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

OIG Draft Report, Evaluation of Compounded Sterile Product Practices in VHA Facilities

Date of Draft Report:

Recommendations/ Actions	Status	Completion Date

OIG Recommendations

Recommendation 1. We recommended that the Acting Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that for employees who prepare compounded sterile products, facilities include in their competency assessment requirements gloved fingertip sampling and the required number of gloved fingertip samplings for initial competency assessment.

VHA Comments: Concur with comments

VHA Response:
VHA would like to clarify that none of the patient deaths or harm cited by OIG on Page 1 of the Background section involved VA facilities. OIG quoted Centers for Disease Control (CDC) report from July 2016 that looked at patient harm related to unsafe compounded sterile products (CSP) preparation at health care facilities in the country. The public needs to avoid misinterpreting the findings of that CDC report; the CDC findings do not reflect care provided at VA facilities.

Pharmacy Benefits Management (PBM) Services will prepare a memorandum for the Office for the Deputy Under Secretary for Health for Operations and Management (DUSHOM) to distribute to the Veteran Integrated Service Network (VISN) Directors that requires the VISNs to certify all VA medical facilities have implemented Recommendation 1.

At completion of this action, VHA will provide the following:
1. A memorandum and notification that all VISNs have certified Recommendation 1 has been implemented by all VA facilities.

Status:	Target Completion Date:
In Process	October 31, 2017

Recommendation 2. We recommended that the Acting Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that facilities include in the competency assessment checklists of employees who prepare compounded sterile products donning of personal protective equipment in the required order and performance of appropriate hand hygiene after personal protective equipment removal.

VHA Comments: Concur

VHA Response:
Pharmacy Benefits Management (PBM) Services will incorporate Recommendation 2 into the memorandum prepared for Recommendation 1 for the Office for the Deputy Under Secretary for Health for Operations and Management (DUSHOM) to distribute to the Veteran Integrated Service Network (VISN) Directors that requires the VISNs to certify all VA medical facilities have implemented Recommendation 2.

At completion of this action, VHA will provide the following:
1. A memorandum and notification that all VISNs have certified Recommendation 2 has been implemented by all VA facilities.

Status:	Target Completion Date:
In Process	October 31, 2017

Recommendation 3. We recommended that the Acting Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, require that facility managers ensure competency assessments for employees who prepare compounded sterile products include gloved fingertip sampling, written tests, and visual observation or "hands-on" skill assessment of aseptic technique at the required risk level frequency.

VHA Comments: Concur

VHA Response:
Pharmacy Benefits Management (PBM) Services will incorporate Recommendation 3 into the memorandum prepared for Recommendation 1 for the Office for the Deputy Under Secretary for Health for Operations and Management (DUSHOM) to distribute to the Veteran Integrated Service Network (VISN) Directors that requires the VISNs to certify all VA medical facilities have implemented Recommendation 3.

At completion of this action, VHA will provide the following:
1. A memorandum and notification that all VISNs have certified Recommendation 3 has been implemented by all VA facilities.

Status:	Target Completion Date:
In Process	October 31, 2017

Recommendation 4. We recommended that the Acting Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, require that facility managers ensure sterile chemotherapy-type gloves are available in areas where hazardous compounded sterile products are prepared.

VHA Comments: Concur

VHA Response:
Pharmacy Benefits Management (PBM) Services will incorporate Recommendation 4 into the memorandum prepared for Recommendation 1 for the Office for the Deputy Under Secretary for Health for Operations and Management (DUSHOM) to distribute to the Veteran Integrated Service Network (VISN) Directors that requires the VISNs to certify all VA medical facilities have implemented Recommendation 4.

At completion of this action, VHA will provide the following:
1. A memorandum and notification that all VISNs have certified Recommendation 4 has been implemented by all VA facilities.

Status:	Target Completion Date:
In Process	October 31, 2017

Recommendation 5. We recommended that the Acting Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, require that facility managers ensure employees clean sterile compounding area floors daily and storage shelving monthly and document the cleaning.

VHA Comments: Concur

VHA Response:
Environmental Programs Service (EPS) will collaborate with the DUSHOM on developing a memorandum to VISN and Facility Directors that outlines the Standard Operating Procedure (SOP) from the EPS Sanitation Procedure Manual template. The memorandum will add and strengthen the current guidance outlined in Chapter 4 of the EPS Sanitation Procedure Manual which addresses Pharmacy Intravenous (IV) room cleaning and the frequency expectation as outlined in the OIG Draft Summary Report for daily cleaning (floors) and monthly cleaning (shelving). To ensure employees clean sterile compounding area floors daily and storage shelving monthly and document the cleaning, the memorandum will include a requirement for facilities to add the required cleaning and documentation to the Environment of Care (EOC) rounds for regular monitoring. Deficiencies found during EOC rounds are required to be addressed within 14 business days. The memorandum will also require facilities to provide confirmation to the VISN that the item has been added to EOC rounds checklist.

At completion of this action, VHA will provide the following:
1. DUSHOM Memorandum to VISN Directors and Facility Directors

Status:	Target Completion Date:
In Process	March 30, 2017

OIG Contact and Staff Acknowledgments

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