DEPARTMENT OF VETERANS AFFAIRS
Washington DC 20420

August 26, 2013

The Honorable Carolyn N. Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

RE: OSC File No. DI-13-2584

Dear Ms. Lerner:

I am responding to your letter regarding alleged violations raised by an anonymous whistleblower at the G.V. (Sonny) Montgomery Veterans Affairs Medical Center, Jackson, Mississippi (hereafter, the Medical Center). The whistleblower alleged that by using pharmacy equipment that had failed certification, and by allowing technicians to improperly provide drug counseling to patients, the Medical Center pharmacy has engaged in conduct that may constitute a violation of law, rule, or regulation, an abuse of authority, and a substantial and specific danger to public health. The Secretary has delegated to me the authority to sign this report and take any actions deemed necessary under 5 U.S.C. § 1213(d)(5).

The Secretary asked the Under Secretary for Health to review this matter and to take any actions deemed necessary under the above code. He, in turn, directed the Office of the Medical Inspector (OMI) to conduct an investigation. In its investigation, OMI did substantiate the first two of the four allegations made by the whistleblower, could not substantiate the third, and did not substantiate the fourth. OMI made seven recommendations for the facility. Findings from OMI's investigation are contained in the enclosed Final Report, which I am submitting for your review.

Thank you for the opportunity to respond.

Sincerely,

Jose D. Riojas
Chief of Staff

Enclosure

OFFICE OF THE MEDICAL INSPECTOR

Report to the
Office of Special Counsel
OSC File Number DI-13-2584

Department of Veterans Affairs
G.V. (Sonny) Montgomery Veterans Affairs Medical Center
Jackson, Mississippi

Veterans Health Administration
Washington, DC

Report Date: July 24, 2013
TRIM 2013-D-742

Executive Summary

The Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) investigate complaints lodged with the Office of Special Counsel by an anonymous complainant (hereafter, the whistleblower) at the G.V. (Sonny) Montgomery Veterans Affairs Medical Center in Jackson, Mississippi (hereafter, the Medical Center). The whistleblower alleged that the Medical Center engaged in conduct that may constitute a violation of law, rule, or regulation, an abuse of authority, and a substantial and specific danger to public health in regard to the use of pharmacy Laminar Air Flow Workstations (hoods) after these were found in March 2013, to be noncompliant with required standards. OMI learned that the type of hood used is actually the Baker ChemoSHIELD® Glovebox (see Attachment B), a compounding aseptic containment isolator (hereafter, the containment glovebox).[1] The whistleblower also alleged that pharmacy technicians were improperly providing drug counseling to Veterans. OMI conducted a site visit to the Medical Center on June 25–27, 2013.

Summary of Allegations

The whistleblower's allegations are as follows:

1. The Medical Center pharmacy's two containment gloveboxes were tested and found to be noncompliant with required standards in March 2013.

2. Pharmacists continued to use the containment gloveboxes to compound sterile chemotherapy drugs until the end of April 2013 despite the finding of noncompliance.

3. The use of the noncompliant containment gloveboxes posed a threat to the health and safety of the pharmacists who compounded the drugs and the patients who received them.

4. Unsupervised pharmacy technicians are improperly permitted to provide telephone drug counseling to patients.

Conclusions

OMI substantiated the allegation that the Medical Center pharmacy's two containment gloveboxes failed to receive certification of compliance in March 2013 as required in Medical Center Policy Memorandum L-119-06, *Environmental and Employee Protection from Hazardous Drugs*.

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[1] The two pharmacy negative pressure airflow hoods at the Medical Center are compounding aseptic containment isolators, Baker Model CS500®. They are containment glovebox units that provide an ISO Class 5 positive and negative pressure environment for the sterile compounding of hazardous or potent pharmaceutical agents, including intravenous (IV) admixtures and chemotherapy agents. They provide protection for the personnel and the product. The ISO Class 5 designation describes the acceptable limits for air particles in the aseptic isolator environment. http://www.bakerco.com.

OMI substantiated the allegation that pharmacists continued to use the containment glovebox to compound sterile chemotherapy drugs until the end of April 2013 despite the finding of noncompliance.

- Pharmacy leadership made the decision to continue to use the active containment glovebox after it failed certification although pharmacists were advised they could opt out of this duty until repairs and recertification occurred. Most pharmacists continued to work with the uncertified containment glovebox.

- There was no reported effort to obtain the intravenous preparations from local health care facilities in spite of reports of existing arrangements for mutual pharmaceutical support among these other hospitals and the Medical Center.

OMI could not substantiate the allegation that the use of the noncompliant containment glovebox posed a threat to the health and safety of the pharmacists who compounded the drugs or the patients who received them.

- There were no reports by pharmacy staff of exposure to hazardous chemicals during fiscal year (FY) 2013, to the date of the OMI site visit.

- There was no data to suggest that any bloodstream infections occurred in patients receiving chemotherapy during FY 2013, to the date of the OMI site visit.

OMI did not substantiate the allegation that unsupervised pharmacy technicians are improperly permitted to provide telephone drug counseling to patients.

- The pharmacy technicians in the Medical Center's Advice Line Call Center are often unable to access or refer calls to the Call Center pharmacist and occasionally experience delays when trying to refer a call to a pharmacist in the main pharmacy. However, where a return phone call to the patient was necessary, a pharmacist always did so within a few hours.

Additional Issue: Cleanliness of the break room

Conclusion

The break room serves as a clean pharmacy supply area, and the break room rug is stained. The whistleblower's complaint that a reptile was found in the pharmacy in 2011 was not substantiated.

Recommendations

The Medical Center should:

1. Ensure compliance with its Policy Memorandum L-119-06, *Environmental and Employee Protection from Hazardous Drugs.*

2. Review the decision to continue use of the containment glovebox in spite of failed certification and take appropriate administrative action.

3. Develop a plan to address the need for intravenous admixture and chemotherapy drug preparations in the event of containment glovebox failure, clean room failure, or other emergencies. Ensure that this information is shared with Medical Center pharmacists.

4. Continue to provide surveillance to employees working with hazardous drugs, per local policy.

5. Continue to monitor any exposures reported by pharmacy staff, per local policy.

6. Develop a call schedule for clinical pharmacist support to the pharmacy technicians working in the Medical Center Advice Line Call Center.

7. Develop and implement a plan to create a break room separate from clean pharmacy supplies and consider noncarpeted flooring for the new break room.

Summary Statement

OMI's investigation and review of its findings did not find violations or apparent violations of statutory laws, mandatory rules, or regulations. However, the Medical Center was not compliant with its Policy Memorandum L-119-06, *Environmental and Employee Protection from Hazardous Drugs*. OMI's investigation and review of its findings did not reveal evidence of a substantial and specific danger to the public health.

I. Introduction

The Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) investigate complaints lodged with the Office of Special Counsel (OSC) by an anonymous complainant (hereafter, the whistleblower) at the G.V. (Sonny) Montgomery Veterans Affairs (VA) Medical Center in Jackson, Mississippi (hereafter, the Medical Center). The whistleblower alleged that the Medical Center engaged in conduct that may constitute a violation of law, rule, or regulation, an abuse of authority, and a substantial and specific danger to public health in regard to the use of pharmacy Laminar Air Flow Workstations (hoods) after these were found in March 2013 to be noncompliant with required standards. OMI learned that the type of hood used is actually the Baker ChemoSHIELD® Glovebox (see Attachment B), a compounding aseptic containment isolator (hereafter, the containment glovebox). The whistleblower also alleged that pharmacy technicians were improperly providing drug counseling to Veterans. OMI conducted a site visit to the Medical Center on June 25–27, 2013.

II. Facility Profile

The Medical Center serves a population of over 45,000 unique Veterans, providing primary, secondary, and tertiary medical, neurological, and mental health inpatient care. The Medical Center also operates a 120-bed Community Living Center. In support of health education and physician residency programs, the Medical Center has affiliations with the University of Mississippi Medical Center, Alcorn State University, and three community colleges.

III. Allegations

1. The Medical Center pharmacy's two containment gloveboxes were tested and found to be noncompliant with required standards in March 2013.

2. Pharmacists continued to use the containment gloveboxes to compound sterile chemotherapy drugs until the end of April 2013 despite the finding of noncompliance.

3. The use of the noncompliant containment gloveboxes posed a threat to the health and safety of the pharmacists who compounded the drugs and the patients who received them.

4. Unsupervised pharmacy technicians are improperly permitted to provide telephone drug counseling to patients.

IV. Conduct of Investigation

An OMI team consisting of John R. Pierce, M.D., the Medical Inspector; Erica Scavella, M.D., Medical Investigator; and Martha Kearns, R.N., F.N.P., Clinical Program Manager, conducted the site visit. The OMI team also included two VA clinical and pharmacy subject matter experts: Janet L. Henderson, Pharm. D., M.D., and Ravi Pathak,

Pharm. D., Ph.D. OMI reviewed relevant policies, procedures, reports, memorandums, and additional documents as listed in Attachment A. Entrance and exit briefings were held with Medical Center leadership. OMI toured the inpatient pharmacy, the intravenous (IV) rooms for compounding sterile preparations, the pharmacy break room, and the Medical Center Advice Line Call Center (hereafter, the Call Center).

OMI interviewed the following individuals during the site visit:

- (b) (6), Acting Chief of Pharmacy;
- (b) (6), Lead Pharmacy Technician;
- (b) (6), R.N., Infection Control Practitioner;
- (b) (6), M.D., Employee Health Physician;
- (b) (6), Acting Chief of Biomedicine;
- (b) (6), Pharmacy IV Room Manager;
- (b) (6), R.N., Nurse Advice Line Manager;
- Clinical Pharmacists: (b) (6) (b) (6); and
- Pharmacy Technicians: (b) (6) (b) (6).

The Office of General Counsel will review OMI's findings to determine whether there was any violation of law, rule, or regulation.

OMI **substantiated** allegations when the facts and findings supported that the alleged events or actions took place. OMI **did not substantiate** allegations when the facts showed the allegations were unfounded. OMI **could not substantiate** allegations when there was no conclusive evidence to either sustain or refute the allegation.

V. Findings, Conclusions, and Recommendations

Allegation 1
The Medical Center pharmacy's two containment gloveboxes were tested and found to be noncompliant with required standards in March 2013.

Findings

The Medical Center's inpatient pharmacy has an IV room that allows for the preparation of sterile IV admixtures and chemotherapy drugs. These activities are in accordance with VA national and local policy on environmental and employee protection from hazardous materials as well as with the applicable United States Pharmocopeial

Convention – National Formulary (hereafter, USP <797>).[2,3,4] The IV room conforms to air particulate standards, which require that preparation of high-risk agents occur in an International Standards Organization (ISO) Class 5 environment, within an ISO Class 7 buffer zone.[5] The Medical Center uses two containment gloveboxes in a clean room to achieve these standards.

When OMI toured the inpatient pharmacy IV room, we observed apparent compliance with the ISO Class 5 and ISO Class 7 requirements. The one containment glovebox in use held current certification stickers from Allometrics™, an accredited ISO certification laboratory.

During an interview with the Acting Chief of Pharmacy, OMI learned that although the inpatient IV pharmacy has two negative pressure containment gloveboxes (Baker ChemoSHIELD® Glovebox Model CS-500, see Attachment B), only one was connected and vented for use. Both units were tested on Friday, March 29, 2013, and failed certification for two negative pressure safety tests: air velocity and air flow smoke pattern testing. At the time of certification failure, Allometrics placed stickers on each containment glovebox, indicating a "Notice of Non-Compliance" in red letters. The sticker also stated that continued use was not recommended (see Attachment C).

On the same day, the Acting Chief of Pharmacy advised the Chief Engineer, the Facilities Manager, the Inpatient Pharmacy Supervisor, and the IV Room Supervisor of the compliance failure. He also submitted work orders for the repair of the two containment gloveboxes. It took almost a month to complete the repairs and to achieve recertification by Allometrics on April 24, 2013.

Conclusion

OMI substantiated the allegation that the Medical Center pharmacy's two containment gloveboxes failed to receive certification of compliance in March 2013 as required in Medical Center Policy Memorandum L-119-06, *Environmental and Employee Protection from Hazardous Drugs.*

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[2] Chemotherapy or antineoplastic drugs inhibit or prevent the growth or development of malignant (cancer) cells.

[3] Medical Center Policy Memorandum L-119-06, *Environmental and Employee Protection from Hazardous Drugs.*

[4] United States Pharmacopeial Convention – National Formulary (USP-NF), The USP-NF is a book of public pharmocopeial standards. It contains standards for chemical and biological drug substances, dosage forms, compounded preparations, excipients, medical devices, and dietary supplements. USP <797> became official with revisions on June 1, 2008; it details the procedures and requirements for compounding sterile preparations and sets standards that are applicable to all practice settings in which sterile preparations are compounded. http://www.ashp.org/s_ashp/docs/files/discguide797-2008.pdf

[5] The ISO defines the safety of clean rooms used in the preparation of hazardous agents through the number of allowable airborne particles in the environment. ISO Class 5 is required for the preparation of these agents and provides a high level of safety with fewer airborne particles. ISO Class 7 allows a greater number of airborne particles and is required in the buffer zone around an ISO Class 5 area. http://www.iso.org/iso/home.html

Recommendation

The Medical Center should:

1. Ensure compliance with its Policy Memorandum L-119-06, *Environmental and Employee Protection from Hazardous Drugs.*

Allegation 2

Pharmacists continued to use the containment gloveboxes to compound sterile chemotherapy drugs until the end of April 2013, despite the finding of noncompliance.

Findings

On March 29, 2013, the day the containment gloveboxes failed compliance testing, the Acting Chief of Pharmacy made the decision to allow continued use of the active containment glovebox. He relayed this decision to the Inpatient Pharmacy Supervisor who informally conveyed this information to the other inpatient pharmacists the following Monday, April 1, 2013. The Acting Chief of Pharmacy reported that he believed the containment glovebox in use would continue to ensure sterility of the IV admixtures with minimal risk to the pharmacist preparing the drugs. Work orders to repair both of the containment gloveboxes were placed on March 29, 2013, but there was no clear estimate as to when they would be repaired and recertified.

During interviews, some pharmacists said that they had observed the Allometrics noncompliance warning stickers advising against continued use; others reported confusion over the implications resulting from the failed certifications. No pharmacist interviewed could recall any formal notification from pharmacy leadership on the failed certification of the containment gloveboxes or the warning against their continued use. Informal discussions were held between some pharmacists and the Inpatient Pharmacy Supervisor. These pharmacists indicated they were verbally advised they could elect not to prepare these mixtures during the interim period prior to recertification. Some of the pharmacists interviewed reported they continued to work with the noncertified containment glovebox; one pharmacist opted out. OMI confirmed that no other personnel working in the pharmacy, other than the pharmacists, prepare IV admixtures and chemotherapy agents in the containment gloveboxes.

OMI learned that while there are existing arrangements with other local hospitals to obtain needed emergency pharmaceuticals, including IV drug admixtures and chemotherapy preparations, these resources were not considered as a remedy to the problem.

Conclusion

OMI substantiated the allegation that pharmacists continued to use the containment glovebox to compound sterile chemotherapy drugs until the end of April 2013 despite the finding of noncompliance.

- Pharmacy leadership made the decision to continue to use the active containment glovebox, after it failed certification, although pharmacists were advised they could opt out of this duty until repairs and recertification occurred. Most pharmacists continued to work with the uncertified containment glovebox.

- There was no reported effort to obtain the IV preparations from local health care facilities in spite of reports of existing arrangements for mutual pharmaceutical support among these other hospitals and the Medical Center.

Recommendations

The Medical Center should:

2. Review the decision to continue use of the containment glovebox in spite of failed certification and take appropriate administrative action.

3. Develop a plan to address the need for IV admixture and chemotherapy drug preparations in the event of containment glovebox failure, clean room failure, or other emergencies. Ensure that this information is shared with Medical Center pharmacists.

Allegation 3

The use of the noncompliant containment gloveboxes posed a threat to the health and safety of the pharmacists who compounded the drugs and the patients who received them.

Findings

The USP <797> (2004, revised 2008) provides guidance and standards on compounding sterile products to prevent work-related injury and illness caused by exposure to hazardous drugs and to prevent harm to patients through avoidance of microbial contamination and unintended chemical and physical contaminants during the compounding process.[6] The Medical Center policies on employee safety and compounding sterile products reference the applicable standards and requirements, including the USP <797>, The Joint Commission, and the National Institute for Occupational Health and Safety.

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[6] The United States Pharmacopeia, 27th rev., and The National Formulary, 22nd ed. *Pharmaceutical compounding-sterile preparations (general information chapter 797).* Rockville, MD: The United States Pharmacopeial Convention, 2004:2350-70.

OMI reviewed Medical Center Policy L-119-06 that provides guidance on how to monitor employees working with hazardous drugs (e.g., chemotherapy agents).[7] OMI confirmed with Employee Health that surveillance, including an annual physical and laboratory evaluation, is offered to all pharmacists working with hazardous drugs. During interviews, OMI learned that only one new pharmacist, working in the outpatient area, was unaware of the surveillance program. All other pharmacists interviewed confirmed their participation in the surveillance provided by the Medical Center. No pharmacist interviewed reported any signs or symptoms of ill health.

As part of its surveillance program, Employee Health also tracks the exposures to hazardous substances, as reported by employees. OMI reviewed the records for pharmacy-related exposures and found no reported cases of exposures from the containment gloveboxes from 2011 through the date of the site visit.

In order to investigate concerns that using the noncompliant containment glovebox posed a threat to patients, OMI reviewed data from Infection Control. While Infection Control does not monitor infections related to chemotherapy because it is usually administered on an outpatient basis, it reviews all positive blood cultures for inpatients and outpatients. In doing so, Infection Control can usually track the incidence of infections back to the source. Infection Control reported that no bloodstream infections had been identified for chemotherapy patients to date in fiscal year (FY) 2013.

Conclusion

OMI could not substantiate the allegation that the use of the noncompliant containment glovebox posed a threat to the health and safety of the pharmacists who compounded the drugs or the patients who received them.

- There were no reports by pharmacy staff of exposure to hazardous chemicals during FY 2013, to the date of the OMI site visit.

- There was no data to suggest that any bloodstream infections occurred in patients receiving chemotherapy during FY 2013, to the date of the OMI site visit.

Recommendations

The Medical Center should:

4. Continue to provide surveillance to employees working with hazardous drugs, per local policy.

5. Continue to monitor any exposures reported by pharmacy staff, per local policy.

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[7] G.V. (Sonny) Montgomery VA Medical Center, Medical Center Policy Number L119-06, April 14, 2011: *Environmental and Employee Protection from Hazardous Drugs*.

Allegation 4

Unsupervised pharmacy technicians are improperly permitted to provide telephone drug counseling to patients.

Findings

The Medical Center hosts a Call Center allowing Veterans to speak with a nurse for clinical concerns, a pharmacy technician for medication questions, or a medical administration clerk for administrative concerns. A clinical pharmacist is assigned to the Call Center to provide support to the Call Center nurses. The lead pharmacy technician supervises the pharmacy technicians and keeps a call log for each of the pharmacy-related calls received and managed by the pharmacy technicians in the Call Center. One pharmacy technician works full-time in the Call Center and the remaining technicians rotate through it.

OMI interviewed the lead pharmacy technician, 5 outpatient pharmacy technicians, and reviewed all 11 outpatient pharmacy technicians' credentialing folders. OMI also reviewed the position description for pharmacy technicians (GS-0661-5), which includes the following functions:

> Advises and helps educate patients, nurses, physician office, etc. of all required information for correct and timely processing of prescription orders, eligibility requirements, status of orders, availability of specific drugs, and similar questions concerning VA policies . . . Answers and/or returns patient telephone calls and resolves problems related to their medication orders.[8]

All pharmacy technician folders reviewed included the appropriate education and required ongoing training. Because all pharmacy technicians are employed at a GS-5 level, they are not required to obtain certification or licensure and, while working at VA, do not fall under any oversight by the State of Mississippi.

During interviews, the pharmacy technicians were knowledgeable of their functional statements and limitations in scope and described the circumstances under which they refer calls to an inpatient pharmacist. The technicians did report occasional delays in initially reaching a pharmacist, but indicated that there were no gaps in following-up with Veterans. If a return phone call to the Veteran was necessary, the pharmacist always did so within a few hours. Pharmacy technicians did state that they were often unable to access or refer calls to the Call Center clinical pharmacist.

OMI reviewed the pharmacy technician call log for appropriateness of advice content and referral to pharmacy experts, and found no evidence to support the allegation that pharmacy technicians offered advice beyond their scope of practice.

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[8] Refer to the Medical Center Pharmacy Service Functional Statement, Pharmacy Technician and Pharmacy Technician/Timekeeper Outpatient GS-0661-05, Position Number 07324-A and 78320 in the Reference List.

Conclusion

OMI did not substantiate the allegation that unsupervised pharmacy technicians are improperly permitted to provide telephone drug counseling to patients.

- The pharmacy technicians in the Call Center are often unable to access or refer calls to the Call Center pharmacist and occasionally experience delays when trying to refer a call to a pharmacist in the main pharmacy. However, where a return phone call to the patient was necessary, a pharmacist always did so within a few hours.

Recommendation

The Medical Center should:

6. Develop a call schedule for clinical pharmacist support to the pharmacy technicians working in the Medical Center Advice Line Call Center.

Additional Issues

The whistleblower reported a cleanliness issue in the pharmacy and specifically disclosed that the inpatient pharmacy and break room contain dirty carpeting covered with crushed medications and shelves covered in dust. The whistleblower alleges that a live reptile was found in the nonchemotherapy clean room during 2011.

Findings

During the OMI tour of the inpatient pharmacy, IV room, clean rooms, and break room, we found no evidence of stained carpeting, crushed medication, or dusty shelves in the inpatient pharmacy, IV room, or unit-dose areas. OMI did observe stained carpeting in the break room, which also serves as a clean supply area. The break room also contains a refrigerator, table, and chairs for employee use but no sink or source of running water. OMI observed no reptiles while on the tour. During interviews with the pharmacists, no one reported seeing a live reptile during 2011 although one pharmacist recalled that he thought someone had found a small lizard in the area about 10 years ago.

Conclusion

The break room serves as a clean pharmacy supply area, and the break room rug is stained. The whistleblower's complaint that a reptile was found in the pharmacy in 2011 was not substantiated.

Recommendation

The Medical Center should:

7. Develop and implement a plan to create a break room separate from clean pharmacy supplies and consider non-carpeted flooring for the new break room.

Attachment A

Documents Reviewed by the OMI

1. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH) (2004). Publication 2004-165, *Preventing occupational exposures to chemotherapy and other hazardous drugs in health care settings.* Retrieved from http://www.cdc.gov/niosh/docs/2004-165/.

2. Department of Health and Human Services, CDC, NIOSH, (April 2012). *Workplace safety and health topics: Occupational exposure to chemotherapy agents.* Retrieved from http://www.cdc.gov/niosh/topics/chemotherapy/.

3. Department of Health and Human Services, CDC. Publication 2012-150, *NIOSH list of chemotherapy and other hazardous drugs in healthcare setting 2012.* Retrieved from http://www.cdc.gov/niosh/docs/2012-150/.

4. Eagleson, D. C., and Stuart, D. G. (2007). *Pharmacy isolator performance testing: The Baker Company compounding isolators and USP <797> requirements. Acumen, 9*(1). The Baker Company: Sanford, ME. Retrieved from http://www.bakerco.com.

5. American Society of Health-System Pharmacists (ASHP). *The ASHP Discussion Guide for Compounding Sterile Preparations: Summary and Implementation of USP Chapter <797>.* No date. Retrieved from http://www.ashp.org/s_ashp/docs/files/HACC_797guide.pdf.

6. USP 32-NF27: United States Pharmacopeial Convention, Inc. 12601 Twinbrook Parkway, Rockville, MD 20852. Retrieved from http://www.usp.org.

7. The United States Pharmacopeia, 27th rev., and The National Formulary, 22nd ed. *Pharmaceutical compounding-sterile preparations (general information chapter 797).* Rockville, MD: The United States Pharmacopeial Convention, 2004:2350-70.

8. Controlled Environment Testing Association (CETA), CAG-001-2005 (revised 12/08/2008): Applications Guide for the use of Compounding Isolators in Compounding Sterile Preparations in Healthcare Facilities. Retrieved from http://www.cetainternational.org.

9. CETA Compounding Isolator Testing Guide, CAG-002-2006 (revised 12/08/2008). Retrieved from http://www.cetainternational.org.

10. G.V. (Sonny) Montgomery VA Medical Center, Medical Center Policy Number: K-05-31, June 8, 2011: *Employees Health Services.*

11. G.V. (Sonny) Montgomery Service Policy Memorandum Number 119-49, April 5, 2011: *Pharmacy Safety, Occupational Health and Fire Protection.*

12. G.V. (Sonny) Montgomery VA Medical Center, Pharmacy Service *Functional Statement, Pharmacy Technician Outpatient, GS-0661-05, Position Number 07324-A.*

13. G.V. (Sonny) Montgomery VA Medical Center, Pharmacy Service *Functional Statement, Pharmacy Technician/Timekeeper, Outpatient GS-0661-05, Position Number 78320.*

14. G.V. (Sonny) Montgomery VA Medical Center, Medical Center Policy Number 119-50, *March 16, 2011: IV Chemotherapy Orders.*

15. G.V. (Sonny) Montgomery VA Medical Center, Service Policy Memorandum 119-46, *April 11, 2011: Quality Assurance for Pharmacy-Prepared Sterile Product.*

16. G.V. (Sonny) Montgomery VA Medical Center, Medical Center Policy Number L119-06, *April 14, 2011: Environmental and Employee Protection from Hazardous Drugs.*

17. The Baker Company, Compliance with USP <797>: *Pharmaceutical Compounding – Sterile Preparations.* Retrieved from http://www.bakerco.com.

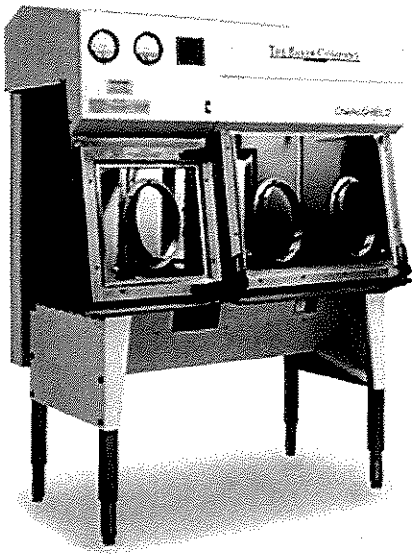
18. Selected patient electronic medical records.

19. Various electronic and paper communications, meeting minutes, and performance documents.

20. G.V. (Sonny) Montgomery Medical Center Policy Number F-119-06, January 18, 2013: *Drug Policy*

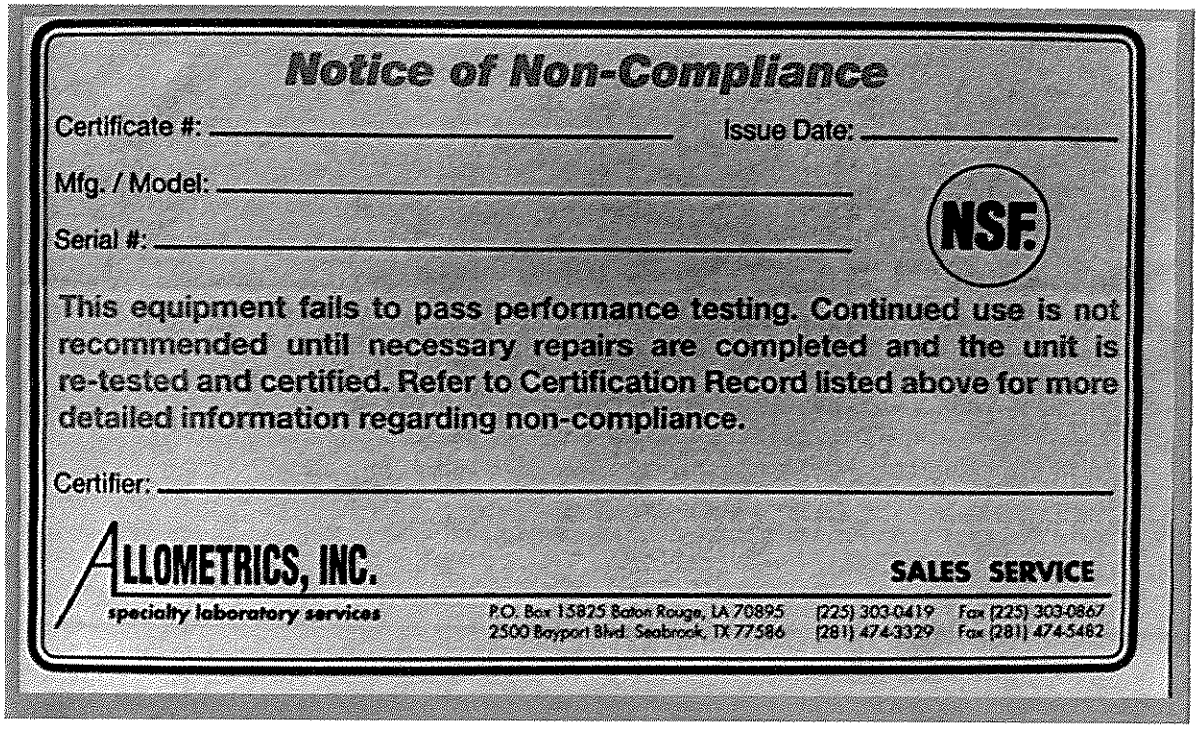
Attachment B

Baker ChemoSHIELD® Compounding Aseptic Containment Isolator



http://www.bakerco.com/products/pharmacy-barrier-isolators/chemoshield.html

Attachment C



Notice of Non-Compliance

Certificate #: _____ Issue Date: _____

Mfg. / Model: _____

Serial #: _____

NSF

This equipment fails to pass performance testing. Continued use is not recommended until necessary repairs are completed and the unit is re-tested and certified. Refer to Certification Record listed above for more detailed information regarding non-compliance.

Certifier: _____

ALLOMETRICS, INC.
specialty laboratory services

SALES SERVICE

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2500 Bayport Blvd. Seabrook, TX 77586 (281) 474-3329 Fax (281) 474-5462