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DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

February 3, 2016

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-15-4557

Dear Ms. Lerner:

I am responding to your letter regarding allegations made by a whistleblower at the Philadelphia Department of Veterans Affairs (VA) Medical Center (hereafter the Medical Center) in Philadelphia, Pennsylvania. The whistleblower alleged that a pathologist is not board certified and is not qualified to serve as Electron Microscopy (EM) director and that the failure of the EM Department to submit written reports in a timely manner hampers clinicians and puts patients at risk. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary as referenced in 5 United States Code § 1213(d)(5).

The Secretary directed the Under Secretary for Health to refer the whistleblower's allegations to the Office of the Medical Inspector, who assembled and led a VA team to investigate these allegations. The team conducted a site visit to the Medical Center on October 19-22, 2015, and substantiated allegations regarding board certification but found that lack of certification to be moot in view of the fact that the EM Department does not function as a diagnostic program; its reports are issued for research, education, and quality control purposes. Therefore, we found no violation of VA and Veterans Health Administration policy, no gross mismanagement, and no substantial and specific danger to public health and safety.

VA made four recommendations to the Medical Center and one to the Veterans Health Administration. Findings from the investigation are contained in the report, which I am submitting for your review.

Thank you for the opportunity to respond.

Sincerely,

A handwritten signature in black ink that reads "Robert D. Snyder".

Robert D. Snyder
Interim Chief of Staff

Enclosure

**DEPARTMENT OF VETERANS AFFAIRS
Washington, DC**

**Report to the
Office of Special Counsel
OSC File Number DI-15-4557**

**Department of Veterans Affairs
Philadelphia VA Medical Center
Philadelphia, Pennsylvania**



Report Date: December 29, 2015

TRIM 2015-D-5709

Executive Summary

The Under Secretary for Health (USH) directed that the Office of the Medical Inspector (OMI) assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Philadelphia VA Medical Center (hereafter, the Medical Center) located in Philadelphia, Pennsylvania. An anonymous whistleblower alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. The VA team conducted a site visit to the Medical Center on October 19–22, 2015.

Specific Allegations of the Whistleblower

1. **Physician 1** is not an American Board of Pathology (Board) certified anatomic pathologist and, as such, is not qualified to serve as Electron Microscopy (EM) Director;
2. Under the leadership of **Physician 1** EM has routinely failed to issue written reports on specimens transmitted for EM study within 10 working days using the Veterans Health Information Systems and Technology Architecture (VistA), as required by the Handbook; and
3. The absence of written reports on EM studies in VistA suggests that clinicians are not being apprised of the results, which negatively affects patient treatment.

VA **substantiated allegations** when the facts and findings supported that the alleged events or actions took place and **did not substantiate allegations** when the facts and findings showed the allegations were unfounded. VA was **not able to substantiate allegations** when the available evidence was not sufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After careful review of findings, VA makes the following conclusions and recommendations.

Conclusions for Allegation 1

- VA **substantiates** that **Physician 1** is not board certified; therefore, he does not meet the Veterans Health Administration (VHA) Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures* (October 6, 2008), requirement, as written to serve as Director of a diagnostic EM program. However, the EM program at the Medical Center is currently not functioning as a diagnostic EM program.
- **Physician 1** is viewed as a clinical expert by all clinical staff with whom he interacts, and functions within the current established guidelines for a non-board-certified pathologist.

Recommendations to the Medical Center

1. Work with the EM national program office to appropriately classify the Medical Center's EM program and its Director.
2. If the Medical Center re-establishes a diagnostic EM program, ensure that the Director meets all requirements.

Conclusions for Allegation 2

- Review of the specimen processing paperwork in EM reveals that they are performing and documenting their work within 10 working days. However, the types of reports issued for research, education, and quality control are different from those required for diagnostic reports and should not be reported in VistA, as the VistA patient file is reserved for diagnostic reports. According to the VHA Handbook, only diagnostic reports are required to be entered within 10 days into VistA.
- Although VA confirms that EM did not routinely issue written reports on specimens accessed for EM study within 10 working days using VistA, we **do not substantiate** that there was a violation of the Handbook. None of the Medical Center's EM cases were used to make a patient's diagnosis.
- Although the paperwork indicates that documentation of EM work is being generated within the required 10-day time frame, the lack of closure of accession for quality control, education, and research is problematic, as it creates the misperception of unfinished diagnostic work.
- The Medical Center was not closing EM accessions within the VistA records.

Recommendations to the Medical Center

3. Appropriately close the Medical Center's current open EM reports within VistA using existing paper records to obtain the actual date of completion. Hereafter, establish a practice of closing cases as the final disposition of each case is determined, regardless of its testing category (quality, research, and education).
4. Establish a monthly monitor of the Pathology Department's unverified reports and address, as appropriate.

Recommendation to VHA

1. Review the accession closure practices at the seven VA EM facilities and ensure that they are closing out all accessions as directed in VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, October 6, 2008.

Conclusions for Allegation 3

- **VA did not substantiate** that the absence of written reports of EM studies in VistA suggests that clinicians are not being apprised of the results, which negatively affects patient treatment.

Recommendations to the Medical Center

None.

Summary Statement

VA has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and specific danger to public health and safety. In particular, the Office of General Counsel (OGC) has provided a legal review, VHA Human Resources (HR) has examined personnel issues to establish accountability, and the Office of Accountability Review (OAR) has reviewed the report and has or will address potential senior leadership accountability. VA found no violations of VA and VHA policy. Because EM at the Medical Center is not in use as a clinical program, there is not a substantial and specific danger to public health and safety.

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I. Introduction

The Under Secretary for Health (USH) directed that the Office of the Medical Inspector (OMI) assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Philadelphia VA Medical Center (hereafter, the Medical Center) located in Philadelphia, Pennsylvania. An anonymous whistleblower alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. The VA team conducted a site visit to the Medical Center on October 19–22, 2015.

II. Facility Profile

The Medical Center, part of Veterans Integrated Service Network (VISN) 4, is a Joint Commission-accredited, tertiary care teaching hospital serving 60,000 Veterans in the Nation's fifth-largest metropolitan area, which includes the city of Philadelphia and surrounding six counties in Southeastern Pennsylvania and Southern New Jersey. The Medical Center is located in West Philadelphia's University City District, while VA outpatient clinics are located at Fort Dix and Gloucester County, New Jersey, and Horsham, Pennsylvania. A clinical annex is located in Camden, New Jersey, a dialysis facility in West Philadelphia, and a Residential Rehabilitation and Treatment Program in Southwest Philadelphia.

III. Specific Allegations of the Whistleblower

1. **Physician 1** is not an American Board of Pathology (Board) certified anatomic pathologist and, as such, is not qualified to serve as Electron Microscopy (EM) Director;
2. Under the leadership of **Physician 1** EM has routinely failed to issue written reports on specimens transmitted for EM study within 10 working days using the Veterans Health Information Systems and Technology Architecture (VistA), as required by the Handbook; and
3. The absence of written reports on EM studies in VistA suggests that clinicians are not being apprised of the results, which negatively affects patient treatment.

IV. Conduct of Investigation

The VA team conducting the investigation included **[REDACTED]** M.D., Deputy Medical Inspector (general surgeon), **[REDACTED]** Registered Nurse (RN), Clinical Program Manager, **[REDACTED]** MA, Health System Specialist, all from OMI; **[REDACTED]** M.D., (pathologist), National Director of Pathology and Laboratory Medicine Services, and **[REDACTED]** PHR-CP, HR Specialist, VISN 8. VA reviewed relevant policies, procedures, professional standards, reports, memoranda, and other documents listed in Attachment A. We toured the Medical Center's Pathology and Laboratory Medicine Services (P&LMS) Department, including cytopathology, immunochemistry, and diagnostic EM sections.

We also interviewed the following Medical Center employees:

- [REDACTED] M.D., Interim Chief of Staff (I/CoS)
- [REDACTED] M.D., Chief of Pathology
- [REDACTED] M.D., Chief, Electron Microscopy
- [REDACTED] M.D., Chief of Surgery
- [REDACTED] M.D., Gastroenterologist
- [REDACTED] M.D., Chief, Nephrology
- [REDACTED] M.D., Chief, Ear, Nose, and Throat
- [REDACTED] M.D., Pathologist
- [REDACTED] M.D., Pathologist
- [REDACTED] M.D., Director of Dialysis
- [REDACTED] Health Science Specialist
- [REDACTED] Supervisor, Anatomic Pathology
- [REDACTED] Chief Technologist
- [REDACTED] Cytotechnologist
- [REDACTED] Histology Technician
- [REDACTED] Histology Technician
- [REDACTED] Histotechnologist
- [REDACTED] Technologist
- [REDACTED] Patient Advocate
- [REDACTED] , Laboratory Information Manager
- [REDACTED] Patient Safety Manager
- [REDACTED] Acting Safety Manager
- [REDACTED] Chief, Risk Management
- [REDACTED] Chief, Quality Management
- [REDACTED] Acting Chief, Credentials
- [REDACTED] Director, HR

V. Background.

Diagnostic EM originated as one of the Veterans Health Administration's (VHA) approximately 23 designated Special Medical Services, along with such modalities as renal dialysis, renal transplant, and cardiopulmonary bypass surgery. Specific appropriations support these Services and are present only in selected hospitals. The former Office of the Assistant Chief Medical Director for Professional Services had the responsibility for nurturing, planning, selecting sites, managing, and evaluating all the Special Services, delegating this duty to the appropriate professional service. For example, the Pathology Service in VA Central Office oversees diagnostic EM. Inherent in the establishment of EM units is the concept that teaching and research are legitimate and important activities. VHA's seven EM laboratory programs are located in Cleveland, Ohio; Durham, North Carolina; Gainesville, Florida; Madison, Wisconsin; Miami, Florida; Philadelphia, Pennsylvania; and Seattle, Washington.

In medical centers, diagnostic EM units are organizationally part of P&LMS. In some instances, the Chief of the Laboratory Service may also be the Director of the local EM program, but more frequently, the responsibility is assigned to another pathologist with particular interest and skill in this field. A national committee of VA and non-VA pathologists monitors EM units by periodic evaluation of workload productivity and annual quality assurance assessment.¹

P&LMS includes the sections of both anatomic and clinical pathology. Anatomic pathology relates to the processing of surgical and gynecological specimens. Its subsections usually include surgical pathology, histology, and cytology. Clinical pathology is the division that processes the test requests more familiar to the general public, such as blood cell counts, coagulation studies, urinalysis, blood glucose level determinations, and throat cultures. Its subsections include chemistry, hematology, microbiology, urinalysis, and blood bank.

EM is the examination of tissue with an electron microscope, which allows much greater magnification, enabling the visualization of organelles (individual cell body parts) within the cells. EM has long been used in the discovery and description of viruses. Organisms smaller than bacteria have been known to exist since the late 19th century, but the first EM visualization of a virus came only after the EM was developed.²

The use of EM has been largely supplanted by immunohistochemistry, but it is still in common use for certain tasks.³ Indications for the use of EM for pathologic diagnosis fall into major categories such as renal disease, neoplasms, infectious disease, metabolic disease, and disease of obscure nature and/or unknown etiology. Even today, in the age of molecular diagnostics, EM is a mainstay in detecting new and unusual outbreaks, such as norovirus (Norwalk agent). EM continues to serve to confirm infection in quality control of molecular techniques.

The quality of all VHA Diagnostic EM laboratories is reviewed annually by a national peer review process organized by the National Electron Microscopy Program Coordinator and is under the direction the National Director of Pathology and Laboratory Medicine. A committee of pathologists from inside and outside VA reviews at least five diagnostic cases annually from each laboratory. Members of the national review committee are typically also members of the United States and Canadian Academy of Pathology (USCAP) and meet to review the annual reports and clinical diagnostic cases prior to the annual USCAP conference.

¹ VHA Diagnostic Electron Microscopy Program Overview. July 1, 2010.

http://www.va.gov/DIAGNOSTICEM/History_of_the_VHA_Diagnostic_Electron_Microscopy_Program.asp

² Goldsmith, C.S. & Miller, S.E., *Modern Uses of Electron Microscopy for Detection of Viruses*, CLINICAL MICROBIOLOGY REVIEWS, Vol. 22, No. 4, Oct. 2009, p. 552-563.

³ Immunohistochemistry refers to a laboratory test that uses antibodies to test for certain antigens in a sample of tissue. The antibody is usually linked to a radioactive substance or a dye that causes the antigens in the tissue to light up under a microscope. Immunohistochemistry is used to help diagnose diseases, such as cancer. It may also be used to help tell the difference between different types of cancer. National Cancer Institute at the National Institutes of Health.

<http://www.cancer.gov/publications/dictionaries/cancer-terms?CdrID=653117>

VA uses EM for multiple purposes: diagnostic use, quality assurance, education, and research. Clinically, EM is mainly used within VA for final diagnosis of renal pathology. For quality assurance, it may serve to confirm a diagnosis made by other tests. In education, it is used to train medical students and residents in anatomic pathology; and in research, it is used for data collection and analysis leading to publication. VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, provides the guidance for clinical pathology. Subparagraph 10j of the Handbook, states:

- (1) EM, an important element in diagnostic pathology, must be provided for renal pathology and when needed for difficult diagnostic cases. EM services can be provided in the following ways:
 - (a) Establishment of a diagnostic EM Program in selected VA medical facilities;
 - (b) Shared use of EM resources acquired primarily for research or education purposes;
 - (c) Referral of material for ultrastructural study to another VA medical facility with EM resources in the geographic area; and
 - (d) Referral of material to, or use of EM resources in, an affiliated medical facility or community hospital after establishment of a formal agreement for those services.

- (2) Functions of a diagnostic EM Program in the VHA Laboratory Service include:
 - (a) Enhancement of morphologic diagnosis;
 - (b) Provision of diagnostic EM services at the parent hospital and to other VA facilities in the geographic area;
 - (c) Provision of training in EM for professional and technical personnel;
 - (d) Inclusion, where appropriate, of the EM findings in facility teaching and conferences; and
 - (e) Development, where indicated, of sharing agreements to provide EM services for non-VA medical institutions.⁴

In addition, subparagraph 10j(5) of the Handbook says that:

1. The Program Director needs to be an academician with excellent skills and training in anatomic pathology and documented interest in research and teaching.
2. Board certification in anatomic pathology is required. At least 1 year of experience in EM, preferably diagnostic EM, is strongly suggested
3. Board certification in clinical pathology is not required but is desirable, since EM laboratories need to serve the entire laboratory in applications, for example, in hematology and microbiology.

Subparagraph 10k of the Handbook states that specimens transmitted for clinical EM study are accessed and documented appropriately. It further states that a written report

⁴ VA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, October 6, 2008.

must be issued promptly on each clinical patient specimen using VistA. If VistA is not available, the report is transcribed onto Standard Form (SF) 515 and placed in the patient's record within 10 working days after the study is requested for cases where ultra-structural findings are of clinical significance. Ideally, a verbal report of the clinically pertinent EM findings needs to be provided to the patient's health care provider within 3 working days after the EM study is requested. The date and content of this verbal report must be noted in the written report.

Regarding certification, paragraph 10 (1e) of the Handbook states, "Only qualified, licensed, and locally privileged pathologists certified by the American Board of Pathology in Anatomic Pathology can provide the written report for all surgical pathology, autopsy, diagnostic electron microscopy, and abnormal cytopathology examinations."

VI. Findings, Conclusions, and Recommendations

Allegation 1

Physician 1 is not an American Board of Pathology (Board) certified anatomic pathologist and, as such, is not qualified to serve as EM Director.

Findings

Physician 1 reported receiving medical school training outside of the United States and completing his residency in the United States. His residency included training on EM. He completed his residency in 1992 and was hired by VA. The VA team confirmed that the provider completed an Accreditation Council for Graduate Medical Education approved program in Pathology, has an active license to practice medicine, and is not board certified, utilizing VA's software that documents prime source verification of credentialing information.

Since he is working as a pathologist without board certification, the Medical Center ensures that all of his cases are always reviewed by a board-certified pathologist prior to any report being issued, in compliance with anatomic pathology requirements. We spoke with the four other pathologists who all confirmed that one of them signs off all of **Physician 1** cases. According to the Chief of Pathology, **Physician 1** has always functioned in the best interests of the Department and the Service; he actively teaches small group instruction at the University of Pennsylvania and provides support at the Medical Center's Tumor Boards. The Chief and the interviewed surgeons all reported that **Physician 1** is well thought of by the surgeons he serves and that they value his work and actively seek out his opinion.

In 1993, he was named Co-Director to the then-EM Director, **Physician 2** responsible for the maintenance of the Medical Center's EM program. He has been serving in this capacity for the last 19 years and has maintained the Medical Center's EM program's quality certification. He became the Director in 1999. The EM program

stopped processing renal biopsies in 1999, thus ceasing to be a diagnostic EM program and changing its nature to one used only for quality assurance, education, and research.

Conclusions for Allegation 1

- VA substantiates that **Physician 1** is not board certified; therefore, he does not meet the Handbook 1106.01 requirement, as written, to serve as Director of a diagnostic EM program. However, the EM program at the Medical Center is currently not functioning as a diagnostic EM program.
- **Physician 1** is viewed as a clinical expert by all clinical staff with whom he interacts and functions within the current established guidelines for a non-board-certified pathologist.

Recommendations to the Medical Center

1. Work with the EM national program office to appropriately classify the Medical Center's EM program and its Director.
2. If the Medical Center re-establishes a diagnostic EM program, ensure that the Director meets all requirements.

Allegation 2

Under the leadership of **Physician 1 EM has routinely failed to issue written reports on specimens transmitted for EM study within 10 working days using the Veterans Health Information Systems and Technology Architecture (VistA), as required by the Handbook.**

Findings

Within VA, EM is currently used mainly for diagnosis of renal biopsy specimens. After conducting a cost-benefit analysis, the Medical Center decided to send all renal biopsy specimens for diagnosis to the University of Pennsylvania, located adjacent to the Medical Center. Therefore, the main purpose of EM within the facility is currently for institutional quality control, research, and education. The Medical Center has ensured the quality of the EM product by participating in VA's national EM program office's clinical certification program. It has produced research as evidenced by a recent publication⁵ and is involved in training medical students and residents from the University of Pennsylvania on EM. The Medical Center's EM program has not been performing any clinical work since **Physician 1** was listed as the director, even though it has maintained the proficiency level of a clinical program.

⁵ Xiong, G., Elking, J.A., Kundu, S., et al., *Traumatic Brain Injury-Induced Ependymal Ciliary Loss Decreases Cerebral Spinal Blood Flow*, Journal of Neurotrauma, 31, 1396-1404; August 15, 2014,

We reviewed the EM accession log book from October 2009 to May 2015. We found that the Medical Center accessed all specimens in VistA and that only 23 of the 2,021 accessed specimens went to final diagnosis. The Medical Center completed these 23 specimen reports for the national EM program office's quality certification evaluation. None of the specimens were used for anything other than for quality control, research, and/or education purposes.

We interviewed the EM director and the technologist and found that they use a stepped specimen processing procedure:

- a) The technician obtains a sample piece of a tissue specimen from surgical cases and fixes it in formaldehyde;
- b) The technician cuts the tissue into smaller pieces and gives each piece an accession number;
- c) The technician makes a thick cut slide of the specimen and gives it to the pathologist for review under the EM;
- d) If further processing is performed, the technician makes a thin cut slide which is reviewed under the EM by the pathologist;
- e) If still further processing is performed, the technician takes an EM photograph, and it is reviewed by the pathologist; and
- f) If the case is to be used for EM clinical certification purposes, a report is generated.

At each step, if the slide does not reveal anything significant, they stop further processing and do not generate a report that verifies the order.

We reviewed the Medical Center's unverified orders report from January 1, 2000, to October 22, 2015, and a turnaround time report on 2,021 accessions. The usual VA practice is to assign an accession number to the primary tissue with secondary pieces of the same tissue annotated as a, b, c, etc. We found at the Medical Center that the 2,021 accessions were for 902 unique patient cases and 54 research cases.⁶ There were 1,998 unverified accessions and 23 verified accessions. We found the average verified turnaround time for the 23 clinical quality certification specimens was 127 days.

While the audit of the EM anatomic pathology VistA computer files revealed pending cases, paper records of the accessions kept in the EM section showed completion of processes within the required time frames. An audit of both sets of records show similar workload accounting and documentation, with the principle difference being the Medical Center did not electronically close out the records when specimens were not needed for clinical quality certification.

⁶ Accession number is a sequential number assigned to each record or volume as it is added to a database (such as a library catalog or index) and which indicates the chronological order of its acquisition. BusinessDictionary.com Copyright©2015 WebFinance, Inc.
<http://www.businessdictionary.com/definition/accession-number.html>

Conclusions for Allegation 2

- Review of the specimen processing paperwork in EM reveals that they are performing and documenting their work within 10 working days. However, the types of reports issued for research, education, and quality control are different from those required for diagnostic reports and should not be reported in VistA, as the VistA patient file is reserved for diagnostic reports. According to the VHA Handbook, only diagnostic reports are required to be entered within 10 days into VistA.
- Although VA confirms that EM did not routinely issue written reports on specimens accessed for EM study within 10 working days using VistA, we **do not substantiate** that there was a violation of the Handbook. None of the Medical Center's EM cases were used to make a patient's diagnosis.
- Although the paperwork indicates that documentation of EM work is being generated within the required 10-day time frame, the lack of closure of accession for quality control, education, and research is problematic, as it creates the misperception of unfinished diagnostic work.
- The Medical Center was not closing EM accessions within the VistA records.

Recommendations to the Medical Center

3. Appropriately close the Medical Center's current open EM reports within VistA, using existing paper records to obtain the actual date of completion. Hereafter, establish a practice of closing cases as the final disposition of each case is determined, regardless of its testing category (quality, research, and education).
4. Establish a monthly monitor of the Pathology Department's unverified reports and address as appropriate.

Recommendation to VHA

1. Review the accession closure practices at the seven VA EM facilities and ensure that they are closing out all accessions as directed in VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, October 6, 2008.

Allegation 3

The absence of written reports on EM studies in VistA suggests that clinicians are not being apprised of the results, which negatively affects patient treatment.

Findings

As noted in Allegation 2, the EM staff was using paperwork to record and document the processing of EM accessions. Interviews with referring physicians and pathologists

revealed that clinicians were involved in the discussion of all pathology results. The referring physicians reported they obtained their pathology diagnoses usually within 2–3 days, unless there were extenuating circumstances and additional review was necessary requiring the slides to be sent to the Joint Pathology Center in Bethesda, Maryland, for diagnoses.⁷

A review of the EM accessions at the Medical Center show that all of them are for quality control, research, education, and EM quality certification purposes. The Medical Center obtains the patient EM specimens from residual tissue that are not needed for the patient's anatomic pathology diagnosis utilizing established laboratory practice for controls and maintenance of personnel competencies. There is a requirement to maintain a connection between the EM specimen and the corresponding surgical pathology and clinical data used for teaching purposes. In none of the specimens reviewed were clinical requests made for EM testing. The Medical Center made all of these patients' diagnoses without the aid of EM.

Conclusions for Allegation 3

- VA did not substantiate the absence of written reports on EM studies in Vista suggests that clinicians are not being apprised of the results, which negatively affects patient treatment.

Recommendations to the Medical Center

None.

Summary Statement

VA has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and specific danger to public health and safety. In particular, OGC provided a legal review, VHA HR examined personnel issues to establish accountability, and OAR reviewed the report and has or will address potential senior leadership accountability. VA found no violations of VA and VHA policy. Because EM at the Medical Center is not in use as a clinical program, there is not a substantial and specific danger to public health and safety.

⁷ The Joint Pathology Center (JPC) is the federal government's premier pathology reference center supporting the Military Health System (MHS), Department of Defense (DoD) and other federal agencies. It provides world class diagnostic subspecialty consultation, education, training, research and maintenance/modernization of the tissue repository in support of the mission of the DoD and other federal agencies. <http://ipc.capmed.mil/>

Attachment A

Documents in addition to the Electronic Medical Records reviewed.

Philadelphia Veterans Affairs Medical Center (VAMC), *American Association of Blood Banks (AABB) Assessment Summary Report*, June 17, 2015.

Philadelphia VAMC, *College of American Pathologists (CAP) accreditation letter*, March 9, 2015.

Philadelphia VAMC, *Delineation of Privileges: Pathology and Laboratory Services*.

Philadelphia VAMC Electron Microscopy, *Internal email for replacement of EM scope*, December 3, 2012.

Philadelphia VAMC Electron Microscopy Procedural Manual, *Logging and Filing of Submitted Specimens*, August 5, 2014.

Philadelphia VAMC Electron Microscopy Procedural Manual, *Slide and Report Review*, August 5, 2014.

Philadelphia VAMC Electron Microscopy, *EM Turnaround Time Report*, January 1, 2000 - October 22, 2015.

Philadelphia VAMC Electron Microscopy, *EM Unique Unverified EM Cases*, January 1, 2000 - October 22, 2015.

Philadelphia VAMC Electron Microscopy, *EM Unverified Reports*, January 1, 1980 - October 21, 2015.

Philadelphia VAMC Electron Microscopy, *EM Workload Capture*, January 1, 2000 - October 22, 2015.

Philadelphia VAMC Otorhinolaryngology/Head and Neck Surgery Tumor Board Minutes, September 15, 2015 - October 19, 2015.

Philadelphia VAMC Pathology and Laboratory Medicine, *Organizational Chart*, August 10, 2014.

Philadelphia VAMC, *Patient Advocate Tracking System email*, October 21, 2015.

VA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, October 6, 2008.