THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

October 26, 2009

Mr. William E. Reukauf
Acting Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 218
Washington, DC 20036

Re: OSC File No. DI-09-1308

Dear Mr. Reukauf:

This is in response to your letter regarding allegations reported by Mr. Jerry Woodward, a former Department of Veterans Affairs (VA) employee who worked in the Biomedical Engineering Section of the VA Gulf Coast Veterans Health Care System in Biloxi, Mississippi (referred to as the Biloxi VA Medical Center (VAMC)). Mr. Woodward alleged that Biloxi VAMC employees failed to properly inspect and maintain medical equipment.

VA has thoroughly investigated Mr. Woodward's allegations. A fact-finding team of Biomedical Engineers investigated these allegations and produced the enclosed report. The evidence substantiates employees violated VA policy concerning the inspection and maintenance of medical equipment.

VA has taken several steps to address these issues to ensure patient safety remains paramount. The Biloxi VAMC is currently taking corrective action based on the findings of the inspection team. VA has detailed a Biomedical Engineer to the Biloxi VAMC to address these concerns. In addition, the Biloxi VA Medical Center began an Administrative Investigation to further investigate these allegations and to determine whether disciplinary action against VA employees is warranted. Finally, the Biloxi VAMC has begun recruitment to hire a full-time Biomedical Engineer to oversee its Biomedical Engineering Program.

I have reviewed the report and concur with the findings, conclusions, and corrective actions.

Thank you for the opportunity to respond to these issues.

Sincerely,

Eric K. Shinseki

Enclosures

INTERNAL INQUIRY REPORT: OSC File No. DI-09-1308

I. SUMMARY OF INFORMATION

An investigation was conducted in response to Office of Special Counsel (OSC) File No. DI-09-1308 regarding allegations made by a former Department of Veterans Affairs (VA) employee, Mr. Jerry Woodward. He disclosed that hundreds of pieces of medical equipment were not given initial inspections or placed on preventive maintenance schedules prior to its use on VA patients at the Biloxi VA Medical Center (VAMC). The whistleblower also alleged that electrical safety checks had not been performed on most equipment received over the last 2 years, including life support equipment. The whistleblower further alleged that certain initial inspection work orders were marked closed even though employees did not inspect the equipment. Additionally, the whistleblower alleged that the facility had not taken any action with regard to the recommendations provided by two outside organizations that inspected the Medical Center's Biomedical Engineering section in the summer of 2008.

II. CONDUCT OF THE INVESTIGATION

A review team consisting of three Biomedical Engineers, representing the Healthcare Technology Management (HTM) Program Office (10NB) in the Office of the Deputy Under Secretary for Health for Operations and Management (DUSHOM) travelled to the Biloxi VAMC and investigated Mr. Woodward's allegations from September 1-3, 2009. The three members of the review team were Megan Friel, Acting Director, HTM; Eric Plaisance, Chief Biomedical Engineer, Bay Pines VAMC; and Kimberly Sekiya, Chief Biomedical Engineer, Coatesville VAMC.

Prior to the on-site review of the Biomedical Engineering section at the Biloxi VAMC, the members of the review team were provided the following documentation pertaining to this matter.

1. The VA Office of Inspector General Investigation conducted after being contacted by VA Police on April 21, 2008.

2. The Joint Commission (TJC), Office of Quality Monitoring inquiry initiated on May 16, 2008.

3. The Biloxi VAMC Quality and Performance Management Service investigation initiated on May 16, 2008.

4. Biomedical Equipment Department, Keesler Air Force Base, Department of the Air Force, Department of Defense (DoD), VA Biomedical Section review initiated May 16, 2008, at the request of the Biloxi VAMC.

5. The Environment of Care Committee minutes from September 2008 until August 2009.

6. The Biloxi VAMC's Medical Equipment Management Program annual reports from Fiscal Years 2006 to 2008.

7. A current organizational chart of the Engineering Service, including the Biomedical Engineering section.

8. The Biomedical Engineering Section Policy No. 19F-05-05, dated August 5, 2005, and recertified in August 2008, which contained the acceptance, inspection, and maintenance provisions for medical equipment acquired by the facility.

The review team interviewed both the former employee, Mr. Woodward, to review the allegations outlined in the above-referenced OSC letter, and facility staff at the Biloxi VAMC.

The following is a summary of the findings from these interviews and review of the medical equipment inventory database:

1. The medical equipment inventory contains many inaccuracies.

2. Without being present when the incoming inspection, preventive maintenance, and general maintenance work orders were completed, we cannot substantiate whether this work was completed or not. However, documentation of this work was subpar. Not all medical equipment was inspected prior to use. For example, items were found on September 2, 2009, that were not tagged or inspected.

   The allegations that equipment was not inspected prior to use were at least partially true. Incoming inspection forms were dated long after the initial equipment record creation which generated the incoming inspection work order. Some equipment was put into service, while other equipment remained in the warehouse until inspected at a later time by Biomedical Engineering and then put into service. Incoming inspection sheets were not always complete.

3. There has been limited follow-up actions taken by the facility following the Keesler review. However, the facility has recently developed a tracking document to follow the progress of these items.

4. The Biomedical Engineering staff possesses limited knowledge of the maintenance processes required to run an effective medical equipment maintenance program. Untimely and inconsistent documentation of work performed during medical equipment maintenance was apparent.

5. There was a lack of demonstrated competencies in the maintenance of medical equipment. For example, staff fumbled through a preventive maintenance procedure on a defibrillator, and took several hours to provide documentation

pertaining to the device's preventive maintenance procedure and the defibrillator analyzer used to test the device.

III. SUMMARY OF EVIDENCE

1. TJC conducted an inquiry into allegations that medical equipment maintenance was not performed according to policy.

    a. Biloxi VAMC received notice from TJC of a complaint regarding the Biloxi VAMC on May 16, 2008. The subject of the complaint was that medical equipment was not being properly checked by Biomedical Engineering staff and test equipment used in these maintenance procedures not being appropriately calibrated.

    b. TJC made a surprise inspection to the facility on June 6, 2008, to perform a "Life Safety Inspection." However, in addition to inspecting life safety issues, the Biomedical Section was also evaluated.

    c. While TJC Life Safety Inspector reported findings during its visit, there were no findings to report concerning the Biomedical Engineering Section.

2. The Biloxi VAMC Quality and Performance Management Service (QPM) performed an investigation into the policies, management, and operation of the Biomedical Section in June 2008.

    a. QPM conducted its investigation through document review, equipment inspection, and staff interviews.

    b. Four pieces of test equipment cited by Mr. Woodward as suspect were identified. Three of these pieces were sent out for calibration on April 21, 2008. Results of the third-party calibration found that all three pieces were in compliance and left as found. The fourth piece of test equipment was purchased February 28, 2008, and was calibrated by the manufacturer and would not require recalibration for 1 year from the purchase date.

    c. QPM found that three different types of stickers were being utilized by the Biomedical Engineering Section to identify equipment that had been processed for maintenance. This has subsequently been standardized with one type of sticker, allowing employees to quickly identify compliance.

    d. QPM found that medical equipment preventive maintenance was performed in the Medical Center by hospital sections rather than by piece of equipment. A process was subsequently devised and implemented to complete preventive maintenance by equipment identification number ensuring more reliable implementation of the program.

3. As a result of the internal facility investigation of the Biomedical Engineering Section, Biomedical Equipment Department, Keesler Air Force Base staff, was invited to conduct a review of the VA Biomedical Engineering Section operations in June 2008. Keesler staff spent several days with the VA Biomedical Section observing day-to-day operations. The findings of this review and a complete report are included in Attachment 1.

    - The Keesler Biomedical Equipment Department provided several recommendations for improvement of the equipment maintenance program. The facility has recently developed a tracking document to follow the progress of these items.

4. TJC – 2009 findings

    - The facility had two specific citings regarding medical equipment; the first in the operating room, and the second was in psychiatry inpatient unit. In both cases, the findings revealed that items were not inspected and tested by the date on the sticker which is required by policy. Facility staff reported to TJC that the medical equipment was inspected after it was identified by the surveyor.

5. The VHA Biomedical Engineering review team conducted a review of the Biloxi Biomedical Engineering Section. The review team systematically examined the inventory included in the open work orders list printed May 2008 by Mr. Woodward and included in the OSC letter. The review team found evidence that some of these medical equipment items were not properly inspected prior to being used on VA patients.

IV. SUSTAINED OR UNSUSTAINED VIOLATIONS

The state of these few medical equipment records is indicative of many of the problems with the Medical Equipment Management Program. Management of medical equipment used in the diagnosis, treatment, and monitoring of patients is primarily the responsibility of the Biomedical Engineering department. This includes activities from selection and acquisition to incoming inspection and maintenance of medical equipment. In none of these areas did we find that Biomedical Engineering staff at this facility was effectively conducting and documenting these activities. There was evidence provided during this investigation to indicate that the Biomedical Engineering Section Policy No. 19F-05-05, dated August 5, 2005, (updated May 21, 2009, as 18F-04-09) which defines the acceptance, inspection, and maintenance provisions for medical equipment acquired by the Biloxi VAMC was violated. Additionally, evidence revealed that the National Fire Protection Association (NFPA) 99, Standard for Health Care Facilities was violated per section 8.5.2.1.2.2, which discusses minimum testing intervals for equipment used in patient care areas.

V. ACTIONS TAKEN

1. The Biloxi VAMC is actively following up on recommendations presented in the attached Keesler report.

2. The Biloxi VAMC leadership temporarily detailed a Biomedical Engineer from Veterans Integrated Service Network 16 to address identified program concerns.

3. The Biloxi VAMC leadership has detailed the Biomedical Engineering Supervisor from their supervisory role, and the Biomedical Engineering Department is now being directly supervised by the Chief Engineer.

4. The Biloxi VAMC convened an Administrative Investigation Board (AIB) to further collect and analyze the evidence. The AIB included a Biomedical Engineer.

5. The Biloxi VAMC has begun the recruitment process to hire a full-time Biomedical Engineer (with a guaranteed home buy-out) to oversee and improve overall management of the program.

6. VA will submit a follow-up report to OSC following completion of the AIB and implementation of any additional recommended actions.

ATTACHMENT 1 - KEESLER AIR FORCE BASE REPORT ON BILOXI VAMC BIOMEDICAL ENGINEERING SECTION, JUNE 2008

VA

Observations and Recommendations for improvement of Equipment Management

1. **Observation:** After Hurricane Katrina, August 2005, millions of dollars were given to the VA to restore. With this they purchased many new medical equipment items. Unfortunately most of these items went directly to the sections to use the equipment without going through the Biomedical Maintenance department. Many of these items have not been identified or added to the equipment inventory list. **Recommendation:** 100% sweep of entire campus to ensure accurate equipment inventory, as well as add items not on the inventory to this list

2. **Observation:** The Biomedical Maintenance sections schedules preventive maintenance by section. This opens the door to miss items due for maintenance, because they might not be in that section during the month the technicians are present. Equipment items move easily from place to place. **Recommendation:** The Biomedical Maintenance sections should schedule preventive maintenance by equipment identification number rather than by section. This is why the inventory list must be accurate. Equipment will not be overlooked if scheduled by identification number.

3. **Observation:** Ventilators are life support equipment. At one point they were on contract, but the contract has expired. VA BMETs are unsure if all ventilators have up to date maintenance performed. **Recommendation:** Check all ventilators to ensure they are not overdue. Either place them under a new contract or complete the calibration verifications in house immediately.

4. **Observation:** After Hurricane Katrina, the VA had very few Biomedical Maintenance technicians. Those that remained also had to consider the needs of their families. Due to this lack of manning/circumstances, a substantial backlog of items due maintenance formed. **Recommendation:** Hire more staff to ensure Joint Commission Compliance can be maintained.

5. **Observation:** In-service training for new equipment must be provided to the VA providers and staff upon receipt of new equipment. With minimal manning in the Biomedical Maintenance department this becomes a challenge. **Recommendation:** Video tape manufactures in-service training or purchase in-service training materials from the manufacture. Create a video library. This way when the different providers need recurrent training on equipment, you can sign out one of the videos instead of assigning one of the few Biomedical Maintenance technicians you have.

6. **Observation:** Equipment Incidents: Poor documentation for what to do in the event of an equipment incident. That is any medical equipment item suspected of causing serious illness, injury, or death. **Recommendation:** Establish strict guidance for compliance with Safe Medical Device Act. Providers and staff should know what to do and who to contact in the event of an equipment incident that is suspected of causing serious illness, injury or death. Add this to every VA employee initial orientation training and annual recurrent training.

7. **Observation:** A quick walkthrough of your inpatient ward identified a problem with documentation stickers on medical equipment. We identified 3 different kinds of stickers that supposedly meant the same thing. This makes it difficult for your providers and staff to determine if the equipment is safe to use. Some stickers were outdated. Specifically one for a defibrillator ID# EE39348. It shows expiration date of DEC 07. We identified this within the first 5 minutes of our walk through. This leads me to believe the problem is throughout the campus grounds. **Recommendation:** Standardize and use one equipment sticker. Make sure enough are on-hand so you don't run out. Perform comprehensive sweep of all equipment to ensure each item requiring preventive maintenance/calibration verification has up-to-date sticker identification regardless of the cost of the item. Train your providers and staff to look for this sticker to ensure equipment they are using has been calibrated and is not overdue.

8. **Observation:** Documentation ensuring complete preventive maintenance and calibration verification is poor. **Recommendation:** Use a different tracking system such as Defense Medical Logistics Standard Support System (DMLSS) or equivalent. There should be documentation of actual parameters completed. Such as defibrillator output, vital signs monitor to include O2 Saturation, ECG and blood pressure readings, etc.

9. **Observation:** Technical Literature Library needs work. Missing more than half the technical reference documentation to ensure correct preventive maintenance/calibration verifications are performed. Each medical equipment item has

preventive maintenance checklists and calibration tolerances. It is impossible to remember all the correct tolerances for 20 pieces of medical equipment let alone over 5000 you have on your campus. **Recommendation:** Identify and purchase all Technical Literature for equipment on hand.

10. **Observation:** Leased, loaned, or consigned equipment not on record. Even though Biomedical Maintenance is not responsible to perform maintenance on these items, they are responsible to ensure it is completed by the manufacturer. With all the new equipment purchase after Hurricane Katrina not on record and leased, loaned, or consigned equipment not on record; how do you know what belongs to you? **Recommendation:** Complete sweep of your campus to identify all medical equipment. Add all medical equipment to your inventory and maintenance management plan. Work orders should be produced to ensure maintenance is completed on leased, loaned or consigned equipment.

11. **Observation:** Biomedical Maintenance is not involved with approval process of new equipment. Biomedical Maintenance should know what equipment is used throughout the campus. They also should receive Health Device Alerts and manufactures recall information. They can use this information to recommend or not recommend purchase of defective equipment. **Recommendation:** Biomedical Maintenance should be involved in the review process for the purchase of any new medical equipment items.

12. **Observation:** Multiple different equipment models for same type of equipment identified. **Recommendation:** Medical Equipment should be standardized as much as possible. This will help your facility in many ways. Such as: Providers and staff will only have to learn how to use one type of vital signs monitor, when your staff moves from one department to the next, they will already be trained on most of the equipment in the new area because it was in their old one. Biomedical Maintenance will only have to maintain literature, test equipment and repair parts for one type. This will ensure cost and time savings for your facility.

13. **Observation:** Code (crash) carts on your inpatient ward are stored in a locked room. Everyone doesn't have a key to that room. During a code you don't have time to search for a key to gain access to the crash cart. **Recommendation:** We identified space along the wall in the patient ward. This recessed space is where the crash carts should be stored. It is equipped with emergency power outlet to continuously charge the equipment. This space should also be easily identified to ensure providers down the hall know exactly where the crash cart is located.