U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

The Special Counsel

February 19, 2013

The President
The White House
Washington, D.C. 20510

Re: OSC File No. DI-12-0023

Dear Mr. President:

Pursuant to 5 U.S.C. § 1213(e)(3), enclosed please find agency reports based on disclosures made by Halley Crumb, a whistleblower at the Department of Veterans Affairs (VA), San Francisco VA Medical Center (VAMC), San Francisco, California. Ms. Crumb alleged that employees engaged in gross mismanagement and created a substantial and specific danger to public health and safety by improperly handling urine samples in the San Francisco VAMC Clinical Laboratory Service (Lab).

The agency determined that the San Francisco VAMC Lab lacks a written policy manual or documentation of employee training on the proper methods of storage and disposal of urine samples. In its report, the agency found that the Lab is not in compliance with its own local policy requiring refrigeration of urine samples, nor is it in compliance with local and national policies on the procedure for documenting the time of sample collection. The agency also found that Lab employees did not have a consistent definition for the criteria necessary to reclassify a sample as medical waste.

However, the reports did not conclude that employees engaged in conduct that constituted gross mismanagement or a substantial and specific danger to public health and safety. In addition, the investigation did not substantiate the allegations that Lab technicians have routinely stored urine samples in an unsafe manner, that the means of disposal of samples is unsafe, or that disposal is accomplished without the use of personal protective equipment (PPE). The agency was also unable to substantiate the allegation that management was aware of these concerns and failed to take action. Based upon my review of the original disclosure, the agency's reports, and Ms. Crumb's comments, I have determined that the reports contain all of the information required by statute and that the findings appear to be reasonable.

The Office of Special Counsel (OSC) is authorized by law to receive disclosures of information from federal employees alleging violations of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health and safety. 5 U.S.C. § 1213(a) and (b). OSC does not have the

authority to investigate a whistleblower's disclosure; rather, if the Special Counsel determines that there is a substantial likelihood that one of the aforementioned conditions exists, she is required to advise the appropriate agency head of her determination, and the agency head is required to conduct an investigation of the allegations and submit a written report. 5 U.S.C. § 1213(c) and (g).

Upon receipt, the Special Counsel reviews the agency report to determine whether it contains all of the information required by statute and that the findings of the head of the agency appear to be reasonable. 5 U.S.C. § 1213(e)(2). The Special Counsel will determine that the agency's investigative findings and conclusions appear reasonable if they are credible, consistent, and complete based upon the facts in the disclosure, the agency report, and the comments offered by the whistleblower under 5 U.S.C. § 1213(e)(1).

On November 22, 2011, OSC referred these allegations to the Honorable Eric K. Shinseki, Secretary of the VA, to conduct an investigation pursuant to 5 U.S.C. § 1213(c) and (d). On January 23, 2012, Secretary Shinseki submitted the agency's report to OSC, based on the results of an investigation conducted by the VA Office of the Medical Inspector (OMI).[1] In response to a request for additional information made by OSC on February 6, 2012, the agency submitted a supplemental report on February 28, 2012. Pursuant to 5 U.S.C. § 1213(e)(1), Ms. Crumb submitted comments on the agency's initial report and supplemental report on March 12, 2012, and on the revised report on January 8, 2013. As

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[1] I note that the report submitted by the VA omitted the names of the employees involved, and instead referred to the employees by title only. The agency did not provide a written legal basis for the omission of the employee names in this matter, as is customary under OSC's accommodation policy for the removal or redaction of employee names. Under the accommodation policy, which was instituted by OSC in April 2011, OSC maintains its objection to the redactions on the basis that the public has an interest in knowing the names of those employees involved, but allows the agency to redact employee names from the public version of its report. The agency still provides an unredacted report for transmittal to you, Congress, and the whistleblower.

Beginning in August 2011 and continuing through 2012, the VA began objecting to the inclusion of information other than employee titles in any version of its reports. As a result, the agency began, in many cases, to provide one version of its reports containing only employee titles. This includes the report received in this matter. In an attempt to address the agency's concerns and OSC's objections to this approach, OSC staff met with VA Office of General Counsel staff on April 13, 2012. No agreement was reached at that meeting, but the agency indicated to OSC that they would submit a final determination on the matter by June 11, 2012. The agency was aware that, while awaiting the agency's response, OSC found it necessary to refrain from transmitting to you and Congress any pending 1213 matters that were affected by the VA's refusal to include employee names. The VA failed to respond to OSC by June 11, 2012, but multiple conversations with OSC, VA General Counsel staff, and the White House Counsel's Office ensued. On August 30, 2012, OSC reached an agreement with the VA, wherein, for all future matters, the VA will provide OSC with an unredacted report containing employee names and titles for you, Congress, and the whistleblower, and a redacted report, containing titles only, for inclusion in our public file. For pending matters, such as this one, the VA provided amended reports and/or addenda containing employee names and titles. OSC received a revised report in this matter on December 5, 2012.

required by 5 U.S.C. § 1213(e)(3), I am now transmitting the reports and Ms. Crumb's comments to you.

I. The Agency Reports

a. Unsafe Storage of Urine Samples

Ms. Crumb disclosed that the Lab routinely stores urine samples unsafely, including positive samples and samples that contain blood, for several days after they have been tested, allowing additional bacteria to grow. She alleged that this placed employees at risk of unnecessary exposure to these pathogens. Specifically, she alleged Lab technicians are required to store urine samples for at least 48 hours (and up to 5 days) and that stored urine samples are not refrigerated or quarantined, but rather stored on modified hospital carts that are labeled with the date of collection. The agency report concluded that the allegation that the Lab routinely stores urine samples in an unsafe manner was not substantiated. The report found that the Lab's current practice of storing urine samples in collection containers labeled with the specimen testing date for 48 hours after being processed comports with Veterans Health Administration (VHA) Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, which states, "samples, slides and records must be retained in accordance with the requirements of VHA Records Control 10-1, Section VIII-Laboratory Service (113)." According to the report, VHA Records Control 10-1 mandates that urine samples taken from patients for lab testing be destroyed 48 hours after reporting results. In addition, the report concluded that there is no evidence that unrefrigerated urine samples create a substantial and specific danger to public health and safety even though bacteria may grow in them. However, the report found that the VAMC is not compliant with its own local policy, *General Laboratory Policies and Procedures* (July 2011), section X, which requires that all stored lab specimens be refrigerated.

Notwithstanding these findings, the report determined that, although employees are aware of the Lab's procedure for storing urine, there are no written guidelines for this procedure. In addition, the Lab was unable to provide documentation showing that employees are adequately trained on urine storage. The report also concluded that the Lab does not track the utilization of the samples, which makes it difficult to determine the utility of its storage policy. Finally, though not disclosed by Ms. Crumb, the report found that the VAMC is not compliant with local and national policies and procedures related to documenting collection times on the labels of urine samples.

b. Improper Disposal of Urine Samples

Ms. Crumb also alleged that Lab employees are required to dispose of stored urine samples in a sink that is used for other lab purposes, including employee hand washing. She asserted that the sink and its drain pipes are in disrepair and have been under a work order for at least eight months. The report substantiated the allegation that the Lab technicians are required to dispose of stored urine samples in a sink that may also be used for

employee hand washing; however, it identified three other easily accessible sinks in the immediate vicinity that are dedicated to hand washing. According to the report, disposal of stored urine into a sink drain is a common practice in labs, provided that the urine is diluted with running water and the sink is rinsed and disinfected after disposal. The report did not substantiate the allegations that the sink used for disposal of urine samples is also used for other laboratory purposes or that the sink and its pipes are not in good working order. Further, the report found that, although a work order related to the sink was in place for eight months, it was for the replacement of a cabinet under the sink, not for the repair of the sink's water supply and drain pipes.

c. Disposal of Urine Samples without PPE

Ms. Crumb further alleged that the disposal of the urine samples is accomplished without PPE and without a policy manual or training for employees on proper disposal methods. The agency report substantiated the allegation that the VAMC does not have a policy manual or documentation of training for employees on proper disposal methods for urine samples. Further, the report noted that Lab technicians did not have a consistent understanding of what criteria reclassifies urine as medical waste but did have knowledge about the procedure for disposal of medical waste. However, the agency report did not substantiate the allegation that Lab technicians disposed of urine samples without wearing appropriate PPE and determined that training on the use of PPE was well documented. Specifically, the report found that the VAMC provides each Lab technician with gloves, goggles, face shields, masks, and three white lab coats, along with laundry service for the coats. The report noted that the VAMC's *Laboratory Safety Policies and Procedures Manual* mandates that Lab technicians wear PPE. Further, all staff members who were interviewed said that they wore PPE when disposing urine and did not observe others disposing of urine without PPE.

d. Management's Failure to Act

Finally, Ms. Crumb disclosed that she brought her concerns about the storage and disposal of urine samples to the attention of Lab Managers Howard Leong and Gina Torres, but no corrective actions were taken. The agency report did not substantiate this allegation. According to the report, all of the members of management who were interviewed, including both of the Lab Managers, stated that they were unaware of these issues prior to OMI's investigation.

e. Agency Recommendations

In its report, the agency made a number of recommendations to the VAMC. The agency advised the VAMC to develop written policies and procedures for the storage and disposal of urine samples and guidance on which tests can be performed on stored samples. The agency also recommended that employees receive training on the handling of samples at all stages from collection to disposal and on the criteria for reclassification of a sample as

medical waste. The agency advised that the VAMC should comply with approved policies pertaining to refrigeration of samples and begin tracking the use of stored urine to evaluate the utility of the Lab's storage policy. With regard to the Lab sink, the agency directed that all employees be made aware of the availability of other sinks for hand washing.

In its supplemental report, dated February 28, 2012, the agency stated that the VAMC created written procedures for the storage, handling, and disposal of urine, which add-on tests can be performed on stored urine samples, and the reclassification of urine as medical waste. Further, training in these areas has been provided to all staff members, with 100% compliance following training. In addition, the VAMC is refrigerating all previously tested urine samples as soon as they are processed, instead of storing the samples unrefrigerated for 48 hours. The VAMC also tracked the use of stored urine for additional testing within 48 hours of initial testing. Finally, the VAMC has posted signs above or next to designated hand washing sinks in the Lab.

II. Ms. Crumb's Comments

Ms. Crumb was provided an opportunity to comment on the report and supplemental report. In those comments, she reasserted the allegation that the storage of urine samples on a rolling cart was unsafe, particularly in an area known for earthquakes, such as California. She also stated that not all Lab employees were selected for interview by the OMI, and that some Lab employees who were not interviewed could attest to the fact that samples were retained for long periods of time, leading to a stockpile of samples on Lab countertops. Ms. Crumb also noted that, with regard to the use of the Lab sink, management was aware prior to the OMI's investigation that pranks had been pulled at the sink related to hand washing, and thus the agency's finding that the sink was not used for purposes other than urine disposal was questionable. Ms. Crumb also restated her assertion that the VAMC's failure to provide clear written policies on the handling of samples constituted gross mismanagement, and that the Lab had a chronic problem with improper labeling of samples.

Ms. Crumb also had an opportunity to comment on the revised report. In those comments she clarified that the samples referenced in the report are received by the Lab from clinics and contain a preservative tablet for transport, whereas the samples she was concerned with were "immediate collect" and do not contain a preservative. She noted that the system in place at other laboratories where she was previously employed was to dispose of an old sample and then collect a new sample at the patient's convenience.

Ms. Crumb also stated her belief that, notwithstanding the agency's findings, disposal of urine samples should not be accomplished using a standard sink such as the sink found in the Lab. She further stated that contagions contained in the samples might not be filtered by water recycling processes, and that samples should consistently be disposed of using a biohazard container instead. Ms. Crumb noted that the companies that collect the used biohazard containers charge by weight and that because the Lab so rarely used the containers, it consistently came in under budget for collection costs.

III. The Special Counsel's Findings

I have reviewed the original disclosure, the agency reports, and Ms. Crumb's comments. It appears that the agency has taken significant steps to improve its process for receiving and storing samples, including refrigeration of samples immediately after testing and additional training for staff. Based on my review, I have determined that the agency's reports contain all of the information required by statute and that the findings appear to be reasonable.

As required by 5 U.S.C. § 1213(e)(3), I have sent copies of the agency reports and the whistleblower's comments to the Chairman and Ranking Member of the Senate Committee on Veterans' Affairs and the Chairman and Ranking Member of the House Committee on Veterans' Affairs.[2] I have also filed copies of the reports and comments in our public file, which is now available online at www.osc.gov, and closed the matter.

Respectfully,

Carolyn N. Lerner

Enclosures

[2] As previously stated, the VA originally provided OSC with a report that omits the names of the employees involved, and instead refers to these employees by title only. The agency did not provide a written legal basis for the omission of the employee names in this matter. The agency subsequently provided a revised report containing the employees' names and corresponding titles. The whistleblower was given an opportunity to comment upon the revised report. OSC objects to the omission of employee names from the public versions of the reports on the basis that the inclusion of the names of subject employees is in the best interest of the public.