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The Special Counsel

November 21, 2011

The President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-10-1669

Dear Mr. President:

Pursuant to 5 U.S.C. § 1213(e)(3), enclosed please find an agency report based on disclosures made by a whistleblower at the Department of Veterans Affairs (VA), VA Medical Center (St. Louis VAMC), Microbiology Laboratory, Pathology and Laboratory Medicine Service, St. Louis, Missouri. The whistleblower, Tai-Hwa Holtz, who consented to the release of her name, is a Medical Technologist at the St. Louis VAMC. Ms. Holtz held this position from January 20, 2009, to January 15, 2010, at which time she was removed from her position. Ms. Holtz alleged that the St. Louis VAMC Microbiology Laboratory consistently failed to meet its safety and proficiency requirements under the Clinical Laboratory Improvement Act (CLIA)[1]. She asserted that these failures caused employees to misread test results, overlook positive test results, and fail to report critical results in a timely manner.

Ms. Holtz's allegations were referred to the Honorable Eric K. Shinseki, Secretary, VA, to conduct an investigation pursuant to 5 U.S.C. § 1213(c) and (d). On March 2, 2011, the Secretary submitted the agency's report to this office. We received supplemental reports in this matter on June 1, 2011, and June 29, 2011. Ms. Holtz provided comments on the reports pursuant to 5 U.S.C. § 1213(e)(1). As required by law, 5 U.S.C. § 1213(e)(3), I am now transmitting the reports and Ms. Holtz's comments to you.

The CLIA was passed by Congress in 1988 to establish quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results.[2] As explained in the Veterans Health Administration (VHA) Handbook 1106.01, although Congress exempted the VHA from the CLIA, it required the VA to publish regulations that would "establish standards equal to that applicable to other medical facility laboratories in

[1] 42 C.F.R. § 493.1 - .2001 (2004).
[2] Department of Health and Human Services, United States Food and Drug Administration, Medical Device Regulation and Guidance, IVD Regulatory Assistance, *Clinical Laboratory Improvement Amendments (CLIA)*, Informational Introduction *at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm (last accessed June 21, 2010).

accordance with the requirements of Section 353(f) of the Public Health Services Act."[3] As a result, VA laboratories must meet the requirements of the CLIA, but VA is responsible for its own oversight and enforcement of those requirements.[4] VHA Handbook 1106.01 substitutes applicable sections of the CLIA where VA regulations do not provide explicit guidance.[5]

VHA Handbook 1106.01 specifically requires VA laboratories to undergo on-site inspections by an approved accrediting agency.[6] Ms. Holtz explained that the St. Louis VAMC Microbiology Laboratory is inspected and accredited by the College of American Pathologists (CAP). CAP produces a Microbiology Checklist that sets out the standards a laboratory must meet to be an accredited site. Section MIC.11150 of the checklist requires that all tests for which positive results likely represent an imminently life-threatening situation must be processed on a schedule that ensures timely reporting of results. Ms. Holtz alleged that the St. Louis VAMC does not have night shift coverage during the week, nor does it have evening or night shift coverage on the weekend. As a result, positive blood cultures could go unprocessed and the results unreported for up to 16 hours, posing a direct threat to the health of patients whose tests results are critical.

VHA Handbook 1106.01 and 42 C.F.R. § 493.1235 also require that laboratories have a system in place to provide training and ongoing assessment of the competency of those individuals performing patient testing. Pursuant to these regulations, VHA Laboratory Directors must ensure that all personnel are appropriately educated and trained and have demonstrated that they can "perform all testing operations reliably to provide and report accurate results." Laboratory Directors must also ensure that policies and procedures are in place to monitor and maintain employee competency and provide education where necessary. In addition, Laboratory Directors must make available an approved procedure manual for any aspect of the testing process. Ms. Holtz disclosed that St. Louis VAMC conducted no monitoring or checking of employee proficiency during her initial tenure there and seemed unconcerned with employee proficiency. She alleged that as a result, no remedial training or continuing education was offered to laboratory employees. She also disclosed that the Microbiology Laboratory lacked the required procedure manual, which she asserted is essential to ensure that tests are conducted using proper methods, and to early detection of positive test results. Ms. Holtz asserted that lacking a procedure manual led to the failure to test for basic infections such as *Gardnerella vaginalis* and Extended Spectrum Beta-Lactamase (ESBL), posing a danger to the health of patients.

Ms. Holtz further disclosed that samples taken from certain technologists in the Microbiology Laboratory had a urine culture contamination rate of approximately twice the documented national hospital average. Ms. Holtz alleged that this was because the

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[3] The VHA is the component of the VA that provides health care benefits and services to veterans. VA is therefore responsible for publishing regulations related to VHA activities.
[4] VHA Handbook 1106.01, para. 2(b) (October 6, 2008), *available at* http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1779 (last accessed June 30, 2010.)
[5] *Id.* at para. 2(c).
[6] *Id.* at para. 3(c).

laboratory performed improper testing on the relevant samples and failed to perform additional testing. She asserted that the failure to identify contaminated urine samples could lead to patient complications and possibly fatal infections.

Ms. Holtz also disclosed that the Microbiology Laboratory consistently mishandled raw stool samples. She explained that proper handling of such samples is critical for the recovery of *Campylobacter*, which is the leading cause of bacterial diarrhea in the United States. Ms. Holtz stated that collection sites must place raw samples into Cary-Blair transport media within one hour of collection. If this is not done, the samples are too old by the time they reach the testing laboratory for accurate tests to be completed. Ms. Holtz alleged that the Microbiology Laboratory was receiving only raw stool samples; none of the samples were properly placed in Cary-Blair transport media. As a result, some of the samples were so old they had started to bubble, indicating that they were no longer viable. Ms. Holtz noted that after she reported the lack of proper transport media, management ordered Cary-Blair transport vials, but they were never delivered to stool collection sites.

Ms. Holtz alleged that in addition to possibly resulting in false test results, the lack of proper transport media also affected the Microbiology Laboratory's samples that were sent to a third-party for testing for ova and parasites. She alleged that the samples that were sent to the third-party laboratory were immersed in proper chemical transport media after they were already invalid, making the third-party test results unreliable.

The agency did not substantiate Ms. Holtz's allegation that St. Louis VAMC Microbiology Laboratory employees misread test results or overlooked positive test results. However, the agency did find that critical blood culture results were not always timely reported, and that stool samples were not properly preserved prior to submission to the laboratory. Specifically, the agency confirmed that prompt reporting of positive blood cultures is essential to providing necessary medical attention, and requires a technician to sample, stain, and review blood cultures. In its report, the agency found that the Microbiology Laboratory was staffed from 8:00 a.m. to 1:00 a.m., Monday through Friday, and from 8:00 a.m. to 4:30 p.m. on holidays and weekends. The report also noted that no provision for initial confirmation of positive blood cultures by the laboratory during off-hours was in place, leaving potentially positive blood cultures unreported. In response, the agency recommended the St. Louis VAMC ensure that blood cultures are processed when a potentially positive result is identified and that clinical staff be notified immediately.

The agency also found that the Microbiology Laboratory Section Supervisor did not record employee competencies in 2009. The section supervisor revised the competencies template in 2009 and wrote assessments of competencies for the staff, but did not record individual competencies until 2010. The agency acknowledged that pursuant to CAP, competencies must be recorded on a yearly basis, and that the laboratory was not in compliance during 2009. However, the agency determined that the competencies are now up-to-date and were found to be appropriate during a 2010 CAP inspection. Despite this, the agency recommended that the Microbiology section conduct employee competency testing and document the results annually.

The agency did not substantiate Ms. Holtz's allegation that employees did not receive sufficient continuing and remedial education. Rather, the report states that employees may qualify for continuing education funding, but that employees with less than one year of current, continuous government service, including Ms. Holtz, would not generally qualify. The agency found that some employees did receive continuing education funding, but that remedial training was rarely necessary within the Microbiology section. The report notes that only one Microbiology employee required such training, and that she received it in 2009.

The agency substantiated that stool samples were often transported to the Microbiology Laboratory without appropriate preservative and without documentation of the date and time of the collection of the sample. The report indicates that the Acting Chief of the Pathology and Laboratory Medicine Service, the Microbiology Section Supervisor, and other employees confirmed that stool samples are often received in a sterile specimen cup without preservatives and without documentation. According to Microbiology staff, proper preservatives were made available to nursing staff, but have not been used, and the Director for Patient/Nursing Services agreed that this problem needs to be addressed. The report also addressed the whistleblower's concern that lack of proper preservative affected test results for ova and parasites in stool samples. The investigation confirmed that in order to ensure full test results, stool samples must be processed within two hours of collection, refrigerated, or immersed in preservative. The report indicated that one positive test result was found on October 18, 2009, but that a significant increase in positive test results occurred following the distribution of proper preservative. The agency found that this may be the result of prior improper preservation, and recommended that stool samples be monitored for six months to ensure they arrive in appropriate preservative.

The agency, however, did not determine that the Microbiology Laboratory's failure to identify a single case of *Campylobacter jejuni* was related to improper preservatives. The reported noted that *Campylobacter jejuni* should remain viable in unpreserved stool samples for up to 72 hours and thus, although no positive test results were found, the absence of such results could not be linked to incorrect resting or the failure to use proper preservative. However, based upon the above findings, the agency did offer several recommendations to the St. Louis VAMC. These included: ensuring that stool samples, including those being tested for ova and parasites, be transported to the Microbiology Laboratory in appropriate preservative; ensuring that the collection date and time for all stool samples is documented; and conducting six months of monitoring of the above recommendations to ensure compliance.

The agency did not find that the laboratory lacked a procedure manual, but did find that the available procedure manual was not regularly updated as required by CAP. Upon questioning, St. Louis VAMC management acknowledged the need for a document control system to ensure timely revisions to the manual and stated that they were in the process of revising the manual. The report suggests that the Microbiology Laboratory update its procedure manual and institute a systematic process for maintaining the manual in the future.

The agency also did not find that Microbiology Laboratory employees failed to test for the presence of *Gardnerella vaginalis* and ESBL. The report noted that an *ad hoc* query of electronic medical record results between January 1, 2009, and January 22, 2010, resulted in more than 20 positive culture results for *Gardnerella vaginalis*. The agency did, however, recommend that references cited in the procedure manual for testing *Gardnerella vaginalis* be current. The report further noted that the Microbiology Laboratory has a proper procedure manual entry for ESBL testing, and has been using a system that provides rapid confirmatory testing for ESBL.

The report was also unable to substantiate Ms. Holtz's assertion that the Microbiology Laboratory has an unusually high rate of urine culture contamination. The report acknowledges that the St. Louis VAMC does not track its urine culture contamination rate, and therefore the investigation could not determine if the rate was high or not. The report confirmed that the Microbiology Laboratory does conduct appropriate testing on potentially positive urine cultures when it is required. However, the agency recommended that the Microbiology section track the rate of contaminated urine cultures for at least six months, and take appropriate action based on the outcome of the tracking project.

In a telephone conversation with Ms. Holtz on October 8, 2010, the agency identified several additional allegations that were not raised in our original referral to the Secretary. First, she asserted that diptheroid bacteria, which do not cause disease, were reported by the Microbiology Laboratory as normal flora, and positive stool samples received no further workup. According to Ms. Holtz, the presence of diptheroids could be a sign of sample contamination, requiring additional testing to determine if their presence could identify a disease-causing organism. The agency reviewed the laboratory's procedure manual and found that it was unclear as to when diptheroid-positive samples require additional workup. The manual also did not outline what steps to take when doing further testing on positive samples. The agency, however, found no evidence that all positive samples were reported as contaminated, and received no additional workup. In response, the agency recommended that the Microbiology procedure manual include instructions on identifying diptheroids and when further workup is necessary.

Ms. Holtz also expressed concern over the Microbiology Laboratory's discontinuation of mycology and mycobacteria testing. She noted that the Laboratory has the instruments required to conduct the testing, but suspended testing in 2010. The agency noted that the discontinuation was accomplished with CAP agreement because the Laboratory did not have adequate staffing, and indicated that no gap in service occurred. Instead, samples to be tested for mycology and mycobacteria were forwarded to the St. Louis VAMC Reference Laboratory for testing.

Further, Ms. Holtz alleged that there were no opportunities for informal on-the-job training in the Microbiology section. The agency found that there is no requirement for such training, and that that there is no need for it, as all Microbiology employees are trained to perform all relevant tasks at the time they are hired. Ms. Holtz also raised the allegation that the Microbiology section's Analytical Profile Index (API), a commercially available system

for identifying microorganisms, was outdated. The agency found that while the hardback versions of the API available in the laboratory were outdated, the book was not being used by staff because they instead accessed the full, updated API via the Internet. Similarly, the whistleblower alleged that the laboratory's Quality Control books were outdated. According to the report, the books document the integrity of the reagents used in clinical testing. The agency found that the laboratory's books were up-to-date, but found the documentation in them to be inconsistent. The report recommended that the St. Louis VAMC ensure that the reference books being used in the Microbiology section are updated and that obsolete and unused references be removed.

Ms. Holtz also raised the concern that Microbiology employees regularly misread Gram stains. The report noted that Gram stains are one of the most common initial clinical tests conducted in the Laboratory. They are used to identify the presence of microorganisms in samples and provide an initial indication of the type of microorganism present. The report found that employees' competency folders all showed they performed Gram stains satisfactorily, and interviews with medical staff indicated that none were aware of a misinterpreted Gram stain.

Finally, Ms. Holtz alleged that Microbiology employees did not check microbiology reports in the computer against culture reports recorded in the work book. She claimed that this leads to mistakes which are not identified in a timely manner. In its report, the agency explained that preliminary identifications of organisms are made after 24 hours of growth. The Microbiology Technologist records this preliminary identification in a laboratory workbook and enters it in the electronic medical record. However, some organisms grow more slowly than others; thus, some samples are held for up to seven days to assure all microorganisms in the sample are identified. Any updates to the preliminary report would be recorded. The Section Supervisor then validates the preliminary report in the electronic medical record by comparing it with the workbook entries. According to the report, up to a week could elapse between the preliminary and final reports. Thus, the agency concluded that the Microbiology section reports final results are not inappropriately late, and that mistakes are detected in a timely manner. However, the agency recommended that the Microbiology section ensure consistency in employees' documentation and certify entries when hand-written changes are made.

In its first supplemental report, the agency clarified that its recommendations were provided to the St. Louis VAMC in a detailed action plan addressing each concern. The VA Office of the Medical Inspector (OMI) discussed the plan with St. Louis VAMC management to ensure each recommendation would be fully addressed. The OMI will receive periodic updates on the progress of implementation, and will monitor the actions until the plan is fully implemented. The agency also addressed OSC's questions regarding the recording of employee competencies and the timing of testing for *Campylobacter*. Finally, the agency recommended that the St. Louis VAMC monitor for six months the timeliness in which stool samples are collected, the type of packaging used, and the time the samples arrive in the central receiving station.

In its second supplemental report, the agency provided OSC with a list of actions taken by the St. Louis VAMC in response to the agency's action plan. These actions include: providing around-the-clock coverage for blood cultures; creating an operator competency review for microbiology testing and a competency calendar; updating the procedure manual to include expiration dates and providing for reference validation within 30 days of the procedure anniversary date; identifying a reference laboratory report on the contamination of urine cultures and developing a tracking tool for area-specific contaminations; ensuring timely transport of samples; drafting of a procedure for identification and workup of diptheroids; and updating time-sensitive reference materials. The second supplemental report also identifies a number of other actions the St. Louis VAMC is in the process of taking to improve service in the Microbiology Laboratory.

Ms. Holtz submitted comments on these reports. In her comments, Ms. Holtz identified several areas that she believes still require attention. These included observations that the Microbiology section's procedure manual is not yet an entirely working manual and that the laboratory is still receiving raw stool samples that are not properly preserved. Ms. Holtz also expressed concern that the Microbiology section lacks guidelines on how to work up and report the full spectrum of diphtheroids. However, Ms. Holtz, who has been returned to her position with the St. Louis VAMC, specifically noted her belief that the recent installation of Cari Oath as the new Microbiology Supervisor will alleviate many of these problems within the section.

I have reviewed the original disclosure, the agency's reports and Ms. Holtz's comments. Based on that review, I have determined that the agency's reports contain all of the information required by statute, and the findings appear to be reasonable.

As required by 5 U.S.C. § 1213(e)(3), I have sent copies of the agency's reports and Ms. Holtz's comments to the Chairmen and Ranking Members of the Senate and House Committees on Veterans' Affairs. I have also filed copies of the reports and Ms. Holtz's comments in our public file, which is now available online at www.osc.gov. This matter is now closed.

Respectfully,

Carolyn N. Lerner

Enclosures