



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

January 23, 2012

The Honorable Carolyn Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036-4505

RE: OSC File No. DI-12-0023

Dear Ms. Lerner:

I am responding to your letter regarding alleged violations at the Department of Veterans Affairs Medical Center in San Francisco, California. You asked me to determine if the alleged misconduct constituted gross mismanagement or a substantial and specific danger to public health and safety.

I asked the Under Secretary for Health to review this matter and take any actions deemed necessary under 5 U.S.C. § 1213(d)(5). The Office of the Medical Inspector (OMI) investigated the disclosures and reported their findings. In its investigation, the OMI did not substantiate the whistleblower's central allegations, but did find at least one example of noncompliance with VA policy. However, the OMI did not find a substantial or specific danger to public health. The OMI made 10 recommendations regarding general compliance with procedures. The Medical Center's implementation of all the recommendations will be tracked by the Under Secretary for Health. The OMI review is contained in the enclosed Final Report, and it is submitted for your review.

Sincerely,

A handwritten signature in black ink, appearing to read "Eric K. Shinseki", written over a horizontal line.

Eric K. Shinseki

Enclosure



DEPARTMENT OF VETERANS AFFAIRS
Office of the General Counsel
Washington DC 20420

NOV 9 2012

In Reply Refer To:

The Honorable Carolyn N. Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M. Street, N.W. Suite 300
Washington, DC 20036-4505
Attn: Catherine A. McMullen, Chief, Disclosure Unit

Re: OSC File Nos. DI-11-0967, DI-11-3203 & DI-12-0023

Dear Ms. Lerner:

This letter responds to your inquiry regarding alleged violations at the Department of Veterans Affairs (VA) Medical Centers in Shreveport, Louisiana; Little Rock, Arkansas; and San Francisco, California, referenced above. Per your recent discussion with VA's General Counsel, we are providing you with revised reports, which contain the names and titles of the individuals interviewed. We will be sending redacted versions of the three reports shortly.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Walter A. Hall", is positioned above the printed name.

Walter A. Hall
Assistant General Counsel

Enclosures

OFFICE OF THE MEDICAL INSPECTOR

**Revised Final Report to the
Office of Special Counsel
OSC File Number DI-12-0023**

Clinical Laboratory Service

Department of Veterans Affairs

San Francisco VA Medical Center

San Francisco, CA



Veterans Health Administration

Washington, DC

Report Date: November 7, 2012

OMI TRIM # 2011-D-1421

Any information in this report that is the subject of the Privacy Act of 1974 and/or the Health Insurance Portability and Accountability Act of 1996 may only be disclosed as authorized by those statutes. Any unauthorized disclosure of confidential information is subject to the criminal penalty provisions of those statutes.

Executive Summary

Summary of Allegations

The Under Secretary for Health (USH) requested the Office of the Medical Inspector (OMI) to investigate complaints lodged with the Office of Special Counsel by (b)(6), an employee at the San Francisco Veterans Affairs (VA) Medical Center, San Francisco, California (hereafter, the Medical Center). (b)(6) (hereafter, the whistleblower) alleged that employees are engaging in conduct that may constitute gross mismanagement and a substantial and specific danger to public health and safety in the Clinical Laboratory Service (hereafter, the Laboratory).

The whistleblower alleged that:

1. the Laboratory routinely stores urine samples unsafely, including positive samples and samples containing blood, for several days after they have been tested, allowing bacteria to grow,
2. the Laboratory employees are required to dispose of stored urine in a sink that is used for other laboratory purposes, including employee hand washing, and which has been under a work order for at least 8 months,
3. the disposal of urine samples is accomplished without personal protective equipment (PPE) and without a policy manual or training for employees on proper urine disposal,
4. management is aware of the employee's concerns about the Laboratory's handling of urine samples but has taken no action.

The OMI conducted a site visit to the Medical Center on November 30 - December 1, 2011.

Conclusions

- The OMI did not substantiate the allegation that the Laboratory routinely stores urine samples unsafely.
- The OMI could not substantiate the allegation that urine samples are kept up to 5 days.
- The Medical Center does not have a written policy addressing the storage of urine samples for 48 hours after testing; however all staff were aware of this practice, and it is in compliance with VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*.
- All interviewed Laboratory technicians could accurately describe the practice; however, the Laboratory could not provide written evidence of training on urine storage.
- Due to the Laboratory's lack of tracking the utilization: e.g., retesting, additional testing, and identification verification of the stored urine, and the technicians' variable responses about which tests could be performed on stored urine samples, it is difficult to determine the utility of their storage policy.
- The Medical Center is not compliant with its own *General Laboratory Policy and Procedures* requiring that all stored laboratory specimens be refrigerated.

- The OMI substantiated the allegation that Laboratory technicians are required to dispose of stored urine samples in a sink that may also be used for employee hand washing; however, there are three other easily accessible sinks in the immediate vicinity that are dedicated to hand washing.
- The OMI did not substantiate the allegation that the sink used for disposal of urine is also used for other laboratory purposes.
- The OMI did not substantiate the allegation that the sink and its pipes are not in good working order.
- The OMI substantiated the allegation that a work order was placed related to the sink more than 8 months ago; however, the work order was for replacement of the cabinet, and not the repair of the sink's water supply or drain pipes.
- The OMI did not substantiate the allegation that disposal of urine samples is accomplished without PPE. Training on the use of PPE was well documented.
- All interviewed technicians, except the whistleblower, understood and could describe the procedure for disposal of urine samples; however, the OMI did substantiate the allegation that the Medical Center does not have a policy manual or documentation of training for employees on the proper method.
- Laboratory technicians did not have a consistent understanding of what criteria reclassifies urine as a medical waste; however they did understand how to dispose of medical waste.
- Staff is aware of the process for medical waste disposal.
- The OMI could not substantiate the allegation that management is aware of the employee's concerns about lab handling of urine samples.
- The Medical Center is not compliant with local and national policies and procedures related to documenting collection times of urine samples, including a VHA policy that facilities meet the standards set forth in 42 CFR 493 (the Clinical Laboratory Improvement Amendments of 1988).
- The Laboratory is not able to determine whether the urine specimen meets the required testing times, without accurate documentation of the collection time.

Recommendations

The Medical Center should:

1. Develop written policies and procedures for the storage of urine samples in the Laboratory,
2. Document their training on the handling of urine samples,
3. Provide clear, written guidance specifying which tests can be performed on stored urine samples.
4. Comply with their approved policies and procedures regarding refrigeration of saved specimens.
5. Begin tracking and trending the use of the stored urine and evaluate the utility of their storage policy.
6. The Medical Center should ensure laboratory technicians in the Communication Unit are aware of the location of dedicated hand washing sinks.
7. Develop a written procedure or policy and provide training related to disposal of urine.

8. Provide training about specific criteria that would result in the reclassification of urine as medical waste.
9. Provide training to all staff involved in collecting, receiving, and processing urine samples.
10. Monitor compliance with the recording of collection times and address non-compliance as indicated.

Summary Statement

The investigation and review of its findings did not reveal any evidence of gross mismanagement or substantial and specific danger to public health and safety. Review of the investigation did not find any violation or apparent violation of statutory laws or mandatory rules or regulations set forth in the Code of Federal Regulations, but did find non-compliance with local and national VA policy, including a VHA policy requiring that facilities meet the standards set forth in 42 CFR 493.

I. Summary of Allegations

The Under Secretary for Health (USH) requested the Office of the Medical Inspector (OMI) to investigate complaints lodged with the Office of Special Counsel by (b)(6), an employee at the San Francisco Veterans Affairs (VA) Medical Center, San Francisco, California (hereafter, the Medical Center). (b)(6) (hereafter, the whistleblower) alleged that employees are engaging in conduct that may constitute gross mismanagement and a substantial and specific danger to public health and safety in the Clinical Laboratory Service (hereafter, the Laboratory).

The whistleblower alleged that:

1. the Laboratory routinely stores urine samples unsafely, including positive samples and samples containing blood, for several days after they have been tested, allowing bacteria to grow,
2. the Laboratory employees are required to dispose of stored urine in a sink that is used for other laboratory purposes, including employee hand washing, and which has been under a work order for at least 8 months,
3. the disposal of urine samples is accomplished without personal protective equipment (PPE) and without a policy manual or training for employees on proper urine disposal,
4. management is aware of the employee's concerns about the Laboratory's handling of urine samples but has taken no action.

The OMI conducted a site visit to the Medical Center on November 30 - December 1, 2011.

II. Facility Profile

The Medical Center, part of Veterans Integrated Service Network 21, is a 124-bed facility with an additional 120 beds in its Community Living Center. It provides a full spectrum of care to over 310,000 eligible Veterans in Northern California in its main facility and its six Community Based Outpatient Clinics (CBOCs) throughout the region. The Department of Pathology and Laboratory Medicine (P&LM) at the Medical Center provides comprehensive diagnostic services for the main hospital and its CBOCs and serves as one of the major training sites for University of California, San Francisco P&LM residency program. The primary areas of service include surgical pathology, cytopathology, electron microscopy, immunofluorescence microscopy, clinical chemistry and toxicology, hematology and hematopathology, blood bank, microbiology, and point-of-care testing. Faculty members in the department are actively engaged in various basic scientific, translational and/or clinical research. The Laboratory's central processing area, known as the Communication Unit, is where accessioning and processing of specimens, and disposal of urine samples occurs. The Laboratory processes up to 125 urine samples per day, nearly 3,000 per month.

III. Conduct of Investigation

An OMI team consisting of the (b)(6), Deputy Medical Inspector, Professional Services, (b)(6), a Clinical Program Manager, and (b)(6) a consulting laboratory supervisor, conducted the site visit. The OMI team toured the main Laboratory and traced the handling of a urine sample through the Laboratory. We also reviewed relevant policies, procedures and reports. A full list of the documents reviewed is in the Attachment. The OMI held an entrance and exit briefing with Medical Center leadership and VISN 21 staff.

During the site visit, the OMI interviewed the following individuals: (b)(6) Acting Medical Center Director; (b)(6) Chief of Staff and Chief, Laboratory Medicine Services; (b)(6) Chief, Facilities Management; (b)(6) Chief, Medical Technologist/Laboratory Manager; (b)(6) Laboratory Medicine Service Quality Manager; (b)(6) Communication Unit Supervisor and whistleblower's direct supervisor; (b)(6) laboratory technician team leader; (b)(6), laboratory technician; (b)(6), laboratory technician; and (b)(6), laboratory technician.

The Office of General Counsel reviewed the findings to determine if there was any violation of law, rule or regulation.

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

IV. Findings, Conclusions, and Recommendations

Allegation #1

The Laboratory routinely stores urine samples unsafely, including positive samples and samples containing blood, for several days after they have been tested, allowing bacteria to grow.

Findings

The Laboratory receives urine samples from both a Laboratory collection point and inpatient wards within the Medical Center and from its outlying CBOCs. Urine collected in the CBOCs has a preservative added to the collection container and does not require refrigeration. All urine samples are delivered to the Communication Unit, where accessioning, processing, storage, and disposal occur.

There are three steps to the Laboratory technicians accessing the urine sample:

1. Verify that all required information is included on the specimen label. If no collection time is reported, the Laboratory technologists state they record the accession time as the collection time.
2. Ensure the urine sample was collected in an appropriate container.
3. Ensure the provider's electronic order for testing is in the Veteran's medical record.

The Laboratory technician then generates identical laboratory barcode labels which are applied to the collection container and the testing vial. A portion of the urine sample is then put in the testing vial. The collection container, with the residual urine, is recapped and placed on a storage rack. Once the initial processing is complete, the vials are delivered to various divisions of the Laboratory for testing.

According to the Chief Medical Technologist, approximately 2 years ago, the Laboratory initiated a practice of storing urine samples (exclusive of 24-hour urine collection specimens) for 48 hours after being processed to address an issue related to the mislabeling of samples. Prior to the initiation of this practice, the laboratory discarded urine samples on the same day as initial processing. All interviewed staff members, with the exception of the whistleblower, were able to articulate the rationale for keeping these samples after initial testing. During OMI's interview with the whistleblower, OMI discussed the rationale for storing the urine and the whistleblower then voiced an understanding.

Retention of urine samples for 24 hours is a common practice within the clinical laboratory community. VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures* states "samples, slides and records must be retained in accordance with the requirements of VHA Records Control Schedule 10-1, Section VIII-Laboratory Service (113)." VHA Records Control Schedule 10-1 mandates that specimens taken from patients for laboratory testing be destroyed 48 hours after reporting results. The Laboratory does not have a written policy or procedure describing their 48 hour storage practice. The Medical Center could not provide written evidence of training. However during interviews, the technologists noted the Chief Medical Technologist communicated the change to 48 hours of storage time via email and verbal communication.

Under the current practice, the Communication Unit stores urine samples in the collection containers. After a sample of the urine has been extracted for testing, the collection container with remaining urine is recapped and placed on a specific shelf on the cart for storage. Each shelf on the cart is labeled with the specimen testing date. These urine samples are not refrigerated. Most urine samples are sterile. Some stored urine samples may contain bacteria which could multiply; however, there is no evidence that this is an unsafe practice. Per the Medical Center's *General Laboratory Policy and Procedures* document, last updated in July 2011, section X, entitled "Retention of Laboratory Records and Materials" states that "...saved specimens are refrigerated to accommodate any test add-on."

Some technicians stated that these samples are retested for toxicology only, while others stated they may be retested for chemistry studies, as well as cultures and sensitivities. All

of the technicians articulated that a urine sample stored for over 4 hours could not be used for culture and sensitivity testing. Laboratory technicians reported a variable frequency of requests for additional testing on the stored urine, with a range of daily to once or twice per week. The Laboratory does not track the utilization: e.g., retesting, additional testing, and identification verification of the stored urine.

All staff members interviewed reported awareness of the policy for disposing of stored urine samples 48 hours after accession. Only the whistleblower reported numerous occasions when urine samples were stored for up to 5 days. All others reported rare instances, usually over a weekend, when the stored urine could have been stored for 72 hours; otherwise, urine samples were consistently disposed of 48 hours after accession.

Conclusions

- The OMI did not substantiate the allegation that the Laboratory routinely stores urine samples unsafely.
- The OMI could not substantiate the allegation that urine samples are kept up to 5 days.
- The Medical Center does not have a written policy addressing the storage of urine samples for 48 hours after testing; however all staff were aware of this practice, and it is in compliance with VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*.
- All interviewed Laboratory technicians could accurately describe the practice; however, the Laboratory could not provide written evidence of training on urine storage.
- Due to the Laboratory's lack of tracking the utilization: e.g., retesting, additional testing, and identification verification of the stored urine, and the technicians' variable responses about which tests could be performed on stored urine samples, it is difficult to determine the utility of their storage policy.
- The Medical Center is not compliant with its own *General Laboratory Policy and Procedures* requiring that all stored laboratory specimens be refrigerated.

Recommendations

The Medical Center should:

1. Develop written policies and procedures for the storage of urine samples in the Laboratory,
2. Document their training on the handling of urine samples,
3. Provide clear, written guidance specifying which tests can be performed on stored urine samples.
4. Comply with their approved policies and procedures regarding refrigeration of saved specimens.
5. Begin tracking and trending the use of the stored urine and evaluate the utility of their storage policy.

Allegation #2

Laboratory employees are required to dispose of stored urine samples in a sink that is used for other laboratory purposes, including employee hand washing, and which has been under a work order for at least 8 months.

Findings

The whistleblower referred to a sink in the Communication Unit, where urine samples are accessioned and processed. Stored urine is disposed of in this sink. Disposal into a sink drain is a common practice in laboratories, with the expectation that the urine will be diluted with running water, and the sink will be rinsed and disinfected after disposal. Per the Laboratory supervisor and interviewed technicians, this sink is used for urine disposal and occasionally hand washing. There are three other hand washing only sinks in the immediate vicinity of the Communication Unit; two are less than 15 feet from the sink used for urine disposal. At least four additional sinks are accessible in the Laboratory area, and there are also sinks in patient bathrooms and the employee lounge.

During the OMI interview, the whistleblower expressed concerns about the functioning of the urine disposal sink and corrosion of its pipes. This stainless steel sink is a large and deep, with a laminate cabinet top, and no under cabinet; its pipes are visible. The water flow for this sink is controlled by foot pedals and functioned. According to the Medical Center's Engineering Service, the hot and cold water supply pipes are copper, patent, and not rusted. The drain pipe is made of acid-rated polyvinyl chloride (PVC), which does not corrode. Visualization of the pipes by OMI did not reveal signs of corrosion or rust. Per interviews with Laboratory staff, there have been no problems with the sink functioning. It has been evaluated by the Engineering staff and no work orders have been placed for repair of the sink or pipes over the past 2 years. In May 2010, a work order was placed to request replacement of this "sink/cabinet" secondary to water damage to the counter top. Engineering evaluated the work order that same month and determined that replacement of the sink was unnecessary and only the cabinet needed replacing. The purchase order for a new cabinet was processed and engineering replaced the cabinet on December 1, 2011, during the OMI site visit.

Conclusions

- The OMI substantiated the allegation that Laboratory technicians are required to dispose of stored urine samples in a sink that may also be used for employee hand washing; however, there are three other easily accessible sinks in the immediate vicinity that are dedicated to hand washing.
- The OMI did not substantiate the allegation that the sink used for disposal of urine is also used for other laboratory purposes.
- The OMI did not substantiate the allegation that the sink and its pipes are not in good working order.

- The OMI substantiated the allegation that a work order was placed related to the sink more than 8 months ago; however, the work order was for replacement of the cabinet, and not the repair of the sink's water supply or drain pipes.

Recommendation

6. The Medical Center should ensure laboratory technicians in the Communication Unit are aware of the location of dedicated hand washing sinks.

Allegation #3

Disposal of the urine samples is accomplished without personal protective equipment (PPE) and without a policy manual or training for employees on proper disposal methods.

Findings

The Laboratory PPE includes gloves, goggles, face shields, masks, and laboratory coats. The Medical Center provides each Laboratory technician with PPE, including three white laboratory coats, and laundry service for these coats. The Medical Center's *Laboratory Safety Policies and Procedures Manual* outlines the expectation to wear PPE, including buttoned, facility-issued laboratory coats while handling specimens, especially when there is a potential exposure to biological and chemical hazards.

The Environmental Protection Agency (EPA) regulates medical waste disposal at the federal level. The EPA sets minimum regulations that all hospitals must follow regarding the disposal of medical waste; however, individual states may enforce stricter laws. Multiple laboratory consultants told OMI that VA medical centers are required to follow federal, state and local rules and regulations with regards to the disposal of medical waste. California's Medical Waste Management Act states that medical waste does not include.....urine, unless it contains recognizable "fluid blood," chemotherapeutic or radioactive material. Without these, urine is considered non-hazardous, and, apart from PPE, no additional precautions are indicated. All staff members interviewed stated they wear PPE when disposing of urine and have not observed others disposing of urine without PPE. All staff wore the appropriate PPE during the OMI tour of the Laboratory. PPE was readily available throughout all areas of the Laboratory. The *Laboratory's General Laboratory Policy and Procedures* document and the *Laboratory's Safety Policy and Procedures Manual* both outline the appropriate use of PPE. Each employee is responsible for reviewing this information on an annual basis, and signing a document stating that they have reviewed these documents. Review of training records showed training compliance by every employee in the Laboratory's Communication Unit, including the whistleblower.

Staff is expected to dispose of retained urine samples 48 hours after testing. After donning the appropriate PPE, the staff member pours the urine down the sink's drain, holding the container close to the drain. The drain is flushed with running water, the sink

is sprayed with the deodorizing disinfect cleaner, and rinsed. With the exception of the whistleblower, all technicians interviewed described the above procedure for disposing of urine. Staff members stated they had on the job training about disposal of urine, but were not aware of an existing Laboratory policy or procedure describing this task. The Medical Center did not document the policy and procedure, or the training of the proper manner for urine disposal.

The Laboratory technicians reported various individual interpretations of the criteria they used to define the presence of “fluid blood” in urine to include the urine’s color and consistency, and/or the presence of clots. The OMI found no evidence of training on the criteria for reclassifying urine as medical waste. All interviewed technicians were able to articulate that when they reclassified the urine sample as a biohazard, they placed the urine collection container with the residual urine into a biohazard box for disposal as medical waste. All used urine collection containers were disposed of as medical waste, to ensure destruction of personal identifiable information on labels.

Conclusions

- The OMI did not substantiate the allegation that disposal of urine samples is accomplished without PPE. Training on the use of PPE was well documented.
- All interviewed technicians, except the whistleblower, understood and could describe the procedure for disposal of urine samples; however, the OMI did substantiate the allegation that the Medical Center does not have a policy manual or documentation of training for employees on the proper method.
- Laboratory technicians did not have a consistent understanding of what criteria reclassifies urine as a medical waste; however they did understand how to dispose of medical waste.
- Staff is aware of the process for medical waste disposal.

Recommendations

The Medical Center should

7. Develop a written procedure or policy and provide training related to disposal of urine.
8. Provide training about specific criteria that would result in the reclassification of urine as medical waste.

Allegation #4

Management is aware of employee’s concerns about the Laboratory’s handling of urine samples but has taken no action.

Findings

The OMI interviewed Laboratory management and Medical Center leadership about the whistleblower's allegations about the handling of urine samples. This group included the Chief, Laboratory Medicine Services, Chief Medical Technologist/Laboratory Manager, the Communication Unit Supervisor (the whistleblower's direct supervisor), one laboratory technician team leader, and the acting Medical Center Director. None of this group stated they were aware of these concerns prior to the OMI visit; however, they were aware of other issues, unrelated to these allegations, raised by the whistleblower.

Conclusion

- The OMI could not substantiate the allegation that management is aware of the employee's concerns about lab handing of urine samples.

Recommendation

None

Additional Information

Findings

The whistleblower did not raise the following issue; however because of a potential impact on the quality of urine samples testing results, it is included in this report.

Urine samples received in the Communication Unit are accessioned prior to testing. During this process, Laboratory technicians are required to document in the computer the date and time of urine collection. The OMI discovered that Medical Center staff does not consistently document the urine sample collection times. Laboratory technicians reported that they frequently receive urine samples, especially from the inpatient units, that lack documented collection times on the labels. They reported that if a urine sample is missing the collection time, they record the time the Laboratory receives the specimen as the collection time, and process it for testing. Some, but not all Laboratory technicians, were able to articulate the effect of the time interval between collection time and testing on results. With the exception of 24-hour urine collection containers, containers used within the Medical Center do not contain preservatives and are not routinely refrigerated upon arrival to the Laboratory.

The Medical Center uses the operator's manual for the UA iChem 200.01 analysis machine to describe specimen requirements. This document states "...if a specimen is not processed within one hour after collection, cap the container tightly and store at 2-8 degrees Celsius." It is necessary to know the time of collection in order to determine whether the specimen requires refrigeration or replacement. While legally VA is exempt from the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88), VHA policy has adopted the CLIA 88 standards. The VHA Handbook 1106.01, *Pathology and*

Laboratory Medicine Service Procedures states “All laboratory testing within VA used for the diagnosis, treatment and prevention of disease in patients must be provided in compliance with the procedures outlined in this Handbook and meet the requirements of 42 CFR 493, CLIA ‘88.” CLIA 88, Section 493.1241 Standard: Test Request, states “the laboratory must ensure the test requisition solicits the following information: ...the date and, if appropriate, time of specimen collection.” In this case, the time is applicable due to the labile nature of the specimen. The CAP standard URN.22300 requires that “urine specimens are examined within 1-2 hours of collection.” The VHA also incorporates guidelines from the Clinical and Laboratory Standards Institute (CLSI), a national laboratory standards organization; the CLSI guidelines for urine analysis, state that, when a urine specimen is received in the laboratory, it is examined for the acceptability of the elapsed time between collecting the specimen and receipt in the laboratory. Identification must include the date and time of collection of the specimen (Urinalysis Approved Guideline 3rd Edition, 2009).

Conclusions

- The Medical Center is not compliant with local and national policies and procedures related to documenting collection times of urine samples, including a VHA policy that facilities meet the standards set forth in 42 CFR 493 (CLIA 88).
- The Laboratory is not able to determine whether the urine specimen meets the required testing times, without accurate documentation of the collection time.

Recommendations

The Medical Center should

9. Provide training to all staff involved in collecting, receiving, and processing urine samples.
10. Monitor compliance with the recording of collection times and address non-compliance as indicated.

Summary Statement

The investigation and review of its findings did not reveal any evidence of gross mismanagement or substantial and specific danger to public health and safety. Review of the investigation did not find any violation or apparent violation of statutory laws, or mandatory rules or regulations set forth in the Cod of Federal Regulations, but did find non-compliance with local and national VA policy, including a VHA policy requiring that facilities meet the standards set forth in 42 CFR 493.

Attachment

Documents Reviewed by OMI

VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*

VHA Records Control Schedule 10-1

The Medical Center's *General Laboratory Policy and Procedures*

The Medical Center's *Laboratory Safety Policies and Procedures Manual*

Excerpt from the UA iChem 200.01 manufacture's guideline

The Clinical Laboratory Improvement Amendment of 1988 section 493.1241

The College of American Pathologist Urinalysis Checklist for CAP Accreditation Program

The Clinical Laboratory Standards Institute Approved Urinalysis Guidelines 3rd Edition

Training records and competency folders for supervisory and non supervisory Laboratory staff

Medical Waste Management Act California Health and Safety Code, Sections 117600-118360