DEPARTMENT OF VETERANS AFFAIRS

Memorandum

Date: AUG 18 2009

From: Director, VHA National Health Physics Program (NHPP) (115HP/NLR)

Subj: Radiation Safety Program Inspection – Notice of Violation and Inspection Report 605-08-I01

To: Director (605/00), VA Loma Linda Healthcare System, Loma Linda, California

1. We inspected the radiation safety program at the VA Loma Linda Healthcare System, Loma Linda, California, during June 17-19 and October 6-8, 2008, and February 10-11, 2009, with in-office review through July22, 2009. This inspection scope included all elements of a routine, core inspection and specific allegations and safety concerns received by NHPP.

2. Attachment A to this memorandum is the narrative for the inspection report with our findings and description of violations. Attachment B is a Notice of Violation (NOV) with four violations cited that together represent a Severity Level III problem based on lack of adequate management oversight. In addition, one non-cited violation is identified.

3. One violation is willful since the violation circumstances involved two separate situations in which former staff members knowingly entered false survey data into a computer database. A willful violation is a very serious concern because we rely, in part, on honesty and integrity by permittees and staff to comply with applicable regulations.

4. We are concerned that management had not facilitated effective communications among key elements of the groups and staff involved with radiation safety practices, but note management is aware of the need to enhance teamwork and communication. We remind you that the healthcare system must establish and maintain a safety conscious work environment in which workers are encouraged to raise safety concerns without fear of retaliation.

5. You must respond to the NOV within 30 days of the date of this memorandum and use the instructions in the NOV to prepare the response. Please contact Thomas E. Huston, Ph.D., at 501-257-1578, if you have any questions or comments about the inspection.

E. Lynn McGuire

Attachments

cc: Chair, National Radiation Safety Committee, and members
Network Director, VISN 22 (10N22)
Nuclear Regulatory Commission

RADIATION SAFETY PROGRAM INSPECTION
Inspection Report Number 605-08-I01
VA Loma Linda Healthcare System, Loma Linda, California
June 17, 2008 – July 22, 2009

1. Introduction

NHPP[1] initiated an announced, reactive inspection of the radiation safety program at LLHS on June 17, 2008. Thomas E. Huston, Ph.D., Paul L. Yurko, and Gary E. Williams completed a series of on-site inspections during June 17-19 and October 6-8, 2008, and February 10-11, 2009, with continued in-office review through July 22, 2009. The scope of the inspection included all elements of a routine, core inspection and specific allegations and safety concerns received by NHPP from LLHS employees.

a. On March 3, 2008, an employee (Individual A) contacted NHPP by telephone and raised several concerns. Individual A followed that contact with a letter dated March 23, 2008. These employee concerns were related to the clinical radiological imaging techniques, clinical quality procedures, and supervisor qualifications and attentiveness. NHPP concluded these concerns did not involve regulatory issues under NRC or NHPP purview and forwarded a copy of the letter to the VHA Nuclear Medicine Program Director for further review.

b. On April 17, 2008, Individual A contacted NHPP by telephone and alleged that LLHS management had attempted to restrict Individual A's ability to report safety concerns and had retaliated against the individual for reporting earlier concerns. During follow-up discussion with Individual A that same day, NHPP determined that the issues were related to radioactive materials use (e.g., security for a hot laboratory).

c. On April 18, 2008, NHPP contacted another employee (Individual B) by telephone to help determine more information about concerns raised by Individual A on April 17, 2008. Individual B opined that LLHS management appeared to have retaliated against Individual A for reporting issues to the LLHS RSO and outside regulatory agencies. Individual B discussed historical and current information on various safety concerns raised by Individual A and other employees and how LLHS had responded.

d. On April 21, 2008, NHPP notified NRC of the allegation circumstances. NHPP updated NRC on the circumstances periodically.

e. On April 21, 2008, NHPP contacted the RSO by telephone to discuss safety issues and the allegation circumstances (including possible restrictions on and retaliation for reporting safety concerns) and to ensure understanding by the RSO about the applicable whistleblower protection regulations. The RSO agreed to inform executive management about the allegations received by NHPP with intent that LLHS would take immediate corrective actions to retrain applicable workers, supervisors, and managers to ensure a safety conscious work environment was achieved

[1] A list of acronyms and terminology is provided in section 13 of this narrative.

for the use of radioactive materials. NHPP also discussed a forthcoming formal task to LLHS to complete an internal investigation into the allegation circumstances.

f. On April 23, 2008, NHPP tasked LLHS to investigate any possible restrictions on and retaliation for employees who stated safety concerns. The tasking memorandum required a written reply within about 2 weeks.

g. On April 23, 2008, the RSO provided NHPP a copy of a memorandum documenting that the RSO had initiated a separate investigation of the allegation circumstances.

h. On April 23, 2008, executive management convened an AIB to investigate circumstances involving Individual A and two other employees, Individuals C and D, within Nuclear Medicine Service. The AIB report was issued May 9, 2008.

i. On or about May 10, 2008, NHPP received a copy of the AIB report, dated May 9, 2008, comprising about 1300 pages of affidavits, exhibits, and final conclusions.

(1) The AIB report did not find any evidence that LLHS staff had engaged in reprisal for whistleblower activity.

(2) The AIB did not find any evidence that nuclear medicine technologists were instructed not to discuss safety concerns with the RSO.

(3) The AIB concluded that three employees, Individuals A, C, and D, engaged in deliberate misconduct that caused, or could have caused if not detected, LLHS to be in violation of NRC regulations.

(4) The AIB concluded that the Radiation Safety Office and Imaging Service had a less than optimal working relationship that was detrimental to the functioning of both services.

j. On June 2, 2008, NHPP received a letter dated May 23, 2008, from Individual A which described the circumstances of alleged retaliation which were communicated to NHPP earlier by the employee, by telephone on April 17, 2008. In this letter, Individual A also provided details about a questionable administration of a Samarium-153 (Sm-153) therapy dosage, a possible security violation in which a door was left unlocked by Individual A on March 27, 2008, and various concerns about the qualifications of the individual's supervisor.

k. On June 5, 2008, NHPP received a memorandum dated June 3, 2008, from the RSO documenting his investigation results (see paragraph 1g) into possible restrictions and retaliation against Individual A for reporting safety concerns. Some conclusions in this RSO memorandum were contrary to the AIB conclusions.

l. On June 6, 2008, NHPP sent a letter to Individual A to acknowledge NHPP had received the employee's concerns through earlier correspondences (i.e., paragraphs 1b and 1j). NHPP informed the individual that an inspection at LLHS would be initiated during the week of

June 16, 2008, to evaluate allegation circumstances.

m. On June 9, 2008, NHPP received a letter dated June 5, 2008, from Individual A. Among other issues, the letter stated the actions taken against this individual due to a possible security violation on March 27, 2008.

n. On June 17-19, 2008, NHPP, initiated the inspection by performing the first on-site inspection at LLHS.

(1) NHPP used earlier correspondence and documents, including the AIB report, as a basis for issues to address during the inspection.

(2) This on-site inspection included all elements for a core inspection of the radiation safety program with focus on the following: treatment of employees who raised safety concerns, possible willful violations for falsification of records in Nuclear Medicine Service, a possible medical event for an Sm-153 procedure in February 2008, a possible security violation for the hot laboratory in March 2008, and a possible issue with a staff physician acting as an "AU" before approval under 10 CFR 35.

(3) During the inspection, the RSO provided NHPP with copies of a June 2, 2008, external audit report, information related to a possible willful violation for falsification of records, and information related to contamination events by a nuclear medicine technologist (Individual C).

(4) An exit meeting was held with executive management on June 19, 2008, to discuss initial findings; however, the inspection was left open pending further review.

o. On June 30, 2008, NHPP received a letter, dated June 25, 2008, from the RSO which provided additional information and clarification of specific items related to the initial on-site inspection effort by NHPP.

p. On July 1, 2008, NHPP received a telephone call from Individual A, who stated that Nuclear Medicine Service management had placed restrictions on the manner in which another employee, Individual D, communicated with the RSO. On July 8, 2008, during a telephone discussion with NHPP, Individual D confirmed receipt of a memorandum from a supervisor dated June 27, 2008, which appeared to place restrictions on communication with the RSO. NHPP contacted LLHS executive management on July 9 and 10, 2008, to request the circumstances be further evaluated.

q. On July 9, 2008, NHPP received a memorandum, dated July 2, 2008, from the RSO. This new memorandum provided follow-up on an RSO memorandum dated June 3, 2008 (Report on Investigative Task) and additional details related to the RSO investigation.

r. On July 22, 2008, LLHS executive management provided NHPP a copy of a memorandum to Individual D, dated July 22, 2008, rescinding the memorandum of June 27, 2008. Also on July 22, 2008, LLHS executive management updated NHPP on a meeting with Nuclear Medicine

Service staff. Based on an e-mail from the Chief of Staff, the meeting emphasized, among other items, the need or desire of individuals to report or discuss safety concerns, including radiation safety concerns, with the Safety and Radiation Safety Offices without fear of reprisal by management.

s. On August 13, 2008, NHPP received an e-mail from the RSO. The e-mail emphasized an apparent chilling effect on one individual and included information about a contamination event on August 7, 2008; a meeting held by a few, but not all, RSC members to plan an external audit; a status report from 2007 prepared by the RSO; and other statements from the RSO regarding the handling of recurrent problems within Nuclear Medicine Service.

t. On September 23, 2008, NHPP received an undated letter from Individual A. Attached to the letter was a copy of a letter dated August 22, 2008, from OSC to Individual A. The OSC letter documented a determination to close Individual A's file on the matter of a potential violation for whistleblower protection with respect to the individual's disclosures, as reported to OSC. OSC did not conclude in that letter that retaliation had occurred for engaging in protected activities.

u. On October 6-8, 2008, NHPP performed a second on-site inspection at LLHS, as part of the ongoing inspection effort.

(1) NHPP reviewed correspondence described above and information from the earlier on-site inspection in preparation for this second on-site inspection.

(2) This on-site inspection focused on issues identified since the first on-site inspection and included the following: treatment of employees who raised safety concerns, willingness of employees to raise safety concerns to management or outside agencies, possible contamination events in the Nuclear Medicine Service areas, and data-entry issues with the Pinestar database system. The inspection process included interviews with nuclear medicine technologists, executive management, supervisors, and human resources specialists.

(3) LLHS staff provided additional information for review during the inspection, including documents related to possible falsification of a survey record in December 2007, information related to a contamination event on August 7, 2008, an LLHS radiation safety program policy document, and an updated nuclear medicine policy and procedure manual.

(4) An exit meeting was held with executive management on October 8, 2008, to discuss preliminary findings; however, the inspection was left open, in part, because the RSO was not available for interview during this on-site inspection due to scheduled leave.

v. On October 17, 2008, NHPP received a telephone call from Individual D stating that s/he had been terminated from employment with LLHS effective October 17, 2008. Individual D claimed that the termination was because s/he had worked with the Radiation Safety Office.

w. On October 20, 2008, NHPP received another phone call from Individual D to discuss circumstances of his/her termination. In the call, Individual D noted a possible shipping issue involving an I-123 capsule and suggested that NHPP evaluate the circumstances. Individual D called a different individual at NHPP to discuss these same circumstances on October 29, 2008.

x. On October 27, 2008, NHPP received a telephone call from Individual A stating that s/he had received a notice of termination from LLHS.

y. On November 7 and 10, 2008, NHPP received telephone calls from Individual A about telephone discussions with the VHA National Nuclear Medicine Program Director. Based on those discussions, Individual A indicated to NHPP that s/he did not intend to pursue earlier issues related to radiological imaging and quality. (See paragraph 1a.)

z. On November 24, 2008, NHPP provided a copy of the RSO investigation report, dated June 3, 2008, to NRC per request. On November 25, 2008, NHPP provided the follow-up RSO report, dated July 2, 2008, to NRC per request. On November 26, 2008, NHPP provided the AIB report, dated May 9, 2008, to NRC per request.

aa. On December 1, 2008, NHPP received a copy of a memorandum, dated November 18, 2008, written by an Acting Assistant General Counsel for VA. The memorandum included a letter from Individual A, dated September 13, 2008, with multiple attachments, and a response from the Acting Assistant General Counsel to Individual A. In the letter, Individual A was appealing and elaborating on parts of the AIB conducted by LLHS. The response from the Acting Assistant General Counsel was that jurisdiction in this case was limited to providing information under the Freedom of Information Act and not to the content of the AIB. The individual was referred to VHA, who in turn forwarded copies of the individual's letter and Acting Assistant General Counsel's reply to LLHS and NHPP, as information.

bb. Between December 15, 2008, and February 12, 2009, NHPP received several letters from Individual A regarding information requested under the discovery process for a court case. The letters were addressed to various NHPP staff. NHPP provided a response on February 17, 2009, through an attorney at the VA Regional Counsel Office in Los Angeles, to a letter from Individual A dated February 2, 2009. NHPP concluded these letters did not present any new information pertinent to our inspection.

cc. On December 23, 2008, NHPP received a telephone call from Individual D, stating that s/he had attended a final mediation board review and was concerned when a management individual at LLHS commented that NHPP had indicated action to fire Individual D was appropriate. During the call, NHPP informed Individual D that NHPP had not made such a statement to LLHS management. NHPP inquired about the concern during a third on-site inspection and did not substantiate that such a statement had been made by LLHS management about either Individual A or Individual D.

dd. On February 10-11, 2009, NHPP performed a third on-site inspection at the LLHS, as part of the ongoing inspection effort.

(1) NHPP reviewed prior correspondence and information described above in preparation for the on-site inspection.

(2) The third on-site inspection focused on issues identified since the previous on-site inspection in 2008 and included the following: circumstances of termination of two employees; treatment of employees who raised safety concerns; willingness of employees to raise safety concerns to management or outside agencies; possible recent spills or contamination events in areas of use; handling of data-entry errors with the Pinestar system; a possible shipping deficiency involving an I-123 capsule; RSC oversight of radioactive materials use; and review of statements made by LLHS management to individuals and NHPP. The on-site inspection included interviews with the RSO, nuclear medicine technologists, executive management, Nuclear Medicine Service management, and a human resources specialist. The on-site inspection also included separate off-site meetings with two former LLHS employees, Individuals A and D.

(3) An exit meeting was held with executive management on February 11, 2009, to discuss preliminary findings; however, the inspection was left open, pending receipt and review by NHPP of approved RSC meeting minutes for a meeting on September 24, 2008, and signed minutes for a meeting which was to be held within 2 weeks after the on-site inspection.

ee. Between March 9 and April 13, 2009, NHPP received multiple letters from Individual D related to jurisdiction and decisions of other government agencies. The letters were dated March 5 and 30, and April 8, 2009. The letters described difficulties in processing a claim for a personal remedy with another government agency. NHPP concluded these letters did not present any new information pertinent to our inspection.

ff. On March 10, 2009, NHPP received minutes for RSC meetings on September 24, 2008, and February 19, 2009.

gg. On March 12, 2009, NHPP received a letter, dated March 9, 2009, from Individual D, which stated the individual believed that s/he was retaliated against for reporting safety concerns to the Radiation Safety Office. The letter was written in response to a meeting between the individual and NHPP on February 11, 2009 (during the third on-site inspection), in which NHPP encouraged the individual to provide details of safety concerns that had been reported to the Radiation Safety Office and RSO.

hh. NHPP held an exit meeting by phone with LLHS executive management on July 13, 2009, and discussed inspection findings. During the exit meeting, the RSO requested that NHPP characterize the willful violation as a non-cited violation since circumstances were self-identified and self-corrected prior to start of the inspection. The RSO correctly noted that NRC's Enforcement Policy provides for a willful violation to be non-cited in certain situations.

ii. NHPP made a follow-up telephone call to the LLHS executive management on July 22, 2009, and closed to the inspection. At that time, NHPP informed executive management that

their decision was to cite the willful violation as part of the overall Severity Level III problem. NHPP noted that, per the master materials license, all known instances of willful violations, whether cited or non-cited, must be reported by NHPP to NRC, who may initiate their own independent inspection and enforcement process.

2. Scope of inspection

The inspection was risk-informed and performance-based. All items on the inspection plan were completed, including, but not limited to, the following:

a. Interviews with LLHS and contract staff,

b. Review of correspondence and records related to allegation circumstances,

c. Review of records related to radiation safety program,

d. Tour of radioactive material use areas,

e. Review of LLHS actions regarding allegation circumstances, including a review of the effectiveness and comprehensiveness of actions to prevent recurrence of any substantiated allegations,

f. Evaluation of root or basic causes for regulatory violations, and

g. All elements of a routine, core inspection.

3. Findings and impressions (background information)

a. Results of most recent inspections: NRC inspected LLHS on August 6, 2002, and did not cite any violations. NHPP inspected LLHS on June 22, 2005, and did not cite any violations.

b. NMED was reviewed on June 5, 2008, and again on April 14, 2009. Reviews did not identify any issues since January 1, 2003, for LLHS.

c. During the initial on-site inspection on June 6-8, 2008, generic issues identified by NRSC for 2008 were reviewed with the following results.

(1) NARM use including locations of use, possession limits, radium and other sealed sources, and mobile positron-emission tomography services were determined to be in compliance with recent rulemaking.

(2) Sealed sources on-site were confirmed to be consistent with those listed on the NHPP Web-based inventory.

(3) Executive management oversight for use of radioactive materials was reviewed.

(a) The LLHS Director and Chief of Staff were both RSC members. The RSO reports to the Chief of Facility Management Service.

(b) LLHS did not appear to have undue reliance on affiliate universities or consultants.

(c) The inspection identified problems with effectiveness of executive management oversight and achieving a safety conscious work environment; these problems are described in more detail in other sections of this narrative.

d. During the initial on-site site visit, NHPP confirmed regulatory compliance for the following.

(1) Methods and records for patient doses, except as noted in later sections of this narrative.

(2) Radiation safety practices, except as noted in later sections of this narrative.

(3) Security and storage for radioactive materials.

(4) RSC approval for AUs in research.

(5) Employee radiation dosimetry.

e. NHPP did not identify any significant health or safety issues during the inspection.

4. Findings and impressions (treatment of workers who report safety concerns)

a. NHPP reviewed available documents and conducted interviews with individuals who had identified safety concerns to NHPP (Individuals A, B, and D), individuals who were allegedly retaliated against for engaging in protected activities (Individuals A and D), Nuclear Medicine Service management, VA Police Service, executive management, key human resources staff, and other nuclear medicine and radiation safety staff (including both employees and contract staff).

b. Based on the available information and results from interviews, NHPP did not conclude LLHS retaliated against Individual A or D for engaging in protected activities.

(1) Title 10 CFR 30.7(a) has regulatory requirements related to protected activities and provides a basis to evaluate regulatory compliance.

(2) NHPP did determine that Individuals A and D provided information on circumstances at LLHS, which the individuals stated were safety concerns, to the Radiation Safety Office and outside agencies.

(3) Overall circumstances of employment at LLHS for each of the individuals involved complex personnel issues and included factors other than reporting of safety concerns.

(4) Various disciplinary actions, including termination, were taken against the individuals; however, the causes presented to NHPP by LLHS management and human resources for the actions taken against each individual did not include reporting of safety concerns.

(5) Based on interviews and discussions with executive management, Nuclear Medicine Service management, human resources staff, and others with knowledge of the personnel actions for Individuals A and D, NHPP did not identify a clear nexus between reporting of safety issues and concerns and subsequent personnel actions taken against the individuals.

c. NHPP did identify a concern in that an "appearance of retaliation" was apparently evident to bystander employees (e.g., Individual B) who did not know all the details and reasons for the various personnel actions taken.

(1) Specific details about personnel actions are not always appropriate to share with all other employees.

(2) Training and reinforcement in the concepts of a safety conscious work environment must be addressed by executive management during circumstances involving personnel actions related to some employees who also might engage in protected activities.

d. NHPP did identify a concern in that a "chilling effect" resulted for some non-managerial staff due to the "appearance of retaliation." However, as of the second and third on-site inspections, this concern appears to have been resolved by LLHS executive management efforts.

(1) During the initial on-site inspection, NHPP conducted around 19 separate interviews and noted numerous employees raised concerns about reporting safety issues.

(2) During the second on-site inspection, NHPP received only one report of a reluctance to report a safety issue. This report was by an individual then under increased scrutiny due to an earlier personnel action, not related to protected activities.

(3) During the third on-site inspection, NHPP did not receive a report related to reporting safety issues by any current employees.

e. NHPP concluded that a violation under 10 CFR 30.7(f) occurred in that on two separate occasions, Nuclear Medicine Service management issued written instructions to individuals, namely Individuals A and D, which NHPP interpreted to restrict the manner in which these individuals could raise safety issues to employees outside the normal chain of command of the individual.

(1) A memorandum dated March 11, 2008, from the Chief, Imaging Service, to Individual A, included as Exhibit 08 of the AIB, stated, "If you have procedural or policy questions you are to follow the appropriate chain of command, starting with the supervisor, regardless of your personal feelings." The memorandum also stated, "failure to follow the instructions outlined in

this memorandum will be considered a failure to follow supervisory instructions and/or insubordination, and will result in immediate corrective action."

(2) A memorandum dated June 27, 2008, from Nuclear Medicine Service management to Individual D, stated that "If you feel you need to leave the department to go to the Radiation Safety Office to have questions answered then you need to let me know so that we can arrange a time that does not impact the department or patient care. Also, if there are issues that need to be addressed, then I need to be involved so that the other Technologists can be given the same information."

(3) NHPP concluded these written instructions were contrary to 10 CFR 30.7(f) which states, in part, that no agreement affecting the terms or conditions of employment may contain any provision which prohibits, restricts, or otherwise discourages an employee from participating in protected activity as defined 10 CFR 30.7(a), including, but not limited to, providing information to NRC, NHPP, or his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

(4) Based on interviews of individuals who signed the memoranda, NHPP concluded the intent of the instructions was not to restrict workers from engaging in protected activities but rather to minimize distribution of inappropriate ad hominem statements about individuals, to ensure continuity of patient care by individuals who might want to leave their normal work area to report safety concerns, and to provide supervisory personnel an opportunity to learn about possible problems within their departments so that issues could be resolved. While the memoranda used poor wording which was interpreted by the recipients as restricting their ability to engage in protected activities, NHPP determined this to be an unintended interpretation. When NHPP identified the recipients' interpretation to permittee management, prompt action was taken to correct the circumstances. In addition, due to the fact that these individuals continued to report possible safety concerns to the RSO and NHPP even after these instructions were issued, NHPP found no evidence that the memoranda actually resulted in a negative outcome with respect to recipients being unwilling to report safety issues.

5. Findings and impressions (executive management and Nuclear Medicine Service management oversight)

a. NHPP reviewed the management structure for Nuclear Medicine Service. The Chief, Imaging Service, who was the primary AU on the permit at the time of the on-site inspections, stated he retained supervisory oversight for the technical and regulatory issues for the safe use of radioactive materials and adherence to clinical standards of practice. A supervisor in Nuclear Medicine Service was assigned administrative duties, without any direct handling of radioactive materials, under direction of the Chief, Imaging Service. NHPP did not identify any programmatic deficiencies or possible regulatory violations related to this management structure.

b. NHPP identified a concern in that frequent poor communication and cooperation occurred among staff and management within Nuclear Medicine Service and the Radiation Safety Office.

(1) This weakness in communication and cooperation resulted in a diminished effectiveness for discussing and resolving safety issues within the Nuclear Medicine Service and between these two groups.

(2) This weakness was evidenced by circumstances, occurring in the July to September 2008 timeframe, in which Individual D worked with the Radiation Safety Office and a biomedical technician to attempt to make corrections to a Pinestar computer database system.

(a) The database system is used to record radiation safety survey results and is under supervisory control of Nuclear Medicine Service management.

(b) Efforts to correct data entries resulted in additional database problems. Nuclear Medicine Service management was apparently not involved in the decision to attempt the corrections or made aware of the additional problems that developed from that attempt. This circumstance was an example of poor communication among the different groups involved and ultimately resulted in a minor problem becoming a more involved problem, not only from a data management perspective but also from a personnel disciplinary perspective.

(c) Given that this system is under supervisory control of Nuclear Medicine Service management and the circumstances involved correction of a simple data entry mistake, an appropriate action would have been for Individual D and other involved individuals to have disclosed the issue and obtained approval for changes from Nuclear Medicine Service management before attempting to make corrections to database records.

(d) NHPP determined these circumstances did not involve reporting of a safety concern by Individual D to the Radiation Safety Office; rather the situation was an administrative data management matter. Other than this concern of poor communication among services, NHPP did not identify a program deficiency or regulatory violation for this circumstance.

(3) NHPP recognizes that, during this overall inspection effort, communication and cooperation within the Nuclear Medicine Service and between that service and the Radiation Safety Office appear to have improved. NHPP recommends that executive management continue to foster an environment of communication and cooperation (i.e., team-building and team-work) within and between these groups such that regulatory problems are not only identified but that groups cooperate in formulating effective solutions to correct problems and prevent their recurrence.

c. NHPP identified the following three concerns for executive management oversight related to the RSC.

(1) Meeting frequency. At the time of the third NHPP on-site inspection, February 10-11, 2009, the last RSC meeting had been on September 24, 2008, about 4½ months earlier. This meeting frequency was compliant with applicable guidelines for a minimum meeting frequency at 6-month intervals. However, given past and recent radiation safety issues, NHPP opined the RSC should hold more frequent meetings. At the exit meeting held February 11, 2009, LLHS

executive management agreed to hold an RSC meeting within the next 2 weeks and at least quarterly thereafter. As follow-up information, on March 10, 2009, LLHS provided documentation for an RSC meeting held February 19, 2009.

(2) Preparation of RSC minutes. Committee minutes were not prepared and distributed to members or executive management in a timely manner. At the time of the third NHPP on-site inspection, minutes from the previous RSC meeting of September 24, 2008, had not been signed by the RSC Chair or distributed to all RSC members, which included LLHS executive management. At the exit meeting held on February 11, 2009, executive management agreed to add a signature line to the minutes for the RSC Chair and set a goal of 30 days for distribution of the signed minutes to members, pending final approval of the minutes by the RSC at the next meeting. As a follow-up action, LLHS finalized and approved minutes for the September 24, 2008, meeting. Also the minutes from the meeting on February 19, 2009, were signed by the RSC Chair on February 23, 2009. Copies of both sets of minutes were provided to NHPP on March 10, 2009, as supporting information.

(3) Tracking for RSC issues. The RSC did not have a formal process to track and resolve open issues. At the exit meeting on February 11, 2009, LLHS executive management agreed to develop a system for tracking open issues to resolution. Evidence of such a system was provided in the RSC meeting minutes for February 19, 2009.

6. Findings and impressions (possible willful violation for falsification of records)

a. NHPP interviewed two individuals identified in the AIB as willfully fabricating data in the Pinestar computer database, which is used to store radiation safety survey records. The Pinestar database is maintained and controlled by Nuclear Medicine Service, though others, such as Radiation Safety Office staff, have access to the system for review and reporting purposes.

(1) One individual (Individual C) admitted that during July 2007 s/he intentionally recounted weekly wipes that had been collected from nuclear medicine use areas the previous week and reported those recount results as if they were new wipe results. A weekly wipe survey is a requirement established by LLHS for regulatory compliance. The circumstance was self-identified by the Radiation Safety Office and adequate and prompt corrective actions were taken by LLHS to address the situation.

(2) Another individual (Individual D) admitted that during December 2007 s/he intentionally entered a radiation survey result into the database after being questioned by Nuclear Medicine Service management about a missing end-of- day survey record from October 2007. An end-of-day radiation survey is a requirement established by LLHS for regulatory compliance in the nuclear medicine use areas. Individual D later noted to management that the record might be deleted but was instructed not to make changes to the record until an investigation into the matter was completed. Contrary to management's instruction, the individual deleted the record from the database. These circumstances were self-identified by management and adequate and prompt corrective actions were taken by LLHS to address the situation.

b. NHPP views these permittee-required surveys to be under NRC's general requirements for radiation protection surveys in 10 CFR 20.1501(a). As such, records of these surveys must be maintained per 10 CFR 20.2301(a) and be accurate per 10 CFR 30.9(a).

c. NHPP concluded the two circumstances described in paragraphs 6a(1) and 6a(2) represented deliberate misconduct per 10 CFR 30.10 and resulted in willful violations of 10 CFR 20.1501(a), 20.2301(a), and 30.9(a).

(1) Willful violations are of particular concern to NHPP because a radiation safety program is based on employees acting with integrity and communicating with candor.

(2) LLHS self-identified and corrected the circumstances with adequate and timely actions after the identification.

(3) NHPP is required to notify NRC about willful violations or intentional wrongdoing per the VA master materials license.

(4) The NRC Enforcement Manual states that willful violations are normally considered for escalated enforcement.

7. Findings and impressions (possible problems with therapeutic dosages)

NHPP reviewed administrations that required a written directive with the following findings.

a. LLHS performed an Sm-153 Quadramet® therapy on February 7, 2008, using a unit dosage provided by a commercial pharmacy.

b. During the initial on-site inspection, LLHS could not locate a written directive for this therapy to demonstrate compliance with 10 CFR 35.40.

(1) LLHS did not have a protocol for the use of Sm-153 at the time of this therapy or the initial on-site inspection.

(2) The written directive template in use at the time of the initial on-site inspection was for I-131 NaI only. The use of the template for radioactive drugs other than I-131 NaI required the AU to cross out I-131 NaI and write in the other drug.

(3) Because of a lack of protocol, the AU failed to prepare a signed written directive. NHPP concluded this circumstance to be a violation of 10 CFR 35.40.

(4) Under current NRC regulations, a medical event did not occur for the Sm-153 therapy on February 7, 2008, because a signed written directive did not exist for the administration. As additional information, based on the radiopharmaceutical order form, the AU administered the intended dosage to the patient.

(5) In addition to the Sm-153 therapy, LLHS self-identified two other therapies performed on May 13 and June 12, 2007, involving I-131 Bexxar®, that did not have signed written directives by the AU. Similarly, the cause was a lack of protocol for preparing written directives for other than I-131 NaI drugs. NHPP concluded these circumstances to be a violation of 10 CFR 35.40.

c. For the Sm-153 therapy on February 7, 2008, LLHS did not have a written procedure for verifying the dosage activity before administration. A direct measurement of the dosage was performed with a dose calibrator prior to administration; however, there was not a written procedure for such measurements involving Sm-153. For administrations requiring a written directive, 10 CFR 35.41 requires the permittee have written procedures to provide high confidence that an administration is per the written directive. NHPP concluded the failure to have written procedures to determine the Sm-153 activity, at the time of administration, to be a violation of 10 CFR 35.41.

8. Findings and impressions (security of a hot laboratory)

NHPP reviewed circumstances involving a possible breach of security for proper storage and surveillance of radioactive materials in a hot laboratory.

a. On March 24, 2008, a nuclear medicine technologist taped the hot laboratory door latch to keep the door unlocked, so that newly hired nuclear medicine technologists, who were waiting receipt of key cards, could access the room.

b. Before taping the door latch, the nuclear medicine technologist asked the receptionist to keep the door under surveillance.

c. The receptionist's desk is right across the hall from the hot laboratory and the door is in a position such that the receptionist might maintain constant visual surveillance.

d. In interviews conducted during the first and second on-site inspections, the receptionist confirmed visual surveillance was maintained for the entire time the door was taped open.

e. Since the area was under constant visual surveillance NHPP determined a violation of 10 CFR 20.1801 or 20.1802 did not occur in this circumstance.

9. Findings and impressions (physician working as a supervised individual)

a. Before the first on-site site visit, NHPP became aware of a physician that had been working in the Nuclear Medicine Service since July 2007 and was not listed on the LLHS permit.

b. The Chief, Imaging Service, who is the primary AU on the permit, stated the physician was working under supervision and in training even though this physician was not in the status of a resident or medical fellow.

c. NHPP verified the physician did not sign a written directive for any of the therapies performed in 2007 or through the first on-site inspection in 2008.

d. NHPP did not identify a program deficiency or regulatory violation for this physician working as a supervised individual under an AU.

e. As additional information, an amendment request to add the physician as an AU on the permit was submitted to NHPP on May 12, 2008. NHPP issued an amendment to add this AU on March 25, 2009.

10. Findings and impressions (other items reviewed)

a. During the second on-site site visit, NHPP reviewed circumstances involving response to an area contaminated with Tc-99m on August 7, 2008.

(1) The contaminated area was a small surface in the hot laboratory which was a restricted area where patient dosages are administered.

(2) In a note initiating an investigation of the circumstances, the RSO expressed concern that the event was not immediately reported to the RSO per LLHS written procedures. However, based on an internal investigation, the time of discovery appears to have been confused.

(3) Based on the location and extent of the contamination and dose rates involved, NHPP concluded employee exposures from the contamination were minimal and did not exceed a limit or a reporting requirement.

(4) NHPP concluded that LLHS had taken appropriate corrective actions to investigate and respond to the circumstances, including reinstructing employees about safe and cautious handling of sharps.

b. During the second on-site inspection, LLHS provided a copy of a policy and procedures manual for the Nuclear Medicine Service. The manual had clinical protocol information with improved written procedures and forms for administrations requiring written directives and procedures for determining activity of the Sm-153 dosage before administration. The written directive form also included a section for verifying that the dosage is administered per the written directive.

c. During the third on-site inspection, NHPP inquired about a possible contamination event in the hot laboratory on October 17, 2008. Neither the Radiation Safety Office nor Nuclear Medicine Service employees interviewed were aware of any specific circumstance in which a contamination event was identified for the hot laboratory on that date. NHPP inquired about the facility's internal procedures for responding to radioactive material spills and contamination events and found nuclear medicine technologists to be knowledgeable regarding these procedures.

d. During the third on-site inspection, NHPP reviewed circumstances involving the return of an I-123 capsule to a commercial pharmacy in which a possible violation of DOT training requirements occurred.

(1) The I-123 capsule was returned by Nuclear Medicine Service on June 25, 2008.

(2) Nuclear Medicine Service did not obtain proper internal approvals for the transfer from the RSO.

(3) The usual practice is to hold unused, short half-life sources for decay in storage and then dispose as non-radioactive under NRC regulations.

(3) Individuals involved in shipping the source had not been trained and tested per DOT regulations.

(4) The Assistant RSO identified the circumstances the day after the shipment, on June 26, 2008, and initiated an investigation.

(5) Nuclear Medicine Service provided a description of, and reasons for, the transportation event in a memorandum dated July 18, 2008.

(6) Appropriate corrective actions, including re-instruction of employees not to return radioactive materials to a commercial pharmacy without prior RSO approval, were taken following the event.

(7) NHPP determined the transfer of the I-123 capsule resulted in a violation of DOT shipping requirements in that individuals involved in shipping had not been trained and tested on DOT requirements; however, the event was self-identified and self-corrected and appears to be an isolated failure.

11. Findings and impressions (violations, root or basic causes, and corrective actions)

a. Title 10 CFR 20.1101 requires a permittee to have a radiation protection program that is adequate and sufficient to comply with applicable regulations. Contrary to this requirement, NHPP concluded through this inspection effort that the permittee failed to have an adequate radiation protection program in that the permittee did not establish and maintain effective executive management oversight and procedures to preclude or prevent the specific regulatory violations summarized below in paragraph 11e.

b. NHPP considers this failure and the resulting regulatory violations described in paragraph 11e to represent a Severity Level III problem.

c. NHPP determined the root causes for this failure to have adequate executive management oversight as the following.

(1) "Management system - oversight/employee relations - employee communications need improvement," in that better communication was needed among staff of both the Nuclear Medicine Service (including management) and Radiation Safety Office. For example, written communication from Nuclear Medicine Service management to two Nuclear Medicine Service employees could be interpreted as inconsistent with a worker's right to engage in protected activities. The lack of proper written directive forms and a procedure to verify dose for Sm-153 was not communicated in a timely manner by Nuclear Medicine Service management to the Radiation Safety Office so that a solution could have been determined before a regulatory violation occurred. Also at the time of NHPP's initial on-site inspection, many employees in the Nuclear Medicine Service expressed a reluctance to raise safety concerns to management for fear of retaliation. While this latter circumstance was not a specific violation, it was indicative of a failure to maintain a safety conscious work environment and was directly related to communication issues.

(2) Additional root causes are described below within the context of each resulting violation.

d. As corrective actions for the root cause in paragraph 11c(1), the inspectors note that executive management has taken some steps to improve communication between groups including meetings involving Nuclear Medicine Service management, the RSO, and executive management, and an additional Nuclear Medicine Service training meeting. In addition, NHPP is aware that a new lead nuclear medicine technologist has been appointed in the past few months, and this action has resulted in an improved interface between the Nuclear Medicine Service and the Radiation Safety Office on technical issues. As an additional corrective action, NHPP recommends that the facility consider developing an improved system, under RSC oversight, for tracking to resolution employee-identified issues related to radiation safety.

e. Paragraphs below summarize the specific regulatory violations that resulted from failure to have adequate executive management oversight and include a restatement of each violation, discussion of root or basic causes, and LLHS corrective actions to prevent recurrence. Paragraph 11f describes a violation related to deliberate misconduct. Paragraph 11g describes a violation related to restriction of protected activities. Paragraph 11h describes a violation for not properly completing a written directive and a violation for failure to have adequate written procedures. Paragraph 11i describes an NCV for shipment of a package by personnel who had not received DOT training.

f. Deliberate misconduct. NHPP determined that, on two separate occasions, individuals had engaged in deliberate misconduct that caused or could have caused, if not detected, LLHS to be in violation of the radiation survey and record keeping requirements. NHPP determined these circumstances to be a violation of 10 CFR 30.10 in addition to the underlying survey and recordkeeping requirements.

(1) NHPP determined that Individual C engaged in deliberate misconduct that caused or could have caused, if not detected, LLHS to be in violation of 10 CFR 20.1501(a), 20.2103(a), and 30.9(a). Specifically, on or about August 15, 2007, the individual intentionally used samples

known to be false to create survey data for a required weekly contamination survey and then willfully entered the sample counts from these false samples into the Pinestar computer system, which is used to record permittee radiation safety survey results.

(2) NHPP determined that Individual D engaged in deliberate misconduct that caused or could have caused, if not detected, LLHS to be in violation of 10 CFR 20.1501(a), 20.2103(a), and 30.9(a). Specifically, on or about December 11, 2007, the individual willfully entered false radiation safety survey data into the Pinestar computer system, which is used to record permittee radiation safety survey results. The individual later intentionally deleted the result despite management instruction to wait for an investigation to be completed regarding the matter. The survey involved was a required end-of-day radiation survey on October 26, 2007, in nuclear medicine use areas.

(3) Both individuals were interviewed during the inspection. When questioned about the circumstances, neither individual denied that the circumstances had occurred.

(4) Both circumstances were self-identified by LLHS, and NHPP confirmed appropriate corrective actions were taken by LLHS.

(5) NHPP did not identify a root or basic cause for these deliberate acts. The deliberate acts are addressed as a personnel issue and not under NHPP guidelines.

(6) NRSC policy for enforcement requires a permittee to take applicable corrective actions.

(7) The inspectors confirmed that for Individual C, the RSC suspended the individual's use of radioactive materials for a period of time. For Individual D, actions under Office of Personnel Management guidelines were taken.

(8) Due to other circumstances, these individuals are no longer employed at LLHS.

(9) These circumstances of deliberate misconduct are cited as one violation, with two specific examples.

g. Restriction of protected activities. NHPP determined LLHS violated 10 CFR 30.7(f) by issuing written instructions to individuals working with radioactive materials which appeared to restrict how possible safety issues or concerns could be reported to the Radiation Safety Office and other entities external to the individuals' normal chain of command.

(1) Title 10 CFR 30.7(f) requires, in part, that no agreement affecting the compensation, terms, conditions, or privileges of employment may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph 10 CFR 30.7(a) including, but not limited to, providing information to NRC [or NHPP] or to his or her employer on potential violations or other matters within NRC [or NHPP] regulatory responsibilities.

(2) Contrary to this requirement, on March 11, 2008, Nuclear Medicine Service management issued an employee written instructions which were interpreted to place restrictions on how, and to whom, the individual could report problems and concerns. On June 27, 2008, Nuclear Medicine Service management issued a different employee written instructions which were interpreted to place conditions on how the individual could interact with the RSO.

(3) Based on interviews with individuals who prepared these memoranda, NHPP concluded the instructions were not issued with the intent of restricting the recipients' rights to engage in protected activities but rather to address other personnel issues.

(4) NHPP evaluated the root cause for the violation and determined it to be "Management System - Oversight/Employee Relations - Employee Communications Need Improvement," in that poor wording was used by management to write the two memoranda to these employees. Management must be sensitive to whistleblower protection regulations and carefully choose words in policies and instructions to employees about reporting of perceived problems and concerns related to matters within NRC's regulatory responsibilities.

(5) NHPP reviewed corrective actions taken by LLHS for this violation. These actions are provided below. NHPP concluded these actions are adequate and sufficient to address the violation and prevent recurrence.

(a) The memorandum dated June 27, 2008, to Individual D, was rescinded by a memorandum from the Chief, Imaging Service, dated July 22, 2009. The memorandum noted that the intent of the earlier memorandum was not to restrict reporting of safety concerns.

(b) The Chief, Imaging Service, held a Nuclear Medicine Service staff meeting which included the RSO and assistant on July 22, 2008. At that meeting, reporting of general safety and radiation safety issues was addressed. The Chief, Imaging Service, stated that management fully supports any worker's need or desire to report or discuss any general safety or radiation safety issues or concerns with those offices. He further stated that workers may contact the appropriate safety office to meet with them to discuss any safety concerns without fear of reprisal by management. He did note that the details of a worker's appointment or meeting do not need to be known by management, but arrangements for absences from the work site must not impact patient care.

(c) The memorandum dated March 11, 2008, to Individual A was not officially rescinded because the individual was placed on administrative leave on April 17, 2008, and did not return to work after that date. The individual's employment with LLHS was eventually terminated on October 27, 2008.

(d) Based on interviews of Nuclear Medicine Service staff during the second and third on-site inspections, NHPP received feedback from workers that they were comfortable reporting safety concerns to the RSO and outside entities if they desired.

h. Written directive not completed and failure to have adequate procedures. NHPP determined LLHS violated both 10 CFR 35.40 and 35.41 for certain administrations requiring written directives.

(1) Title 10 CFR 35.40 requires preparation of a written directive signed and dated by an AU for therapeutic administrations of radionuclides. In addition, this regulation specifies the contents of such written directives. Contrary to this regulation, NHPP determined therapeutic administrations of Sm-153 on February 7, 2008, and I-131 on May 13, 2007, and June 12, 2007, did not involve properly prepared written directives signed by an AU.

(2) Title 10 CFR 35.41(a) requires that a permittee develop, implement, and maintain written procedures to provide high confidence each administration requiring a written directive is per the written directive. Contrary to this requirement, LLHS written procedures in place at the time of the administration did not describe how therapeutic dosages of Sm-153 were to be verified.

(3) NHPP evaluated the root causes for the violations as the following.

(a) "Procedures – Followed Incorrectly – Format Confusing," in that the template used for written directives had a default entry for the radioactive drug (I-131 NaI). Use of this template for other radioactive drugs (e.g., Sm-153 Quadramet, I-131 Bexxar) would have required the AU to strike manually through the I-131 NaI entry and write in the correct drug.

(b) "Procedures - Not Used - No Procedure," in that a written procedure had not been developed to specify how dosages of Sm-153 were to be verified in order to show that the administered activity was per the written directive.

(4) NHPP determined that, per current NRC regulations, medical events had not occurred for these administrations because no signed written directives were prepared. Available information indicated the intended dosage and radioactive drug was administered in each of these circumstances.

(5) These failures to follow NRC requirements are cited as two separate violations.

(6) NHPP observed the following corrective actions for these two violations. NHPP concluded these corrective actions are sufficient to address these two violations and prevent recurrence.

(a) The written directive template form was revised by LLHS to remove the default value of I-131 NaI as the radioactive drug and now requires the user to enter/write in the radioactive drug upon each completion of the written directive.

(b) A written procedure guideline was developed by LLHS, dated June 11, 2008, which provides a method for determining administered activity using the calibrated dose reported by the commercial pharmacy coupled with decay factors.

i. Failure to complete DOT training. NHPP determined LLHS violated 10 CFR 71.5(a), which invokes training requirements in Subpart H of 49 CFR 172, when Nuclear Medicine Service staff shipped a radioactive package containing an I-123 capsule.

(1) Title 49 CFR 172.702 requires that employees who prepare and offer for transport packages containing radioactive materials be trained and tested in specific topics as HazMat employees.

(2) Contrary to that regulation, on June 25, 2008, Nuclear Medicine Service employees, who were not properly trained and tested per DOT requirements, shipped a radioactive materials package containing an unused I-123 dosage.

(3) LLHS does not normally package and ship radioactive materials, including unused radiopharmaceutical dosages.

(4) LLHS self-identified and investigated the problem and took adequate and timely corrective actions to address the issue by re-instructing Nuclear Medicine Service employees not to ship radioactive materials without approval of the RSO (discussed in the July 22, 2008, Nuclear Medicine Service staff meeting). Because this problem was an isolated failure which was self-identified and self-corrected, and did not appear to involve willful wrongdoing on the part of individuals involved, this violation is categorized as an NCV per NRC enforcement policy.

12. Notice of Violation: The inspection identified one Severity Level III problem based on four violations and one NCV. These violations are cited in the NOV (Attachment B).

13. Acronyms and terminology used

AIB	Administrative Investigation Board
AU	Physician authorized user (as listed on permit)
CFR	Code of Federal Regulations
DOT	U. S. Department of Transportation
Employee	Workers or staff, including contract staff, at LLHS
Executive management	Director or Chief of Staff at LLHS
Individual	Employees who raised safety issues or concerns at LLHS
I-123	Iodine 123
I-131 NaI	Iodine 131 sodium iodide
Management	Chief, Imaging Service or Supervisor, Nuclear Medicine Service
NARM	Naturally-occurring and accelerator-produced radioactive materials
NCV	Non-Cited Violation
NHPP	VHA National Health Physics Program
NMED	Nuclear Materials Events Database (managed by NRC)
NOV	Notice of Violation
NRC	U. S. Nuclear Regulatory Commission
NRSC	VHA National Radiation Safety Committee

OSC	U. S. Office of Special Counsel
RSC	Radiation Safety Committee at LLHS
RSO	Radiation Safety Officer at LLHS
Sm-153	Samarium 153
Tc-99m	Technetium 99m
VHA	Veterans Health Administration

Attachment B

Notice of Violation (NOV)
Inspection Report Number 605-08-I01

VA Loma Linda Healthcare System,
Loma Linda, California

VHA Permit Number 04-17862-01

1. Violations

a. Radiation protection program. Title 10 CFR 20.1101 requires a permittee to have a radiation protection program adequate and sufficient to comply with applicable regulations. Contrary to this requirement, the permittee failed to have adequate management oversight and procedures to preclude or prevent the following regulatory violations.

(1) Worker or staff conduct: 10 CFR 30.10 requires employees of a permittee not to engage in deliberate misconduct that causes or would have caused, if not detected, the permittee to be in violation of any Nuclear Regulatory Commission (NRC) rule, regulation, or order; or any term, condition, or limitation of the permit.

Violation: Contrary to the above, two nuclear medicine technologists caused the permittee to be in violation of radiation survey requirements under 10 CFR 20.1501 by engaging in deliberate misconduct by entering false survey data into the permittee record keeping system. Specifically, one technologist entered false data for a weekly wipe survey into the system on or about August 15, 2007. The other technologist entered false data for an end-of-day radiation survey into the system on or about December 11, 2007.

(2) Protected activities: 10 CFR 30.7(f) requires that no agreement affecting the terms or conditions of employment may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in any protected activity including, but not limited to, providing information to NRC, National Health Physics Program (NHPP), or management.

Violation: Contrary to the above, on March 11 and June 27, 2008, permittee management provided written instructions to two separate employees which could be interpreted to restrict the employee's participation in protected activities.

(3) Written directives: 10 CFR 35.40 requires that written directives for administrations of therapeutic dosages of unsealed byproduct material be dated and signed by an authorized user before the administration. In addition, for dosages other than sodium iodide I-131, the written directive must contain patient name, radioactive drug, dosage, and route of administration.

Violation: Contrary to the above, at least three therapeutic administrations, including Sm-153 on February 7, 2008, and I-131 on May 13 and June 12, 2007, did not have a properly prepared written directive with all required elements.

(4) Procedures for administrations requiring written directives: 10 CFR 35.41(a) requires that permittees develop, implement, and maintain written procedures to provide high confidence that each administration requiring a written directive is per the written directive.

Violation: Contrary to the above, at the time of the administration of a therapeutic dosage of Sm-153 on February 7, 2008, the permittee did not have written procedures to describe how to verify administered dosages of the radioactive drug.

These violations are considered to represent a Severity Level III problem based on lack of management oversight for the radiation protection program.

b. Shipping of radioactive materials: 10 CFR 71.5(a) requires that a permittee, who acts as a shipper comply with Department of Transportation requirements in 49 CFR Parts 107, 171-180, and 390-397, to include training for employees.

Violation: Contrary to the above, on June 25, 2008, employees who had not completed the required training shipped a package with I-123.

This is a Non-Cited Violation.

2. Required action

a. The healthcare system must ensure the actions outlined in the inspection report have been taken and/or are ongoing, adequate, and sufficient to prevent recurrence of the violations.

b. The healthcare system must send a written response to NHPP within 30 days of the date of the memorandum transmitting this NOV. For the Severity Level III problem and the individual violations, the response must describe the following.

(1) Basic cause(s) for the problem or violation and/or concurrence with the basic cause(s) outlined in the inspection report, or, if contested, the basis for disputing the problem, violation, or severity level.

(2) Corrective steps already taken and/or concurrence with description of corrective actions outlined in the inspection report narrative, or, if needed, clarification of corrective steps outlined in the inspection report.

(3) Additional corrective steps, if any, which will be taken. Corrective actions must include, but not be limited to, the corrective actions outlined in the inspection report and any other actions by the healthcare system deemed necessary to prevent recurrence of the problem and violations.

(4) Date full compliance was or will be achieved.

c. A written response is not required for the non-cited violation in paragraph 1b.

d. Where good cause is shown, NHPP will consider extending the response time.