`DEPARTMENT OF THE ARMY
HEADQUARTERS, USA MEDICAL DEPARTMENT ACTIVITY
126 MISSOURI AVENUE
FORT LEONARD WOOD, MISSOURI 65473-8952

REPLY TO
ATTENTION OF

March 25, 2009

Radiation Protection Office

SUBJECT: Reply to a Notice of Violation, Docket No. 030-08561, License No. 24-15095-01

United States Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352

To Whom It May Concern:

Reason for each violation: The Nuclear Regulatory Commission (NRC) findings show that General Leonard Wood Army Community Hospital (GLWACH) failed to provide complete and accurate information to the NRC when submitting a license amendment request. The information that was provided to the NRC was submitted through the Department of the Army and provided to GLWACH by an outside organization, St. Luke's Hospital of Kansas City. While it was found that there was no evidence of deliberate misconduct, the reason, or proximate cause, for this violation, was a failure to investigate and verify all documentation submitted through the Radiation Protection Office (RPO).

Corrective steps that have been taken and results achieved: The corrective steps taken center on awareness and transparency in order to be sure that all parties potentially involved in future processes understand the regulations and ramifications governing their actions. The steps taken are as follows:

a. The events surrounding the violation, the cause of the violation, and the changes to the resulting standard operating procedures provided an opportunity for training, education, and process improvement for the RPO staff members, the Nuclear Medicine Clinic, the Department of Radiology, the Deputy Commander of Clinical Services (DCCS) and the Hospital Command Group.

b. The issues surrounding this violation were brought to the Radiation Control Committee (RCC), chaired by the Deputy Commander of Nursing/Hospital Services, for review and input. These issues will be discussed and debated in greater detail during the next RCC meeting which is scheduled for 7 April 2009. This will result in additional measures to ensure future compliance.

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c. A comprehensive rereading of 10 CFR (Code of Federal Regulations) along with all other pertinent NRC policies and procedures has begun and will be completed as soon as practicable. This has and will increase the depth and breadth of the RPO's knowledge of material licensing practices and requirements and cement the understanding of the intricacies involved.

Corrective steps that will be taken to avoid future violations and results achieved: In the future all documents whether prepared by or submitted through our organization will be checked and double checked for accuracy and completeness. This will occur in three phases:

a. All documents submitted through our organization will require supporting documentation to prove their validity, i.e. a copy of the materials license, showing that the preceptor is in fact an authorized user on an NRC license, will be required. This will ensure that only authorized users and authorized preceptors sign NRC forms.

b. All correspondence from other NRC licensed organizations will be verified in the NRC documents room, via the online Agencywide Documents and Access Management System, in order to check their validity. A comprehensive search of all documents related to the said license will be read thoroughly in order to determine if any inconsistencies or misrepresentations are present. This will provide confirmation that documents submitted through the RPO match documents on file with the NRC.

c. All amendment packets and supporting documentation will be submitted to higher, Great Plains Regional Medical Command, for a thorough review prior to submission to the NRC. This will ensure that, at a minimum, two independently qualified RPOs agree that the supporting documentation is complete and correct.

Date when full compliance will be achieved: Full compliance has been achieved on this date, 25 March 2009, and compliance will be maintained and enforced indefinitely by the RPO, the RCC, and the DCCS.

For additional information concerning this report, contact CPT Kevin S. Mattern at the Radiation Protection Office, General Leonard Wood Army Community Hospital, Fort Leonard Wood, MO 65473-8952, Commercial: (573) 329-1907/1908.

Sincerely,

for Tempsie R. Jones
Judith Ruiz
Colonel, US Army
Commander

**UNITED STATES**
**NUCLEAR REGULATORY COMMISSION**
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

March 9, 2009

Colonel Tempsie L. Jones
Box 1268, USA MEDDAC
126 Missouri Avenue
Fort Leonard Wood, MO 65473

SUBJECT: NRC OFFICE OF INVESTIGATIONS REPORT NO. 3-2008-016

Dear Colonel Jones:

This refers to an investigation conducted by the U.S. Nuclear Regulatory Commission (NRC), Office of Investigations (OI) to determine whether the Residency Program Director at St. Luke's Hospital of Kansas City deliberately failed to provide complete and accurate information to the Department of the Army, which was then subsequently submitted to the NRC regarding a proposed authorized user at your facility. Based on the evidence developed during the investigation, we did not substantiate any deliberate misconduct on the part of the employees at St. Luke's Hospital of Kansas City or your facility. The synopsis from the OI Report of Investigation is enclosed.

Notwithstanding, the NRC determined that information submitted to the NRC in your memorandum dated February 6, 2008, requesting Derek Staner, M.D., as authorized user of 10 CFR 35.100, 200 and 300 materials at your facility was not complete and accurate in all material aspects contrary to 10 CFR 30.9(a). Specifically, the supervising individual/preceptor was not and had not been an authorized user on an NRC or Agreement State license as required by NRC regulations. In addition, the individual did not meet the requirements of 10 CFR 35.290 and 390 as a "supervising individual" or "preceptor."

Based on the results of the investigation, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforcement-pol.html. The violation is cited in the enclosed Notice of Violation (Notice). The violation is being cited because it was identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your

response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

We appreciate your cooperation and will gladly discuss any questions you have concerning this matter.

Sincerely,

Steven Reynolds, Director
Division of Nuclear Materials Safety

License No. 24-15095-01
Docket No. 030-08561

Enclosures:
1. Notice of Violation
2. NRC Information Notice 96-28
3. OI Synopsis

cc: Captain Kevin S. Mattern
Chief, Radiation Protection and Health Physics
126 Missouri Avenue, BLDG 310
MCXP-PM-RP (Box 1232)
Fort Leonard Wood, MO 65473

Kevin Thorpe, Vice President
St. Luke's Hospital of Kansas City
4401 Wornall Road
Kansas City, MO 64111

NOTICE OF VIOLATION

Department of the Army
Fort Leonard Wood, MO

Docket No. 030-08561
License No. 24-15095-01

During an NRC investigation conducted on May 27, 2008, through November 24, 2008, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee be complete and accurate in all material respects.

Contrary to the above, the licensee did not provide to the Commission information that was complete and accurate in all material aspects. Specifically, the licensee submitted a memorandum dated February 6, 2008, to the NRC requesting an amendment to License 24-15095-01 to add a physician authorized user (AU). As required by 10 CFR 35.290 and 35.390, the licensee provided the training and experience for the proposed AU using NRC Forms 313A(AUD) and 313A(AUT). The physician who signed the forms, as the supervising individual and preceptor for the proposed AU, claimed to be an authorized user on an NRC license when in fact this individual had never been an authorized user on an NRC or Agreement State license. In addition, the signing individual did not meet the requirements of 10 CFR 35.290 and 390 as a "supervising individual" or "preceptor" and therefore had no authority to sign the forms. The information is material because it is used by NRC to make licensing decisions.

This is a Severity Level IV violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, Department of the Army is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html to the extent possible. Therefore, to the extent possible, the response should not include any personal privacy, proprietary or safeguards information so that it can be made available to the Public without redaction.

Dated this 9TH day of March 2009.

NOTE: The following information is an updated excerpt from NRC Information Notice 96-28 issued in 1996.

# NRC INFORMATION NOTICE 96-28

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION

## Addressees

All material and fuel cycle licensees.

## Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

## Background

On June 30, 1995, NRC revised its Enforcement Policy, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VI.A of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as

required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence.

In some cases, such violations are documented on Form 591 (for materials licensees) which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional enforcement conference may be held to discuss those actions.

The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation. Typically, such reviews include:

    - Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.

    - Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that

may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

- Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the **current** requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide an record that can be audited and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

   Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns **and** prevent recurrence of the violation.

   It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, **immediate** corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?

2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?

3. Have precursor events been considered and factored into the corrective actions?

4. In the event of loss of radioactive material, should security of radioactive material be enhanced?

5. Has your staff been adequately trained on the applicable requirements?

6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?

7. Has your staff been notified of the violation and of the applicable corrective action?

8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?

10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?

11. Is a system in place for keeping abreast of new or modified NRC requirements?

12. Does your staff appreciate the need to consider safety in approaching daily assignments?

13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?

14. Have work hours affected the employees' ability to safely perform the job?

15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?

16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

18. Has management placed a premium on production over compliance and safety? Does

management demonstrate a commitment to compliance and safety?

19. Has management communicated its expectations for safety and compliance?

20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

Robert C. Pierson, Director
Division of Fuel Cycle Safety and Safeguards
Office of Nuclear Material Safety
and Safeguards

Donald A. Cool, Director
Division of Industrial and Medical Nuclear
Office of Nuclear Material Safety and
and Safeguards

Technical contacts: (Updated as of March 5, 2009)

Nick Hilton, Office of Enforcement
(301) 415-3055
Internet: Nick.Hilton@nrc.gov

Daniel J. Holody, RI
(610) 337-5312
Internet: Daniel.Holody@nrc.gov

Carolyn Evans, RII
(404) 562-4414
Internet: Carolyn.Evans@nrc.gov

Kenneth O'Brien, RIII
(630) 810-4373
Internet: Kenneth.Obrien@nrc.gov

William Jones, RIV
(817) 860-8182
Internet: William.Jones@nrc.gov

## SYNOPSIS

This investigation was initiated on May 27, 2008, by the U.S. Nuclear Regulatory Commission, Office of Investigations, Region III, to determine whether the Residency Program Director at St. Luke's Hospital of Kansas City deliberately failed to provide complete and accurate information to another NRC licensee, which was then subsequently submitted to the NRC, regarding a proposed authorized user at the facility.

Based on the evidence developed, the investigation did not substantiate the allegation that the Residency Program Director at St. Luke's Hospital of Kansas City deliberately failed to provide complete and accurate information to another NRC licensee, which was then subsequently submitted to the NRC, regarding a proposed authorized user at the facility.

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