UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

January 15, 1999

EA 99-005

Roger Kerr
Vice President of Ancillary Services
Central Michigan Community Hospital
1221 South Michigan Drive
Mount Pleasant, MI 48858-3234

SUBJECT: NRC INVESTIGATION REPORT NO. 3-98-031 (INSPECTION REPORT INSPECTION REPORT 030-02078/98001(DNMS))

Dear Mr. Kerr:

This letter refers to an investigation, conducted by the NRC's Office of Investigation, into activities identified in NRC Inspection Report 030-02078/98001(DNMS) at Central Michigan Community Hospital, in Mount Pleasant, Michigan. The investigation was to look into potential wrongdoing by members of your staff in August 1996, relating to a diagnostic administration of technetium-99m. The enclosed synopsis presents the results of that investigation. You were provided the inspection report via our July 21, 1998 letter.

Based on the results of the inspection and the investigation, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600. Specifically, on August 2, 1996, an individual not under the supervision of an authorized user, used byproduct material contrary to the requirement of 10 CFR 35.11. Exacerbating this situation was the apparent deliberate nature of the violation. During the inspection and subsequent investigation, the NRC became aware that your staff had identified that on August 2, 1996, an emergency lung scan, using technetium-99m, was conducted by an unauthorized individual. The on-call nuclear medicine technician (NMT) was unable to respond to the hospital's page and arranged for another hospital technician to conduct the scan. The NMT apparently talked the other individual through the procedure. While all activities were properly performed, the second individual was not supervised by an authorized user. The circumstances surrounding the apparent violation, the significance of the issue, and your corrective actions were discussed with you and members of your staff at the inspection exit meeting on July 7, 1998.

During the inspection, the inspector also verified that you had conducted a very prompt and comprehensive investigation of the event and had effectively implemented corrective actions, including disciplinary action against the individuals and changes in your policies and procedures. While this level of event response would normally result in the NRC utilizing discretion in issuing a violation, because of the deliberate nature of the violation and our policy to hold licensees accountable for the action of the employees, we are considering action in this case. However, because of your actions, it may not be necessary to conduct a predecisional enforcement conference or require a response from you in order for the NRC to make an enforcement decision. In addition, since you identified the violation and based on our

understanding of your corrective actions, a Civil Penalty may not be warranted in accordance with Section VI.B.2 of the Enforcement Policy.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond to the apparent violation addressed in the inspection report within 30 days of the date of this letter or (2) request a predecisional enforcement conference. If a conference is held, it will be closed to public observation. The NRC will also issue a press release to announce the conference. Please contact Geoffrey C. Wright at (630) 829-9602 within 7 days of the date of this letter to notify the NRC of your intended response.

If you choose to respond, it should be clearly marked as a "Response to An Apparent Violation in Inspection Report 030-02078/98001(DNMS)" and should include: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation, (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. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful. Your response should be submitted under oath or affirmation and may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response (if you choose to provide one) will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

Sincerely,

/s/ P. L. Hiland for

Roy J. Caniano, Acting Director
Division of Nuclear Materials Safety

Docket No. 030-02078
License No. 21-08966-01

Enclosures: 1. Synopsis, OI Case 3-98-031
2. Excerpts from NRC Information Notice 96-28

See Attached Distribution

DOCUMENT NAME: G:\LTRS2LIC\MTLS\030\99302078.L02 (* See Previous Concurrence)

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Roy J. Caniano, Acting Director
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SYNOPSIS

This investigation was initiated by the U.S. Nuclear Regulatory Commission (NRC), Office of Investigations (OI), Region III, on July 13, 1998, to determine whether two employees of Central Michigan Community Hospital (CMCH), caused CMCH to be in violation of their NRC license. It was alleged that a nuclear medicine technician (NMT) telephonically instructed a X-ray/Computed Tomography (CT) technician, through a nuclear lung scan procedure, in violation of the CMCH license condition relating to authorized use of nuclear byproduct material.

OI concluded that on August 2, 1996, the X-ray/CT technician and the NMT conspired to deliberately cause CMCH to be in violation of their license condition, by inappropriately performing a nuclear medicine procedure and thereby using nuclear byproduct material without having been authorized as required.

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 (NUREG-1600)[1] 60 FR 34381, 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 VII.B.1 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)

[1]Copies of NUREG-1600 can be obtained by calling the contacts listed at the end of the Information Notice.

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 auditable record 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.

Elizabeth Q. Ten Eyck, Director
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

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

Technical contacts: Nader L. Mamish, OE
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Gary F. Sanborn, RIV
(817) 860-8222
Internet:gfs@nrc.gov

Attachments:
1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
96-27	Potential Clogging of High Pressure Safety Injection Throttle Valves During Recirculation	05/01/96	All holders of OLs or CPs for pressurized water reactors
96-26	Recent Problems with Overhead Cranes	04/30/96	All holders of OLs or CPs for nuclear power reactors
96-25	Transversing In-Core Probe Overwithdrawn at LaSalle County Station, Unit 1	04/30/96	All holders of OLs or CPs for nuclear power reactors
96-24	Preconditioning of Molded-Case Circuit Breakers Before Surveillance Testing	04/25/96	All holders of OLs or CPs for nuclear power reactors
96-23	Fires in Emergency Diesel Generator Exciters During Operation Following Undetected Fuse Blowing	04/22/96	All holders of OLs or CPs for nuclear power reactors
96-22	Improper Equipment Settings Due to the Use of Nontemperature-Compensated Test Equipment	04/11/96	All holders of OLs or CPs for nuclear power reactors
96-21	Safety Concerns Related to the Design of the Door Interlock Circuit on Nucletron High-Dose Rate and Pulsed Dose Rate Remote Afterloading Brachytherapy Devices	04/10/96	All U.S. NRC Medical to the Licensees authorized to use brachytherapy sources in high- and pulsed-dose-rate remote afterloaders
96-20	Demonstration of Associated Equipment Compliance with 10 CFR 34.20	04/04/96	All industrial radiography licensees and radiography equipment manufacturers

OL = Operating License
CP = Construction Permit

LIST OF RECENTLY ISSUED NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
96-21	Safety Concerns Related to the Design of the Door Interlock Circuit on Nucletron High-Dose Rate and Pulsed Dose Rate Remote Afterloading Brachy-therapy Devices	04/10/96	All NRC Medical Licensees authorized to use brachy-therapy sources in high- and pulsed-dose-rate remote
96-20	Demonstration of Associ-ated Equipment Compliance with 10 CFR 34.20	04/04/96	All industrial radiography licensees and radiography equipment manufacturers
96-18	Compliance With 10 CFR Part 20 for Airborne Thorium	03/25/96	All material licensees authorized to possess and use thorium in unsealed form
96-04	Incident Reporting Requirements for Radiography Licensees	01/10/96	All Radiography Licensees and Manufacturers of Radiography Equipment
95-58	10 CFR 34.20; Final Effective Date	12/18/95	Industrial Radiography Licensees.
95-55	Handling Uncontained Yellowcake Outside of a Facility Processing Circuit	12/6/95	All Uranium Recovery Licensees.
95-51	Recent Incidents Involving Potential Loss of Control of Licensed Material	10/27/95	All material and fuel cycle licensees.
95-50	Safety Defect in Gammamed 12i Bronchial Catheter Clamping Adapters	10/30/95	All High Dose Rate Afterloader (HDR) Licensees.
95-44	Ensuring Combatible Use of Drive Cables Incorporating Industrial Nuclear Company Ball-type Male Connectors	09/26/95	All Radiography Licensees.