

## ENCLOSURE 1

### NOTICE OF VIOLATION

Oklahoma State University  
Stillwater, Oklahoma

Docket No.: 030-00945  
License No.: 35-00237-03

During an NRC inspection completed June 9, 1997, seven violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

A. License Condition 28 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letters dated November 20, 1995, and January 16, 1996, including any enclosures.

1. Paragraph (4) of the November 20, 1995, letter, titled "Training for Individuals Working In or Frequenting Restricted Areas," states:

"All individuals working in areas where radioactive material is used, such as technicians and graduate students, will be required to take a training session prior to being allowed access to these areas.

"The session will include a study guide on fundamentals of radioactivity and safe use of radioactive materials which the participants will read prior to the session. There will be a discussion of the study guide material at the training session.

"The participants will then view three video tapes dealing with (a) fundamentals of radioactivity, (b) safe use of radioactive materials in the laboratory, (c) radiation instrumentation, and (d) handling radioactive emergencies.

"A brief exam, covering the material in the study guide and the video tapes, will be administered at the end of the session. Participants who do not pass the exam will be required to retake the session.

"Professional individuals, such as veterinary radiologists and radiological technologists will be evaluated by the University Radiological Safety Officer and the Radiological Safety Committee on the basis of training and experience. If deficiencies are found the individuals will be required to take specific training and experience. If deficiencies are found the individuals will be required to take specific training off-campus at a site which can provide appropriate training in veterinary nuclear medicine and safety."

Contrary to the above, on May 22, 1997, a nuclear medicine technologist and an "Evaluated Clinical Foreign Veterinary Graduate" worked in restricted areas of the Boren Veterinary Medical Teaching Hospital (BVMTH) and worked with radioactive materials and these individuals had not received

radiation safety training nor been evaluated by the Radiation Safety Committee for deficiencies in training and experience.

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

2. An enclosure to the letter dated January 16, 1996, changed, among other things, the "General Safety Procedures" of the "Nuclear Medicine Laboratory Boren Veterinary Teaching Hospital, Oklahoma State University, Standard Operating Procedures."

- a. Item 23 of the modified "General Safety Procedures" states:  
"Following the completion of each imaging procedure, the students and staff will be monitored with the G-M survey meter for possible contamination of clothing, hands, and footwear [sic] before being permitted to proceed with other duties."

Contrary to the above, on May 22, 1997, a staff member of the BVMTH nuclear medicine department, following the completion of an imaging procedure, proceeded with other duties before monitoring with a survey meter for possible contamination of clothing, hands, and footwear.

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

- b. Item 29 of the modified "General Safety Procedures" states, in part,  
"Small animals containing radioisotopes will be transported to and from holding areas in a utility cart designated for that purpose. The cart has a top area with two inch high sides and will be lined with plastic backed absorbent paper. This will contain any leakage of body fluids that may occur during transportation."

Contrary to the above, on May 22, 1997, a small dog containing technetium-99m was not transported to and from a holding area in a utility cart designed to contain any leakage of body fluids that may have occurred during transportation. Specifically, the small dog was hand carried, while partially wrapped in absorbent paper, from the BVMTH nuclear medicine laboratory to the BVMTH Room 136 and later from Room 136 to the BVMTH intensive care unit.

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

- B. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

10 CFR 71.5(b) requires, in part, that if DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in paragraph (a) of this section to the same extent as if the shipment or transportation were subject to DOT regulations.

1. 49 CFR 172.324(b) requires that for each non-bulk package that contains a hazardous substance, the letters "RQ" be marked on the package in association with the proper shipping name.

Contrary to the above, on May 16, 1996, July 9, 1996, and May 22, 1997, a moisture density gauge containing 10 millicuries of americium 241, a hazardous substance, was transported outside the confines of the University and the non-bulk package containing the hazardous substance was not marked with the letters "RQ."

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

2. 49 CFR 172.702 requires that each hazmat employer shall ensure that each hazmat employee is trained and tested, and that no hazmat employee perform any function subject to the requirements of 49 CFR Parts 171-177 unless trained, in accordance with Subpart H of 49 CFR Part 172. The terms hazmat employer and hazmat employee are defined in 49 CFR 171.8.

Contrary to the above, during the period between July 13, 1995, to May 22, 1997, the licensee did not provide training for its hazmat employees, as required by Subpart H to 49 CFR Part 172, and the licensee otherwise met the definition of hazmat employer in 49 CFR 171.8.

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

- C. 10 CFR 20.1906(b)(1) requires, in part, that each licensee monitor the external surfaces of a package labeled with a Radioactive White I, Yellow II, or Yellow III label for radioactive contamination, unless the package contains only radioactive material in the form of a gas, or in special form as defined in 10 CFR 71.4.

Contrary to the above, from April 23, 1996, to March 19, 1997, the licensee did not monitor the external surfaces of labeled packages received in Room 114C of the Animal Science Building for radioactive contamination and the exemptions listed above did not apply. During the period above noted, no labeled packages received in this laboratory were monitored for radioactive contamination.

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

- D. 10 CFR 20.1501 requires that each licensee make, or cause to be made, surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation

levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Contrary to the above, as of May 21, 1997, the licensee had failed to adequately evaluate the quantities of radioactive material and potential radiological hazards present in Room 350 of the Noble Research Center. Specifically, a survey was done by the licensee's staff on May 19, 1997, but this survey failed to identify phosphorous-32 contamination on the outside edge of a fume hood. This contamination was identified on May 21, 1997, during a survey performed by an NRC inspector.

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

Pursuant to the provisions of 10 CFR 2.201, Oklahoma State University is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with copies to the Regional Administrator, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, and the Walnut Creek Field Office, 1450 Maria Lane, Walnut Creek, California 94596, 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, (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.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information).

Dated at Arlington, Texas  
this 2<sup>nd</sup> day of July 1997

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)<sup>1</sup> 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)

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<sup>1</sup>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?

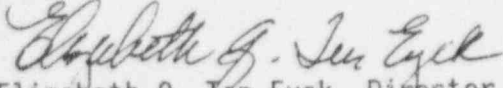
LIST OF RECENTLY ISSUED  
NMSS INFORMATION NOTICES

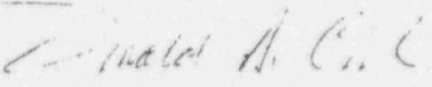
Information Notice No.	Subject	Date of Issuance	Issued to
96-21	Safety Concerns Related to the Design of the Door Interlock Circuit on Nucletron High-Dose Rate and Pulsed Dose Rate Remote Afterloading Brachy- therapy Devices	04/10/96	All NRC Medical Licensees authorized to use brachy- therapy sources 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
95-04	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 Compatible Use of Drive Cables Incorporating Industrial Nuclear Company Ball-type Male Connectors	09/26/95	All Radiography Licensees.

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 Over-head 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

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  
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Attachments:

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