DEPARTMENT OF THE NAVY
NAVY ENVIRONMENTAL HEALTH CENTER
2510 WALMER AVENUE
NORFOLK, VIRGINIA 23513-2617

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Ser OMDMC/ 08594
26 NOV 1996

From: Commanding Officer, Navy Environmental Health Center

Subj: NAVY RADIOACTIVE MATERIAL PERMIT (NRMP) PROGRAM INFORMATION NOTICE 96-04

Encl: (1) U.S. Nuclear Regulatory Commission (NRC) Information Notice No. 96-28: Suggested Guidance Relating to Development and Implementation of Corrective Action
(2) NRC NMSS Licensee Newsletter, NUREG/BR-0117, No. 96-1, Mar 96/Apr 96
(3) NRC Information Notice No. 95-51: Recent Incidents Involving Potential Loss of Control of Licensed Material

1. Enclosure (1) emphasizes the importance of identifying the root causes of minor and non-cited violations so that appropriate action can be taken to prevent recurrence. The corrective action process should include a complete and thorough review of the circumstances that led to the violation, identification of the root cause(s) of the violation, and prompt and comprehensive corrective action that will address immediate concerns and prevent recurrence. Training, security, and audits may need to be considered in determining and evaluating root causes.

2. Enclosures (2) and (3) pertain to the two phosphorus-32 internal contamination events at National Institutes of Health and Massachusetts Institute of Technology in 1995. In both cases loss of control of licensed materials contributed to the events, which are suspected to be deliberate. Review this information for applicability to your program, and take appropriate action. The security, inventory and accountability, detection equipment, bioassays, and food and beverage storage elements of your program may need to be reviewed. Procedures should be in place to contact Navy Environmental Health Center in lieu of the NRC within two days if deliberate misuse is suspected.

3. For further information, please call Mrs. Dorothy M. Clark, at (757) 363-5574, DSN 864-5574, FAX (757) 444-3672, or E-mail at clarkd@ehc50.med.navy.mil.

S. J. WOLFF
By direction

Distribution:
All Medical NRMP Radiation Safety Officers

Copy to:
CNO (N455)
BUMED (MED-211)
NSHS Bethesda MD (ATTN: Clinical Nuclear Medicine School)
NAVUSEAMEDINSTITUTE NSHS DET Groton CT (ATTN: LCDR R. Long)

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, minor 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.

End (1)

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
(301) 415-2740
Internet:nlm@nrc.gov

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

Bruno Uryc, Jr., RII
(404) 331-5505
Internet:bxu@nrc.gov

Bruce L. Burgess, RIII
(708) 829-9666
Internet:blb@nrc.gov

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

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DATE	4/ /96		3/11/96		4/15/96		4/16/96		4/19/96	

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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.

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 the	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 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

NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

NUREG/BR-0117
No. 96-1
Mar. '96/Apr. '96

RECENT EVENTS INVOLVING POTENTIAL - LOSS OF CONTROL OF LICENSED MATERIAL

In 1995, the U.S. Nuclear Regulatory Commission (NRC) was informed of, and responded to, two similar events involving phosphorus-32 (P-32) internal contamination of individuals at biomedical research facilities. Although these events both involved P-32, the inherent issues of security of radioactive material extend to all facilities using licensed material.

National Institutes of Health (NIH). This event initially involved the internal contamination of one female researcher. The researcher was in her fourth month of pregnancy at the time of the event. Phosphorus-32 contamination was detected when the researcher's husband, who worked with her at the licensee's facility, performed a routine survey of their laboratory. Accidental contamination appeared unlikely because the woman had stopped working with radioactive material in their laboratory about a month before, and because the radioisotope (P-32) identified in bioassay samples is not of the same type her laboratory used. Licensee security officials and the Federal Bureau of Investigation are investigating the matter.

In late June 1995, NRC sent an Augmented Inspection Team (AIT) to investigate the circumstances surrounding the contamination event. NRC also contracted with Lawrence Livermore National Laboratory and Oak Ridge Institute for Science and Education to do independent dose assessments of the urine sample data and whole body data. Initial licensee surveys identified P-32 on the floor in front of a refrigerator in a lounge adjacent to laboratories the female researcher used, and subsequently found an internally contaminated water cooler in the same building. NRC calculations showed that the female researcher received a total effective dose equivalent (TEDE) of between 80 to 127 millisieverts (8.0 to 12.7 rem) and her fetus received a fetal dose equivalent of between 51 to 81 millisieverts (5.1 to 8.1 rem). In addition to this researcher, 26 additional individuals were identified through urine bioassays as having received low levels of internal P-32 contamination.

While investigation into the cause of this event is still ongoing, the licensee has agreed to improve the control of radioactive materials used in its biological and medical research programs.

Massachusetts Institute of Technology (MIT). On October 16, 1995, this licensee informed NRC of an event involving researcher ingestion of P-32 at the MIT Center for Cancer Research. The licensee informed NRC that a researcher had reported the event on August 19, 1995, after he discovered that he was contaminated, during a routine survey of his work area. On October 12, 1995, the licensee informed the researcher that his final intake estimate was 21 megabecquerel (579 microcuries), just under the 22 megabequerel (600 microcuries) that would represent an overexposure. Because the researcher told licensee campus police that he believed the contamination was not accidental, NRC and campus police investigated the event.

Because of the similarity to the earlier internal contamination event at NIH, on October 17, 1995, NRC dispatched an Incident Investigation Team (IIT) to the licensee's site to begin an immediate investigation of the event. NRC also contracted with Lawrence Livermore National Laboratory and Oak Ridge Institute for Science and Education to do independent dose assessments of the urine sample data and whole body measurement data. NRC sent a Confirmatory Action Letter (CAL) to the licensee requiring that certain steps be taken, ensuring, among other things, that control of radioisotopes be improved. The licensee initially secured all radioactive

Enc 1 (2)

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MARCH–APRIL 1996

Page

Comments, and suggestions you may have for information that is not currently being included, that might be helpful to licensees, should be sent to:
E. Kraus
NMSS Licensee Newsletter Editor
Office of Nuclear Material Safety and Safeguards
Two White Flint North, Mail Stop 8–A–23
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555–0001

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materials in the laboratory where the event occurred, after discovery of the contamination event, but since then has permitted work with radioactive material to resume, after requiring more stringent inventory and accountability in the laboratory and tightening security.

NRC concluded that the licensee's final intake and dose estimates were in accordance with accepted scientific references and NRC guidance. However, recognizing the uncertainties involved in the use of models to simulate human characteristics, NRC determined the intake would be better characterized as likely falling within a range of between 19 to 28 megabequerel (500 to 750 microcuries). An NRC medical consultant concluded that no symptoms or acute effects should be observed from an intake of this level.

In November 1995, the IIT published a comprehensive report of its investigations and findings, as NUREG–1535, entitled, "Ingestion of Phosphorus-32 at Massachusetts Institute of Technology, Cambridge, Massachusetts, Identified on August 19, 1995." This report is available from:

The Superintendent of Documents
U.S. Government Printing Office
P.O. Box 37082
Washington, D.C. 20402-9328

To date, NRC has taken several actions related to these events:

1. Information Notice 95-51, issued on October 27, 1995, informed all material and fuel cycle licensees of their responsibilities for radioactive material security, accountability, survey procedures, preparation for bioassays, and applicable reporting requirements when deliberate misuse of licensed material is suspected.

2. Based on information from the AIT inspection and a subsequent special team inspection, a CAL was issued to NIH on October 27, 1995, regarding increased security and control requirements for radioactive materials in use, in waste, or in storage. Two subsequent revisions to this CAL were issued in November and December 1995. Based on the results of these inspections, several apparent violations were identified and are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions." A predecisional enforcement conference is currently being scheduled, and subsequent enforcement actions are pending, depending on the results of this conference.

3. Based on information from the IIT inspection, a CAL was issued to MIT in October 1995, also regarding increased security and control requirements. Based on the results of these inspections, one apparent violation was identified. Appropriate enforcement action is being considered.

4. NRC issued a proposed rule, for comment, on January 31, 1996 (61 FR 3334), which would add a new requirement for licensees to notify the NRC Operations Center within 24 hours of discovering an intentional or allegedly intentional diversion of licensed radioactive material from its intended or authorized use. The proposed rule would also require licensees to notify NRC when they are unable, within 48 hours of discovery of the event, to rule out that the use was intentional. The proposed rule would require reporting of events that cause, or have the potential to cause, an exposure of individuals, whether or not the exposure exceeds the regulatory limits. The comment period ended March 31, 1996. (See related *NMSS Licensee Newsletter* article in this issue regarding this rulemaking.)

5. **Staff Action Items.** These two recent P-32 internal contamination events raise a number of safety and regulatory issues for NRC. As a consequence, staff is reviewing its regulations, as well as its internal event response procedures, to determine if they need to be revised in light of these events. These issues are discussed below:

   a. **Security and Control of Radioactive Materials.** The team found that MIT's program for control and security of radioactive materials was not effective enough to deter or detect diversion of byproduct materials. Weak security and control of radioactive materials have also contributed to recent events at other facilities. In addition, the team found that regulatory guidance for the application of security and control of small quantities of unsealed byproduct material was inconsistent. Consequently, staff will evaluate existing regulations, guidance, and standard review plans, for security and control of radioactive materials, as well as for establishment of restricted, unrestricted, and controlled areas. In addition, NRC staff will review current regulations, guidance, and review standards with regard to accounting for, and inventory of, radioactive materials.

   b. **Adequacy of NRC's Events Databases.** The team found that NRC's failure to disseminate information about known precursor events, to licensees, was a contributing cause to the MIT event. Consequently, NRC will be reviewing the current mechanisms for the collection, review, and dissemination of nuclear materials events and implement appropriate modifications.

   c. **Reporting Requirements.** The team found that NRC reporting requirements were unclear for radioactive material intake and were not specific regarding internal contamination. As a result, staff evaluated the regulations and guidance on the reporting of internal contamination and determined that 10 CFR 20.2202(b)(1)(i) should be clarified through additional guidance, such as an information notice or generic letter.

d. **Management Oversight**. The team found weak management oversight of the Radiation Protection Program at MIT. The licensee did not use a process of management review and self-assessment (audits) to find weaknesses in its program and to take appropriate remedial actions. Unlike 10 CFR Part 35 for medical licensees, 10 CFR Part 33 does not provide broad-scope licensees with a detailed description of the duties and responsibilities of the radiation safety officer or the radiation safety committee. Staff will be evaluating existing regulations, guidance, and review standards for management oversight of broad-scope licensed programs, with regard to the roles of the radiation safety officer, the radiation protection committee, supervision, and the authorized user, as well as the use of audits, for possible incorporation into Part 33.

e. **Adequacy of NRC's Guidance and Procedures for NRC Response.** Staff will evaluate the adequacy of procedures and guidance for conduct of an AIT or an IIT, and issue, if appropriate, revised procedures to cover: exit and entrance interviews; exchange of information with individuals; use of transcribed interviews; media coverage; and when to recommend when an AIT should be upgraded to an IIT.

f. **Adequacy of NRC's Guidance and Procedures for Licensee Response to Intakes of Radioactive Material by Individuals.** During both the NIH and the MIT events, initial data about the magnitude of the intake of P-32 were lost because clear instructions were not provided, to the exposed individuals, about the collection of urine samples. Staff will be evaluating the adequacy of regulatory guidance. It will issue revisions, as necessary, to the guidance on collection of data both to analyze intakes of radioactive materials and to analyze fetal dose, based on maternal intake, for licensees seeking outside medical expertise, and for NRC staff who monitor the licensee's analysis of an intake.

(Contact: Cynthia Jones, 301–415–7853)

LICENSEE PERFORMANCE REVIEW PROGRAM

The Office of Nuclear Material Safety and Safeguards, of the U.S. Nuclear Regulatory Commission (NRC), has recently initiated a new Fuel Cycle Facility Licensee Performance Review (LPR) program to assess overall licensee performance at each major fuel cycle facility. The objective is to assess, annually, overall licensee performance by integrating and evaluating the observations and findings from both regional and Headquarters inspection and licensing activities. The results will be used to identify areas in the licensee's programs that may require increased NRC or licensee management attention, or be candidates for reduced NRC inspection.

NRC will, on completion of each review, prepare a brief LPR Report that summarizes the results of the review. NRC senior management will meet with the licensee senior management to discuss the results of the report after the report has been provided to the licensee.

The performance review will be based on an evaluation of existing NRC documentation, such as inspection reports, licensing correspondence, and licensee event reports. The review will not require any additional NRC site visits. Functional areas such as chemical safety, criticality safety, material control and accounting, licensing, emergency preparedness, environmental protection, maintenance/surveillance, radiological controls, and security will be evaluated in the review. The staff goal is to keep the program simple and streamlined, to minimize costs and to keep the focus of the review on overall performance.

NRC conducted pilot reviews at two fuel facilities: Westinghouse-Columbia, in December 1995; and Combustion Engineering-Hematite, in February 1996; and scheduled a third at Siemens-Richland, in April 1996. The LPR program will be finalized, based on the lessons learned from the three pilot reviews. The staff will publish staff guidance for the LPR program in the NRC Inspection Manual in mid-1996. Plans are to complete annual reviews of all major fuel facilities by December 1996. Reviews will be conducted annually thereafter. The gaseous diffusion plants in Paducah, Kentucky, and Portsmouth, Ohio, will be included in the program after certification, but are not scheduled for review under the LPR program until FY 1997.

(Contact: Lance Lessler, 301–415–8144)

TO ALL APPLICANTS FOR NRC LICENSES:

TO SERVE YOU BETTER, PLEASE BE SURE TO SEND A COPY ALONG WITH THE ORIGINAL APPLICATION FOR A LICENSE, AMENDMENT, OR RENEWAL!

(Our licensing assistance team has been reduced. Thus, we have few resources available to help make the required copy for you, if you have not sent a copy with the original.)

STATUS OF THE TRANSPARENCY AGREEMENT ASSOCIATED WITH THE U.S. PURCHASE OF DOWNBLENDED RUSSIAN HIGHLY ENRICHED URANIUM

In 1993, the United States and the Russian Federation reached agreement on the disposition of highly enriched uranium (HEU) recovered from decommissioned Russian nuclear warheads. The bilateral agreement allows the United States to purchase at least 500 metric tons of HEU, extracted from dismantled nuclear weapons, for fabrication into light-water reactor fuel. In Russia, the HEU will be downblended with low enriched uranium (LEU) to various commercial-level enrichments. An issue related to the disposition agreement that is still being negotiated concerns transparency measures. The transparency measures will be administered by separate agreements, which should enable both sides to meet the following three objectives:

1. Provide assurance that the HEU comes from dismantled Russian nuclear weapons;

2. Confirm that the LEU is derived from HEU; and

3. Ensure that LEU purchased by the United States is fabricated into commercial reactor fuel.

The U.S. Department of Energy (DOE) is the lead agency responsible for negotiating the transparency agreements. The United States Enrichment Corporation (USEC) is the executive agent responsible for implementation of the purchase contract. Several agencies are represented on the Interagency Transparency Working Group, which was formed to assist in the negotiations. Since the third objective of transparency pertains to verification activities at U.S. Nuclear Regulatory Commission (NRC) licensed facilities, NRC is a member of this group. NRC's role is to serve as a coordinator between DOE and U.S. fuel fabricators, to ensure that transparency measures in fabrication facilities are practical, and that fuel fabricators' concerns are addressed.

Representatives from Siemens, General Electric, Westinghouse, and ABB/Combustion Engineering met at DOE Headquarters on January 30–31, 1996, to discuss proposed Russian Federation monitoring rights at U.S. fuel fabrication plants. These rights are still under negotiation, pending resolution of issues arising from Russian Federation requests for further access to U.S. fuel fabrication processes. The fabricator representatives also provided input on tracking the Russian material, using the Nuclear Materials Management and Safeguards System, a nuclear material tracking and reporting database maintained for NRC and DOE. Other issues to be resolved include reimbursement to U.S. fuel fabricators for unusual expenses associated with Russian Federation monitoring activities, and the fungibility of the downblended HEU in U.S. fabrication processes. These issues will be discussed with Russian Federation negotiators at the next meeting of the bilateral Transparency Review Committee, to be held this spring.

(Contact: Steve Caudill, 301–415–8104)

PUBLIC WORKSHOP ON IMPROVING NRC'S REGULATION OF FUEL CYCLE FACILITIES

The U.S. Nuclear Regulatory Commission (NRC) held a workshop on November 30–December 1, 1995, at NRC Headquarters in Rockville, Maryland, to gather information on improving the regulation of major fuel cycle licensees under 10 CFR Part 70. The workshop was conducted to collect information from affected parties for staff's use in developing a recommended course of action to upgrade the regulatory base for fuel cycle facility licensing activities.

This information exchange allowed both the NRC staff and affected parties to develop a better understanding of the objectives of the Part 70 rulemaking effort and to discuss alternative approaches to upgrading the regulatory base. The staff was also interested in receiving information from possible applicants for new licenses.

Workshop discussions were conducted by a meeting facilitator, in the form of a round-table discussion among invited parties. Representatives from NRC and the nuclear fuel cycle industry served as panel members, along with representatives from the U.S. Environmental

Protection Agency, the U.S. Department of Energy, the Defense Nuclear Facilities Safety Board, the Tennessee Division of Radiological Health, the Tennessee Valley Energy Reform Coalition, and a consultant interested in the licensing of new facilities. In addition, attendees who were not serving as panel members were provided opportunities to present issues or to provide comments on the topics discussed during the workshop. This diversified forum contributed to ensuring that the concerns and views expressed included those of all interested parties.

Staff is reviewing the information received from this latest workshop; in March 1996 staff will provide the Commission with a recommended approach for improving the Part 70 regulatory base.

(Contact: Joan Higdon, 301–415–8082)

MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

The U.S. Nuclear Regulatory Commission's (NRC's) Advisory Committee on the Medical Uses of Isotopes (ACMUI) held a meeting on February 21–22, 1996, at the NRC Headquarters office in Rockville, Maryland. The ACMUI reviewed the National Academy of Science, Institute of Medicine (IOM) report and provided comments on the possible impacts of the report, including any policy, legislative rulemaking, and guidance issues. The committee also discussed a proposed rule requiring licensees to notify the NRC Operations Center within 24 hours of discovering an intentional or allegedly intentional diversion of licensed radioactive material from its intended or authorized use. The proposed rule would also require licensees to notify NRC when they are unable, within 48 hours of discovery of the event, to rule out that the use was intentional. The proposed rule would require reporting of events that cause, or have the potential to cause, an exposure of individuals regardless of whether the exposure exceeds the regulatory limits as identified in 10 CFR 20.2202. The comment period for this rule closed March 1, 1996. The NRC staff also discussed the lessons learned and action items resulting from the Augmented Inspection Team and Incident Investigation Team reviews of internal contamination events at both the National Institutes of Health and the Massachusetts Institute of Technology.

Copies of the transcripts and summary minutes for the meeting are available through the public Document Room (phone 202–634–3273). Contact Torre Taylor with any questions.

The next meeting of the ACMUI will be noticed in the *Federal Register*.

(Contact: Torre Taylor, 301–415–7900)

BUSINESS PROCESS RE-ENGINEERING UPDATE

To ensure the success of the Business Process Re-engineering initiative, the staff is holding a series of meetings and workshops with Agreement States, licensees, and the public to gather suggestions and ideas. On April 25, 1996, a public workshop was held in Rockville, Maryland, to receive input, from licensees and the public, on the new process. All interested licensees and members of the public were invited to attend. The U.S. Nuclear Regulatory Commission (NRC) prepared a workshop agenda and background information on the project that was available for review after April 11, 1996. Interested parties unable to attend the workshop were encouraged to provide written comments pertinent to the process, by May 11, 1996. A transcript of this workshop is available (as of the last week in May) for inspection, and copying for a fee, at the NRC Public Document Room, 2120 L Street N.W., Lower Level, Washington, DC 20555.

Additionally, the staff is developing a series of NUREGS that will document the development of NRC's re-design of the licensing process. A draft of the first NUREG, describing the approach and progress to date, was available in mid-April 1996.

(Contact: Sally Merchant, 301–415–7874)

RECEIPT OF NATIONAL ACADEMY OF SCIENCES, INSTITUTE OF MEDICINE REPORT, "RADIATION IN MEDICINE: A NEED FOR REGULATORY REFORM"

The U.S. Nuclear Regulatory Commission (NRC) is seeking public comments on a report on "Radiation in Medicine: A Need for Regulatory Reform," prepared by the National Academy of Sciences, Institute of Medicine (IOM). NRC contracted with the IOM to develop the report as part of an external review of the Agency's program for the regulation of medical uses of byproduct material. The external review was intended to assess the adequacy and appropriateness of the current regulatory framework. The report provides recommendations to Congress, NRC, the States, and the Conference of Radiation Control Program Directors.

NRC is currently reviewing and analyzing the report. As part of the initial review, and as indicated in a *Federal Register* notice published on January 22, 1996, NRC is seeking comments on the report's possible impacts, including any views on policy, legislative, rulemaking, and guidance issues. Copies of the report may be obtained from the National Academy Press, Office of News and Public Information, 2101 Constitution Avenue, N.W., Washington, DC 21048, telephone: 202–334–3313 or (toll-free) 800–624–6242.

NRC's Advisory Committee on Medical Uses of Isotopes met with the staff to discuss the report on February 21 and 22, 1996. Members of the IOM committee briefed the Commission on February 27, 1996.

(Contact: Patricia K. Holahan 301–415–7847)

JOINT AGREEMENT STATE–NRC WORKING GROUP REVIEWING RADIOACTIVE DEVICE REGULATION

In June 1995, the Commission approved a staff proposal to form an agreement State-NRC Working Group (WG) to review the regulation of devices containing radioactive material and to develop recommendations to improve licensee control of these sources. This action was taken in response to concerns expressed by the metal scrap recycling industry about radioactive materials becoming mixed with metal scrap. A review of this problem was published in the April, 1995 issue of *Health Physics* ("Radioactive Materials in Recycled Metals," by J.O. Lubenau and J.G. Yusko). In the United States, metal mills have inadvertently smelted radioactive sources on 24 occasions. Costs for U.S. steel mills for decontamination, waste disposal, and losses resulting from temporary plant shutdowns have been as much as $23 million. Scrap processors are also at risk. An unshielded (13.69–GBq) (370–mCi) 137-cesium (Cs) source was found buried in soil at a scrap processing plant in Illinois in 1994. Also in 1994, a shredder at a Kentucky scrap processing plant separated a 12.21-GBq (330–mCi) 137–Cs source from its shield source holder. Fortunately the source capsule was not breached. There have been no documented cases of worker or public overexposures in the United States, but radiation doses from radioactive sources in metal scrap have caused injury or death in Mexico and in Estonia.

The WG is co-chaired by Robert Free, Texas, and John Lubinski, NRC/Office of Nuclear Material, Safety and Safeguards. Other members are Robin Haden, North Carolina; Martha Dibblee, Oregon; Rita Aldrich, New York (alternate); Lloyd Bolling, NRC/Office of State Programs; and John Telford, NRC/Office of Nuclear Regulatory Research. Joel Lubenau, NRC, was a WG co-chair until March 1996, when he accepted a position as a technical assistant to Commissioner Dicus. John Lubinski has been serving as WG co-chair since March 1996.

The WG has held four public meetings and a public workshop between October 1995 and April 1996. Attendees have included device manufacturers and users, and representatives from the metal recycling industry and steel mills, labor, professional health and safety organizations, and government. All meetings of the WG are open to the public and are announced in the NRC Public Meeting Announcement System. Copies of the minutes of WG meetings and relevant correspondence and technical documents are available for inspection, and copying for a fee, in the NRC Public Document Room. The NRC contact is John Lubinski. He can be reached by telephone at 301–415–7868 or by e-mail at JWL@NRC.GOV.

(Contact: John Lubinski, 301–415–7868)

NEW DECOMMISSIONING GUIDANCE

U.S. Nuclear Regulatory Commission (NRC) staff is continuing efforts to complete regulations on the radiological criteria applicable to decommissioning. A significant part of this task involves the resolution of issues that do not directly address the specifics of the regulation, but rather the supporting regulatory guides on surveys and dose modeling. Interactive meetings have taken place to further the staff's understanding of these issues and, most recently, a "table top" exercise on fuel cycle facility decommissioning was held on January 16–19, 1996.

The *draft*, for-comment documents that "spell out" the approaches being considered in the development of supporting regulatory guidance are: (1) "A Nonparametric Statistical Methodology for the Design and Analysis of Final Status Decommissioning Surveys," NUREG–1505, August 1995; (2) "Measurement Methods for Radiological Surveys in Support of New Decommissioning Criteria," NUREG–1506, August 1995; and (3) "Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions," NUREG–1507, August 1995. [On the subject of methods applicable to radiological

surveys, it should be noted that NRC, together with the U.S. Environmental Protection Agency, U.S. Department of Energy, and U.S. Department of Defense, is in the process of developing a multiagency radiation survey and site investigation manual (MARSSIM) that, among other topics, would provide additional suggestions and recommendations applicable to final surveys.] Although all these documents are currently being revised, the underlying concepts and information are still subjects for which the staff remains interested in specific technical comments pertinent to implementation of a final rule.

Until the regulation is completed, and to ensure timely remediation of contaminated sites, the criteria that are applicable to decommissioning, if included in an NRC-approved decommissioning plan before promulgation of the final rule, are those contained in the NRC-published Action Plan (57 *FR* 13389, dated April 16, 1992). In similar context, interim guidance on conducting radiological surveys is available in the draft "for comment" report NUREG/CR-5849, "Manual for Conducting Radiological Surveys in Support of License Termination," dated June 1992, and NUREG-1505.

Electronic versions of these and other documents related to decommissioning can be obtained from the Enhanced Participatory Rulemaking Bulletin Board System at (800) 880-6091 [n,8,1]. Implementation guidance is also available for comment on a dedicated web site. The internet address is *http://www.nrc.gov/RES/offproj.html*, then select *Decommissioning Implementation*.

(Contact: William Lahs, 301-415-6756)

NRC ISSUES DRAFT TECHNICAL POSITION ON DISPOSAL OF RADIOACTIVELY CONTAMINATED BAGHOUSE DUST

Over the past decade, the improper disposal of industrial devices containing radioactive material, primarily Cesium-137 (Cs-137), has resulted in these devices being included in scrap metal supply that was being recycled as part of the steel production process. The subsequent melting of the devices with the scrap metal has resulted in the contamination of the steel facility's air pollution control system and the emission control dust. Although many steel producers have installed radiation monitors to scan incoming shipments, the monitors cannot always detect the cesium because of the shielding provided by its container or by the scrap metal. Steel producers across the country currently are storing more than 10,000 tons of contaminated dust and other incident-related materials. In most cases, this material is classified as mixed waste because it contains radioactive and other hazardous materials such as lead, cadmium, and chromium that are common to the recycle metal supply. Disposal options for the incident-related materials have been limited, principally because of their mixed-waste classification, and the costs associated with the disposal of large volumes of mixed or radioactive waste.

Because appropriate disposal of the existing waste is preferable to indefinite storage on site, NRC is developing specific guidance for the potential disposal of this incident-related material. This guidance, summarized in a staff technical position, would establish the bases under which NRC, or an Agreement State, could permit, with the agreement of other applicable regulatory authorities and the disposal facility operator, disposal of this waste in a hazardous waste disposal facility.

The draft Technical Position entitled "Disposition of Cesium-137 Contaminated Emission Control Dust and Other Incident-Related Material" was published for public comment in the *Federal Register* of January 22, 1996 (61 FR 1608).

In addition to developing this guidance for the disposal of the incident- generated material, NRC is focusing on approaches for improving licensee control over radioactive material, to reduce the likelihood of its uncontrolled entry into the public domain, and specifically into the country's scrap metal supply.

(Contact: William R. Lahs, 301-415-6749)

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

Integrated Materials Performance Evaluation Program (IMPEP) is a framework that will allow the U.S. Nuclear Regulatory Commission (NRC) to conduct consistent reviews of Regional and Agreement State materials programs, using a set of five common performance indicators:

Status of Materials Inspections
Technical Staffing and Training
Technical Quality of Licensing
Technical Quality of Inspection
Response to Incidents and Allegations

By using the same indicators for Regional and Agreement State reviews, NRC will better be able to ensure that a consistent level of protection of public health and safety is provided nationwide. Reviews are performance-based and are

conducted by inter-office teams of three to four persons from the Office of Nuclear Material Safety and Safeguards (NMSS), the Office of State Programs, the NRC Regions, and the Agreement States. Performance relative to each indicator is judged against criteria for three levels: Satisfactory, Satisfactory with Recommendations for Improvement, and Unsatisfactory.

A total of nine Agreement State and two regional IMPEP reviews are scheduled for FY96. Ten Agreement States identified staff to participate in IMPEP reviews along with NMSS, Office of State Programs, and regional personnel, and four Agreement State personnel have been identified to serve as liaisons to the MRB. After that session, the first full Agreement State review under this program was held in North Carolina in December 1995. Subsequent reviews have been held in North Dakota and Georgia, with the first regional review scheduled for March 1996.

(Contact: George Pangburn, 301–415–7206)

GENERIC COMMUNICATIONS ISSUED
November 1, 1995 – February 1, 1996

Note that these are only summaries of U.S. Nuclear Regulatory Commission generic communications. If one of these documents appears relevant to your needs and you have not received it, please call one of the technical contacts listed below.

Administrative Letters (ALs)

AL 95–04, "NRC Program Office Responsibilities for (Reactor) Decommissioning Activities and Planning for Dry Cask Storage of Spent Fuel," was issued on November 1, 1996. This letter discusses the benefit of early NRC notification when dry storage facilities for spent fuel are planned, and outlines the respective responsibilities of NRC program offices for reactor decommissioning activities.
Contacts: Andrew J. Kugler, NRR, 301–415–2828.
Patricia L. Eng, NMSS, 301–415–8577.

AL (unnumbered), "Proposed Revisions to 10 CFR Parts 170 and 171 on License, Inspection, and Annual Fees for FY 1996," was issued on January 29, 1996. This letter transmits the proposed revisions to the fee requirements for fiscal year 1996. The proposed annual fees have been reduced about 6 percent from last year.
Contact: C. James Holloway, OC, 301–415–6213.

Generic Letters (GLs)

GL 95–09, "Monitoring and Training of Shippers and Carriers of Radioactive Materials," was issued on November 3, 1995. This letter clarifies the requirements for monitoring and training of shipping and carrier personnel during pickup and delivery of packaged radioactive materials at NRC-licensed facilities.
Contacts: Sami Sherbini, NMSS, 301–415–7902.
Cynthia Jones, NMSS, 301–415–7853.

Information Notices (INs)

IN 95–55, "Handling Uncontained Yellowcake Outside of a Facility Processing Circuit," was issued on December 6, 1995. This notice alerts uranium recovery licensees to the discovery of an unorthodox method of drying yellowcake that could have resulted in exposure of workers to significant airborne contamination.
Contact: Chuck Cain, RIV, 817–860–8186.

IN 95–58, "10 CFR 34.20; Effective Date," was issued on December 18, 1995. This notice reminds industrial radiography licensees that a final provision of the regulations in 10 CFR 34.20 becomes effective on January 10, 1996.
Contacts: J. Bruce Carrico, NMSS (general information), 301–415–7826.
Thomas W. Rich, NMSS (device information), 301–415–7893.

IN 96–04, "Incident Reporting Requirements for Radiography Licensees," was issued on January 10, 1996. This notice reminds radiography licensees of the reporting requirements in 10 CFR 34.30. Audits of manufacturer records indicate that a substantial number of equipment failure incidents are not being reported to NRC.
Contact: Douglas Broaddus, NMSS, 301–415–5847.

(General Contact: Kevin Ramsey, 301–415–7887)

FEDERAL REGISTER NOTICES
November 1, 1995 – February 1, 1996

Final Policy Statement

"Communications between the NRC and Licensees; Policy Statement," 60 FR 56068, November 6, 1995.
Contact: Cynthia Carpenter, Office of the Executive Director for Operations, 301–415–1733.

Draft Regulatory Guides

DG–8016, Proposed Revision 1 to RG 8.37, "Constraints for Air Effluents for Licensees

Other than Power Reactors," 61 FR 1647, January 22, 1996.

DG-5005, Proposed Revision 1 to RG 5.15, "Tamper-Indicating Seals for the Protection and Control of Special Nuclear Material," 61 FR 3508, January 31, 1996.

Proposed Rules

10 CFR Part 20, "Constraint Level for Air Emissions of Radionuclides," 60 FR 63984, December 13, 1996.
Contact: Charleen Raddatz, 301-415-6215 or *CTR@NRC.GOV.*

10 CFR Parts 170 and 171, "Revision of Fee Schedules; 100% Fee Recovery, FY 1996," 61 FR 2948, January 30, 1996.
Contact: C. James Holloway, Office of the Controller, 301-415-6213.

10 CFR Part 20, "Reporting Requirements for Unauthorized Use of Licensed Radioactive Material," 61 FR 3334, January 31, 1996.
Contact: Mary L. Thomas, RES, 301-415-6230.

Final Rule

10 CFR Parts 30, 40, 70, "One-Time Extension of Certain Byproduct, Source, and Special Nuclear Materials Licenses," 61 FR 1109, January 16, 1996.
Contact: John M. Pelchat, RII, 404-331-5083. C. W. Nilsen, RES, 301-415-6209

(General Contact: Paul Goldberg, 301-415-7842)

SIGNIFICANT ENFORCEMENT ACTIONS

More detailed information concerning these enforcement actions will be published in NUREG-0940, "Enforcement Actions: Significant Actions Resolved," Volume 14, No. 4, Parts 1 and 3.

Medical

Advacare Management Services, Inc., Bala Cynwyd, Pennsylvania, EA 94-089. A $2500 civil penalty was assessed for a number of violations indicative of a breakdown in control of licensed activities.

Hospital Center at Orange, Orange, New Jersey, EA 95-130. A $2500 civil penalty was assessed because the licensee discriminated against an employee for engaging in protected activity. The employee had provided information regarding an earlier violation to a U.S. Nuclear Regulatory Commission (NRC) inspector.

James Bauer, M.D., IA 94-011. An Order prohibiting involvement in NRC-licensed activities for 5 years was issued because the individual used strontium-90 for a purpose not authorized by the license, failed to provide complete and accurate information to NRC inspectors, and failed to have a radiation survey performed. A subsequent settlement agreement reduced the prohibition to 3 years.

Hung Yu, Ph.D., IA 95-037. An Order prohibiting involvement in NRC-licensed activities pending further Order was issued because the individual knowingly provided inaccurate information to the licensee regarding the cause of a misadministration, deliberately failed to perform contamination surveys, and falsified the contamination survey records.

Radiography

Western Industrial X-Ray Inspection Company, Inc., Evanston, Wyoming, EAs 93-238 and 94-131. Orders suspending and revoking the license were issued based on deliberate violations involving evaluation of an employee's radiation exposure, surveys of the radiography device after each exposure, supervising assistant radiographers performing radiographic operations, reporting an individual's radiation exposure to NRC, and use of calibrated ratemeters. After a hearing request, a settlement was reached that allowed the licensee to resume its conduct of NRC-licensed activities with modifications of the license.

Larry D. Wicks, IA 94-024. An Order prohibiting involvement in NRC-licensed activities for 5 years was issued because the individual deliberately violated NRC requirements regarding evaluation of an employee's radiation exposure and use of calibrated ratemeters, and provided false information to NRC.

Measuring Gauges

Champion International Corporation, Hamilton, Ohio, EA 95-184. A $2500 civil penalty was assessed for loss of a gauge containing byproduct material.

Energy Technologies, Inc., Knoxville, Tennessee, Ea 95-187. A $2500 civil penalty was assessed for deliberate failure to obtain a specific NRC license or file for reciprocity before installing fixed gauges in areas under NRC jurisdiction.

GCME, Inc., De Pere, Wisconsin, EA 95-154. A Notice of violation was issued November 16, 1995, based on willful failure to ensure that personnel monitoring devices were distributed and used. The licensee identified the violation and took comprehensive corrective actions.

Nekoosa Papers, Inc., Nekoosa, Wisconsin, EA 95-221. A Notice of Violation was issued based on unauthorized service and relocation of a gauge and inadvertent exposure of maintenance workers to the radiation beam. Credit was given for the licensee's good enforcement history and corrective action.

North Star Steel Ohio, Youngstown, Ohio, EA 95-208. A Notice of Violation was issued based on a breakdown in the control of licensed activities involving an incident in which molten steel damaged a gauge. Credit was given for the licensee's good enforcement history and corrective action.

(Contact: Joseph DelMedico, 301-415-2739)

OCCUPATIONAL AND PUBLIC DOSE

The U.S. Nuclear Regulatory Commission (NRC) published final rules on July 13, 1995, and September 20, 1995, that revised the definition of occupational dose. The new definition is:

> *Occupational dose* means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation and/or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the public.

Radiation exposure must be considered occupational, regardless of where it occurs, if an individual receives the exposure while employed *and* when performing any *assigned duties* that involve exposure to radiation or radioactive material. The important change is that being ". . . in a restricted area . . ." is no longer a necessary or sufficient reason to determine that an individual is receiving occupational dose. This change prevents members of the public from becoming eligible for occupational dose limits because they occasionally enter a restricted area. Licensees must control doses to individuals who are not employees with assigned duties involving radiation to within the public dose limit of 1 milliseivert (100 millirem) in a year. Also, if an individual is likely to exceed 1 millisievert (100 millirem) in a year, then the licensee must provide radiation protection procedures, such as training, that are required for occupationally exposed individuals.

Additional changes occurred in the exceptions statement for the definition of occupational and public dose regarding doses from medical administrations. The former rule provided that dose received as a patient from medical practices was not included in occupational dose. The change to ". . . any medical administration the individual has received. . ." was incorporated to clarify that any medically administered radiation dose, even dose to a wrong patient or other misadministrations, could not be considered occupational.

Coordinated with the change in the definition of occupational dose are changes in the definition of "Member of the Public" and "Public Dose." "Member of the public" means any individual except when that individual is receiving an occupational dose regardless of where the individual may be. "Public dose" was changed so that it is not limited to controlled or unrestricted areas.

The net results of these changes are: (1) workers and members of the public are distinguished by the kinds of activities they are involved in; (2) the degree of control licensees can exercise, and (3) greater assurance that members of the public will not be permitted to exceed public dose limits. For further information regarding the background information and "Statements of Consideration" for this rule, see 60 *FR* 36038-36043, published July 13, 1995.

(Contact: Alan K. Roecklein, 301-415-6223)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

October 27, 1995

NRC INFORMATION NOTICE 95-51: RECENT INCIDENTS INVOLVING POTENTIAL LOSS OF CONTROL OF LICENSED MATERIAL

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission is issuing this information notice to alert addressees to two recent incidents involving potential loss of control of licensed material, resulting in internal contamination of individuals. It is expected that recipients will review the 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.

Description of Circumstances

Recently, NRC was informed of and responded to two incidents involving phosphorus-32 (P-32) internal contamination of individuals at biomedical research facilities. P-32 is widely used in research institutions, as are many other radionuclides. Although these incidents both involved P-32, the inherent security issues extend to all facilities using licensed material.

Case 1: On June 30, 1995, a licensee informed NRC that an incident involving internal contamination of a female researcher had been reported to the licensee's radiation safety office the previous evening. The researcher was in her fourth month of pregnancy at the time of the incident. Contamination was detected when the researcher's husband, who worked with her at the licensee's facility, performed a routine survey of their lab. The licensee identified the radionuclide as P-32. Accidental contamination appeared unlikely because the woman had stopped working with radioactive material in their lab about a month before, and because the radioisotope (P-32) identified in bioassay samples is not of the same type her lab used. Licensee security officials and the Federal Bureau of Investigation are investigating the possibility that the woman ingested food or liquids deliberately contaminated with the radioisotope. Initial calculations (now being refined by NRC, the licensee, and the researcher's own technical experts) estimated that the researcher ingested tens of megabecquerels (hundreds of microcuries) of P-32.

Encl (3)

Subsequent licensee surveys identified a few droplets of P-32 on the floor in front of a refrigerator in a lounge adjacent to labs the couple use and an internally contaminated water cooler in the same building. Urine bioassays of other workers identified approximately 25 additional individuals who have low-level internal P-32 contamination. In early July 1995, NRC sent an Augmented Inspection Team to investigate the circumstances surrounding the contamination incident. While the inspection and investigations are ongoing, NRC has obtained licensee agreement to improve the control of radioactive materials used in its biological and medical research programs.

Case 2: On October 16, 1995, a licensee informed NRC that an incident involving internal contamination of a researcher had occurred at its facility almost 2 months earlier. Licensee officials told NRC staff that they had not reported the incident earlier because their analyses suggest that the researcher's internal dose was below the 10 CFR Part 20 reporting criteria.

According to the licensee, the researcher discovered that he was contaminated during a routine survey of his work area. Also according to the licensee, it subsequently detected P-32 contamination on an item of clothing that the researcher had worn earlier that week, when he had last handled P-32 in the laboratory. The licensee performed urine bioassays, and informed the researcher that he may have ingested what was described as a drop of P-32 containing 21.4 megabecquerel (579 microcuries). The researcher has told licensee campus police that he believes the contamination was not accidental. NRC and campus police are investigating his allegation. Also, the researcher has requested that an independent consultant prepare a second dose estimate.

The licensee initially secured all radioactive materials in the lab after discovery of the contamination event. Since then, the licensee has permitted work with radioactive material to resume, after requiring more stringent inventory and accountability in the lab and tightening security. On October 17, 1995, NRC dispatched an Incident Investigation Team to the licensee's site to begin an immediate investigation of the incident. NRC also sent a letter to the licensee requiring that certain steps be taken, ensuring among other things that control of radioisotopes is adequate to provide reasonable assurance against another such incident. NRC's investigation is ongoing.

Discussion

The two recent P-32 internal contamination incidents raise a number of safety and regulatory issues. NRC is reviewing its regulations to determine if they need to be revised in light of these events. Among these issues are radioactive material security and accountability, survey procedures, preparation for bioassays, and reporting requirements. Each of these issues is addressed separately below.

a. Security. In controlled or unrestricted areas, licensees are required by 10 CFR 20.1801 and 20.1802 to secure stored material, and to control and maintain, under constant surveillance, licensed material that is not in storage. Access to restricted areas is required to be controlled to prevent unauthorized access to licensed material. Licensees should review their programs to ensure that they have a radiation safety program in place that will prevent deliberate misuse of radioactive materials in all licensee areas.

b. Accountability. 10 CFR Part 20 requires the reporting of theft or loss of materials above defined levels. In addition, the Draft Regulatory Guide DG-0005, "Applications for Licenses of Broad Scope," published for comment in October 1994, states that license applicants:

> ... should develop and maintain a strong inventory and accountability system. The institution should have the capability to continually track incoming shipments of licensed material and account for material usage, decay, transfer, and disposal. A licensee's inventory and control system should have the capability to ensure that licensed possession limits are not exceeded and that material is accounted for throughout the institution at any given time.

In light of these events, licensees should review their programs to determine whether they need to improve their radioactive material accountability systems, commensurate with the scope of their programs.

c. Detecting licensed material. NRC emphasizes that conducting surveys with adequate, calibrated equipment is a crucial step in conducting safe operations. Many commercially available survey instruments, such as Geiger-Mueller detectors, are capable of detecting P-32, even after ingestion, in the activity range used in research facilities. In both of these cases, internal contamination was originally detected when the researchers conducted routine surveys of their laboratories and detected high background readings. Licensees should review their programs to ensure that they are conducting surveys with adequate, calibrated equipment.

d. Bioassay preparation. All licensees are responsible for responding to incidents. Some licensees already have bioassay programs in place to comply with the requirement in 10 CFR 20.1502 to monitor workers whose intake is likely to exceed 10 percent of the occupational dose limits. Interpretation of bioassay data, when regulatory thresholds are approached, may be difficult. Important information on the proper conduct of a bioassay program is provided in Regulatory Guide 8.9, Rev. 1, July 1993, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program" and NUREG/CR-4884, "Interpretation of Bioassay Measurements." Licensees that need immediate medical consultation to respond to an ongoing internal contamination event can contact the Radiation Emergency Assistance Center/Training Site (REAC/TS), which is funded by the U.S. Department of Energy to provide consultation in such situations. The NRC Operations Center can connect callers with REAC/TS.

   If internal contamination is detected, health physics consultants are commercially available to assist with bioassay and other response measures. However, licensees that plan to use consultants may want to identify and make arrangements for those resources now, rather than wait until an incident occurs. Licensees that need help in identifying health physics services should contact professional societies or organizations for references.

e. Food and beverage storage. Generally, licensees have procedures prohibiting eating, drinking, and smoking in radiologically restricted areas. In light of these events, licensees should review their programs to determine how food, particularly lunches, snack foods, and beverages in unsealed containers, are permitted or stored in their facilities.

f. Contact NRC if deliberate misuse of licensed material is suspected. NRC considers deliberate misuse of licensed material to be of significant regulatory interest, and expects to be contacted in such situations. Although the magnitude of the dose could be within NRC's regulatory limits, the possibility that such a dose was delivered intentionally, and possibly with malice, raises concerns about a licensee's, a contractor's, or any employee's deliberate misconduct, as addressed in 10 CFR 30.10, 40.10, 70.10, and 72.12. In addition, pursuant to 10 CFR 30.9(b), 40.9(b), 70.9(b), and 72.11(b), each licensee is required to "... notify the Commission of information identified ... as having for the regulated activity a significant implication for public health and safety ...." Notification shall be provided in such cases to the Regional Administrator within 2 working days.

The issues raised in these two cases should lead licensees to consider reexamining their own methods to prevent and, if necessary, respond to internal contamination incidents.

The information in this notice is preliminary, and the investigations and inspections in these two cases are ongoing. NRC may issue further guidance, as necessary, once results are known and conclusions drawn on these two cases.

This information notice requires no specific action or written response. If you have any questions about the information in this notice, please contact the technical contacts listed below or the appropriate regional office.

Donald A. Cool

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

Technical contacts:

Scott Moore, NMSS (301) 415-7875	B. J. Holt, RIII (708) 829-9836
Mohamed Shanbaky, RI (610) 337-5209	Thomas Kozak, RIII (708) 829-9866
John Potter, RII (404) 331-5571	Linda Howell, RIV (817) 860-8213

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

LIST OF EMERGENCY CONTACTS

I. NRC Operations Center
Telephone: 301-816-5100 (will accept collect calls)

II. Radiation Emergency Assistance Center/Training Site (REAC/TS)
Daytime Telephone: 423-576-3131
24-hour Telephone: 423-481-1000 (ask for REAC/TS)
(to consult with a physician)

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
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.
95-39	Brachytherapy Incidents Involving Treatment Planning Errors	09/19/95	All U.S. Nuclear Regulatory Commission Medical Licensees.
95-29	Oversight of Design and and Fabrication Activities for Metal Components Used in Spent Fuel Dry Storage Systems	06/07/95	All holders of OLs or CPs for nuclear power reactors. Independent spent fuel storage installation designers and fabricators.
95-28	Emplacement of Support Pads for Spent Fuel Dry Storage Installations at Reactor Sites	06/05/95	All holders of OLs or CPs for nuclear power reactors
95-25	Valve Failure during Patient Treatment with Gamma Stereotactic Radiosurgery Unit	05/11/95	All U.S. Nuclear Regulatory Commission Medical Licensees.
94-64, Supp. 1	Reactivity Insertion Transient and Accident Limits for High Burnup Fuel	04/06/95	All holders of OLs or CPs for Nuclear Power Reactors and all fuel fabrication licensees.
95-07	Radiopharmaceutical Vial Breakage during Preparation	01/27/95	All U.S. Nuclear Regulatory Commission medical licensees authorized to use byproduct material for diagnostic procedures.

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
95-50	Safety Defect in Gammamed 12i Bronchial Catheter Clamping Adapters	10/30/95	All High Dose Rate Afterloader (HDR) Adapters.
95-49	Seismic Adequacy of Thermo-Lag Panels	10/27/95	All holders of OLs or CPs for nuclear power reactors.
95-48	Results of Shift Staffing Study	10/10/95	All holders of OLs or CPs for nuclear power reactors.
95-47	Unexpected Opening of a Safety/Relief Valve and Complications Involving Suppression Pool Cooling Strainer Blockage	10/04/95	All holders of OLs or CPs for nuclear power reactors.
95-46	Unplanned, Undetected Release of Radioactivity from the Exhaust Ventilation System of a Boiling Water Reactor	10/06/95	All holders of OLs or CPs for nuclear power reactors.
95-12, Supp. 1	Potentially Nonconforming Fasteners Supplied by A&G Engineering II, Inc.	10/05/95	All holders of OLs or CPs for nuclear power reactors.
95-45	American Power Service Falsification of American Society for Nondestructive Testing (ASNT) Certificates	10/04/95	All holders of OLs or CPs for nuclear power reactors.
95-44	Ensuring Compatible Use of Drive Cables Incorporating Industrial Nuclear Company Ball-Type Male Connectors	09/26/95	All Radiography Licensees.
95-43	Failure of the Bolt-Locking Device on the Reactor Coolant Pump Turning Vane	09/28/95	All holders of OLs or CPs for nuclear power reactors designed by Westinghouse Electric Corporation (W).

OL = Operating License
CP = Construction Permit