NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

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MANAGEMENT AND RADIATION SAFETY OFFICER RESPONSIBILITIES FOR FIXED GAUGE OPERATIONS

In 1995, Nuclear Regulatory Commission (NRC) inspectors identified several cases of inadequate management control and oversight of NRC-licensed operations involving the use of fixed industrial gauges. These cases led to safety problems and escalated enforcement sanctions against the licensees. In each case, the licensee failed to fulfill radiation safety responsibilities for its NRC-licensed operations.

In one case, the Radiation Safety Officer (RSO) of a large steel mill failed to provide proper oversight of a manufacturer testing a prototype gauge in a room within its plant. The licensee relied primarily on the gauge manufacturer to ensure that proper access controls were in place. The gauge being tested contained several cesium-137 sources capable of producing high radiation levels in the room. Room entry controls established by the gauge manufacturer did not satisfy the requirements of 10 CFR 20.1601, for access to a high-radiation area. The licensee failed to verify that proper room entry controls were established before testing began. As a result of this failure, several plant workers were unnecessarily exposed to radiation after entering the room unchallenged, with the gauge shutters open.

In another case, a new RSO of another steel mill was unfamiliar with specific requirements in his NRC license, general regulatory requirements, and previous NRC inspection findings. As a result, the licensee was unaware of requirements for control and posting of a high-radiation area (10 CFR 20.1601 and 20.1902); requirements for event reporting (10 CFR 30.50); and commitments for surveys and personnel monitoring in its license. A previous NRC inspection of this licensee's operations identified a violation for failure to report an event involving damage to one of its gauges, as required by 10 CFR 30.50. Had the RSO been aware of previous NRC inspection findings, a repeat problem would likely not have occurred. In addition, during a subsequent event in which a gauge's lead shielding was melted by a molten steel spill, RSO and management oversight were not sufficient to ensure that the licensee's response actions complied with regulatory requirements, because of competing demands to bring the plant back on line. Excessive turnover in the RSO position and plant operational responsibilities other than radiation safety also diluted oversight of the program.

In other cases, gauges were removed from service or maintenance was performed in vessels without the RSO's knowledge and consent. As a result, gauge shutter closure was not properly confirmed, leading to unnecessary radiation exposure to plant workers and the public.

Licensees should be aware that although an RSO may be assigned day-to-day radiation safety responsibilities, management retains ultimate responsibility to ensure that radiation safety activities are performed in accordance with both internal procedures and NRC requirements. The amount of time necessary for RSO and management oversight will depend on the size and scope of the NRC-licensed program. Management should support and monitor the RSO and safety staff to ensure they have adequate resources to do their jobs and are not devoting an inordinate amount of time to other duties.

The licensee's responsibility for control of its operations also extends to consultants and contractors. Licensees are reminded that the responsibility for the safety of its operations and compliance with NRC requirements remains with the licensee.

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Comments, and suggestions you may have for information that is not currently being included, that might be helpful to licensees, should be sent to:
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NRC expects RSOs and licensee management to be aware of the conditions of their license and the regulations, and understand their responsibilities for conducting NRC-licensed activities. Management should be involved in the operational details of the radiation safety program both during normal plant operations and during events, to verify that program implementation complies with all requirements. As a result, licensees can avoid potentially significant adverse health and safety consequences to their employees and the public, and the financial costs that can result from failure to follow NRC requirements and from associated escalated enforcement sanctions.

(Contact: Wayne J. Slawinski, RIII, 708–829–9820)

EVENTS INVOLVING COMPUTERIZED RADIATION THERAPY TREATMENT SYSTEMS

The Nuclear Regulatory Commission (NRC) has been collecting and reviewing events involving computer errors that resulted in misadministrations. As part of this effort, an analysis of events reported to NRC by NRC licensees and Agreement States was performed covering 22 events that involved 172 patients. The

analysis addressed treatment planning and dose delivery systems with emphasis on software, hardware, and human-machine interface issues that could potentially affect the system's operational safety. Although the risk associated with these types of misadministrations may be about the same as for other types not involving computer errors, we believe that we should share the following highlights of the study with licensees as lessons learned.

- The number of computer-based misadministrations per year has been increasing based on the number of events reported to NRC from 1981 through 1993.

- The number of reported misadministrations involving the treatment planning process has been higher than that associated with the dose delivery process. In part, this is because treatment planning-related misadministrations are more likely, than the dose delivery process, to affect multiple patients.

- Events resulting in reported misadministrations to multiple patients occur more often in a computer-based radiation therapy process than in a manual therapy process.

- There have been much greater delays in the detection and reporting of multiple misadministrations in computer-based radiation therapy than in manual treatments, because licensee personnel do not have readily available information on computer system errors, so they can quickly detect them.

- Nearly three-quarters of the computer-error-related medical misadministrations of byproduct material are directly linked to human errors and procedural deficiencies.

- Nearly one-half of the events have involved user interface deficiencies.

- Neither the software nor the hardware limited the consequences of a misadministration, in any of the events evaluated, because of the following reasons:

  - In most cases a computer-based radiation therapy misadministration was not discovered until the therapy was completed.

  - In the application of computerized therapy, the task of detecting a misadministration in progress is left to the computer-based system. Its design may be inadequate for the task.

  - Computer-based therapy permits rapid setup, high-dose rates, and short treatment periods, all of which provide fewer opportunities for detecting and limiting misadministrations.

The analysis also identified the causes and contributing factors of the computer-based events reported to NRC. A frequent factor was licensee personnel lack of training in computer use. In some cases evaluated, licensees such as small hospitals and private clinics used outside consultants to perform computer-based system operations, because they lacked in-house expertise. Licensees are reminded that it is their responsibility to ensure that administered doses accord with written directives and to ensure that employees have the proper training and experience to perform computer-based radiation therapy treatments. Because both technology and operational practice are rapidly evolving in computer applications in radiation therapy, quality work in this area requires that there must be properly trained licensee staff members available who understand current applications and the latest evolutions of computer technology.

(Contacts: Harriet Karagiannis, AEOD, 301-415-6377; James Smith, NMSS, 301-415-7904)

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES MEETINGS

On September 27-29, 1995, the Nuclear Regulatory Commission's (NRC's) Advisory Committee on the Medical Uses of Isotopes (ACMUI) held a subcommittee meeting at the NRC Headquarters office in Rockville, Maryland. The meeting was held to discuss draft licensing modules of certain types of medical uses to be included in the revision to Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs." The following draft licensing modules were discussed: 1) Mobile Medical Services, 2) Radioactive Drug Therapy, 3) Remote Afterloaders, 4) Manual Brachytherapy, 5) Teletherapy, and 6) Gamma Stereotactic Radiosurgery.

On October 18 and 19, 1995, the ACMUI held its regularly scheduled semi-annual meeting at the NRC Headquarters office in Rockville, Maryland. Agenda items included a discussion of: 1) the role of the medical consultant; 2) the ACMUI review process for training and experience exemptions; 3)

intravascular brachytherapy issues; 4) NUREG reports on human factors evaluations of teletherapy and brachytherapy; 5) the petition for rulemaking for the commercial distribution of byproduct material for *in vivo* testing; 6) report on subcommittee review of draft licensing modules; 7) status report on National Academy of Sciences study; 8) update on rulemakings and regulatory guides; 9) discussion of STEP device; and 10) discussion of a manual chapter on patient follow-up. In addition, in a closed session, an individual physician's training and experience were reviewed by the ACMUI, in connection with the physician's application to be a medical authorized user.

Copies of the transcripts and summary minutes for the meetings are available through the Public Document Room, 202-634-3273. The next meeting of the ACMUI will be noticed in the *Federal Register*.

(Contact: Torre Taylor, NMSS, 301-415-7900)

BUSINESS PROCESS RE-ENGINEERING UPDATE

The materials licensing Business Process Re-engineering (BPR) project, which began in October of 1994, is currently proceeding as scheduled. The BPR staff briefed the Commission on the results of Phase I of the BPR on May 11, 1995. The Commission approved the staff proposal to: (1) extend qualified materials licensees for 5 additional years; (2) proceed with Phase II of the BPR, and (3) separate the payment of fees from the process of issuing a license and continue streamlining the fee structure for materials licensees. Additionally, the staff was encouraged to actively seek the views of the Agreement States in developing the new process and to seek the views of the public, regulated community, and the Agreement States on the proposal to grant a one-time 5-year extension of licenses to qualified materials licensees.

The staff has visited selected Agreement and Non-Agreement States suggested by the Council of Radiation Control Program Directors, to evaluate existing licensing systems for incorporation into the new Nuclear Regulatory Commission (NRC) process, and has engaged in a rulemaking effort on the one-time license extension.

During Phase I, the BPR team made significant progress on:

1. Creation of a Technical Assistance Request Database to provide, in an easily retrievable format, access to guidance developed in response to licensing questions. This database encompasses the years 1983 to the present, and is continuously updated.

2. Development of an Electronic Licensing Manual designed to synthesize and update all materials licensing guidance. This effort involves representatives from each NRC Regional Office (including the Walnut Creek Field Office) and some Agreement States.

Completion of both of these items is projected for June of 1996.

The staff began the second phase of the project on November 13, 1995. This phase includes the design, development, and prototyping of a computer-assisted licensing process, using the guidance databases developed in Phase I.

(Contact: Patricia A. Rathbun, NMSS, 301-415-7178)

WHAT'S NEW AT FEDWORLD

The decommissioning criteria rulemaking implementation discussion area "Interactive Implementation Project" is online. Send questions and comments to Chris Daily at *cxd@nrc.gov* or call 301-415-6026.

"Occupational Radiation Exposure Data" is online. Send questions and comments to Mary Lynne Thomas at *mlt1@nrc.gov* or call 301-415-7000.

The Nuclear Regulatory Commission (NRC) recently launched a public responsiveness initiative to develop public responsiveness improvement plans. The draft "Report on Responsiveness to the Public" contains those plans and is listed under the home page for the Office of the Executive Director for Operations.

(General Contact: Arthur Davis, IRM, *axd3@nrc.gov*, 301-415-5780)

NRC COST CONTROLS FOR THE URANIUM RECOVERY PROGRAM

The High-Level Waste and Uranium Recovery Projects Branch (HLUR) is developing and implementing an automated cost control system to provide Nuclear Regulatory Commission (NRC) managers with an accurate and timely

mechanism for tracking all staff and contractor licensing work concerning uranium recovery (UR) licensees. As a full-cost recovery agency, NRC is obligated to pass on all associated licensing review charges to industry. Thus, the UR cost control system was developed by HLUR in response to licensee concerns over escalating charges associated with the staff's review of licensing actions.

In general, concerns focused on staff time expenditures and the lack of internal cost control measures to adequately monitor the status of site-specific projects. To address these concerns, HLUR formed a cost control group to research each of these pending issues and devise a system whereby staff review efforts would be more efficiently streamlined and managed from a project's inception to completion. The conclusion of the group's study resulted in the development and implementation of the UR cost control system.

The UR cost control system is an automated database that tracks the status of licensing casework from initial submission to project completion. Once entered into the system, each project is identified by a general description and assigned a specific case number. The next entry is an estimation of hours for completion of the project. This estimate is made by the responsible HLUR Project Manager (PM) based on the staff's preliminary acceptance review assessment, and historical cost data for similar types of projects. A biweekly computer print-out is generated, showing the cumulative hours charged for staff review efforts, from the project's inception to the present—and indicating an overall percentage completion, based on dividing the cumulative hours by the total estimated hours. These figures can be compared to the projected hours total, derived by using a linear estimating approach—whereby the project start date is subtracted from the targeted completion date—then multiplying this amount by the average number of staff review hours expended per bi-weekly period. This allows the PM to compare projected hours to estimated hours—providing a snapshot of the project's overall completion status for any given bi-weekly period. In addition, staff and contractor cumulative fees are also tracked on this system.

The UR cost control system becomes a useful tool in monitoring the progress of a particular project, and allows the PM to keep the licensee and NRC management abreast of any actual or potential cost overruns. HLUR is committed to reducing licensees' expenses through initiating a combination of cost control measures that facilitates an effective and efficient review process by the staff.

(Contact: Robert D. Carlson, NMSS, 301-415-8165)

NRC STAFF UPDATES THE SITE DECOMMISSIONING MANAGEMENT PLAN

On August 11, 1995 (in SECY-95-209) the Nuclear Regulatory Commission (NRC) staff provided the Commission with the biennial update of the program management issues and site remediation activities for sites on the Site Decommissioning Management Plan (SDMP). NRC established the SDMP in March 1990 to help ensure the timely cleanup of sites warranting special attention by the Commission. The update summarizes the progress made at SDMP sites since 1993 and describes the staff's expectations for completing decommissioning actions at SDMP sites through 1997. The update also provides detailed descriptions of the decommissioning activities at each site, as well as the activities undertaken by the staff to support the SDMP program.

The update summarizes the staff's Program Management Plan, which was developed to identify approaches that can be used to reduce the level of NRC resources devoted to decommissioning, while ensuring the effective oversight of projects listed on the SDMP. Staff initiatives discussed in the plan include revising the procedures for reviewing site characterization plans and reports and reducing the scope of confirmatory surveys, while placing greater reliance on the licensee's termination survey. In the past, NRC staff has reviewed and approved a licensee's site characterization plans and report before reviewing and approving the decommissioning plan. In the future, NRC staff will review information on the radiological status of most sites as part of its review of the decommissioning plan. For complex decommissioning actions, such as SDMP sites, NRC staff routinely conducts a confirmatory radiological survey to validate, as an audit, the data in the licensee's termination survey. NRC staff plans to reduce the scope of these confirmatory surveys by basing the extent of confirmatory surveys on past licensee performance, the results of NRC staff inspections of the licensee's survey while it is being performed, and on the results of the licensee's quality assurance/quality control efforts, as

reported in the termination survey report and as observed during inspections.

The update also summarizes several potential policy issues under review by the staff such as: concentration averaging; assumptions used in exposure assessment scenarios; coordination of decommissioning actions with States and other parties; generic conclusions on the disposal of uranium and thorium based on the results of site-specific environmental impact statements; and institutional controls. Finally, the update summarizes other activities undertaken by the staff to support the SDMP program, including the development of a decommissioning manual chapter and database, revising decommissioning performance measures, and instituting an interactive process with licensees to resolve issues related to decommissioning sites. The staff intends to publish the 1995 update as a supplement to NUREG-1444.

(Contact: David N. Fauver, NMSS, 301-415-6625)

FEDERAL REGISTER NOTICES
August 1, 1995 - November 1, 1995

DRAFT POLICY STATEMENTS

"Conversion to Metric System," 60 FR 49928, September 27, 1995.
Contact: Dr. Frank A. Costanzi, RES, 301-415-6250.

INTERIM POLICY STATEMENTS

"Evaluation of Agreement State Radiation Control Programs," 60 FR 54734, October 25, 1995.
Contact: Kathleen N. Schneider, OSP, 301-415-2320.

FINAL POLICY STATEMENTS

"Status and Notice of Availability of Two Policy Statements Concerning the Agreement State Program," 60 FR 39463, August 2, 1995.
Contact: Kathleen N. Schneider, OSP, 301-415-2320.

"Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities," 60 FR 42622, August 16, 1995.
Contact: Anthony Hsia, NRR, 301-415-1075.

DRAFT GUIDANCE

"Joint Nuclear Regulatory Commission/Environmental Protection Agency Guidance on the Storage of Mixed Radioactive and Hazardous Waste," 60 FR 40204, August 7, 1995.

PROPOSED RULES

10 CFR Parts 20, 30, 40, 50, 51, 70, and 72, "Radiological Criteria for Decommissioning (extension of schedule for final rule)," 60 FR 40117, August 7, 1995.
Contacts: John E. Glenn, RES, 301-415-6187; Frank Cardile, RES, 301-415-6185.

10 CFR Parts 60, 72, 73, and 75, "Safeguards for Spent Nuclear Fuel or High-Level Radioactive Waste," 60 FR 42079, August 15, 1995.
Contacts: John L. Telford, RES, 301-415-6229; Sandra D. Frattali, RES, 301-415-6261; Priscilla A. Dwyer, NMSS, 301-415-8110.

10 CFR Parts 30, 40, and 70, "One-Time Extension of Certain Byproduct, Source, and Special Nuclear Material Licenses," 60 FR 46784, September 8, 1995.
Contacts: John Pelchat, RII, 404-331-5083; C.W. Nilsen, RES, 301-415-6209.

40 CFR Part 61, "National Emissions Standards for Radionuclide Emissions from Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Covered by Subpart H (Reopening of Comment Period on Rescinding Subpart I)," 60 FR 50161, September 28, 1995.
Contact: Eleanor Thornton, EPA, 202-233-9773.

FINAL RULES

10 CFR Parts 20 and 35, "Medical Administration of Radiation and Radioactive Materials," 60 FR 48623, September 20, 1995.
Contact: Stephen A. McGuire, RES, 301-415-6204.

10 CFR Part 71, "Compatibility with the International Atomic Energy Agency," 60 FR 50248, September 28, 1995.
Contact: John R. Cook, NMSS, 301-415-8521.

49 CFR Parts 171, 172, 173, 174, 175, 176, 177, and 178, "Hazardous Materials Transportation Regulations; Compatibility with Regulations of the International Atomic Energy Agency," 60 FR 50292, September 28, 1995.
Contacts: A. Wendell Carriker, DOT, 202-366-4545; John A. Gale, DOT, 202-366-8553.

10 CFR Parts 50, 70, and 72, "Physical Security Plan Format Changes," 60 FR 53505,

October 16, 1995.
Contact: Carrie Brown, NMSS, 301-415-8092.

10 CFR Part 110, "Import and Export of Radioactive Waste; Correction," 60 FR 55183, October 30, 1995.
Contact: Ronald Hauber, OIP, 301-415-2344.

(General Contact: Kevin Ramsey, NMSS, 301-415-7887)

GENERIC COMMUNICATIONS ISSUED AUGUST 1, 1995 - NOVEMBER 1, 1995

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, 1995. This letter informs addressees that early notification of plans to install dry cask storage facilities is desirable, 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

Information Notices (Ins)

IN 95-39, "Brachytherapy Incidents Involving Treatment Planning Errors," was issued on September 19, 1995. This notice alerts addressees to recent incidents involving treatment planning errors.
Contact: James A. Smith, NMSS, 301-415-7904

IN 95-44, "Ensuring Compatible Use of Drive Cables Incorporating Industrial Nuclear Company Ball-Type Male Connectors," was issued on September 26, 1995. This notice alerts addressees to two radiography source disconnects involving use of incompatible equipment.
Contact: John W. Lubinski, NMSS, 301-415-7868

IN 95-50, "Safety Defect in GammaMed 12i Bronchial Catheter Clamping Adapters," was issued on October 30, 1995. This notice alerts addressees to the manufacturer's recommendation to discontinue use of 1.8-millimeter bronchial catheter adapters.
Contact: Robert L. Ayres, NMSS, 301-415-5746

IN 95-51, "Recent Incidents Involving Potential Loss of Control of Licensed Material," was issued on October 27, 1995. This notice alerts addressees to two recent incidents involving potential loss of control that resulted in internal contamination of individuals.
Contacts: Scott Moore, NMSS, 301-415-7875,
Mohamed Shanbaky, RI, 620-337-5209,
John Potter, RII, 404-331-5571,
B.J. Holt, RIII, 708-829-9836,
Thomas Kozak, RIII, 708-829-9866,
Linda Howell, RIV, 817-860-8213

(General Contact: Kevin Ramsey, NMSS, 301-415-7887)

SIGNIFICANT ENFORCEMENT ACTIONS

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

Medical

Carlisle Hospital, Carlisle, Pennsylvania, EA 95-021. A $5000 civil penalty was assessed because the licensee deliberately allowed physicians who were not named on the Nuclear Regulatory Commission (NRC) license to perform teletherapy treatments.

Logan General Hospital, Logan, West Virginia, EA 94-008. An $8000 civil penalty was assessed for deliberate violations including pervasive falsification of patient dose records and routine, unauthorized administration of radiopharmaceuticals to patients in excess of the dosage prescribed by the authorized user.

Veterans Affairs Medical Center, Long Beach, California, EA 95-149. A Notice of Violation was issued for unauthorized disposal of licensed material by release to the normal trash.

Jose Barba, M.D., IA 95-038. A Notice of Violation was issued for deliberate misconduct involving discrimination against an employee for engaging in protected activity. The employee had provided information regarding an earlier violation to an NRC inspector.

Hartsell S. Phillips, IA 94-001. An Order prohibiting involvement in NRC-licensed activities for 5 years was issued based on deliberate false statements to NRC officials and

deliberate violations including administration of excessive radiopharmaceutical dosages to patients. The individual was also convicted and sentenced based on a violation of the Atomic Energy Act and NRC's Deliberate Misconduct Rule.

Radiography

Mid American Inspection Services, Inc., Gaylord, Michigan, EA 94-256. A Notice of Violation was issued for deliberate failure to supervise radiographer's assistants while conducting radiographic operations. The licensee identified the violation, reported it to NRC, and took strong corrective action.

Quality Inspection Services, Inc., Buffalo, New York, EA 95-046. A $13,000 civil penalty was assessed for willful violations involving: (1) failure to file for reciprocity before working in a non-Agreement State, and (2) submittal of inaccurate information to an inspector; and for failures to wear alarm ratemeters during the performance of radiography.

Steven Cody, IA 95-029. An Order prohibiting involvement in NRC-Licensed activities for 1 year was issued because the individual deliberately violated 10 CFR 34.44 by failing to supervise radiographer's assistants on multiple occasions.

Russell Hamilton, IA 95-030. A Notice of Violation was issued because the individual deliberately conducted radiographic operations without wearing proper dosimetry.

Daniel J. McCool, IA 94-017. An Order prohibiting involvement in NRC-Licensed activities for 5 years was issued based on deliberate failure to train and certify personnel, creation of false records, and provision of false information to NRC. The individual also was convicted of criminal violations of the Atomic Energy Act and was incarcerated.

Measuring Gauges

CTI and Associates, Inc., Brighton, Michigan, EA 95-150. A Notice of Violation was issued for failure to maintain surveillance over a moisture/density gauge in an unrestricted area.

J&L Testing Company, Inc., Canonsburg, Pennsylvania, EA 95-183. An Order Suspending License was issued for willful violations of NRC requirements, including providing inaccurate information to NRC and use and possession of licensed material without a valid NRC license.

Professional Inspection and Testing Services, Inc., Chambersburg, Pennsylvania, EA 95-127. A Notice of Violation was issued for failure to maintain surveillance over a moisture/density gauge in an unrestricted area.

Soil Testing, Inc., Fort Wayne, Indiana, EA 95-092. A $250 civil penalty was assessed for failure to maintain surveillance over moisture/density gauges in an unrestricted area.

Maria Hollingsworth, IA 95-028. An Order prohibiting involvement in NRC-licensed activities for 1 year was issued because the individual: (1) knew that she should no longer use gauges containing NRC-licensed material because her company's NRC license had expired, but did so anyway; and (2) made a false statement to an NRC inspector.

Other Materials Licensees

Amersham Corporation, Burlington, Massachusetts, EA 95-058. A Notice of Violation was issued for failure to perform adequate surveys to assess exposure to hot particles, and two overexposures caused by hot particles.

Atlas Corporation, Denver, Colorado, EA 94-117. A $5000 civil penalty was assessed for release for unrestricted use of contaminated scrap material from a dismantled uranium mill.

Bethlehem Steel Corporation, Bethlehem, Pennsylvania, EA 95-134. A Notice of Violation was issued for failure to implement controls at each entrance or access point of a high radiation area, and failure to provide training in emergency and operating procedures.

Cabot Corporation, Boyertown, Pennsylvania, EA 95-086. A $5000 civil penalty was assessed for failure to perform adequate surveys to assure compliance with occupational dose limits and effluent release limits, and failure to establish as low as is reasonable achievable controls.

Dyna Jet, Inc., Gillette, Wyoming, EA 95-047. A Notice of Violation was issued for violations of NRC requirements applicable to well logging and transportation of radioactive material packages.

HNU Systems, Inc., Newton Highlands, Massachusetts, EA 95-116. A Notice of Violation was issued for violations demonstrating a breakdown in control of licensed activities.

Marc W. Zuverink, IA 95-022. An Order prohibiting involvement in NRC-licensed activities for 10 years was issued because the individual stole tritium from his employer's facility and transferred it to members of the public.

(Contact: R. Joseph Delmedico, OE, 301-415-2739)

A SAMPLING OF SIGNIFICANT EVENTS REPORTED BY NRC LICENSEES (JULY-SEPTEMBER 1995)

Event 1: Medical Brachytherapy Misadministration

Date Reported: June 8, 1995

Licensee: Marshfield Clinic
Marshfield, Wisconsin

A patient was prescribed a dose of 1640 centigray (cGy) (1640 rad) for a low-dose-rate brachytherapy treatment of the cervix, using cesium-137 sources. After the sources were implanted, but before completion of the treatment, the physician entered the wrong date for removal of the sources, into the final treatment plan. Because of this error the treatment was extended an additional day. As a result, the calculated administered dose was 2440 cGy (2440 rad) which was approximately 50 percent greater than the prescribed dose. The licensee determined that there would be no adverse health effects.

The licensee failed to notice that the time documented in the final treatment plan did not represent the prescribed treatment time documented in the written directive. Also, the licensee's written directive/low-dose-rate brachytherapy log form, used to record events occurring during low-dose-rate brachytherapy treatments, did not have a place to document the prescribed time for source removal.

The licensee revised its written directive/ low-dose-rate brachytherapy log form to include documentation of the actual implantation time, and the time for the prescribed and actual removal of sources. Additionally, the revised form will include licensee staff member verification of such times.

Event 2: Medical Brachytherapy Misadministration

Date Reported: July 25, 1995

Licensee: Providence Hospital
Southfield, Michigan

A patient was prescribed a dose of 1230 centigray (cGy) (1230 rad) for a palliative manual brachytherapy treatment of the brain, using an iridium-192 seed. After implantation, confirmatory x-rays were taken but could not confirm the location of the seed and the treatment was ended about 31 hours after implantation. The licensee determined that the seed was implanted about 4 centimeters (1.57 inches) from the intended treatment site of the brain. Consequently, the wrong treatment site received an unintended radiation dose of about 739 cGy (739 rad) and the tumor received only about 72 cGy (72 rad). The licensee determined that no adverse health effects would result from the misadministration.

The licensee said that the seed became detained at the elbow of the applicator during implantation and changed direction. The physician consequently encountered resistance while inserting the source and assumed that it had reached the intended treatment site. A confirmatory x-ray taken at the time of insertion did not show the location of the source. (The licensee had used a fluoroscope [real-time imaging] during simulation of the treatment, but a fluoroscope was not used to observe the actual seed implantation.) The licensee reported that when using this type of applicator in the future, fluoroscopy will be used to ensure proper implantation of radioactive material.

(Contact: Walter Leschek, AEOD, 301-415-7887)

ALTERNATIVES TO THE LOW-LEVEL WASTE PROGRAM

The Nuclear Regulatory Commission (NRC) budget submitted to the Office of Management and Budget in August 1994 included full-time equivalent (FTE) reductions designed to meet goals established by the Administration as a result of the National Performance Review. For fiscal year 1999 (FY99) and beyond, the NRC low-level waste (LLW) disposal program was "zeroed out," meaning that no FTE would be devoted to the activities performed within that program element. The proposed elimination of the LLW program was developed as a budget exercise, to meet reduced targets for NRC staffing levels. The proposal was not supported by a policy nor legal analysis. On July 31, 1995, the staff forwarded to the Commission SECY-95-201, "Alternatives to Terminating the Nuclear Regulatory Commission Low-Level Radioactive

Waste Disposal Program." In this paper, the staff analyzed the implications of both terminating the LLW program altogether, and reducing it substantially to achieve budget goals for the Agency while ensuring the minimal program necessary to protect the public. The staff recommended an approach ("Option 2") that would reduce the program by approximately two-thirds, to perform only those functions required by law, and to perform a few others that are necessary and essential to the national program. The Chairman returned the paper to the staff on September 1, 1995, so that it might be considered as part of the Agency's on-going strategic assessment and rebaselining initiative, and so that the Commission would have the benefit of the Advisory Committee on Nuclear Waste's (ACNW's) views on the subject.

NRC's budget for the LLW program for FY96 and beyond presumed Commission acceptance of Option 2. In view of the Chairman's September 1, 1995, decision, the staff has begun to "ramp down" present activities in the LLW program, during FY96, instead of immediately implementing Option 2. Using this approach, the staff is terminating on-going LLW projects that fall outside of Option 2 after their significant milestones have been completed. No new work will be initiated outside this scope until completion of the rebaselining initiative.

The staff briefed the ACNW on this topic on October 24, 1995. In addition, the staff is sending a letter to other interested parties, including the States, licensees, industry groups, and the public, seeking their input. The staff will reassess the alternatives after: (1) the completion of the strategic assessment and rebaselining initiative; (2) the receipt of ACNW recommendations; and (3) the receipt of stakeholder comments. The staff is currently scheduled to forward the results of this reassessment to the Commission in March 1996.

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EPA AGREES TO RESCIND 40 CFR PART 61, SUBPART I

At this time, the U.S. Nuclear Regulatory Commission and the U.S. Environmental Protection Agency (EPA) have reached agreement on the mechanisms for rescission of 40 CFR Part 61, Subpart I (radionuclide emission standards under the Clean Air Act). EPA agreed to rescind its existing regulations in Subpart I, as applied to all NRC and Agreement State licensed facilities, in a March 31, 1995, letter from EPA Administrator Browner to Chairman Selin. The two agencies are coordinating rulemakings to transfer the responsibility for regulating airborne effluents of radioactive materials to NRC. To provide a basis by which EPA can rescind Subpart I, NRC is proposing to amend 10 CFR Part 20 to add a 100 microsievert/year (μSv/yr) [10 millirem/year (mrem/yr)] constraint level for air emissions of radionuclides. The proposed rule was published for comment in the December 13, 1995, *Federal Register*.

The implementation of Subpart I for nuclear power reactors had been stayed, pending discussions between NRC and EPA concerning rescission of Subpart I for the other licensees. EPA promulgated a final rule rescinding Subpart I for power reactors; this rule was published in the *Federal Register* on September 5, 1995.

In the September 28, 1995, *Federal Register*, EPA published a notice of the reopening of the comment period on the EPA proposal to rescind Subpart I for NRC and Agreement State licensees other than nuclear power reactors. The comment period was extended to January 20, 1996. EPA will take final action concerning rescission of Subpart I for licensees other than power reactors as soon as practicable after the Part 20 rulemaking becomes final.

Several environmental groups are suing EPA over its decision to rescind Subpart I for nuclear power plants. On November 3, 1995, the Sierra Club, the Nuclear Information & Resource Service, and the Environmental Coalition on Nuclear Power petitioned the U.S. Court of Appeals for the District of Columbia Circuit to set aside EPA's final rule. The environmentalists are concerned that NRC's ALARA (as low as is reasonably achievable) program is heavily reliant on cost considerations and that the reactors will no longer be covered under the Clean Air Act, which, unlike the Atomic Energy Act, includes citizen suit and public participation provisions.

As discussed in the December 1993/January 1994 *NMSS Licensee Newsletter*, air emissions of radionuclides from Agreement State licensees and NRC-licensed facilities other than nuclear power plants are currently regulated by EPA under 40 CFR Part 61, Subpart I. The standard in Subpart I states that radionuclide air emissions shall not cause any member of the public to receive more than an effective dose equivalent of 100 μSv/yr (10 mrem/yr) from all radionuclides of which no more than 30 μSv/yr (3 mrem/yr) can be from

radioiodine. Beginning with the year 1993, licensees were required to submit to EPA an annual report if the estimated public dose from their emissions exceeded 10 μSv/yr (1 mrem/yr).

In 1989, Congress enacted amendments to the Clean Air Act, including the Simpson Amendment in section 112(d)(9), that allows EPA to decline regulation of airborne radionuclide emissions from NRC-licensed facilities if it determines, through a rulemaking, that NRC's program provides protection of the public health with an ample margin of safety. This legislative initiative created the framework for cooperative activities between the agencies over the last several years in support of rescinding Subpart I. EPA has historically identified two components to this finding: (1) that the facilities licensed by NRC and the Agreement States are currently in compliance with the quantitative emission limit in Subpart I, and (2) that the NRC program is sufficient to ensure that emissions will remain below this level in the future, thereby protecting the public with an ample margin of safety. Although NRC believes that the existing NRC regulatory program provides an ample margin of safety to protect the public, EPA found that certain changes in NRC's regulatory program were necessary before EPA would rescind Subpart I.

The proposed Part 20 constraint on dose from air effluents is different than a limit. Exceeding this constraint would not necessarily result in a Notice of Violation (NOV). Rather, a NOV would be issued only on failure to report that a facility has exceeded the constraint value or failure to institute appropriate measures to correct and prevent further emissions in excess of those that would result in dose at or above the constraint level.

NRC is developing new Agreement State review procedures that should provide a consistent approach for evaluating the adequacy and compatibility of Agreement State programs. This constraint would be a matter of Division Level 2 compatibility. Division Level 2 compatibility requires Agreement States to incorporate the principles in NRC rules into their regulatory programs (e.g., similar but not identical). Once the NRC constraint rule goes into effect, Agreement States would adopt similar regulations within a few years.

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