NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

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UPDATE ON U.S. ENVIRONMENTAL PROTECTION AGENCY'S STANDARD FOR RADIONUCLIDE EMISSIONS FROM FACILITIES LICENSED BY THE U.S. NUCLEAR REGULATORY COMMISSION

The U.S. Environmental Protection Agency (EPA) is currently preparing a notice, for the *Federal Register*, which will re-confirm that 40 CFR Part 61, Subpart I, is in effect for facilities licensed by the U.S. Nuclear Regulatory Commission or Agreement States other than nuclear power reactors. Subpart I limits radionuclide emissions to the ambient air, from NRC-licensed facilities, to that amount that would cause any member of the public to receive, in any year, an effective dose equivalent (EDE) of 10 millirem, of which no more than 3 millirem EDE may be from radioiodines. The Subpart I standard has been in effect since November 16, 1992.

The EPA *Federal Register* notice will state that each affected facility must demonstrate compliance with the rule, as set forth in 40 CFR 61.102, using the procedures specified in 40 CFR 61.103. Those facilities that are not exempt from reporting requirements, under 40 CFR 61.104(b), must submit the annual report, concerning emissions, for calendar year 1993, required by 40 CFR 61.104(a), to EPA, *by March 31, 1994*.

Background. On October 31, 1989, EPA promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPS) to control radionuclide emissions to the ambient air from several source categories (54 FR 51654). At the time of promulgation of the NESHAPS rule, EPA granted a stay, pending reconsideration of Subpart I, based on information received late in the rulemaking from NRC and the National Institutes of Health (NIH). NRC was concerned about duplicative regulation of its licensees by NRC and EPA, whereas NIH was concerned with the potential negative effects of the standard on the use of nuclear medicine in patient treatment and diagnosis.

In 1990, Congress enacted legislation comprehensively amending the Clean Air Act (CAA), which included a section addressing the issue of regulatory duplication between EPA and NRC. Section 112(d)(9) of the CAA provides that no standard for radionuclide emissions from any category or subcategory of facilities licensed by NRC (or an Agreement State) is required to be promulgated, under Section 112, if the Administrator determines, by rule, and after consultation with NRC, that the regulatory program established by NRC, pursuant to the Atomic Energy Act, for such category or subcategory, provides an ample margin of safety to protect the public health. This provision enables EPA to eliminate duplications of effort between EPA and NRC, so long as public health is protected with an ample margin of safety.

On April 24, 1991, EPA issued a final rule, staying until November 15, 1992, the effectiveness of Subpart I for all categories of facilities licensed by NRC or NRC Agreement States, except nuclear power reactors (56 FR 18735). The purpose of this stay was to avoid the costs and disruption associated with formal implementation of Subpart I while EPA was collecting additional information necessary to make the substantive determination for those facilities contemplated by CAA Section 112(d)(9). (On August 5, 1991, EPA proposed to rescind Subpart I for commercial nuclear power reactors (56 FR 37196) and issued a final rule staying the effectiveness of Subpart I for nuclear power reactors, during the pendency of the substantive rulemaking on rescission (56 FR 37158).)

The Natural Resources Defense Council (NRDC) petitioned for judicial review of the rule, staying Subpart I for NRC and Agreement State licensees other than nuclear power reactors. EPA completed its investigation of radionuclide emissions by NRC and Agreement State licensees, other than nuclear power reactors, while the litigation in the D.C. Circuit Court concerning the rule staying Subpart I for these facilities was still pending. On September 18, 1992, EPA announced that it intended to propose rescission of Subpart I for these facilities and proposed a rule that would further stay Subpart I during the pendency of the substantive rulemaking on rescission (57 FR 43173). However, on September 25, 1992, the D.C. Circuit Court of Appeals issued a decision holding that EPA had exceeded its authority by staying Subpart I, while it was collecting the information required to make a finding under CAA Section 112(d) (9) [*NRDC v. Reilly*, 976 F.2d 36 (D.C. Cir. 1992)].

Although EPA did propose to rescind Subpart I for NRC and Agreement State licensees other than nuclear power reactors on December 1, 1992 (57 FR 56877), EPA did not adopt the proposed stay. EPA concluded that the Court's ruling in *NRDC v. Reilly* had left substantial doubt

Continued on page 2, column 2

Page

1. Update on U.S. Environmental Protection Agency's Standard for Radionuclide Emissions from Facilities Licensed by the U.S. Nuclear Regulatory Commission
(Contact: Cynthia Jones, 301-504-2629) 1

2. NRC Responds to Frequently Asked Questions about Low-Level Waste Storage
(Contact: Richard Turtil, 301-504-3447) 4

3. Uranium Mill Tailings Regulations
(Contact: Catharine Mattsen, 301-492-3638) .. 6

4. NRC Recognizes Additional Professional Boards for Authorization under 10 CFR Part 35
(Contact: Janet Schlueter, 301-504-2633) 6

5. NRC Develops NUREG to Provide Guidance on Management of Radioactive Material Safety Program at Medical Facilities
(Contact: Janet Schlueter, 301-504-2633) 6

6. The Advisory Committee on Medical Uses of Isotopes
(Contact: Sally Merchant, 301-504-2637) 7

7. Medical Workshop Held in Region III
(Contact: Toye Simmons, 708-790-5525) 7

8. Quality Management Notes
(Contact: Sally Merchant, 301-504-2637) 7

9. It's Time to Implement Revised Part 20
(Contact: Scott Moore, 301-504-2514) 8

10. Advance Notice of Proposed Rulemaking to Address Sewer Reconcentration Issues
(Contact: Cheryl Trottier, 301-492-3640) 8

11. Sanitary Sewerage Radioactive Waste Disposal
(Contacts: Joe De Cicco, 301-504-2067; Cynthia Jones, 301-504-2629) 8

12. NRC View of the Use of Electronic Dosimeters
(Contact: Sam Sherbini, 301-504-3680) 9

13. Attention, Region I Medical Licensees, 1-Day Workshop on Medical Quality Management Rule and New Part 20
(Contact: Jim Dwyer, 215-337-5309) 10

14. Information Notices and Bulletins Issued
(September 1993 - November 1993)
(Contact: Kristin Westbrook, 301-504-3444) . 10

15. Regulatory Guides Issued
(September 10, 1993 - November 30, 1993)
(Contact: Kristin Westbrook, 301-504-3444) . 11

16. Rules Published
(September 10, 1993 - November 30, 1993)
(Contact: Kristin Westbrook, 301-504-3444) .. 11

17. A Sampling of Significant Events Reported to NRC by Nuclear Material Licensees
(Contacts: Bob Prato, 301-492-4498; Harriet Karagiannis, 301-492-4258) 11

18. A Sampling of Significant Enforcement Actions against Material Licensees
(Contact: Pat Santiago, 301-504-3055) 12

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
One White Flint North, Mail Stop 6-E-6
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Continued from page 1

concerning the legality of any further stay of Subpart I for these facilities and decided not to issue any further stay. As a result, the rule staying Subpart I for NRC and Agreement State licensees other than nuclear power reactors expired by its own terms on November 15, 1992, and Subpart I took effect for these facilities on November 16, 1992 (the official mandate implementing the D.C. Circuit Court's decision in *NRDC v. Reilly* was not transmitted until after the stay had already expired).

At this time, EPA has not taken final administrative action concerning the rule to rescind Subpart I for NRC and Agreement State licensees other than commercial nuclear power reactors, which it proposed on December 1, 1992. The Commission believes that the existing NRC regulatory program provides an ample margin of safety to protect the public health under the existing NRC regulatory program. EPA is recommending that NRC make certain changes in its regulatory program in order to fully support the substantive finding that is required by CAA Section 112(d)(9), before EPA may rescind Subpart I for NRC licensees other than commercial nuclear power reactors. EPA and NRC are presently engaged in consultations concerning specific actions that could strengthen the basis for rescinding Subpart I for this category, but it is unlikely that any agreement between EPA and NRC concerning additional measures could be implemented quickly. Although the rulemaking concerning rescission is still pending, EPA advises all facilities not to presume that EPA will take any particular action in that rulemaking and to proceed, in the meantime, with all legally required compliance activities.

Demonstrating Compliance. Because Subpart I first took effect for NRC and Agreement State licensees other than nuclear power reactors near the end of 1992, EPA has determined that affected facilities were not required to demonstrate compliance with Subpart I for calendar year 1992. However, each NRC or Agreement State licensed facility other than nuclear power reactors, sealed source users, and certain other categories of licensees is now subject to all provisions of Subpart I. Each affected facility

must demonstrate compliance for calendar year 1993, with the annual emission standard set forth in 40 CFR 61.102, using the procedures specified in 40 CFR 61.103. Those facilities that are not exempt from reporting requirements, under 40 CFR 61.104(b), must submit the *annual* report concerning emissions, for calendar year 1993, required by 40 CFR 61.104(a), to EPA, by March 31, 1994.

As required in 40 CFR 61.04, all requests, reports, applications, submittals, and other communications to EPA, pursuant to the standards in Subpart I, shall be submitted in duplicate to the appropriate EPA Regional Office, to the attention of the Director of the Division of Air Management. For further information regarding EPA regulations, contact the nearest EPA regional office at the phone numbers listed at the end of this article.

NRC and EPA are cooperating to minimize, to the extent practical, the regulatory burden associated with dual regulation of air emissions of radionuclides. To minimize the impact on NRC licensees, NRC and EPA are coordinating on several actions. In addition to this newsletter article, NRC is preparing two information notices that will: (1) transmit the *Federal Register* notice codifying Subpart I and the EPA Guide for Determining Compliance; and (2) provide NRC guidance and inspection procedures related to air emission limits.

EPA will have information on Subpart I available on the Office of Air Quality Planning and Standards Technology Transfer Network bulletin board system. Currently, the bulletin board named "COMPLI" includes the COMPLY computer code, the COMPLY User's Guide, the EPA Guide for Determining Compliance, and Windrose files for several locations.

To access the bulletin board, set the following parameters on your communication software: Data bits: 8; Parity: N; Stop Bits: 1. Call the network on (919) 541–5742, for a 1200, 2400, or 9600 bps modem. Log on to the system, and answer the questions that appear on the screen. The service is free except for the cost of using the phone. If you need help, call the systems operator at (919) 541–5384, in Research Triangle Park, NC, during the normal business hours, EST.

Licensees should be aware that NRC has committed to share inspection information with EPA in each case where potential doses from air emissions appear to exceed EPA's 10 millirem/year standard, or where available information is not sufficient to determine compliance with the dose standard. However, NRC will not inspect licensed facilities to determine compliance with EPA's standard in Subpart I nor enforce the Subpart I standard. The cooperative efforts between NRC and EPA will be described in greater detail in the information notices, which NRC intends to distribute in early 1994. In addition, NRC and EPA are continuing to explore appropriate mechanisms to provide a sufficient basis for rescinding the Subpart I standard.

EPA REGIONAL RADIATION PROGRAM MANAGERS

Regional Office	Telephone No.
Tom D'Avanzo Radiation Program Manager, Region 1 Environmental Protection Agency John F. Kennedy Federal Building One Congress Street Boston, MA 02203	(617) 565–4502
Paul A. Giardina Radiation Program Manager, Region 2 Environmental Protection Agency Room 1137–L 26 Federal Plaza New York, NY 10278	(212) 264–4110
Lewis Felleisen Radiation Program Manager, Region 3 Special Program Section (3AM12) Environmental Protection Agency 841 Chestnut Street Philadelphia, PA 19107	(215) 597–8326
Chuck Wakamo Radiation Program Manager, Region 4 Environmental Protection Agency 345 Courtland Street, NE Atlanta, GA 30365	(404) 347–3907
Jack Barnette Radiation Program Manager, Region 5 (5AR26) Environmental Protection Agency 77 West Jackson Boulevard Chicago, IL 60604–3507	(312) 886–6175
Donna Ascenzi Radiation Program Manager, Region 6 Environmental Protection Agency Air Enforcement Branch (6T–E) 1445 Ross Avenue Dallas, TX 75202–2733	(214) 655–7224
Robert Dye Radiation Program Manager, Region 7 Environmental Protection Agency 726 Minnesota Avenue Kansas City, KS 66101	(913) 551–7605
Milton W. Lammering Radiation Program Manager, Region 8 (8HWM–RP) Environmental Protection Agency Suite 500 999 18th Street Denver, CO 80202–2405	(303) 293–1440
Michael S. Bandrowski Radiation Program Manager, Region 9 (A1–1) Environmental Protection Agency 75 Hawthorne Street San Francisco, CA 94105	(415) 744–1048

Jerry Leitch (206) 553-7660
Radiation Program Manager, Region 10
(AT-082)
Environmental Protection Agency
1200 Sixth Avenue
Seattle, WA 98101

Facility operators and owners desiring further information should write to Eleanor Thornton, Air Standards and Economic Branch, Criteria and Standards Division (6602J), Office of Radiation and Indoor Air, Environmental Protection Agency, Washington, D.C. 20460.

NRC RESPONDS TO FREQUENTLY ASKED QUESTIONS ABOUT LOW-LEVEL WASTE STORAGE

Under the Low-Level Radioactive Waste Policy Amendments Act of 1985, compacts with operating low-level waste (LLW) disposal sites can deny access to their sites. This authority became effective on January 1, 1993. The two compacts with operating disposal sites have elected to deny access to some States outside of their region. As of this date, generators of LLW in the States of Michigan, Rhode Island, and New Hampshire, and in the Commonwealth of Puerto Rico, are not eligible for access to either of the two LLW disposal facilities at Barnwell, South Carolina, and Hanford, Washington. On June 30, 1994, the Southeast Compact, which regulates LLW shipments into the Barnwell facility, expects to deny access to all States located outside the Southeast compact. Some 28 additional States and the District of Columbia will then have no access to any operating LLW disposal site.

Licensees are encouraged to monitor the status of current siting and disposal developments in their LLW compacts or States, and to anticipate potential needs for storage of LLW. The U.S. Nuclear Regulatory Commission recognizes the need for interim storage of LLW while new LLW disposal capacity is developed. However, NRC does not look favorably on long-term, onsite storage of LLW, and NRC's preference is that LLW be permanently disposed of as soon as possible after it is generated.

NRC staff previously developed the following guidance on storage of LLW:

1. Information Notice No. 90-09: "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees"

2. Information Notice No. 89-13: "Alternative Waste Management Procedures in Case of Denial of Access to Low-Level Waste Disposal Sites"

3. Generic Letter 85-14: "Commercial Storage at Power Reactors of Low-Level Radioactive Waste Not Generated by the Utility"

4. Generic Letter 81-38: "Storage of low-level Radioactive Waste at Power Reactors"

The following additional information answers various technical and licensing questions about LLW storage, and is meant to assist generators in meeting needs for interim storage of LLW. If you have additional questions about this information, please check with a technical contact listed below.

Region I:	(Betsy Ullrich 215-337-5040)
Region II:	(John Potter 404-331-5571)
Region III:	(Loren Hueter 708-790-5632)
Region IV:	(Jack Whitten 817-860-8197)
*Region V:	(Jim Montgomery 510-975-0249)
NMSS:	(Richard Turtil (301-504-3447)

1. How do I determine if my license requires an amendment to allow storage of LLW?

   A determination of whether an amendment to your license is needed should be based on current conditions of your license, especially those governing the total possession limits, the type and form of material, and places of use, as authorized in the current license. If a new storage facility is to be built, a license amendment will likely be required. If the specific radionuclides, type, form, and total activity specified in a license need to be modified or increased to allow storage, or if other terms and conditions of a license need to be modified, the licensee will need to apply for a license amendment to store LLW.

   If an amendment is needed, materials licensees should review Information Notice 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees." This notice identifies specific information needed in such an amendment request, including:

   * Identification of Waste to be Stored;
   * Plans for Final Disposal;
   * Physical Description of Storage Area;
   * Packaging and Container Integrity;
   * Radiation Protection;
   * Training;
   * Financial Assurance; and
   * Emergency Preparedness.

   Many byproduct materials licensees have questioned whether their plans to store LLW will require a separate, new, 10 CFR Part 30 license. In most cases, a new license would not be required. An amendment to the current license would be sufficient to cover the increased scope of activities. However, a separate Part 30 license may be required if the licensee intends to significantly broaden or expand operations or facilities to provide LLW storage or LLW processing operations to other licensees. Expansion into such commercial services, in most cases, will require the licensee to apply for a separate Part 30 license. For source and special nuclear materials licensees, an amendment to the current license also would be sufficient to authorize most requests for increases in the scope of LLW storage activities.

   Under 10 CFR 50.59, power reactor licensees do not need to apply for license amendments to store LLW

*Region V Licensees likely will need to communicate with the Region IV contact after mid- to late-1994.

onsite if the intended storage or proposed construction of the storage facility does not present an unreviewed safety question or result in a change in the technical specifications in the license. Generic Letter 81-38, "Storage of low-level Radioactive Waste at Power Reactor Sites," provides guidance in this area.

2. What level of detail is required to fulfill criteria identified in Information Notice 90-09?

Each of the areas in Attachment 1 of Information Notice 90-09 should be explicitly addressed in the application. The information should be sufficiently detailed so that the NRC reviewer can conclude that the stored waste is unlikely to create a radiation hazard to surrounding areas, any significant release in excess of Part 20 limits, or expose facility personnel to doses in excess of those prescribed in Part 20. The level of detail should reflect the magnitude of potential health and safety impacts associated with characteristics of the specific wastes, waste forms, and other circumstances of the proposed storage operation.

3. *Decay-In-Storage*

3a. Will NRC consider requests by non-medical materials licensees for decay-in-storage of low-activity radioactive materials with short half-lives, before disposal in ordinary trash?

NRC will accept and consider requests from non-medical materials licensees for decay-in-storage of short half-lived radioisotopes before disposal in ordinary trash. The licensee should address the following areas in its amendment request:

a. Survey procedures to be used during storage and before disposal in ordinary trash. The procedures should describe the type of instrument to be used for surveys, a statement of the minimum detectable activity, and a commitment that the final survey will be performed in a low radiation background area, with all shielding removed. The survey procedures and instruments used before disposal in ordinary trash must be capable of detecting all radioactive constituents within the waste package.

b. Procedures for segregating and tracking waste from placement in storage to final disposal. The procedures would include: (1) how waste will be segregated to ensure that decay-in-storage isotopes are separately identified from interim storage wastes; (2) how waste containers will be labeled; and (3) how records are maintained, such as date placed in storage, date removed, and survey results.

c. A commitment that waste will be held for a minimum of 10 half-lives, before performing the final radiation survey described in Paragraph a, above.

d. The decayed radioactive waste will not be disposed of as ordinary trash unless the final survey results are indistinguishable from background radiation, using the survey procedures discussed in Paragraph a, above, and radiation labels are obliterated or removed. Before disposal, the licensee should monitor the radioactive material in the container at the container surface, to determine that its radioactivity cannot be distinguished from background radiation levels. The licensee shall retain a record of each disposal concerning decay-in-storage materials for 3 years. The record must include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed of, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

For medical licensees (Part 35 licensees), 10 CFR 35.92 allows for decay-in-storage of LLW, before disposal in ordinary trash. The licensee is authorized to hold byproduct material with a physical half-life of less than 55 days, for a minimum of 10 half-lives. Before disposal, and after the 10 half-lives storage period, the licensee must monitor the surface of the container of radioactive material to determine that its radioactivity cannot be distinguished from background radiation levels. No shielding should be interposed between the container and the survey meter.

3b. Can licensees employ decay-in-storage for isotopes with half-lives greater than 65 days?

Yes, in some cases. NRC will consider requests for decay-in-storage for isotopes with half-lives greater than 65 days. Such requests should be directed to the NRC Regional Office issuing the original license. In its request, the licensee should identify those radioisotopes it plans to store with half-lives greater than 65 days, and should address the areas identified in response to Question 3a, above.

3c. Can institutions continue to perform decay-in-storage once disposal sites are available?

Yes. Decay-in-storage will continue to be a viable LLW management option that will remain available to licensees.

4. Can small generators consolidate with other small generators and store the waste with a third party (e.g., waste brokers)? Can licensees simply combine their wastes with other licensees?

NRC will consider any such requests by licensees to consolidate LLW for storage purposes. In general, however, NRC will not grant requests from licensees to consolidate LLW from more than one licensee, for storage purposes, unless a specific license or license amendment is requested by an individual or institution, for the express purpose of receipt, handling, and temporary storage of radioactive material. In addition, 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related

Regulatory Functions," would require most waste consolidation requests to have an enviroamental review performed before approval.

However, in those instances where an institution has several separate byproduct materials licenses under one corporate structure, NRC may allow requests for consolidation of LLW. These institutions may be eligible for a categorical exclusion from 10 CFR Part 51.

URANIUM MILL TAILINGS REGULATIONS

The U.S. Nuclear Regulatory Commission has published proposed amendments to Appendix A of 10 CFR Part 40 concerning uranium mill tailings (November 3, 1993; 58 FR 58657). These revisions bring NRC's regulations into conformity with the proposed amendments to the U.S. Environmental Protection Agency's (EPA's) generally applicable environmental standard in 40 CFR Part 192, Subpart D, published June 8, 1993 (58 FR 32174). EPA has since published the final amendments to 40 CFR Part 192 (November 15, 1993; 58 FR 60340). The final NRC amendment to Appendix A of 10 CFR Part 40 must conform to EPA's final amendments.

The intent of these regulatory changes is to improve the timeliness of completion of the final radon barrier that must be placed on non-operational uranium mill tailings piles or impoundments and also to add to the design standard for this barrier a one-time verification of the radon release levels.

EPA also has proposed rescinding similar requirements in 40 CFR Part 61, Subpart T, issued under the Clean Air Act, if it finds that the NRC program in this area provides an ample margin of public safety. This would eliminate dual regulation of releases of radon from disposed of uranium mill tailings piles. These actions were planned initially in a Memorandum of Understanding between EPA, NRC, and the affected Agreement States of Colorado, Texas, and Washington.

NRC RECOGNIZES ADDITIONAL PROFESSIONAL BOARDS FOR AUTHORIZATION UNDER 10 CFR PART 35

The U.S. Nuclear Regulatory Commission received queries from the American Board of Medical Physics (ABMP) and the Royal College of Physicians and Surgeons of Canada (Canadian Royal College) on accepting certification by these boards as adequate demonstration for meeting various training and experience criteria described in 10 CFR Part 35, "Medical Use of Byproduct Material," Subpart J. In response, NRC reviewed the certification criteria submitted and determined that certification by each of these professional boards was adequate to meet certain training and experience criteria described in Part 35. A proposed rulemaking to recognize ABMP and the Canadian Royal College was published in the *Federal Register* on June 17, 1993 (58 FR 33396). Until a final rule is effective, NRC has provided guidance to its regional offices to review each license amendment request, for authorization of applicants certified by either board, on a case-by-case basis. As a result, NRC will recognize individuals certified by ABMP and the Canadian Royal College for authorization, as follows:

- Applicants certified in Radiation Oncology Physics by ABMP are recognized for authorization under 10 CFR 35.961, "Teletherapy physicist:" and
- Physician applicants certified in Nuclear Medicine by the Canadian Royal College are recognized for authorization under 10 CFR 35.900, "Radiation Safety Officer"; 35.910, "Uptake, Dilution, and Excretion Studies"; 35.920, "Imaging and Localization studies"; and 35.930, "Radiopharmaceuticals for Therapy."

Additionally, in 1987, the American Board of Radiology renamed "therapeutic radiology" as "radiation oncology," but the certification criteria remained the same. Therefore, it is necessary to recognize both certifications in 10 CFR 35.940, 35.950, and 35.960. This was also addressed in the proposed rulemaking in 58 FR 33396.

NRC DEVELOPS NUREG TO PROVIDE GUIDANCE ON MANAGEMENT OF RADIOACTIVE MATERIAL SAFETY PROGRAMS AT MEDICAL FACILITIES

U.S. Nuclear Regulatory Commission and Agreement State staffs concluded through licensing, inspection and enforcement activities, that licensee executive management, members of the radiation safety committee (RSC), and the radiation safety officer (RSO) do not always fully understand their respective roles. Executive management may not be familiar with the scope of the licensed program, resources needed to effectively manage the program, the roles of the RSC and RSO, or necessary qualifications for an effective RSO. The RSC does not always take an active role in providing oversight of the program and feedback to executive management and the RSO. Further, some individuals authorized as RSOs are unaware of their full responsibilities, unwilling to accept them, unable to secure adequate resources from executive management to adequately perform their duties, or unable to dedicate the necessary time to successfully perform their duties, because of other duties.

NRC's Office of Nuclear Material Safety and Safeguards established a Task Force to develop a NUREG entitled, "Management of Radioactive Material Safety Programs at Medical Facilities." The NUREG will clarify the role of the licensee's responsible parties in effectively managing the radioactive material safety program at medical facilities. The Task Force includes two representatives from NRC Headquarters, one representative from each of the five NRC regional offices, and two representatives from Agreement States. The Task Force is seeking information from members of the medical community by making presentations at meetings of professional organizations such as the American Association of Physicists in Medicine, American College of Nuclear Physicians, Society of Nuclear Medicine, Radiological Society of North America, American College of Health Care Executives, and American College of Radiology, as well as NRC's Advisory Committee on the Medical Uses of Isotopes. Additionally, the NRC staff is securing contract support, for the conduct of a literature search to enhance the NUREG's bibli-

ography, and a peer review of the NUREG, to include members of the National Council on Radiation Protection and Measurements. This NUREG will be made available to medical use licensees, on completion in mid-calendar year 1994.

THE ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

The Advisory Committee on Medical Uses of Isotopes (ACMUI) held its regularly scheduled semi-annual meeting on November 1–2, 1993, at the Sheraton Reston Hotel, in Reston, Virginia. The agenda included discussions on: 10 CFR 20.1301, "Dose limits for individual members of the public"; pulsed-dose-rate remote afterloading brachytherapy; the impact of fees on medical programs; medical indications associated with calibration of strontium–90 eye applicators and their use in brachytherapy; an overview of the Management Plan for the medical use regulatory program; the Memorandum of Understanding between the U.S. Nuclear Regulatory Commission and the Food and Drug Administration, clarifying their respective roles in regulating the medical use program; a discussion of the term "referring physician," as used in 10 CFR Part 35; and status reports on: High-Dose-Rate Remote Afterloading programs, Implementation of the Quality Management Program and Misadministration rule, the NUREG entitled "Management of Radioactive Material Safety Programs at Medical Facilities," the National Academy of Science study to perform an external review of the medical use regulatory process, and Abnormal Occurrence Criteria. Additionally, the ACMUI was provided with updates on three proposed rulemakings: "Proposed Amendments to 10 CFR 35.75, Release of Patients Containing Radiopharmaceuticals or Permanent Implants"; "Proposed Amendments on Preparation, Transfer, and Use of Byproduct Material for Medical Use"; and "Administration of Byproduct material to Patients Who May Be Pregnant or Nursing."

The ACMUI will conduct a public meeting with the Commission early in February, to provide the Commission with information on a variety of issues associated with NRC's medical use program.

Questions about the ACMUI and its activities may be directed to Sally L. Merchant, at 301 504–2637.

MEDICAL WORKSHOP HELD IN REGION III

Parallel workshops were held in Chicago, Illinois, on September 21–22, 1993, to address topics such as the quality management rule and its implementation; the duties, responsibilities and supervision of medical radiation safety programs; and to briefly discuss changes to 10 CFR Part 20 that will directly affect medical licensees as of January 1, 1994. The purpose of these meetings was to inform medical licensees of recent changes in NRC regulation and philosophy and how these changes will affect radiation safety programs. Approximately 300 individuals from all eight regional Agreement and NonAgreement States, Region III, and the Office of Nuclear Material Safety and Safeguards (NMSS) attended.

One major complaint voiced by licensee representatives during the Quality Management Program (QMP) discussion was that the U.S. Nuclear Regulatory Commission did not provide a model program, as with other major rule changes. Sally Merchant, NMSS, explained that a model was not provided because QMP is a performance-based rule. Each licensee must develop a QMP that meets its own specific needs. A generic model program could not do this. Dr. Carl Paperiello, Director of the Division of Industrial and Medical Nuclear Safety, and other NRC staff members discussed NRC's view of the duties and responsibilities of the Radiation Safety Officer and stressed the importance of management oversight of the radiation safety program. Dr. Paperiello emphasized NRC's position that management is ultimately responsible for all licensed activities and must play an active rather than passive role in ensuring that policies and procedures are followed.

The workshop participants had opportunities to express individual points of view and to ask questions of the speakers and other NRC staff members.

QUALITY MANAGEMENT NOTES

The U.S. Nuclear Regulatory Commission recently initiated a "pilot" program to compare submitted Quality Management (QM) programs with their actual implementation in licensee facilities. Ten QM programs were selected, based on location (Regions I and III) and inspection cycle (inspections due). An augmented inspection team, consisting of regional inspectors, the QM coordinator from NRC's Headquarters, and the contractor reviewing the programs, visited each facility. In 9 of the 10 facilities visited, the team found that the implemented programs met the requirements of the QM rule more closely than did the submitted program. (In one case—a broadscope licensee—the written program did not meet the five objectives listed in the rule, nor was an adequate program implemented.) Based on this aforementioned limited sampling, it appears that many licensees have implemented more complete programs than were actually documented in their submitted QM programs. This finding is similar to the results of the pilot program conducted to provide a real-world test of the proposed rule, "Basic Quality Assurance Program, Records and Reports of Misadministrations or Events Related to the Medical use of Byproduct Material," published January 16, 1990. The QM "pilot" program also provided an opportunity for NRC staff, along with the contractor, to evaluate the procedures used by NRC inspectors in evaluating licensees' implementation of their QM programs.

During the last 3 months, NRC has conducted workshops and seminars for medical licensees on the topic of compliance with the QM rule. These workshops have focused on the content of the QM rule, Regulatory Guide 8.33, and the results of reviews of submitted QM programs, to date. Increased licensee understanding of the QM rule has resulted in an increase in the number of revised programs received by the regional offices. Licensees may modify their QM programs to increase the program's efficiency, provided the program's effectiveness is not decreased. Licensees are to submit modifications to their

QM programs, to the appropriate NRC Regional Office, within 30 days after making the modification.

Questions about QM requirements and programs should be directed to Sally L. Merchant, at 301 504–2637.

IT'S TIME TO IMPLEMENT REVISED PART 20

The Office of Nuclear Material Safety and Safeguards (NMSS) recently issued an Information Notice (IN 93–80) informing material licensees of the need to start planning immediately to implement the revised Part 20. The strongly worded IN reminded licensees that on January 1, 1994, the revised Part 20 becomes effective for all licensees. The IN noted that, "Licensees who have not yet prepared to implement the revised Part 20 are late. Licensees who are not even knowledgeable about the new regulations will have difficulty in meeting the January 1, 1994, implementation date and risk being out of compliance with the regulations once they become effective for all licensees." The IN encouraged licensees to take action before January 1, 1994, to develop procedures for implementing the revised Part 20.

The notice was sent to all material licensees and contained instructions to ensure that licensee management and radiation safety staff review the IN. It also noted that licensees have had over 2 years to prepare for the revised Part 20 regulations.

The IN stated that the revised Part 20 made fundamental changes in the standards for protection against radiation. As a result, these changes require corresponding changes in licensees' radiation protection programs. Licensees should look carefully at the new regulations and consider how their program and internal written procedures should be changed in order to be in compliance with the regulations by January 1, 1994. NRC encourages licensees to carefully review the regulations, associated regulatory guides, and related guidance documents, and to begin to prepare to implement the revised Part 20. An attachment to the IN provided phone numbers and addresses where licensees can obtain guidance documents regarding the revised Part 20.

NMSS issued the IN because of concerns, stemming from recent workshops with byproduct material licensees, that some licensees were not knowledgeable about the revised Part 20, even though the implementation date is so close. Licensees who have questions about the revised Part 20 may contact their regional office or the contacts listed in IN 93–80.

Note: In the publication of the revised 10 CFR Part 20, the NRC Operations number that is currently in 10 CFR Part 20 was inadvertently left out. The correction is being handled formally by publication in the *Federal Register* and also by this notice in the *NMSS Licensee Newsletter.* The Emergency Operations Center number is 301–951–0550. Collect calls to this number will be accepted if the caller is reporting a nuclear emergency.

ADVANCE NOTICE OF PROPOSED RULEMAKING TO ADDRESS SEWER RECONCENTRATION ISSUES

The U.S. Nuclear Regulatory Commission is considering whether modifications in 10 CFR Part 20 may be needed to address sewer reconcentration issues. As a result of several cases in which radionuclides were found to concentrate in sewer sludge, the 1990 revision to Part 20 included revised criteria for permitting release of radioactive material into sanitary sewers, as described in more detail in the article on sanitary sewage disposal in this issue. Since insoluble materials were involved in a number of these cases, the revised rule eliminated the option to release readily dispersible material unless it were biological material, such as laboratory animal carcasses, etc. Additionally, the release concentrations were lowered, along with the overall lowering of release limits for other effluents in Part 20. At the time the revised Part 20 was published, the Commission indicated that additional studies were underway to clarify the potential for human exposure. These studies were published in 1992 and demonstrated that, under certain conditions, the potential to exceed the public dose limit existed.

Since few licensees have implemented the revised Part 20, it may be too early to determine whether these changes are sufficient to prevent future incidents that could lead to public health effects. Currently, NRC has contracted with Pacific Northwest Laboratory to perform additional studies on possible mechanisms, in use today, at sewage treatment plants, that could lead to reconcentration of radionuclides. Concurrent with that effort, the staff is proposing to issue an advance notice of proposed rulemaking (ANPR) to address some policy issues associated with sewer releases. The policy issues addressed in the ANPR include questions soliciting information on the current regulations that specify the total quantity, form, and concentrations of material that can be released. It is anticipated that this notice would be published in the next few months.

SANITARY SEWERAGE RADIOACTIVE WASTE DISPOSAL

One of the major changes in the revised Part 20 is the modification of the regulations on the disposal of radioactive material into sanitary sewers. The new requirements in 10 CFR 20.2003, "Disposal by Release into Sanitary Sewerage," are less complicated to calculate and to determine compliance with, but are more restrictive in terms of what can be disposed of and in what concentrations.

The revised Part 20 clarifies the meaning of sanitary sewerage system and defines it in 10 CFR 20.1003. Sanitary sewerage includes a system of public sewers for carrying off waste water and refuse. It does not include septic tanks, leach fields, or sewage treatment facilities owned or operated by the licensee. Therefore, disposal into these excluded systems is not covered under 10 CFR 20.2003, or its associated Table 3 of Appendix B to 10 CFR 20.1001 – 20.2402.

Another significant change is that paragraph (a)(1) of 10 CFR 20.2003 requires the disposal material to be readily

soluble (easily dissolved), or if it is a biological, it can be readily dispersible. Non-dispersible or insoluble nonbiological materials are not permitted in sewer disposal, under the new regulations. Biological material pertains to material from living organisms such as plants and animals. The statements of consideration (56 FR 23360-23474) mentioned the allowance of disposal of ground animal tissue into a sanitary sewer system as a good method, compared with present alternatives.

Animal fats, if dispersible, would also be authorized under this provision. The prohibition of insoluble materials is to prevent the accumulation of this material in the sewer systems or reconcentrations at sewer treatment facilities, in light of the several past incidents where this has occurred.

The means of determining concentration and quantity disposal rate limits has been simplified, in that there is only a monthly average that need be determined, and an annual quantity limit, eliminating the additional daily concentrations and daily quantity limits of 10 CFR 20.303. Paragraph (a)(2) of 10 CFR 20.2003 requires that the quantity of licensed *or other* radioactive material, divided by the average monthly volume of water released by the licensee into the sewer (giving a concentration), does not exceed the concentration listed in Table 3 of Appendix B to 10 CFR 20.1001-2402. The majority of the isotopes listed have only one quantity in Table 3; that is because the category "non-soluble" material has been eliminated. A few isotopes have more than one quantity, but this is due to the metabolic differences caused by different chemical states of the same isotope; the few radionuclides with two Table 3 concentrations are all for soluble forms of the isotope. The derivations of these concentrations and assumptions made are explained in the introduction of Appendix B, under Table 3, "Sewer Disposal."

You may also notice that the concentrations in Table 2, Column 2, for water effluents, are an order-of-magnitude smaller. This reflects the dose basis used to calculate the concentrations — 0.05 rem, 10 times less than the basis for the sewer release concentrations.

Paragraph 20.2003(a)(3) stipulates requirements if more than one isotope is disposed of via the sanitary sewer, dictating use of the "sum of the fractions less than unity" rule. One must take every isotope concentration for the month, divide it by its limit concentration in Table 3 to get a fraction, then sum all the fractions. This sum must not exceed 1.

The total quantity that is allowed to be disposed of in the sewer system for the year is listed in 10 CFR 20.2003(a)(4). These quantities have not changed from 10 CFR 20.303. In a year, releases are not to exceed 5 curies of tritium, 1 curie of carbon-14, and 1 curie for all *other* radioactive material combined. Paragraph 20.2003(b) exempts excreta, from individuals undergoing medical treatment with radioactive material, from the limitations of quantity or concentrations.

It should be noted that the requirements of 10 CFR 20.2003(a)(1) through (4) must be met simultaneously; that is, the sewer disposal must be soluble (or dispersible biological), *and* must not exceed monthly concentration limits, and must not exceed annual total quantities.

In summary, the revised concentration limits for sewer disposal are more restrictive (smaller concentrations) than the old values of Table I, Column 2, quantities. The reduction of the new concentration from the old varies from isotope-to-isotope, for several reasons, but primarily because of the change in the internal dosimetry methodology used. This reduction in concentration and the further restriction of allowing only soluble material into the sewer system will hopefully eliminate some of the problems that have been identified, with the increased sophistication of sewer treatment facilities. Because of the increased concern with toxic hazards, sewer treatment facilities have been changing their methods of treating sewage, to meet environmental health and safety requirements. The sewer sludge can be concentrated and solidified as part of some facilities' treatment methodology

Over the past several years, the U.S. Nuclear Regulatory Commission has become aware of instances where radioactive material has been identified in concentrations above background at sewer treatment facilities, primarily because of treatment processes reconcentrating previously diluted material, and because of the particulate state of the isotope in question. The sanitary sewer concentration limits in the revised Part 20 and the allowance of only soluble radioactive material will decrease the potential of this occurrence. However, because of this past experience, and the submission by a sewage treatment facility of two petitions for license modification and one petition for rulemaking, NRC is pursuing research into existing physical and chemical processes of the treatment of sewage and their impact on reconcentration of radionuclides.

NRC VIEW OF THE USE OF ELECTRONIC DOSIMETERS

Electronic dosimeters consist of a radiation detector, such as a Geiger-Miller (GM)1 tube, connected to electronic circuitry that produces outputs in the form of dose rate and integrated dose readings, as well as providing the capability to produce an alarm at pre-set doses and dose rates. They were adopted for field use several years ago, and are rapidly gaining acceptance for a number of important reasons. They are sufficiently reliable and stable to be used as the dosimetry of record, to satisfy the U.S. Nuclear Regulatory Commission's personnel monitoring requirements. But unlike film and thermoluminescent dosimeters (TLDs), they do not require processing. And like self-reading dosimeters (SRDs), they provide real-time readings of accumulated dose. They, therefore, have the potential for replacing film, TLDS, SRDs, and alarming dosimeters, and combining all the functions previously performed by these systems into one unit. In addition, these systems can be used for access control into restricted areas. They can be programmed to deny access to any worker who is not authorized to enter a restricted area, and also to verify the worker's available dose before entry, to ensure it is sufficient to allow completion of his/her specified job without exceeding an administrative limit. The system can also be used to automatically update the worker's dose and other tracking records each time the worker exits the restricted area. Such systems,

therefore, provide the potential for significant improvements in access control, as well as better tracking of a worker's dose status and a reduction or elimination of the clerical burden of collecting and codifying large amounts of access control data.

Despite these advantages, the use of electronic dosimeters as the dosimetry-of-record system has met with objections. The objections stem from the fact that electronic dosimeters do not require processing, and that regulations and standards for dosimetry systems are directed at systems that require processing. Regulations and standards were, therefore, developed only for those systems that required processing. According to 10 CFR Part 20, dosimeters that require processing to determine the dose, and that are used by the licensee to show compliance with 10 CFR 20.1201, must be processed and evaluated by a dosimetry processor accredited by the National Voluntary Laboratory Accreditation Program (NVLAP). Accreditation involves testing of the dosimeters by an independent testing laboratory, and the testing methods and passing criteria are specified in American National Standards Institute (ANSI) N13.11. Film and TLDs, therefore, are subject to minimum performance criteria before they can be accepted as dosimetry of record. The industry, in effect, had decided to control the quality of the data through controlling the processor. Electronic dosimeters, since they do not require processing, are not subject to the performance criteria specified in ANSI N13.11. In fact, there are currently no performance criteria directly applicable to electronic dosimeters.

Some workers in the field believe that these concerns, although valid, are insufficient to eliminate such a potentially revolutionary technology. NRC has stated that the use of electronic dosimeters as dosimetry of record is acceptable, provided programs are established to ensure the reliability of the systems and the accuracy of the data, and that specific regulations do not prohibit their use (10 CFR 34.33 and 10 CFR 39.65). The elements of such a program include: calibrations that are traceable to the National Institute of Standards and Technology (NIST); function checks before use; a comprehensive quality assurance program; administrative oversight to ensure the accuracy and security of the data; and specialized and highly trained personnel, to operate and service the systems. Such a program is prohibitively expensive to implement for the smaller licensees, and it is expected that only large operations, such as nuclear power stations, will be able to use this technology. This has, in fact, already occurred, and many nuclear power stations now operate electronic dosimetry systems in parallel with their TLD systems. Such operation provides experience in using these systems and also provides data on their reliability under field conditions. It is also not unlikely that electronic dosimeters may be offered in the future as part of a dosimetry service similar to that used with film and TLDs, thus making these dosimeters available to the smaller licensees. In the meantime, NRC is developing guidance on the use of electronic dosimeters, in the form of an health physics position or an information notice. An ANSI standard is also being contemplated, but this is many years away.

ATTENTION, REGION I MEDICAL LICENSEES, 1-DAY WORKSHOP ON MEDICAL QUALITY MANAGEMENT RULE AND NEW PART 20

The Office of Nuclear Material Safety and Safeguards will be offering a 1-day workshop on the Medical Quality Management Rule and New Part 20 for Region I medical licensees on Tuesday, April 19, 1994, from 8:00 a.m. to 5:00 p.m. This workshop, which has been previously offered in other U.S. Nuclear Regulatory Commission regions, will be presented by Sally Merchant, NMSS Quality Management (QM) Coordinator, and Cynthia Jones, Section Leader, NMSS Operations Branch. A meeting room for 200 participants is reserved at the Sheraton Valley Forge Hotel. The workshop may be repeated on Wednesday, April 20th, and Thursday, April 21st, if demand for the workshop exceeds capacity. It is currently planned that a nominal charge of $10 per attendee will be collected at the door, to help defray workshop costs. For reservations or information, licensees should contact Judy Joustra, 215-337-5257, or Jim Dwyer, 215-337-5309.

INFORMATION NOTICES AND BULLETINS ISSUED

September 1993 (not listed in the last edition) and October and November 1993.

Note that these are only summaries of information notices and bulletins. If one of these publications appears relevant to your licensed operation and you have not received it, we recommend that you obtain the notice from the U.S. Nuclear Regulatory Commission contact listed here, or speak with the contact about its provisions.

A. "Radiography Events at Operating Power Reactors," IN 93-69, September 2, 1993
Technical Contacts:
William G. Snell, RIII 708-790-551
John Carrico, NMSS 301-504-2634

This notice informs licensees about three events involving radiography at operating nuclear power plants. During three events in late 1992 and early 1993, employees at nuclear reactor facilities circumvented controls established to ensure the safe conduct of radiography. In each event, licensee personnel made unauthorized entries into areas where radiography was either just about to occur or was in progress. No significant exposures resulted from these events; however, such events indicate a potential for significant exposures.

B. "Criminal Prosecution of Nuclear Suppliers for Wrongdoing," IN 93-73, September 15, 1993
Technical Contacts:
Keven Ramsey, NMSS 301-504-2534
Stephen Alexander, NRR 301-504-2995

This notice provides information about two cases of wrongdoing that the U.S. Nuclear Regulatory Commission staff referred to the U.S. Department of Justice. Licensees are also reminded of the penalties that could result from the intentional violation of Federal regulatory requirements and criminal statutes.

C. "Human Errors That Result in Inadvertent Transfers of Special Nuclear Material at Fuel Cycle Facilities," IN 93-77, October 4, 1993
Technical Contact:
Marc Klasky, NMSS 301-504-2504

This information notice is to alert addressees to possible sampling program deficiencies that may arise at nuclear fuel cycle facilities because of the human factors component of nuclear criticality sampling programs. Licensees were asked to review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems.

D. "Implementation of the Revised 10 CFR Part 20," IN 93-80, October 8, 1993
Technical Contacts:
Joseph De Cicco, NMSS 301-504-2067
Scott Moore, NMSS 301-504-2514

This notice was prepared to ensure that licensees prepare for the revised Part 20 immediately. The implementation date of this revised rule is January 1, 1994.

E. "Identification of Isotopes in the Production and Shipment of Byproduct Material at Non-Power Reactors," IN 93-86, Oct. 29, 1993
Technical Contacts:
A. Adams, Jr., NRR 301-504-1127
C. Cox, RIII 301-790-5298

This notice provides an alert to addressees about a problem with the identification of isotopes in byproduct material produced and shipped at non-power reactors. A task force reviewed shipping information for byproduct material produced in a reactor. The task force determined that less than 90 percent of the total sample activity was reported on the shipping papers, for 17 specific isotopes reviewed.

REGULATORY GUIDES ISSUED
September 10, 1993 - November 30, 1993

No final or draft guides were issued, during this period, that pertain to Office of Nuclear Material Safety and Safeguards licensee programs.

RULES PUBLISHED
September 10, 1993 - November 30, 1993

FINAL RULES

- List of Approved Spent Fuel Storage Casks; Additions
  1. Published: October 5, 1993, 58 FR 51762
  2. Contact: Gordon Gundersen 301-492-3803
- Export and Import of Nuclear Equipment and Material; Export of Highly Enriched Uranium
  1. Published: October 28, 1993, 58 FR 57962
  2. Contact: Elaine Hemby 301-504-2341

PROPOSED RULES

- Interim Storage of Spent Fuel in an Independent Spent Fuel Storage Installation; Site-Specific License to a Qualified Applicant (Extension of Comment Period)
  1. Published: September 14, 1993, 58 FR 48004
  2. Contact: William Reamer 301-504-1640
- Notification of Events at Independent Spent Fuel Storage Installations and the Monitored Retrievable Storage Installation
  1. Published: September 14, 1993, 58 FR 48004
  2. Contact: William Reamer 301-504-1640
- Restoration of the Generic Exemption from Annual Fees for Nonprofit Educational Institutions
  1. Published: September 29, 1993, 58 FR 50859
  2. Contact: C. James Holloway, Jr. 301-492-4301
- Annual Physical Fitness Performance Testing for Tactical Response Team Members, Armed Response Personnel, and Guards at Category I Licensees
  1. Published: October 6, 1993, 58 FR 52035
  2. Contact: Harry Tovmassian 301-492-3634
- Uranium Mill Tailings Regulations; Conforming NRC Regulations to EPA Standards
  1. Published: November 3, 1993, 58 FR 58657
  2. Contact: Catherine Mattsen 301-492-3638

MEMORANDUM OF UNDERSTANDING

- Memorandum of Understanding between the U.S. Nuclear Regulatory Commission and the U.S. Department of Health and Human Services, Food and Drug Administration
  1. Published: September 8, 1993, 58 FR 47300
  2. Contact: James Smith 301-504-2613

A SAMPLING OF SIGNIFICANT EVENTS REPORTED TO NRC BY NUCLEAR MATERIAL LICENSEES

A. NRC LICENSEES

Event 1: Medical Sodium Misadministration at Ingham Medical Center, in Lansing, Michigan

Date Reported: May 1992

Licensee: Ingham Medical Center, Lansing, Michigan

In May 1992, a patient received a whole-body scan using iodine-131 (I-131) instead of a thyroid scan, which uses technetium-99m. The misadministration occurred

because of an apparent misunderstanding during a telephone conversation between the referring physician's office and a technologist at Ingham Medical Center.

On September 9, 1993, the U.S. Nuclear Regulatory Commission issued a notice of violation and proposed imposition of a fine to the licensee. The licensee was cited for failing to have the physician authorized to use radioactive materials prepare a written directive, as required for the dosage of I-131 involved in a whole-body scan, and for failing to follow the hospital's written instruction that I-131 whole-body scans be used only for patients who had their thyroids removed. Since the patient in this case had an intact thyroid, the whole-body I-131 scan should not have been performed.

A SAMPLING OF SIGNIFICANT ENFORCEMENT ACTIONS AGAINST MATERIAL LICENSEES

One way to avoid regulatory problems is to be aware of enforcement problems others have faced.

A. CIVIL PENALTIES AND ORDERS

1. Babcock and Wilcox Company, Lynchburg, Virginia Supplement VI, EA 93-012

   A Notice of Violation and Proposed Imposition of Civil Penalties was issued April 6, 1993, to emphasize the importance of appropriate management attention to, and oversight of, the nuclear criticality safety program, to ensure that operational activities are conducted safely and in accordance with requirements. The action was based on a number of violations concerning the failure to establish or adhere to nuclear criticality safety limits and controls, and the failure to conduct audits and correct audit findings.

2. Capital Materials Testing, Inc., Ballston Spa, New York Supplement VI, EA 92-203

   A Notice of Violation and Proposed Imposition of Civil Penalty was issued November 20, 1992, to emphasize (1) the importance of appropriate management attention to regulatory responsibilities, to ensure that all personnel strictly adhere to all regulatory requirements, and (2) the need to ensure that all corrective actions are properly implemented and are long-lasting. The action was based on a violation involving the failure to adequately perform a survey of a radiographic device after the completion of a radiography operation.

3. Eastern Testing and Inspection, Inc., Thorofare, New Jersey Supplement VI, EA 92-136

   A Notice of Violation and Proposed Imposition of Civil Penalty was issued September 17, 1992, to emphasize the importance of adequate attention to, and oversight of, the radiation safety program. The action was based on, in part, the failure to (1) survey the entire circumference of an iridium-192 exposure device after each exposure, (2) perform audits at the required quarterly frequency for radiographers, and (3) calibrate pocket dosimeters and alarm rate meters at intervals not to exceed 1 year.

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WASHINGTON, D.C. 20555-0001

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