NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

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NMSS Licensee Newsletter
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NUREG-1556, "CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES"

In 1998, the Division of Industrial and Medical Nuclear Safety, in the Office of Nuclear Material Safety and Safeguards, used a Business Process Redesign technique to redesign its materials licensing process. One of the elements of the new process was an aggressive program to update and consolidate numerous guidance documents into a NUREG series of subject-specific documents over a 3-year period. NUREG-1556, containing Volumes 1-20, was developed and entitled, "Consolidated Guidance about Materials Licenses." These NUREGs are for use by the U.S. Nuclear Regulatory Commission (NRC), Agreement State regulators, and licensees/applicants.

We are pleased to announce that, as of December 2000, all 20 NUREGs, with the exception of Vol. 9, "Program Specific Guidance about Medical Use Licenses," have been published in final form. Volume 9 will not be issued until publication of the final 10 CFR Part 35 rulemaking. The Commission approved Part 35 in a Staff Requirements Memorandum dated October 23, 2000; it will be published after Office of Management and Budget approval of the information collection requirements. The development of the NUREG-1556 series supports the performance goals of maintaining safety, protection of the environment, and the common defense and security, as well as reducing unnecessary regulatory burden.

We encourage licensees/applicants and Agreement State regulators to use the NUREG-1556 guidance documents in preparing new and renewal applications. We believe that use of these NUREGs will help the NRC staff make timely and thorough reviews of these applications. It is particularly important that licensees and applicants use these documents, since they supersede much of the guidance previously used for licensing.

These NUREGs are available electronically by visiting NRCs Home Page (http://www.nrc.gov/NRC/NUREGS/indexnum.html #-1-3). A list of these NUREGS follows.

Vol. No.	Volume Title	When Published
1	"Program-Specific Guidance about Portable Gauge Licenses"	05/97
2	"Program-Specific Guidance about Radiography Licenses"	08/98
3	"Applications for Sealed Source and Device Evaluation and Registration"	07/98
4	"Program-Specific Guidance about Fixed Gauge Licenses"	10/98
5	"Program-Specific Guidance about Self-Shielded Irradiators"	10/98
6	"Program-Specific Guidance about 10 CFR Part 36 Irradiators"	01/99
7	"Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope"	12/99
8	"Program-Specific Guidance about Exempt Distribution Licenses"	09/98
9	"Program-Specific Guidance about Medical Use Licenses"	Not issued at this time
10	"Program-Specific Guidance about Master Material Licenses"	12/00
11	"Program-Specific Guidance about Licenses of Broad Scope"	04/99
12	"Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution"	12/00
13	"Program-Specific Guidance about Commercial Radiopharmacy Licenses"	09/99
14	"Program-Specific Guidance about Well Logging, Tracer, and Field Flood Study Licenses"	06/00
15	"Guidance about Changes of Control and about Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses"	11/00
16	"Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees"	12/00
17	"Program-Specific Guidance about Licenses for Special Nuclear Material of Less Than Critical Mass"	11/00
18	"Program-Specific Guidance about Service Provider Licenses"	11/00
19	"Guidance for Agreement State Licensees Proposing to Work in NRC Jurisdiction (Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters) and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)"	12/00
20	"Guidance about Administrative Licensing Procedures"	12/00

(Contact: Carrie Brown, 301-415-8092; e-mail:cxb@nrc.gov)

RECENT POLICY CHANGES IN THE URANIUM RECOVERY LICENSING PROGRAM

Background

U. S. Nuclear Regulatory Commission (NRC) staff prepared four Commission Papers, in 1999, to address uranium recovery issues. One Commission Paper (SECY-99-011, "Draft Rulemaking Plan: Domestic Licensing of Uranium and Thorium Recovery Facilities—Proposed New 10 CFR Part 41") addressed the need to revise and update uranium recovery regulations, particularly with respect to *in situ* leach (ISL) facilities, and recommended the initiation of rulemaking to create a new Part 41 specific to uranium recovery. The other three Commission Papers addressed issues raised by the National Mining Association (NMA) in its April 1998 paper, "Recommendations for a Coordinated Approach to Regulating the Uranium Recovery Industry." The first of those papers (SECY-99-012, "Use of Uranium Mill Tailings Impoundments for the Disposal of Other than 11e.(2) Byproduct Material, and Reviews of Applications to Process Material Other than Natural Ore") discussed the disposal of radioactive waste, other than byproduct material defined in section 11e. (2) of the Atomic Energy Act (AEA) of 1954, as amended, in mill tailings impoundments, and the processing of material, other than natural ore, for source material at licensed uranium mills. The second of those papers (SECY-99-013, "Recommendations on ways to Improve the Efficiency of NRC Regulation at in Situ Leach (ISL) Uranium Recovery Facilities") discussed the regulation of ground water at ISL sites and the issue of which waste streams at ISL facilities come under NRC regulatory jurisdiction as 11e.(2) byproduct material. The last paper (SECY-99-277, "Concurrent Jurisdiction of Non-Radiological Hazards of Uranium Mill Tailings") addressed the issue of concurrent jurisdiction (with States that do not have Agreement State regulatory authority for 11e. (2) material under section 274 of the AEA) of the non-radiological hazards of uranium mill tailings.

In July and August 2000, the Commission issued Staff Requirements Memoranda (SRMs) on all these issues. The decisions and directions, in these SRMs, and the staff actions in response, were discussed in Regulatory Issue Summary 2000-23, November 30, 2000 (sent to all holders of materials licenses for uranium and thorium recovery facilities) and are summarized in sections that follow.

Part 41 Rulemaking (SECY-99-011)

The Commission approved the staff's recommendation to provide a draft Rulemaking Plan (RP), for comment, to the Agreement States, with the preferred option being the creation of a new Part 41 dedicated to uranium recovery regulation. The Commission directed the staff to revise the draft RP to reflect the Commission's guidance in the other uranium recovery SRMs.

On September 11, 2000, the staff transmitted the draft RP to all States for comment. NRC has received comments on the draft RP, which included information on the current depressed state of the uranium industry, and a recent proposal, from the National Materials Program Working Group, to pilot-test its rulemaking.

In the time since this action was initiated, the uranium industry has changed sufficiently to warrant revisiting the previous alternatives proposed for issuing regulations for the industry. The price of uranium has dropped by about half, over the last 3 years, and is not expected to increase soon. Presently, there are only five NRC-licensed facilities that produce uranium. There have not been any applications for a new license since 1998 and no new applications are anticipated for several years. Based on the current state of the uranium recovery industry and on the additional information received in comments, the staff has presented to the Commission other alternative approaches for updating the regulatory regime for uranium recovery. The Commission is considering holding a public meeting, in mid-April, to receive input on the issues related to uranium recovery regulations.

Disposal of Non-11e.(2) Byproduct Material in Tailings Impoundments (SECY-99-012)

In 1995, the staff published guidance, in the *Federal Register* (60 FR 49296), for the disposal, in uranium mill tailings impoundments, of radioactive material that is not byproduct material, as defined in section

11e.(2) of the AEA. The guidance consisted of 10 items that had to be met, for the staff to approve a proposed disposal of non-11e.(2) byproduct material in a uranium mill tailings impoundment. In its 1998 white paper, the NMA argued that the requirements were too restrictive, pointing out that no requests for such disposals have been made since the guidance was issued. The Commission, in the SRM for SECY-99-012, approved an option that would allow more flexibility in permitting non-11e.(2) byproduct material to be disposed of in tailings impoundments. To comply with the direction in the SRM, the staff is revising the 1995 guidance in the following manner:

- The staff will remove the prohibitions, found in items 2, 4, and 5, regarding non-AEA radioactive material and material subject to regulation under other legislative authorities, such as the Toxic Substance Control Act (TSCA) or the Resource Conservation and Recovery Act (RCRA).

- The staff will add a requirement to obtain approval, from the appropriate regulators of TSCA, RCRA, and non-AEA radioactive material, for disposal of such material in the tailings impoundment.

- The staff will revise the requirement, in item 8, for approval by Low-Level Waste Compacts, to allow for the situation in which material proposed for disposal does not fall under the jurisdiction of Low-Level Waste Compacts (e.g., radioactive material not regulated under the AEA).

Processing of Material Other Than Natural Uranium Ores (SECY-99-012)

In 1995, the staff published its position and guidance, in the *Federal Register* (60 FR 49296), on the use of uranium feed material other than natural ores (alternate feed material), in uranium mills. The guidance identified three determinations that the staff had to make to approve an alternate feed request. The third determination, whether the ore is being processed primarily for its source material content, generated considerable controversy. This determination was required to address the concern that wastes that would otherwise have to be disposed of as radioactive or mixed waste would be proposed for processing at a uranium mill primarily to be able to dispose of it in the tailings pile as 11e.(2) byproduct material. This determination was essentially a determination of the motives of the mill operator in requesting approval of a specific stream of alternate feed material. In many cases it involved questioning the financial aspects of acquiring and processing the alternate feed material, and selling the resultant uranium product.

The Commission, in the SRM for SECY-99-0012, directed the staff to allow processing of alternate feed material without inquiry into a licencee's motives, and referred to a Commission decision (CLI-00-01 51 NRC 9) on a specific instance of proposed processing of alternate feed, that was brought before the Atomic Safety Licensing Board and then appealed to the Commission. The Commission also addressed the second determination in the 1995 guidance (i.e., whether the feed material contains hazardous waste). It directed the staff to allow more flexibility with regard to this issue consistent with its direction to the staff on the disposal of non-11e.(2) byproduct material in tailings piles.

To comply with the SRM, the staff is revising the 1995 position and guidance in the following manner:

- The staff will modify the prohibition, in item 2, on feed material containing hazardous waste, to allow such feed material provided that the licensee obtains approval of the U.S. Environmental Protection Agency (EPA) (or the State) and a commitment from the long-term custodian to take the tailings after site closure.

- The staff will revise the manner in which it determines whether the ore is being processed primarily for its source material content to focus on the product of the processing, and eliminate any inquiry into the licensee's motives for the processing.

Classification of Liquid Wastes at ISL Facilities (SECY-99-013)

Before 1995, the staff practice for addressing the disposal of evaporation pond sludges relied on a broad reading of the definition of 11e.(2) byproduct material. This broad reading only addressed discrete surface wastes capable of controlled disposal and did not distinguish between wastes generated at

various phases of an ISL operation. All waste materials generated during ISL operations and ground-water restoration activities were designated 11e.(2) byproduct material and disposed of at licensed uranium mill tailings impoundments in accordance with 10 CFR Part 40, Appendix A, Criterion 2.

The staff issued two guidance documents in 1995 to address issues raised by the industry in the uranium recovery program. The first, "Staff Technical Position on Effluent Disposal at Licensed Uranium Recovery Facilities" (hereinafter, the effluent guidance), was intended to provide uranium recovery licensees with flexibility regarding the disposal of various types of liquid effluents generated during the operation of their facilities. In issuing this guidance, the staff took a more narrow view of the definition of 11e.(2) byproduct material. It differentiated between the various waste waters generated during ISL operations on the basis of their origin and whether uranium was extracted for its source material content during that phase of the operation. Waste waters and the associated solids produced during the uranium extraction phase of site operations, called "production bleed," were classified as AEA section 11e.(2) byproduct material and therefore subject to regulation by NRC. Conversely, waste waters and the resulting solids produced after uranium extraction (i.e., during ground-water restoration activities) are classified as "mine waste waters," and therefore are subject to regulation by individual States under their applicable mining programs. These wastes are considered naturally occurring radioactive material (NORM). However, because licensees often dispose of waste waters from uranium extraction and post-extraction activities in the same evaporation ponds, the resulting solids are a commingled waste consisting of 11e.(2) byproduct material and sludges derived from mine waste water.

In the second guidance document, "Final Revised Guidance on Disposal of Non-Atomic Energy Act of 1954, Section 11e.(2) Byproduct Material in Tailings Impoundments" (hereinafter, the disposal guidance), the staff identified 10 criteria that licensees should meet before NRC could authorize the disposal of AEA material other than 11e.(2) byproduct material in tailings impoundments. One of these criteria prohibited the disposal of radioactive material not covered by the AEA, including NORM (see earlier discussion for policy revisions). This criterion was intended to avoid the possibility of dual regulation of the radioactive constituents in the impoundments, since individual States are responsible for radioactive materials not covered by the AEA.

The industry expressed concerns, in NMA's white paper, that, taken together, these two guidance documents leave no option for the disposal of radioactively contaminated sludges from ISL evaporation ponds. The reason for this concern is that the 11e.(2) byproduct material was commingled with a NORM waste, which is prohibited from disposal in a tailings impoundment by the disposal guidance. The industry contends that the staff's waste classification, based on the origin of the waste water (i.e., from the extraction or restoration phase) at an ISL facility, makes the disposal of such sludges in a mill tailings impoundment, as required under Criterion 2 of Part 40, Appendix A, impossible—even though the sludges derived from waste waters produced throughout a facility's life cycle are physically, chemically, and radiologically identical.

The staff recommended several options, in SECY-99-013, for addressing the industry's concerns. The Commission determined that all liquid effluents at ISL uranium recovery facilities are 11e.(2) byproduct material. NRC takes the position that any waste water generated during or after the uranium extraction phase of site operations, and all evaporation pond sludges derived from such waste waters, are classified as 11e.(2) byproduct material. The staff will make no legal distinction among the waste waters produced at different stages in a facility's life cycle.

Ground-water Issues at ISL Facilities (SECY-99-013)

Over the past several years, the industry has argued that NRC's regulation of ground water at ISLs is duplicative of the ground-water protection programs required by the Safe Drinking Water Act (SDWA), as administered by EPA or EPA-authorized States. EPA and the States protect ground-water quality through the Underground Injection Control (UIC) program, under the SDWA. The States often require additional measures in the UIC permitting that are more stringent than the Federal program. Additionally, NMA also had argued that NRC did not have authority to regulate ground water at ISLs.

The industry's preferred approach for addressing dual regulation in the wellfield is for NRC to determine that it does not have jurisdiction in the wellfield. NRC's position on its authority and jurisdiction over ISL operations is that NRC does have jurisdiction over ground water in the wellfield. However, to address the industry's dual regulation concerns, staff requested that the Office of the General Counsel (OGC) determine whether NRC could rely on the actual (or expected) existence of a permit, issued by EPA or an EPA-authorized State, under the UIC program, as a basis for NRC to withdraw from active regulation of the ground water at ISL facilities currently under its jurisdiction. OGC concluded that the Commission could exercise its discretion and rely on the UIC permit for the protection of ground water. NRC would still retain jurisdiction over the wellfield and ground water, under the Agency's AEA authority, but would simply defer active regulation to EPA or the EPA-authorized State, not unlike the way transportation issues are addressed with the Department of Transportation.

In the SRM for SECY-99-013, the Commission approved the staff continuing discussions with EPA and appropriate States to determine the extent NRC can rely on the EPA UIC program for ground-water protection issues, thereby potentially minimizing NRC review of ground-water protection issues at ISL facilities. In the interim, it is recognized that NRC/EPA dual regulation of the ground water at ISL facilities will continue until such time that NRC can defer to EPA's UIC program.

Discussions between NRC and EPA began in late 2000, and discussions with the appropriate States should begin by mid-2001.

In February 1998, staff institutionalized its review process for ISLs, including a detailed evaluation of ground-water activities, in a draft Standard Review Plan (draft SRP) for ISL facility license applications (NUREG-1569), that was published for public comment. After the comment period, staff held a public workshop on the SRP to discuss the issues raised. The staff intends to use the draft SRP in licensing reviews until any rulemaking for a new Part 41 (SECY 99-011) has been completed and NUREG-1569 is finalized.

Concurrent Jurisdiction of Non-Radiological Hazards of Uranium Mill Tailings (SECY-99-277)

In 1980, the staff considered the issue of whether the Uranium Mill tailings Radiation Control Act (UMTRCA) preempts a non-Agreement State's authority to regulate the non-radiological hazards associated with 11e.(2) byproduct material and concluded that it did not. The NRC legal staff concluded that NRC and the State exercised this authority concurrently. As a result, the staff has followed the practice of sharing jurisdiction of the non-radiological hazards with States. In its 1998 white paper, the NMA argued that the 1980 staff legal analysis interpreted UMTRCA incorrectly. The Commission, in the SRM for SECY-99-0277, disapproved the staff's recommendation to formally adopt the staff practice. Rather, the Commission determined that NRC has exclusive jurisdiction over both the radiological and non-radiological hazards of 11e.(2) byproduct material.

As a result of this decision, the staff will implement its exclusive authority over the non-radiological hazards of 11e.(2) byproduct material and not recognize State authority in this area.

(Contacts: Myron Fliegel, 301-415-6629; e-mail: mfh1@nrc.gov;
Dan Gillen, 301-415-7295; e-mail: dmg2@nrc.gov).

PRIVACY INFORMATION IN LICENSEE DOCUMENTS

Occasionally, a licensee will submit, to the U.S. Nuclear Regulatory Commission (NRC), license applications, event reports, and other documents, including personal information on individuals. Documents coming into NRC are captured electronically or scanned into NRC's automated Agencywide Documents Access and Management System and are normally made widely available, both within NRC, and to the public. An effort is made to screen these documents for material that should not be disseminated, but it is sometimes not possible to screen large documents that have personal identifying information, such as names, addresses, telephone numbers, Social Security Numbers or other identifying numbers, personnel information, or medical records. Such

information should not be included in reports to NRC unless it is relevant to and necessary for Agency action. Any such information that is included should be clearly marked and accompanied by a request to treat the information as exempt from public disclosure under 10 CFR 2.790(a)(6). A 10 CFR 2.790 affidavit is not required where Exemption 6 is being claimed. However, a bracketed proprietary version and a nonproprietary version, with the proprietary information blacked out, are required. Before formal use of the material, NRC will determine whether the information is exempt from disclosure and notify the licensee, by letter, of the staff's determination.

(Contact: Paul Goldberg, 301-415-7842; e-mail: pfg@nrc.gov)

DUAL-PURPOSE INTERIM STORAGE/ TRANSPORTATION CASKS—THE STATUS

In the late 1970s and early 1980s, the need for alternative methods for spent fuel storage was recognized when pools at many nuclear power reactors began to fill up with stored spent fuel. Utilities began looking at options for increasing spent fuel storage capacity. One option for increasing on-site storage capacity is storage in U.S. Nuclear Regulatory Commission (NRC)-approved dry storage cask systems. These systems provide safe storage for spent fuel assemblies, in a sealed canister that is then placed in a storage overpack. The filled canister, along with its storage overpack, is a dry cask storage system that provides above-ground interim storage for spent fuel. These dry cask storage systems are located in an independent spent fuel storage installation (ISFSI). As of February 2001, 19 sites have opted to store spent fuel in an ISFSI. Such storage may be either at the reactor site or another NRC-approved location. Although the spent fuel may be stored in wet or dry ISFSIs, all but one ISFSI store the spent fuel in dry casks.

Anticipating the availability of a geologic repository for disposal of the Nation's spent fuel, utilities began working with cask designers on the development of a cask system that could be used both to store the spent fuel, on an interim basis, while the repository was being built, and to transport the spent fuel to the repository. Such cask systems are called "dual-purpose" cask systems.

Dual-purpose cask systems generally consist of three main parts: the inner canister, a storage overpack, and a transport overpack. The spent fuel is initially placed into the inner canister, which is filled with helium and sealed. This sealed inner canister is then placed into the storage overpack for interim storage at an ISFSI. This storage cask system is evaluated against the 10 CFR Part 72 requirements, as well as the review guidance and acceptance criteria for interim storage described in NRC's "Standard Review Plan for Dry Cask Storage Systems," NUREG-1536. NUREG-1536 may be found on the NRC web site at: http://www.nrc.gov/NRC/NUREGS/SR1536/index.html.

When the licensee decides to ship the spent fuel away from the ISFSI, it can transfer the sealed inner canister containing the spent fuel out of the storage overpack into the transport overpack. This transport cask system configuration is evaluated against the design requirements of 10 CFR Part 71 and the review guidance and acceptance criteria for spent fuel transportation described in NRC's "Standard Review Plan for Transportation Packages for Spent Nuclear Fuel," NUREG-1617. NUREG-1617 may also be found on NRC's web site at: http://www.nrc.gov/NRC/NUREGS/SR1617/index.html.

Thus far, NRC has approved five dual-purpose cask systems for use. They are the NAC-MPC/NAC-STC cask system; the NUHOMS-24P/NUHOMS MP-187 cask system; the Holtec Hi-Storm/Holtec Hi-Star-100 cask system; and most recently, the TN-68/TN-68 cask system. Four more dual-purpose cask systems are in various stages of NRC review.

(Contact: Patricia Eng, 301-415-8577; e-mail: ple@nrc.gov)

OPERATIONAL EXPERIENCE

The U.S. Nuclear Regulatory Commission (NRC) is providing a summary of these events to inform licensees of conditions they may encounter and of actions that may be taken to deal with them.

Events Involving Damage to I-125 Brachytherapy Seeds during Use of a Popular Seed Implant Applicator.

NRC has been notified of four incidents involving Iodine-125 (I-125) brachytherapy seeds being damaged during the use of a cartridge (magazine) with a seed implant applicator.

Two separate licensees experienced the following incident. On completion of a brachytherapy implant, unused seeds from the procedure were being unloaded from the cartridge into a storage container. After unloading, a survey performed on the cartridge showed that all the seeds had not been removed. An inspection of the unloaded seeds and the cartridge found that one seed had been sheared in half. One portion of the seed was left in the cartridge and another was unloaded with the others. All seeds were inspected before loading the cartridge, with no irregularities noted. It is suspected that the damage occurred during the process of loading the seeds into the cartridge.

In the third instance, an I-125 seed broke—while still in the applicator—during a prostate implant procedure. After several seeds were implanted in the patient, one seed in the magazine became jammed as the physician attempted to push the seed from the magazine into the applicator. The handle of the applicator would not move and the magazine was stuck in the applicator. After the procedure, the magazine was forcibly removed from the applicator. There should have been nine seeds left in the magazine, but only eight were found. Part of the ninth seed was found at the tip of the stylet, and the other piece of the seed was found in the magazine cartridge channel.

The fourth event occurred during a brachytherapy implant procedure. The last seed in a cartridge became jammed while the magazine was still attached to the applicator. Some force was required to remove the magazine from the applicator. On inspection, the jammed cartridge was discovered to contain half of the final seed. The partial seed was removed and found to be severed. The other half of the seed was not found.

Based on NRC's review of these events, two possible causes resulted in sheared or cut seeds: 1) human error in loading the cartridge; and 2) malfunction of the cartridge/magazine when attached to the applicator. Problems involving brachytherapy seeds and the applicator mechanism can be prevented by careful attention during preparation of seed loading and use of the magazine and applicator.

(Contact: Linda Psyk, 301-415-0215; e-mail: lmp1@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS

Detailed information about these enforcement actions can be accessed via the U. S. Nuclear Regulatory Commission's (NRC's) homepage [http://www.nrc.gov/OE/]. Click on "Enforcement Actions." Cases are listed alphabetically. To access the complete enforcement action, click on the highlighted text after the name of the case.

Gauge

Alfonso DeLeo, Jr., Ardmore, Pennsylvania, EA 99-057 & EA 99-217

On October 23, 2000, the licensee transferred his gauges to an authorized recipient. In response, NRC terminated the license on November 9, 2000, and on December 26, 2000, NRC withdrew civil penalties that had been issued to the licensee in 1999 for willful unauthorized possession of two nuclear density gauges.

Medical

Temple University Hospital, Philadelphia, Pennsylvania, EA 00-156

On October 19, 2000, a Notice of Violation and Proposed Imposition of Civil Penalty, in the amount of $8,800, was issued for a Severity Level II violation based on discrimination against a former Nuclear Medicine Technologist for raising safety concerns.

Radiography

NDT Services, Inc. (NDTS) Caguas, Puerto Rico, EA 00-031

On October 17, 2000, a Notice of Violation was issued for a Severity Level I violation based on multiple failures of two former Radiation Safety Officers to ensure that radiation safety activities were performed in accordance with approved procedures and regulatory requirements. Discretion was exercised pursuant to Section VII.B.6 of the Enforcement Policy, and a civil penalty was not proposed because NDTS transferred all licensed material to authorized recipients; NDTS is no longer conducting business on licensed activities, and it has requested that the license be terminated.

Testing Technologies, Woodbridge, Virginia, EA 00-231

On November 14, 2000, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $5500 was issued. The action was based on a Severity Level III problem involving the failure to: (1) limit unrestricted area doses to less than 20 microsievert (2 millirem) in any 1 hour; (2) post each radiation and high radiation area with the appropriate sign; and (3) perform surveys necessary to demonstrate compliance with the regulations and to evaluate the radiological hazards present.

Other

Oklahoma State University, Stillwater, Oklahoma, EA 00-203

On December 7, 2000, a Notice of Violation was issued for a Severity Level III violation associated with the use of licensed material (tritiated thymadine) in an unapproved and unauthorized location. Although a civil penalty would normally be proposed by the assessment process, NRC exercised discretion and did not propose a penalty because of the licensee's corrective actions and the low risk associated with the small amount of radioactive material.

Mallinckrodt, Inc., Harrisburg, Pennsylvania, EA 00-180

On October 4, 2000, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2750 was issued for violations that occurred at a Mallinckrodt, Inc., radiopharmacy in Harrisburg, Pennsylvania. The action was based on the failure to control the occupational dose to the skin, or to any extremity of an individual, below the annual dose limit of 500 millisieverts (50 rems) shallow-dose equivalent, and the failure to make adequate surveys to assure compliance with 10 CFR 20.201.

Mallinckrodt, Inc., Maryland Heights, Missouri, EA 00-178

On December 21, 2000, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $125,000 was issued for a Severity Level I problem that occurred at Mallinckrodt, Inc. manufacturing facility in Maryland Heights, Missouri. The Notice of Violation was based on numerous failures to: (1) control activities to keep occupational doses to workers within regulatory limits; (2) use procedures and engineering controls to maintain doses as low as is reasonably achievable; and (3) make necessary surveys to ensure compliance with the regulations for protection against radiation. Although the normal civil penalty assessment process would have resulted in a base civil penalty in the amount of $27,500, NRC exercised discretion in accordance with Section VII.A.1 of the Policy and increased the penalty because of: (1) the number of overexposures (31); (2) the severity of the overexposures; (3) the time frame over which the exposures occurred; (4) the failure to identify the exposures despite multiple precursor events, and (5) the licensee's poor enforcement history. A Notice of Violation was also issued for a Severity Level III violation for a subsequent failure to properly survey.

National Institutes of Health (NIH), Bethesda, Maryland, EA 01-001

On January 17, 2001, a Notice of Violation was issued for a Severity Level III violation involving the licensee's failure to make surveys that were necessary to assure compliance with the regulations that limit radiation exposure to the skin of a minor

to 50 millisieverts (5 rems). The violation resulted from an August 8, 2000, contamination incident, at the facility, that resulted in an unplanned exposure to a minor who was a student working at NIH as an intern.

(Contact: Sally Merchant, 301-415-2747; e-mail: slm2@nrc.gov)

GENERIC COMMUNICATIONS ISSUED (December 1, 2000 - January 31, 2001)

Note that these are only summaries of U.S. Nuclear Regulatory Commission (NRC) 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. The Internet address for the NRC library of generic communications is—www.nrc.gov/NRC/GENACT/GC/index.html. Please note that this address is case-sensitive and must be entered exactly as shown.

Information Notices (INs)

IN 2000-19, "Implementation of Human Use Research Protocols Involving U.S. Nuclear Regulatory Commission Regulated Materials" was issued on December 5, 2000. This notice was issued to all medical use licensees to remind them of their responsibility to ensure compliance with NRC requirements and all their license conditions, when participating in research involving human subjects, using NRC's regulated materials. It is also intended to remind licensees that Title10 of the U.S. *Code of Federal Regulations* (10 CFR) Section 35.6, "Provisions for research involving human subjects," is not a blanket authority to conduct research involving human subjects.

Contacts: Robert L. Ayres, NMSS, 301-415-5746, e-mail: rxa1@nrc.gov.
Donna-Beth Howe, NMSS, 301-415-7848, e-mail:dbh@nrc.gov.

IN 2000-22, "Medical Misadministrations Caused by Human Errors Involving Gamma Stereotactic Radiosurgery (Gamma Knife)" was issued on December 18, 2000. This notice was issued to all medical licensees authorized to conduct gamma stereotactic radiosurgery treatments to remind them of the importance of following written directives and treatment-planning procedures, and the need to pay attention to detail during preparation and administration of gamma stereotactic radiosurgery.

Contact: Roberto J. Torres, NMSS, 301-415-8112, e-mail: rjt@nrc.gov.

Regulatory Issue Summaries (RIS')

RIS 2001-03, "Changes, Tests, and Experiments" was issued on January 23, 2001. This summary was issued to all NRC Part 50 and Part 72 licensees and Part 72 Certificate of Compliance holders, to provide guidance to them in making the transition to the requirements of recently amended regulations in Title 10 of the U.S. *Code of Federal Regulations* (10 CFR), namely, 10 CFR 50.59 and 10 CFR 72.48. Both sections are titled "Changes, tests, and experiments."

Contacts: Eileen M. McKenna, NRR, 301-415-2189, e-mail: emm@nrc.gov.
Christopher Jackson, NMSS, 301-415-2947, e-mail: cpj@nrc.gov.

RIS 2000-04, "Issuance of Updated Guidance on the Transfer of Ownership or Control of Licensed Activities (NUREG-1556, VOLUME 15)" was issued on January 24, 2001. This summary was issued to all materials and fuel cycle licensees to inform them of the availability of NUREG-1556, "Consolidated Guidance about Materials Licenses," Volume 15, "Program-Specific Guidance about Changes of Control and about Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses." NUREG-1556, Volume 15, supersedes all previous guidance that has been issued concerning changes in ownership or control of licensed activities.

Contacts: John Pelchat, Region II, 404-562-4729, e-mail: jmp2@nrc.gov.
Loren Hueter, Region III, 630-829-9829, e-mail: ljh1@nrc.gov.
David Everhart, Region I, 610-337-6936, e-mail: dbe@nrc.gov.

(General Contact: Mark A. Sitek, NMSS, 301-415-5799, e-mail: mas3@nrc.gov)

SIGNIFICANT EVENTS

The U.S. Nuclear Regulatory Commission (NRC) is providing summaries of these events to inform licensees of conditions they may encounter and of actions that may be taken to deal with them.

Event 1: Gamma Stereotactic Radiosurgery (Gamma Knife) misadministration at University of California in San Francisco, California.

Date and Place: September 11, 1998; University of California; San Francisco, California. The California Department of Health Services, Radiologic Health Branch, was notified of the misadministration on September 17, 1998. The NRC staff was informed of this event in July 2000. The State of California indicated that the delay in reporting this event to NRC was caused by a computer error.

Nature and Probable Consequences: A patient was prescribed a radiation therapy treatment, for two metastatic lesions of the brain, which used a gamma stereotactic radiosurgery (GSR) device. The patient was prescribed a dose of 16 Gray (Gy)(1600 rad) to one of the brain lesions. However, because of an error, the wrong site of the brain received more than 10 Gy (1000 rad). The patient was treated for two metastatic brain lesions, one in the left thalamus and the other in the right parietal region of the brain. A treatment plan was developed, for the lesion in the left thalamus, to deliver a single dose of 16 Gy (1600 rad), at the 60 percent isodose line. However, one of the seven parameter settings of the GSR, the "left Y" coordinate, was erroneously set at 111 millimeters (mm) (4.37 in.) instead of 101 mm (3.98 in.), resulting in a 5-mm (0.20-in.) translocation of the treatment volume. This error resulted in an underdose of a portion of the intended treatment volume and an unintended dose of more than 10 Gy (1000 rad) to brain tissue outside of the prescribed treatment volume. The misadministration was discovered when the licensee performed a quality control verification of the GSR parameters after the radiation treatment. The licensee reported that the patient experienced no acute side effects from this misadministration. The physician who was involved in this treatment notified the patient of this misadministration. An additional treatment was added to the treatment plan to complete the prescribed dose to the intended treatment volume of the left thalamus, and the treatment was completed. The patient died as a direct result of the metastatic condition on March 3, 1999. The misadministration was caused by a human error. One member of the treatment team set a wrong coordinate and another member of the treatment team failed to independently verify the coordinate setting.

Actions Taken To Prevent Recurrence

Licensee: The licensee's initial corrective actions included decreasing distractions to the treatment team by limiting telephone calls in the treatment control area and restricting conversations in the treatment room to conversations required for the treatment of the patient. The State requested the licensee to contact other GSR facilities, to review their methods of operation. The licensee found that another GSR facility had performed a study comparing the frequency of incorrect coordinate settings by licensees who did one independent verification and licensees who did two. The licensee used this study as a guide and has adopted the procedure of performing two independent checks of the coordinate settings before each treatment and retaining the follow-up check of the coordinate settings after each treatment, to determine if an error was made.

State Agency: The findings of the State staff's on-site investigation agreed with the findings of the licensee's quality assurance review. The State also shared the licensee's study findings with other Agreement States and with NRC, because of the study's generic implications. The State was satisfied with the licensee's corrective actions and believes they should be adequate to prevent recurrence. The State did not take any enforcement actions for this misadministration.

Event 2: Brachytherapy misadministration at Aultman Hospital, Canton, Ohio.

Date and Place: August 22, 2000 through October 30, 2000; Aultman Hospital; Canton, Ohio.

Nature and Probable Consequences: As a result of a common error, four patients who were prescribed manual brachytherapy gynecological procedures were administered doses higher than those prescribed.

The first patient was given a brachytherapy dose of 33.3 Gray (Gy) (3330 rad) iridium-192 , (Ir-192), instead of the prescribed dose of 20 Gy (2000 rad). Approximately 3 weeks later, the same patient was administered another brachytherapy dose of 35 Gy (3500 rad) Ir-192, instead of the prescribed dose of 22.5 Gy (2250 rad). The second patient was administered a brachytherapy dose of 35.2 Gy (3520 rad) Ir-192, instead of the prescribed dose of 19.8 Gy (1980 rad) Ir-192. The third patient was administered a brachytherapy dose of 32.4 Gy (3240 rad) Ir-192, instead of the prescribed dose of 18.9 Gy (1890 rad) Ir-192. The fourth patient was administered a brachytherapy dose of 31.5 Gy (3150 rad) Ir-192, instead of the prescribed dose of 20.3 Gy (20.25 rad) Ir-192.

The misadministrations were discovered on November 3, 2000, and November 13, 2000, during an internal audit of the licensee's Quality Management Program (QMP) by the Radiation Safety Officer (RSO) and the Radiation Protection Staff. The licensee's RSO made a telephone report to the Ohio Department of Health, Bureau of Radiation Protection, on November 4, 2000, and November 13, 2000.

The first, second, and fourth patients were notified of the misadministrations. The notification of the third patient is pending because the patient was hospitalized for an unrelated infection. The licensee stated that the clinical treatment of these patients has not been affected by misadministrations.

The licensee indicated that this event was primarily caused by an operator error when entering source strength data in the treatment planning computer. The facility obtained a new computer in August 2000, and the operator made a mistake and entered the source strengths in milligram-radium-equivalent instead of millicurie. Also, the quality assurance of the treatment planning was inadequate, and the second checks of treatment plans, to which the licensee committed in its QMP, were inadequate.

Actions Taken To Prevent Recurrence

Licensee: As soon as the licensee's management determined that a reportable event had occurred, the licensee took action to provide additional training to the staff involved in brachytherapy procedures. The licensee submitted a written report to the Ohio Department of Health, Bureau of Radiation Protection, within 15 days of discovering the misadministrations.

State Agency: The Ohio Department of Health, Bureau of Radiation Protection, performed an on-site investigation on November 21 and 22, 2000, to review the procedures and the findings of the licensee's quality management review and to confirm that the licensee's corrective action proposal is adequate to prevent recurrence. Enforcement actions or penalties, if any, will be determined at a later date.

Event 3: Gamma Stereotactic Radiosurgery (Gamma Knife) misadministration at Wills Eye Hospital, Philadelphia, Pennsylvania

Date and Place: October 4, 2000; Wills Eye Hospital; Philadelphia, Pennsylvania.

Nature and Probable Consequences: On October 5, 2000, the licensee notified the U.S. Nuclear Regulatory Commission's (NRC's) Operations Center of a misadministration to a patient undergoing gamma knife treatment for an acoustic tumor. The licensee stated that the patient's treatment plan called for the administration of 1200 CentiGray (cGy) (rad) to a tumor volume in three shots. While setting up for the first shot, which used the 8-mm (0.31-in.) collimated helmet, the physician correctly read the X-coordinate and Y-coordinate from the treatment plan, and these coordinates were used to position the patient for treatment; however, when asked for the Z-coordinate, the physician incorrectly provided the treatment plan value for the X-coordinate. Therefore, the wrong Z-coordinate was used to position the patient for the treatment. The licensee identified this error while setting up to perform the second shot, and the physician was notified. The licensee determined that the positioning error resulted in the treatment of an area approximately 8-mm (0.31-in.) superior to the intended treatment site. The licensee stated that this area would have received some radiation exposure during the normal course of treatment, but not the 400 cGy (rad) that resulted from the positioning error. The treatment was appropriately modified for the second and third shot, and a fourth shot was added to make up for the dose that was missed in the first shot. The licensee stated that the patient and the

patient's physician were immediately advised of the error. The licensee does not believe that the patient will develop any adverse effects from this event.

Actions Taken to Prevent Recurrence

Licensee: In a letter dated October 18, 2000, the licensee has provided its corrective and preventive actions. The actions include: 1) written procedures have been expanded to explicitly state that all team members must verify coordinates from the treatment protocol sheet before setting or checking a patient's treatment coordinates; 2) this policy has been posted in and also outside the Gamma Knife suite: and 3) training was conducted to re-familiarize the team members with the Quality Management Program and the revised procedure involving the verification of the treatment coordinates from the treatment protocol sheet.

NRC: Staff from NRC Region I office reviewed the event and evaluated the licensee's corrective and preventive actions during a special inspection conducted during the week of October 9, 2000. NRC also contracted a medical consultant to review the event, its effect on the patient, and the licensee's corrective actions to avoid recurrence of similar incidents.

Correction

There is an error in Event #5 in the Significant Events section of the Dec 2000 - Jan 2001 (No. 00-4) issue of the *NMSS Licensee Newsletter*. The error is in the following sentence: "The conversion is supposed to be the mCi divided by 1.27, but the licensee multiplied by 1.27 instead." The correct sentence should be: "The conversion is supposed to be air kerma strength divided by 1.27 to obtain mCi; however, the licensee multiplied by 1.27 instead."

In the event in question, the seed strength obtained from the treatment planning computer was in air kerma units, which required conversion to units of millicuries when ordering the seeds from the vendor. For I-125, the air kerma strength must be divided by 1.27 to obtain millicuries. The conversion factor for I-125 is 1.27 U/mCi according to "Dosimetry of interstitial brachytherapy sources: Recommendations of AAPM Radiation Therapy Committee Task Group No. 43," Med. Phys. 22, pp. 209-234, Table IV (1995).

SELECTED *FEDERAL REGISTER* NOTICES
(October 1, 2000 - March 31, 2001)

NOTE: U.S. Nuclear Regulatory Commission (NRC) contacts may be reached by mail at the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

FINAL RULES

"Adjustment of Civil Penalties for Inflation; Miscellaneous Administrative Changes," 65 FR 59270, October 4, 2000.

Contact: Norman St. Amour, 301-415-1589; e-mail: NXS1@nrc.gov.

"List of Approved Spent Fuel Storage Casks: HI-STAR 100 Revision," 65 FR 60339, October 11, 2000 (Direct Final Rule).

Contact: Gordon Gundersen, 301-415-6195; e-mail: geg1@nrc.gov.

"List of Approved Spent Fuel Storage Casks: NAC-UMS Addition," 65 FR 62581, October 19, 2000.

Contact: Stan Turel, 301-415-6234; e-mail: spt@nrc.gov

"Export and Import of Nuclear Equipment and Materials," 65 FR 70287, November 22, 2000.

Contact: Suzanne Schuyler-Hayes, 301-415-2333; e-mail: ssh@nrc.gov.

"List of Approved Spent Fuel Storage Casks: TN-32 Revision," 65 FR 75853, December 5, 2000.

Contact: Roger W. Broseus, 301-415-7608; e-mail : rwb @nrc.gov.

"New Dosimetry Technology; Confirmation of Effective Date of January 8, 2001 (Direct Final Rule), 66 FR 1573, January 9, 2001."

Contact: Betty Ann Torres, 301-415-0191; e-mail: bat@nrc.gov.

"List of Approved Spent Fuel Storage Casks: HI-STAR 100 Revision; Confirmation of Effective Date of December 26, 2000 (Direct Final Rule)," 66 FR 1573, January 9, 2001.

Contact: Gordon Gundersen, 301-415-6195; e -mail: geg1@nrc.gov.

"List of Approved Spent Fuel Storage Casks: Fuel Solutions Addition," 66 FR 3444, January 16, 2001.

Contact: Stan Turel, 301-415-6234; e-mail: spt@nrc.gov.

"Termination of Section 274i Agreement Between the State of Louisiana and the Nuclear Regulatory Commission," 66 FR 5441, January 19, 2001.

Contact: Stephanie P. Bush-Goddard, Ph.D., 301-415-6257; e-mail: spb@nrc.gov.

"List of Approved Spent Fuel Storage Casks: NAC-UMS Revision, Confirmation of Effective Date," 66 FR 10569, February 16, 2001.

Contact: Keith K. McDaniel, 301-415-5252; e -mail: kkm@nrc.gov.

"List of Approved Spent Fuel Storage Casks: TN-32 Revision, Confirmation of Effective Date," 66 FR 10569, February 16, 2001.

Contact: Roger W. Broseus, 301-415-7608; e -mail: rwb@nrc.gov.

"List of Approved Spent Fuel Storage Casks: Fuel Solutions Revision," 66 FR12435, February 27, 2001.

Contact: Gordon Gundersen, 301-415-6195; e-mail: geg1@nrc.gov.

"List of Approved Spent Fuel Storage Casks: VSC-24 Revision (Direct Final Rule)," 66 FR 13407, March 6, 2001.

Contact: Stan Turel, 301-415-6234; e-mail: spt@nrc.gov.

"List of Approved Spent Fuel Storage Casks: HI-STAR 100 Revision (Direct final rule)," 66 FR 14483, March 13, 2001.

Contact: Stan Turel, 301-415-6234; e-mail: spt@nrc.gov.

PROPOSED RULES

"List of Approved Spent Fuel Storage Casks: HI-STAR 100 Revision," 65 FR 60384, October 11, 2000.

Contact: Gordon Gundersen, 301-415-6195; e-mail: geg1@nrc.gov.

"Medical Use of Byproduct Material - Speciality Boards and Medical Speciality Boards: Solicitation," 65 FR 65793, November 2, 2000.

Contact: Sam Jones, 301-415-6198; e-mail: szj@nrc.gov.

"List of Approved Spent Fuel Storage Casks: Fuel Solutions Revision," 66 FR12439, February 27, 2001.

Contact: Gordon Gundersen, 301-415-6195; e-mail: geg1@nrc.gov.

"List of Approved Spent Fuel Storage Casks: VSC-24 Revision," 66 FR 13459, March 6, 2001.

Contact: Stan Turel, 301-415-6234; e-mail: spt@nrc.gov.

Storage Casks: HI-STAR 100 Revision, 66 FR 14503, March 13, 2001.

Contact: Stan Turel, 301-415-6234; e-mail: spt@nrc.gov.

"Revision of Fee Schedules; Fee Recovery for FY 2001," 66 FR 16982, March 28,2001.

Contact: Glenda Jackson, 301-415-6057.

OTHER NOTICES

"Draft Regulatory Guide DG-3020, 'Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments,' " 66 FR 390, January 24, 2001.

Contact: C.P. Jackson, 301-415-2947; e-mail: cpj@nrc.gov.

"Notice of Availability, NUREG-1556, Volume 17, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Special Nuclear Material of Less Than Critical Mass Licenses' " 66 FR 2461, January 11, 2001.

Contact: Carrie Brown, 301-415-8092; e-mail: cxb@nrc.gov.

"Notice of Availability of final NUREG-1556, Volume 18, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses,' " 66 FR 6704, January 22, 2001.

Contact: Carrie Brown, 301-415-8092; e-mail: cxb@nrc.gov.

"Notice of availability of final NUREG-1556, Volume 19, 'Consolidated Guidance about Materials Licenses: Guidance for Agreement State Licensees about NRC Form 241, "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters," and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity),' " 66 FR 6704, January 22, 2001.

Contact: Carrie Brown, 301-415-8092; e-mail: cxb@nrc.gov.

"Notice of Availability of final NUREG-1556, Volume 15, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Change of Control and about Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses.' " 66 FR 7518, January 23, 2001.

Contact: Carrie Brown, 301-415-8092; e-mail: cxb@nrc.gov.

"United Plant Guard Workers of America; Denial of Petition for Rulemaking (Parts 73, 76, and 95) (PRM-76-1)," 66 FR 10839, February 20, 2001.

Contact: Merri Horn, 301-415-8126; e-mail: mlh1@nrc.gov.

"Withdrawal of Regulatory Guide 8.14, 'Personnel Neutron Dosimeters (Revision 1),' " 66 FR 11611, February 26, 2001.

"Proposed Revision of the NRC Enforcement Policy," 66 FR14224, March 9, 2001.

Contact: Nick Hilton, 301-415-2741; e-mail: ndh@nrc.gov.

(General Contact: Paul Goldberg, 301-415-7842; e-mail: pfg@nrc.gov)

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