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NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

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THE LICENSING PROCESS FOR DRY CASK STORAGE SYSTEMS

Part 72 of Title 10 of the *U.S. Code of Federal Regulations* (10 CFR Part 72) allows licensing of spent fuel storage cask designs under either general or site-specific provisions. The Spent Fuel Project Office (SFPO) reviews and certifies storage and transportation cask systems. Additionally, SFPO maintains and implements the inspection program for cask designers and fabricators.

The general objectives of the design criteria for dry cask storage systems are to: (1) ensure the safe confinement of the spent fuel; (2) prevent the degradation of the fuel cladding; and (3) maintain compatibility with future strategies for transportation and disposal. The economics of objective (3) have resulted in the overall design trend toward cask systems that combine to meet both the storage and transportability requirements (dual-purpose).

Site-Specific License Process

A site-specific license is one of the two options available for utilities to store spent fuel in an independent spent fuel storage installation (ISFSI) at the operating reactor site. The procedure for acquiring a site-specific ISFSI license is similar to the licensing process for a power reactor, in that a safety review and an environmental review are carried out by the U.S. Nuclear Regulatory Commission (NRC). An opportunity for public hearing is provided before issuance of the site-specific license, and license amendments are processed in a manner similar to those for reactors.

A utility is usually the applicant for a site-specific license and must submit an application containing a Safety Analysis Report (SAR) and an Environmental Report. NRC reviews the application and completes a technical evaluation and an assessment of the potential environmental impacts, including reasonable alternative actions. After completing its safety review and the resolution of comments, NRC issues a Safety Evaluation Report (SER), the final Environmental Assessment (EA), and reaches a decision on the issuance of the license. A hearing, if necessary, is carried out concurrently with the safety and environmental reviews.

NRC has issued six site-specific licenses for dry storage ISFSIs at reactor sites, under Part 72. The site-specific license is applicable for a term of 20 years and is renewable. Additionally, the staff is currently reviewing site-specific dry fuel storage applications at four additional locations, two of which are at permanently shut-down reactors.

General License Process

When the U.S. Congress passed the Nuclear Waste Policy Act (NWPA) of 1982, it contained a directive to streamline the licensing process for dry cask storage at reactor sites. The NWPA called for NRC to establish a dry cask storage technology licensing method, for use at reactor sites, that would establish the acceptability of the cask system design, precluding the need for additional site- specific approvals. In 1990, NRC amended its Part 72 regulations to provide utilities with the option to store spent fuel at reactor sites under a general license. To use the general license, the utility must be authorized to operate a nuclear power reactor, under 10 CFR Part 50, and must use a cask system that has been granted a Certificate of Compliance (CoC) by NRC.

Since the technical acceptability of a particular cask storage system is addressed by the process of obtaining the CoC, the use of the general license to store spent reactor fuel does not require a new application nor a specific licensing review. The general license for a storage cask design is valid for a period of 20 years after first use and is renewable.

The certification process for a dry cask storage system design requires a technical review similar to that performed for site-specific licensing. The CoC is obtained by a vendor that submits an application, including an SAR, for approval of a dry spent fuel storage cask design. NRC reviews the SAR and prepares a draft SER, EA, and CoC.

All documents relied on for the safety review are made publicly available, and a public comment period is provided. The use of the general license does not provide the public with hearing rights. After resolving the public comments, NRC prepares and issues the finalized documents, adding the cask to the approved list of designs in Part 72.

Before use of a general license, the utility must perform written evaluations that establish that the conditions of the CoC have been met. These include verification that reactor site parameters such as extreme temperatures, seismic design criteria, and wind velocities are enveloped by the cask design bases. The utility must also determine whether activities related to the storage of spent fuel in the ISFSI could have an impact on the safety of the operating reactor plant.

NMSS* LICENSEE NEWSLETTER
(MARCH 1998 - APRIL 1998)

*All authors are from the Office of Nuclear Material Safety and Safeguards, NRC, except for those noted.

Comments, and suggestions you may have for information that is not currently being included, that might be helpful to licensees, should be sent to:

E. Kraus
NMSS Licensee Newsletter Editor
Office of Nuclear Material Safety and Safeguards
Two White Flint North, Mail Stop 8-A-23
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Safety Review

The technical safety review and the programmatic requirements are similar and essentially independent of the selected licensing process. The applicant's SAR for dry cask storage provides the primary source of information by which NRC conducts the appropriate safety review. NRC Regulatory Guides are available to applicants for format and implementing technical guidance. Additionally, the "Standard Review Plan for Dry Cask Storage Systems" (NUREG-1536) has been developed to provide guidance to NRC's technical staff in performing a safety review of the dry cask storage application. NRC's safety review evaluates the SAR in the following principal technical areas: (1) thermal; (2) shielding; (3) criticality; (4) structural; and (5) confinement.

The Part 72 regulations also require the consideration of a host of potential accidents. Among the events that are considered and analyzed are cask drops and tipovers, acts of sabotage, and the occurrence of natural phenomena (e.g., earthquakes, tornadoes, wind-driven missiles, and floods).

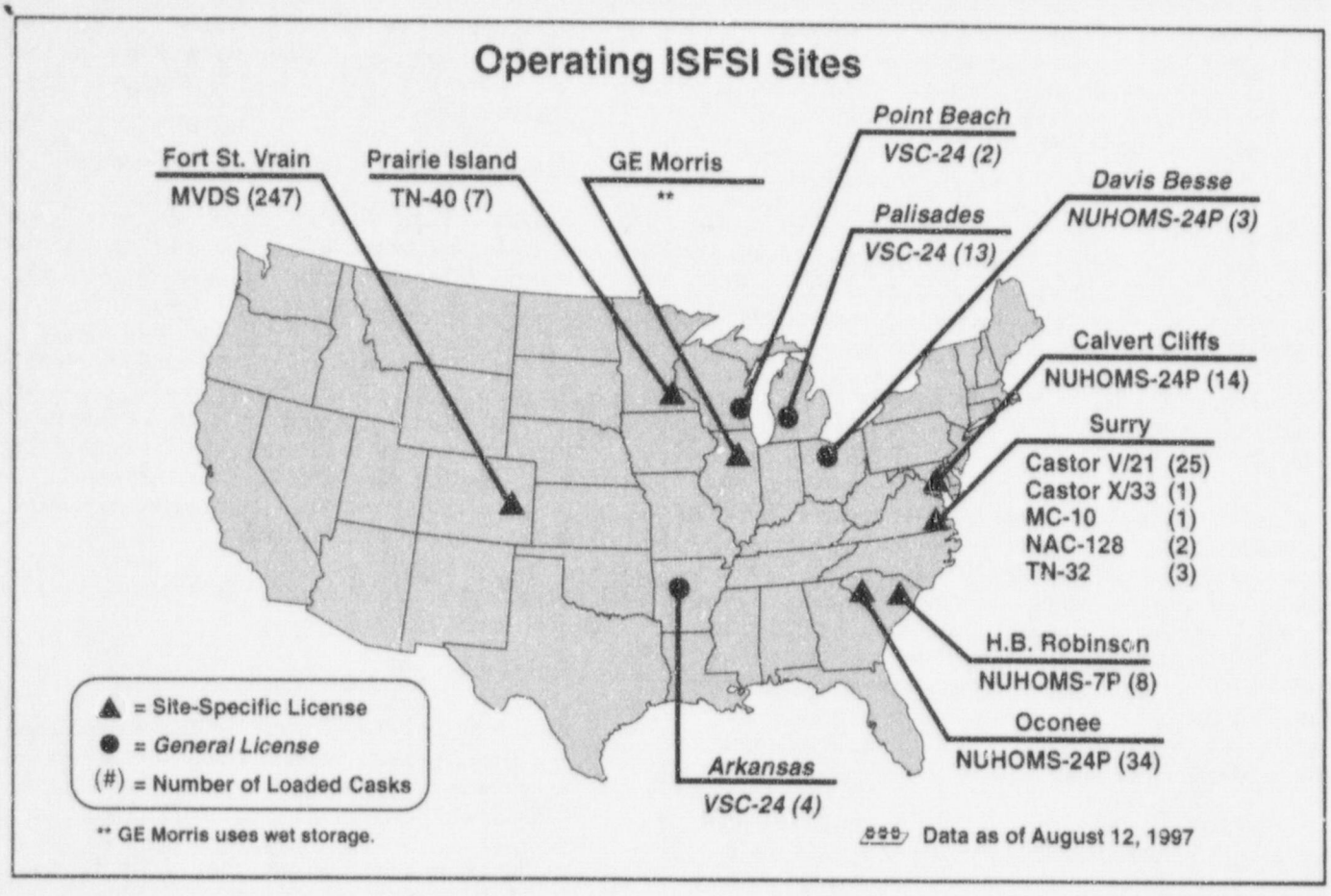
Furthermore, the following programs are subject to NRC review and approval (site-specific license) or inspection (general license): (1) quality assurance; (2) training; (3) operations and maintenance; (4) facility security; (5) radiation protection; and (6) emergency preparedness.

Whether the dry cask system is to be used at a reactor site under the general license or under the terms of a site-specific license, Part 72 specifies dose criteria that must be met as a result of normal operations and in the event of an accident. During normal operations, the annual dose equivalent to an individual member of the public located at the site's controlled area boundary must not exceed 25 mrem (.25 mSv) to the whole body, or 75 mrem (.75 mSv) to the thyroid. Under accident conditions, the dose to an individual located at the site's controlled area boundary must not exceed 5 rem (50 mSv) to the whole body or any organ. The ISFSI must be located a minimum of 100 meters (300 ft) from the reactor site's controlled area boundary. The attached figure shows the names and locations of Operating ISFSI sites.

(Contact: Tim McGinty, 301-415-8580,
e-mail: tjm1 @nrc.gov)

TRANSFER OF RULEMAKING RESPONSIBILITY TO NMSS

In Staff Requirements Memoranda dated September 16, 1997, and December 5, 1997, the Commission directed the staff to transfer rulemaking resources and responsibilities from the Office of Nuclear Regulatory Research to the program offices. All rulemakings related to byproduct, source, and special nuclear material; fuel cycle; transportation; and radioactive waste management were transferred to the Office of Nuclear Material Safety and Safeguards (NMSS), whereas reactor-related rulemakings were transferred to the Office of Nuclear Reactor Regulation. The lead responsibility for 10 CFR Parts 19 and 20 resides with NMSS. This transfer was effective February 27, 1998. Within NMSS, the Division of Industrial and Medical Nuclear Safety has



primary responsibility for the rulemaking function. The Divisions with programmatic responsibility will be providing technical support, as needed, for rulemaking.

(Contact: Patricia K. Holahan, 301-415-8125, e-mail: pkh@nrc.gov)

PROPOSED OHIO AGREEMENT

The State of Ohio Bureau of Radiation Protection has submitted a draft application for an Agreement under section 274b of the Atomic Energy Act of 1954, as amended. The U.S. Nuclear Regulatory Commission (NRC) is reviewing the draft application and plans to forward staff comments to the State before the end of May.

The draft application proposes a "full Agreement" covering the regulation of source material, 11(e).1 byproduct material, 11(e).2 byproduct material (i.e., mill tailings), special nuclear material in quantities not sufficient to form a critical mass, the disposal of low-level waste, and the safety evaluation of sealed sources and devices.

Following submission of a formal application by Governor George Voinovich, publication of the proposed agreement in the *Federal Register* for public comment, and approval by the Commission, Ohio would become the 31st Agreement State. Ohio has about 600 NRC licenses, of which about 500 would be transferred to the State under the proposed agreement.

(Contact: Jim Lynch, Region III, 630-829-9661, e-mail: jll2@nrc.gov)

NRC STAFF DEVELOPS DECOMMISSIONING HANDBOOK

Since June 1988, the U.S. Nuclear Regulatory Commission (NRC) has amended its regulations at 10 CFR Parts 30, 40, 50, 70, and 72 several times to establish the technical and financial criteria for decommissioning licensed nuclear facilities (53 FR 24018). NRC promulgated these amendments to ensure that the decommissioning of all licensed nuclear facilities is performed in a safe and timely manner, and that adequate funds are available to ensure that the decommissioning of licensed facilities can be accomplished.

Reviews of the Site Decommissioning Management Plan (SDMP) program by the U.S. General Accounting Office and the NRC Office of the Inspector General, in 1994 and 1995, as well as continuing NRC management reviews, found that, although NRC was overseeing the decommissioning program at nuclear facilities in a manner that was protective of public health and safety, progress in decommissioning many sites was slow. As a result of the conclusions drawn from these reviews, and recommendations made by the reviewers, NRC determined that formal written procedures should be developed to facilitate the timely decommissioning of licensed nuclear facilities in a manner that was consistent throughout NRC, as well as in accordance with all applicable regulatory requirements.

To achieve this goal, the staff developed the "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees" in late 1996. It is intended to be used as a reference document to, and in conjunction with, NRC

Inspection Manual Chapter 2602, "Decommissioning Inspection Program for Fuel Cycle and Materials Licensees." The policies and procedures discussed in the handbook are used by staff overseeing the decommissioning program at licensed fuel cycle and materials sites; formerly licensed sites for which the licenses were previously terminated; sites involving source, special nuclear or byproduct material subject to NRC regulation for which a license was never issued; and sites in NRC's SDMP program. (Note that staff overseeing the decommissioning program at nuclear reactor and uranium recovery facilities does not necessarily use the procedures described in the Handbook.)

To provide materials licensees with information on how the staff oversees the decommissioning of materials facilities, staff published the Handbook as NUREG/BR-0241, in March 1997. Licensees currently decommissioning their facilities, or approaching cessation of operations, are encouraged to obtain a copy of the Handbook to better understand the manner in which the staff conducts activities associated with the decommissioning of facilities subject to NRC's regulatory oversight. Staff intends to update the Handbook shortly, and periodically, thereafter, to conform to the requirements in NRC's recently promulgated requirements for license termination, as well as changes that occur in NRC policies and procedures for decommissioning licensed nuclear facilities.

Copies of the Handbook are available from the Government Printing Office at (202) 512-1800. Licensees with questions about the Handbook should contact Nick Orlando at (301) 415-6749.

(Contact: Dominick Orlando, 301-415-6749,
e-mail: dao@nrc.gov)

NRC FINALIZES ENFORCEMENT GUIDANCE FOR SECURITY AND CONTROL ISSUES

On April 24, 1998, the U.S. Nuclear Regulatory Commission (NRC) finalized Enforcement Guidance Memorandum 98-004, which provides new guidance for categorizing the severity level of violations involving security and control of radioactive material, in accordance with 10 CFR 20.1801 and 1802. This guidance was developed from comments received from several licensee workshops held over the past 2 years, and uses a risk-informed, performance-based approach to determine the types of security violations that should be considered significant, vs. those of less serious concern and those of minor significance. The highlights of the policy are:

Severity Level III - Violations Involving, for example:

> (1) failure to secure, or maintain surveillance over, licensed material in any aggregate quantity greater than 1000 times the quantity specified in Appendix C to 10 CFR Part 20, or that results in a substantial potential for exposures or releases in excess of the applicable limits in Part 20; or (2) failure to secure or maintain surveillance over licensed material not characterized above and involving an aggregate quantity greater than 10 times the quantity specified in Appendix C or Part 20, where such failure is accompanied by the absence of, or a breakdown in, a program, to detect and deter security violations, that includes training, staff awareness, detection (including auditing), and corrective action (including disciplinary action).

Severity Level IV- Violations involving, for example:

> Isolated failures to secure, or maintain surveillance over, licensed material not characterized above and involving an aggregate quantity greater than 10 times the quantity specified in Appendix C to Part 20, provided that: (1) the material is labeled as radioactive or located in an area posted as containing radioactive materials; and (2) such failure is non-programmatic in that the failure occurs despite a functional program to detect and deter security violations—that includes training, staff awareness, detection (including auditing), and corrective action (including disciplinary action).

Minor (non-cited) Violations – Violations involving, for example:

> Failures to secure, or maintain surveillance over: (1) licensed material involving aggregate quantities equal to or less than 10 times the quantity specified in Appendix C to Part 20; or (2) properly labeled sealed sources or waste forms measuring less than 0.02 mSv/hr (2 mrem/hr) at 30 cm. (11.8 in.).

Readers interested in reading more about this policy may view it on NRC's web site at www.nrc.gov/OE.

(Contact Cyndi Jones, 301-415-7853,
e-mail: cgj@nrc.gov).

THE RADIOGRAPHY "TWO-MAN" RULE

With June 28, 1998, quickly approaching, the Radiography community is preparing for a change in operating methods. This is the date from which time it is required that a radiographer and at least one other qualified radiographer or radiographer's assistant be present at all radiography performed at a location other than a permanent radiographic installation. This new rule is described in 10 CFR 34.41. Some licensees may be asking, "What must we do to be in compliance with this requirement?

Section 34.41(a) states, "Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of 10 CFR 34.43(c). The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present." This requires that a second individual must observe the operation, to prevent entry into restricted area, so as to prevent unnecessary exposure to radiation.

Licensees are reminded that the requirement on surveillance—10 CFR 34.51— states, "During each radiographic operation the radiographer, or the other individual present, as required by 10 CFR 34.41, shall maintain continuous

direct visual surveillance of the operation to protect against unauthorized entry into a ***high radiation area*** (emphasis added), as defined in 10 CFR Part 20 of the chapter...."

The U.S. Nuclear Regulatory Commission (NRC) Inspection Procedure 87120, which is used by inspection staff to conduct radiography inspections, simply states that the inspector should verify that, "...on or after June 27, 1998, the operations are conducted by a least two qualified individuals; and radiography personnel maintain continuous surveillance of the restricted area."

NUREG 1556, Vol. 2. "Consolidated Guidance about Materials Licenses, Program-Specific Guidance about Industrial Radiography Licenses" is a document designed to guide an applicant in preparing a radiography license application. In clarifying this matter for potential licensees, NUREG 1556 states, "Both individuals must maintain constant surveillance of the operations and be capable of providing immediate assistance to prevent unauthorized entry to the restricted area. Operating procedures must comply with the two-man rule for radiographic operations at any locations other than permanent radiographic facilities.

From a practical safety perspective, the additional qualified individual is present in the area of the radiography operations for two purposes: (1) prevent entry to restricted areas associated with the radiography operations; and (2) be available to assist the radiographer operating the radiography device, if necessary. However, the additional qualified individual does not have to maintain continuous direct surveillance of the radiography device. Generally, during the course of operations, the additional qualified individual must focus on the radiography operation or focus on securing the area restricted for radiography, to prevent unauthorized entry. If the additional qualified individual fails to maintain surveillance, this failure will be considered an apparent violation of 10 CFR 34.41 and will be considered for possible enforcement action. It is not acceptable for the second individual to be in the truck dark room or some other location at the site where he/she is not performing surveillance of the restricted area and is not cognizant of the radiography activities. Audio or video links with the second individual are not satisfactory and do not meet the intent of the regulation.

Licensees should also note that if the second individual is a radiographer's assistant, then, in accordance with 10 CFR 34.46(c), the radiographer must be directly observing ("eye-to-eye contact") the assistant, whenever the assistant uses radiographic exposure devices, associated equipment, or sealed sources, or conducts required radiation surveys.

If this regulation applies to you and you have any additional questions about implementing this rule, please contact your Regional Office's Materials Inspections staff.

(Contact: Mark Mitchell, Region III, 630-829-9855, e-mail: mwm2@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS

Complete enforcement actions can be accessed via the U.S. Nuclear Regulatory Commission (NRC) homepage [http://www.nrc.gov/]. Click on "Program Offices," then "Office of Enforcement," then "Enforcement Actions Issued." Cases are listed alphabetically. To access a complete enforcement action, click on the highlighted text following each case description.

Academic

Ohio State University, Columbus, Ohio, EA 97-258. A $13,000 civil penalty was assessed for numerous violations indicative of a breakdown in control of licensed activities and Licensee officials' careless disregard of NRC requirements.

Measuring Gauges

Anheuser-Busch, Inc., St. Louis, Missouri, EA 97-291. A $2750 civil penalty was assessed for the inadvertent disposal of two gauges, each containing 3.7 GBq (100 mCi) of Am-241, to a scrap metal processing plant.

Hagerstown Construction Services, Inc., Hagerstown, Maryland, EA 97-193. A $2750 civil penalty was assessed for willful failure to file NRC Form-241 before conducting work in non-Agreement States.

S. C. Johnson & Sons, Inc., Racine, Wisconsin, EA 97-338. A $2500 civil penalty was assessed for unauthorized removal of a gauge containing 11.1 GBq (300 mCi) of Am-241 and for disposal of the gauge as non-radioactive waste.

Terracon Companies, Inc., Lenexa, Kansas, EA 97-425. A $5000 civil penalty was assessed for deliberate failure to provide a required safety/training course to gauge operators.

Other Materials Licensees

U.S. Army Tank-Automotive and Armaments Command, Rock Island, Illinois, EA 97-350. A $16,000 civil penalty was assessed for a number of violations indicative of a breakdown in control of licensed material.

(Contact: Joseph Delmedico, OE, 301-415-2739, e-mail: rjd@nrc.gov)

Note: "GENERIC COMMUNICATIONS ISSUED" (Aug.7, 1997-Jan. 31, 1998) will appear in the June- August newsletter (98-2).

SELECTED FEDERAL REGISTER NOTICES
(January 1, 1998 - March 30, 1998)

NOTE: Contacts may be reached by mail at the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555

Final Rules

"Deliberate Misconduct by Unlicensed Persons," 63 FR 1890, January 13.1998. (Contact: Tony DiPalo, 301-415-6191, e-mail: ajd@nrc.gov)

"Electronic Freedom of Information Act: Implementation," 63 FR 2873, January 20, 1998. (Contact: Russell A. Powell, 301-415-7169, e-mail: rap1@nrc.gov)

Proposed Rules

Extension of comment period, "Procedures Applicable to Proceedings for the Issuance of Licenses for the Receipt of High-Level Radioactive Waste at a Geologic Repository," 63 FR 5315, February 2, 1998. (Contact: Kathryn L. Winsberg, 301-415-1641, e-mail: klw@nrc.gov)

"Minor Revision of Design Basis Accident Dose Limits for Independent Spent Fuel Storage and Monitored Retrievable Storage Installations," 63 FR 13372, March 19, 1998. (Contact: Naiem S. Tanious, 301-415-6103; e-mail: nst@nrc.gov)

Other Notices

Issuance and Availability of Draft Regulatory Guide, DG-5008, "Reporting of Safeguards Events," 63 FR 275, January 5, 1998.

Withdrawal of Regulatory Guides 3.2; 3.93;3.33; 3.34, Rev. 1; 3.35, Rev 1; 5.1; 5.14, Rev. 1; 5.24; 5.29, Rev. 1; 5.30; 5.45; 8.3; and DG-0008, 63 FR 2426, January 15, 1998.

Issuance and Availability of Draft Regulatory Guide DG-3013, "Nuclear Criticality Safety Standards for Fuels and Material Facilities," 63 FR 3008, January 20, 1998.

Withdrawal of Proposal, "Safety-Conscious Work Environment," 63 FR 6235, February 6, 1998. (Contact: James Lieberman, OE, 301-415-2741)

Availability of "Multi-Agency Radiation Survey and Site Investigation Manual," 63 FR 6915, February 11, 1998. (Contact: Robert A. Meck, 301-415-6205, e-mail: ram2@nrc.gov)

"Interagency Procedures for the Implementation of the US-IAEA Safeguards Agreement" (Department of State) 63 FR 7041, February 11, 1998. (Contact: Alex Burkart, 202-647-4413, Office of Nuclear Energy Affairs, Bureau of Political-Military Affairs (PM/NE), Department of State, Washington, DC 20520)

"Petition for Rulemaking to Eliminate Special Requirements for Plutonium Shipments" (PRM 71- 12), International Energy Consultants , Inc., 63 FR 8362, February 2, 1998.

Withdrawal of Advance Notice of Proposed Rulemaking, " Specific Domestic Licenses of Broad Scope for Byproduct Material," 63 FR 14381, March 25, 1998. (Contact: Torre Taylor, 301-415-7900)

"Privacy Act of 1974, as Amended; Revisions to System of Records," 63 FR 14497, March 25, 1998. (Contact: Jona L. Souder, 301-415-7170)

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

SIGNIFICANT EVENTS

Event 1: Iodine-131 Medical Misadministration at Virginia Beach General Hospital, Virginia Beach, Virginia

Date: November 21, 1997

Place: Virginia Beach General Hospital; Virginia Beach, Virginia

Nature and Probable Consequences - A patient received a dosage of 200 MBq (5.4 millicuries) of iodine-131, when a dosage of 11.1 MBq (300 microcuries) of iodine-123 was the standard dosage used at this facility for the test requested. As a result, the patient's thyroid received a dose of approximately 40 Gy (4000 rad), instead of the intended dose of approximately 0.02 Gy (2 rad).

On November 20, 1997, the referring physician prescribed a thyroid function test to a patient to evaluate possible thyroid nodules. A thyroid function test at this facility requires the administration of approximately 11.1 MBq (300 microcuries) of iodine-123. Because of a miscommunication between the referring physician and the individual responsible for scheduling the test, the patient was scheduled for a whole-body scan, which called for the administration of approximately 85 MBq [5 millicuries (5000 microcuries)] of iodine-131. A written directive was not prepared for the administration. On November 21, 1997, a technologist questioned the appropriateness of the order and attempted to contact the referring physician. The referring physician was unavailable, but the staff nurse who had originally taken the order from the referring physician and scheduled the procedure confirmed that the doctor wanted an iodine-131 scan. The technologist administered a dose of 200 MBq (5.4 millicuries) of iodine-131, and asked the patient to return on November 24, 1997, for a 72 hour whole-body scan. On November 24, the misadministration was identified when the scan revealed that the patient had an intact thyroid.

The licensee estimated the dose to the patient to be approximately 20 mSv (2.0 rems) total body and 40 Sv (4000 rems) to the thyroid. The licensee did not expect any adverse effect on the patient from the misadministration.

The U.S. Nuclear Regulatory Commission's (NRC's) medical consultant reviewed the circumstances and evaluated the effect on the patient and concluded that the impact of the misadministration on the patient's health should be negligible, with no expected long-term disability.

Cause or Causes - The root cause of the event was the licensee's failure to prepare a written directive before the administration of the iodine-131 and inadequate followup when the technologist questioned the appropriateness of the procedure.

Actions Taken to Prevent Recurrence

Licensee - New procedures were initiated that required all iodine-131 procedures to be scheduled through the Nuclear Medicine Department, and that implemented additional quality management measures. In addition, changes were made to the computerized scheduling system and retraining of the staff was completed. NRC - An inspection was conducted to review the circumstances of the misadministration. A Notice of Violation was issued for failure of the licensee to prepare a written directive before the administration of iodine-131.

Event 2: Medical Brachytherapy Misadministrations, by José N. De León, M.D., in Rio Piedras, Puerto Rico

Date: Between April 27, 1995, and June 26, 1996

Place: José N. De León, M.D., Rio Piedras, Puerto Rico

Nature and Probable Consequences

Nine patients each received a dose of 4000 cGy (4000 rad) during treatments with a strontium-90 (Sr-90) eye applicator, when a dose of 2000 cGy (2000 rads) was intended.

In April 1995, Dr. De León contracted the services of a health physics consultant (consultant) to calculate a decay correction for the surface dose rate of his 4.625-gigabecquerel (125-millicurie) Sr-90 eye applicator device. (Eye applicator devices are used for the supplemental treatment of non-malignant growths on the eye after surgery is performed.) Dr. De León provided the consultant with all the necessary information to calculate a proper decay correction (basic source data).

On April 27, 1995, Dr. De León submitted a revised Quality Management Program (QMP), to NRC, incorporating the surface dose rate corrections performed by the consultant. In the revised QMP, Dr. De León specified that the Sr-90 eye applicator device would deliver a 2000-cGy (2000-rad) dose in 60 seconds.

During a routine inspection of Ryder Memorial Hospital, Humacao, Puerto Rico, conducted on November 17 and December 11, 1997, NRC learned that Dr. De León had used his Sr-90 eye applicator device at Ryder Memorial Hospital. Dr. De León had been previously authorized to use his Sr-90 eye applicator at Ryder Memorial Hospital; however, authority to use the applicator at Ryder Memorial Hospital had been withdrawn by the hospital. As a result of the inspection findings at Ryder Memorial Hospital, NRC reviewed Dr. De León's license file in detail. During this review, NRC noted that in the original QMP submittal, in his June 1, 1994, letter, Dr. De León indicated that a 2000-cGy (2000-rad) dose would be delivered in 26 seconds.

On December 11, 1997, NRC conducted a special inspection of Dr. De León's licensed activities. During this inspection, NRC determined that in April 1995 Dr. De León's consultant had made a calculational error that resulted in the revised surface dose rate underestimating the actual dose by approximately 100 percent. Without verifying the consultant's calculations, Dr. De León adjusted the treatment time from 26 seconds to 60 seconds. Dr. De León indicated that: (1) he had notified all patients or next of kin; (2) offered free exams, which all had declined; and (3) no patient was reported to have any problems or complications associated with the misadministration. With respect to future health effects on the patients, Dr. De León indicated that it is unlikely that individuals will have any harmful effects from the overdoses received and will not have increased risks of cancer, in any clinically or statistically significant way. NRC contracted a medical consultant to review the medical aspects of the misadministrations.

The NRC medical consultant reviewed the information obtained from NRC, Dr. De León, and Ryder Memorial Hospital, and concluded that: (1) the patients are at a higher risk because normal tissue tolerates less dose if the dose is given as a single fraction; (2) the general range for treatment as a single fraction is 1800 to 3000 cGy (1800 - 3000 rad); and (3) the highest single dose recommended in published reports is 3000 cGy (3000 rad).

Cause or Causes

Dr. De León's consultant made a calculational error in correcting the surface dose rate of the Sr-90 applicator for radioactive decay and Dr. De León failed to verify or question the consultant's calculation before using the revised surface dose rate in patient treatments.

Actions Taken To Prevent Recurrence

Licensee - Dr. De León has retired and does not plan on using the Sr-90 eye applicator in the future. He is currently authorized under NRC License No. 52-19206-01 for possession for storage only.

NRC - NRC's Advisory Committee on the Medical Uses of Isotopes offered possible courses of action for Sr-90 eye applications. NRC is performing additional inspections of licensees authorized to possess and use Sr-90 eye applicators in Puerto Rico to confirm the use of proper decay corrections and source calibrations. NRC is also surveying Sr-90 eye applicators for calibration accuracy. In addition, NRC will review this case with the Secretary of Health of the Commonwealth of Puerto Rico, for possible action.

Event 3: Medical Brachytherapy Misadministrations at Ryder Memorial Hospital, Humacao, Puerto Rico

Date: Between April 22, 1995, and February 21, 1996

Place: Ryder Memorial Hospital; Humacao, Puerto Rico

Nature and Probable Consequences - Twelve patients received a dose of 4000 cGy (4000 rad) during treatments with a strontium-90 (Sr-90) eye applicator, when a dose of 2000 cGy (2000 rad) was intended. Two patients received a second treatment dose of 4000 cGy (4000 rad) to the same eye. These misadministrations are in addition to those involving Dr. José De León's private practice.

On June 28, 1994, Ryder Memorial Hospital notified NRC that it had canceled the authorization given to the ophthalmologists named on its license to use strontium-90 (Sr-90) at its facility; therefore, a Quality Management Program (QMP) was not needed for this activity. During a routine inspection of Ryder Memorial Hospital, conducted on November 17 and December 11, 1997, NRC learned that Ryder Memorial Hospital had found that Dr. De León, although he was authorized to practice at the hospital, had used his Sr-90 eye applicator at the hospital without authorization from the hospital. It is unclear as to whether Dr. De León had been informed by Ryder Memorial Hospital that it had withdrawn his authority to use his Sr-90 eye applicator device at Ryder Memorial Hospital. As a result of the inspection findings at Ryder Memorial Hospital, NRC reviewed Dr. De León's license file in detail and identified a discrepancy among the two different dosimetry calculations specified in two separate submittals of his QMP.

On December 11, 1997, NRC conducted a special inspection of Dr. De León's licensed activities. During this inspection, NRC determined that in April 1995, Dr. De León's

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consultant had made a calculational error that resulted in the revised surface dose rate underestimating the actual dose by approximately 100 percent. Without verifying the consultant's calculations, Dr. De León adjusted the treatment time from 26 seconds to 60 seconds.

Ryder Memorial Hospital, along with Dr. De León, notified the patients or next-of-kin. Ryder Memorial Hospital based its statements on the effects on the patients from these misadministrations on information provided by Dr. De León. Specifically, Dr. De León indicated that the delivered dose of 4000 cGy (4000 rad) falls within the dose range prescribed or in current use for this type of treatment and that he does not expect any adverse effect.

The NRC medical consultant reviewed the information obtained from NRC, Dr. De León, and Ryder Memorial Hospital, and concluded that the patients are at a higher risk because: (1) normal tissue tolerates less dose if the dose is given as a single fraction; (2) the general range for treatment as a single fraction is 1800 to 3000 cGy (1800 - 3000 rad); and (3) the highest single dose recommended in published reports is 3000 cGy (3000 rad).

Cause or Causes

Dr. De León's consultant made a calculational error in correcting the surface dose rate of the Sr-90 applicator for radioactive decay and Dr. De León failed to verify or question the consultant's calculation before using the revised surface dose rate in patient treatments. In addition, Dr. De León performed ophthalmic brachytherapy using his Sr-90 eye applicator device at Ryder Memorial Hospital, under Ryder Memorial Hospital's NRC license, without the hospital's authorization.

Actions Taken To Prevent Recurrence

Licensee - Ryder Memorial Hospital reiterated its withdrawal of Dr. De León's authority to use his Sr-90 eye applicator device at Ryder Memorial Hospital and does not intend to authorize the use of Sr-90 in ophthalmic brachytherapy. In addition, Dr. De León has retired and does not plan on using the Sr-90 eye applicator in the future. He is currently authorized under NRC License No. 52-19206-01 for possession for storage only.

NRC - NRC is performing additional inspections of licensees authorized to possess and use Sr-90 eye applicators in Puerto Rico to confirm the use of proper decay corrections and source calibrations. It is also surveying the sources for calibration accuracy. In addition, NRC will review this case with the Secretary of Health of the Commonwealth of Puerto Rico, for possible action.

(Contact: Gary Purdy, 301-415-7897,
e-mail: gwp1@nrc.gov)