NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

NUREG/BR-0117
No. 00-4
Dec 2000-Jan 2001

IMPLEMENTATION PLAN FOR REVISED 10 CFR PART 35, "MEDICAL USE OF BYPRODUCT MATERIAL"

The Office of Nuclear Material Safety and Safeguards (NMSS) is requesting input from stakeholders on the development of the implementation plan for the revised 10 CFR Part 35, "Medical use of byproduct material." The U.S. Nuclear Regulatory Commission (NRC) recognizes the need for early participation of our stakeholders in this process, to achieve a smooth implementation of the rule. Therefore, we are seeking input on the following:

1) How can we best communicate the changes involved in the revised Part 35 with the organizations that you (the reader) represent?

2) What methods and ideas would be best suited to communicate revised Part 35 to your specialty group?

3) Whom, within your organization, should NRC contact, to arrange presentations, and discuss ideas to get the message out in an effective way?

4) What meetings should NRC attend to present the revised Part 35 and what topics does this audience want NRC to address?

NMSS staff is currently evaluating: 1) training sessions for NRC and Agreement State staffs; 2) workshops for licensees and stakeholders; 3) information notices about publication and implementation of the rule; 4) personal or video conference presentations to societies and organizations, like the Conference of Radiation Control Program Directors, Organization of Agreement States, and others; and 5) creation of an NRC Part 35 website. NMSS staff is proposing that the Part 35 website contain a comparative table of the old rule versus the new rule, frequently asked questions, training schedules, and a section in which stakeholders and licensees can submit questions, to NRC staff, related to revised Part 35.

Comments and suggestions can be directed by mail to: U.S. Nuclear Regulatory Commission, Mail Stop T8 F5, Attn: Roberto J. Torres, Washington, DC 20555-0001. Suggestions can also be sent by electronic mail to Roberto J. Torres, at rjt@nrc.gov (301-415-8112), and/or Joseph DeCicco, at jxd1@nrc.gov (301-415-7833).

(Contacts: Roberto J. Torres, 301-415-8112, e-mail: rjt@nrc.gov; Joseph DeCicco, 301-415-7833, e-mail: jxd1@nrc.gov)

LOST INDUSTRIAL RADIOACTIVE SOURCE CAUSES TWO DEATHS AND INJURIES IN EGYPTIAN FAMILY

Disclaimer: This article is based on information contained in International Atomic Energy Agency incident response reports and news media reports on the incident. Although the overall circumstances and consequences of the event are believed to be correct, some details of the actual event may be different than information presented in this article.

In Egypt, a farmer and his son died in June 2000 as a result of radiation exposure received from an iridium-192 sealed source that was apparently lost and abandoned by personnel performing industrial radiography. The farmer, his wife, and five children lived in the village of Mit Halfa, located 30-40 kilometers (18-25 miles) North of Cairo, Egypt. In May 2000, the farmer and his 9-year-old son went to a local physician complaining of burns to the skin. Their physician diagnosed skin inflammation from some kind of virus or bacterial infection. The prescribed medical treatment did not help. In June 2000, the farmer, who was 60 years old, took his wife, sister and four children, including the son, to a nearby

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

LOST INDUSTRIAL RADIOACTIVE SOURCE CAUSES TWO DEATHS AND INJURIES IN EGYPTIAN FAMILY (continued)

hospital, after the whole family developed skin discoloration. Within hours after arriving at the hospital, the farmer's 9-year-old son died. At some period after the farmer's son died, other family members, including the farmer, were admitted to a second hospital in Cairo. Several days after being admitted to this hospital, the farmer died.

The deaths of the farmer and his son were linked to radiation exposure, after a blood test undergone by the remaining family members revealed that they had severe depressions in their white blood cell count. The results prompted officials to dispatch a radiation monitoring team to the village where the farmer had lived. The team performed radiation surveys and found high radiation levels within the farmer's house. A radioactive source in a cylinder shape 6.25-centimeters (cm) (2.5-inches) long and 2.5 cm (1 inch) in diameter was later located. It was subsequently secured in a shielded container and removed to a waste disposal site. There was no evidence that the source was leaking. The source was later identified as iridium-192, used for industrial radiography, and having an activity of 1.8 terabecquerel (Tbq) [50 curies (Ci)] at the time it was found.

Information developed during an inquiry into the event revealed the following circumstances surrounding the event. The farmer apparently found the iridium-192 sealed source in a load of material procured for a home construction project. He took the radioactive source into his home. He apparently thought it was valuable. It is not known how long the farmer had the source in his home before experiencing symptoms. The 1.8-Tbq (50-Ci) iridium-192 source was found to belong to an industrial maintenance company performing work in the area. Personnel from the company were using the iridium-192 source for industrial radiography work near the village of Mit Halfa where the farmer and his family lived. Technicians from the industrial maintenance company left the cylinder at a site where they were fixing liquefied gas pipes, believing it was buried with the pipes. The owner of the consulting firm failed to notify authorities that the cylinder had disappeared.

As many as 160 people, neighbors plus relatives and friends of the farmer, had their white blood cell counts checked and were evaluated for a need

for medical follow-ups. The results of the evaluations are not known. However, there have not been more reports of high acute doses of radiation being received by other persons associated with this event.

Egyptian officials accused the company personnel of losing the source, abandoning the source, and failing to report the loss to competent authorities. Three men have been arrested and charged with gross negligence, manslaughter, and unintentional injury.

The scenario involving the lost radiography source resembles that of other reported radiological accidents involving lost sources, including the loss of a cobalt-60 source at Samut Prakan near Bangkok, Thailand, February 20, 2000, which resulted in the death of three people. A similar incident also occurred in Goiania, a small town in central Brazil. In that incident, scavengers pried open a metal canister from a radiation therapy (teletherapy) machine abandoned by a cancer treatment clinic. The machine contained 51.8 Tbq (1400 Ci) of cesium-137. Four people died as a result of the incident; 244 people were contaminated.

Events of this type underscore the severe consequences that can result from the loss of radioactive material in the public domain and the failure to report the loss to competent authorities so that actions can be taken to find the source and warn the public. To prevent losses of the type that led to the exposures in Egypt, proper radiation surveys must be done to ensure that radiation sources are properly stored and contained, on completion of work.

Although there have been several incidents reported in the U.S. involving the loss of a radioactive source in circumstances similar to the Egyptian event, personnel radiation exposures of the type that occurred in the Egyptian event fortunately have been avoided.

(Contact: Sam Pettijohn, 301-415-6822; e-mail: slp@nrc.gov)

THE NATIONAL MATERIALS PROGRAM WORKING GROUP

Agreement States currently regulate 75 percent of the nuclear materials licensees in the U.S., and have the potential of regulating 80 percent of U.S. licensees by fiscal year 2003 when three more Agreement States are expected to be in place. On November 23, 1999, the Commissioners of the Nuclear Regulatory Commission (NRC) requested the creation of a National Materials Program (NMP) Working Group (WG) through a Staff Requirements Memorandum (SECY 99-250). The purpose of the WG is to provide the Commission with options for maintaining an infrastructure of supporting regulations, guidance and other program elements needed for the nationwide materials program, considering the anticipated increase in the number of Agreement States. Part of the purpose of this group is to look at the future of radiation protection programs and define what a "national materials program" should look like and how it should work.

The NMP WG consists of representatives from NRC Headquarters and regions; the Organization of Agreement States (OAS); and the Conference of Radiation Control Program Directors (CRCPD). There are 12 members on the WG and one NRC management advisor. In addition, a steering committee consisting of senior NRC management and one representative each from OAS and CRCPD was created in January 2000.

This WG began meeting in the winter of 2000. Rather than dictating a top-down structure, the WG decided to take a bottom-up approach, to develop a good foundation before designing an organizational structure.

The WG began by identifying the key elements of a radiation protection program based on CRCPD publications and those concepts used in NRC's Integrated Material Performance Evaluation Program (IMPEP) (e.g., licensing, inspection, guidance development, regulation development, etc.). Then the WG identified the current methods of accomplishing those program elements, in addition to brain-storming new options for meeting the program needs. The options developed were then evaluated against the current method of accomplishing the objective, using the following criteria:

- Does the option optimize resources of Federal, State, professional, and industrial organizations?
- Does the option account for individual agency needs and abilities?
- Does the option promote consensus on regulatory priorities?
- Does the option harmonize regulatory approaches?
- Does the option recognize State and Federal needs for flexibility?

On further review, the WG found that the most efficient and effective options shared certain common attributes:

- They used a consensus process.
- They recognized successes.
- They maintained flexibility.
- They shared resources.
- They made use of alternative resources.
- They increased communications and decreased duplication.
- They recognized shared responsibility.

By August 2000, the program's goals were clearly defined. The next question facing the WG was how to use the common attributes to design and build a supporting structure. The WG evaluated several types of interagency relationships to find successful mechanisms that could meet all of the attributes and goals. Several ideas have been considered: there could be numerous autonomous organizations in the national materials program, the consultive process presently used could be retained, an advisory committee could be an option, or, a consensus mechanism similar to an alliance could be developed.

At the OAS meeting October 2-4, 2000, NRC and the Agreement States participated in a tabletop exercise designed to test methods for arriving at concurrence on what issues are "national" priorities. There was a lot of discussion about establishing priorities, determining resources available to address the issues, and the whole "alliance" concept. The WG has evaluated the comments received during that exercise and is incorporating them into the final product.

The WG needs more information from stakeholders and the public as it continues to develop options related to the structure, function, and implementation of a national materials program. To further this initiative, the WG will be holding a stakeholders' meeting at NRC's Region IV Office, Arlington, Texas, on February 21-22, 2001. Information on the WG's meeting and other information, such as the charter, list of members, and notes or outlines of proposals can be found on the web at the following URL: www.hsrd.ornl.gov/nrc/home.html. Additional information about the national materials program may be found in the November 2000 issue of The Health Physics Society's Newsletter, or you may contact the WG Co-Chairs, Jim Myers, at 301-415-2328, e-mail: jhm@nrc.gov, or Kathy Allen, at 217-785-9931, e-mail: or k_allen@idns.state.il.us.

(Contact: Jim Myers, 301-415-2328, email: ghm@nrc.gov)

NRC STAFF SPONSORS DECOMMISSIONING WORKSHOP

On November 8 and 9, 2000, U.S. Nuclear Regulatory Commission (NRC) staff sponsored a workshop at NRC's Headquarters in Rockville, MD. The purpose of the workshop was to provide a forum for industry and non-industry stakeholders to discuss NRC's processes and procedures for managing the decommissioning of nuclear facilities, as well as current issues facing the staff and licensees as they implement NRC's decommissioning requirements with NRC staff. The theme of the workshop was "Inform, Listen, Learn." To promote this theme, the staff first made presentations on NRC's decommissioning requirements and processes for both material and reactor facilities and on NRC staff expectations for license termination plans and decommissioning plans. Presentations were followed by a series of facilitated, roundtable discussions on the decommissioning process, and current issues in decommissioning, such as releasing portions of sites before license termination, and requirements for institutional controls for sites contemplating license termination with restrictions on future site use.

To ensure that both industry and non-industry stakeholders were represented at the workshop, staff invited representatives from the nuclear industry, various public interest groups, and other Federal and State agencies with responsibilities for regulating the use of radioactive material to participate in the roundtable discussions. Approximately 130 individuals representing the nuclear industry, citizens' organizations and the public, Federal and State regulatory agencies, and the media, attended the workshop.

Based on the discussions at the workshop, it appears that although the NRC staff has made progress in developing and implementing the decommissioning program, some members of the public are concerned about the timing of the submission of the License Termination Plan for power reactors undergoing decommissioning; the appropriateness of a general license for a dry cask storage area; and, the closure of NRC's local Public Document Rooms.

NRC staff is currently developing a summary of the workshop as well as a set of recommendations that will be forwarded to the Commission for its

consideration. Transcripts of the meeting and material used by the NRC staff during presentations will be posted at: http://www.nrc.gov/NMSS/DWM/DECOM/decomm.htm as soon as they are available.

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

THE NMSS RISK TASK GROUP: RISK-INFORMED REGULATION IN THE MATERIALS AND WASTE ARENAS

The Risk Task Group (RTG) was created to develop the best approach for incorporation of risk information into the regulation of nuclear materials and disposal of radioactive waste. Currently, the task group reports to the Office of the Director, office of Nuclear Material Safety and Safeguards (NMSS). As the focal point for NMSS risk-informed initiatives and activities, RTG will identify and support new regulatory initiatives that use risk assessments and risk insights to add value to the NMSS decision-making process. Additionally RTG will review new regulatory applications, and technical products to ensure consistent and appropriate application of risk methodology, and to ensure that any change to our existing regulatory position is consistent with the risk significance. Further details can be found in SECY-99-100, "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards."

One of RTG's first undertakings for fiscal year 2001 will be a series of case studies in the material and waste arenas. The objectives of the case studies will be to: (1) illustrate what has been done, and what could be done, in the materials and waste arenas, to alter the regulatory approach in a risk-informed manner; and (2) establish a framework for using a risk-informed approach by testing the draft screening criteria, and determining the feasibility of safety goals for the material and waste arenas. The intent of the case studies is not to reopen or reassess previous decisions made by the staff and the Commission. However, the information gained by performing the case studies may impact future decisions. Individual case study areas include: fixed gauges; gas chromatographs; static eliminators; site decommissioning; uranium recovery facilities; radioactive material transportation; 10 CFR Part 76; and spent fuel interim storage. Each case study will be of limited scope, but collectively the case studies will cover a broad spectrum of regulatory applications. When the case studies are completed, the results will be presented to the Commission.

RTG is also involved in developing and implementing training classes designed to increase familiarity with risk assessment techniques in NMSS. The first class, "Introduction to Risk Assessment in NMSS," will be offered periodically throughout the year. RTG will also lend support to Division activities related to risk information. Additionally, in support of the Agency's effort to incorporate consensus standards and international guidance into our regulatory framework, a member of RTG serves as the U.S. representative of the International Atomic Energy Agency's Technical Committee on Standards for Use of Probabilistic Safety Assessment in Non-Reactor Nuclear Facilities.

(Contact: Raeann. M. Shane, 301-415-7832, e-mail: rms2@nrc.gov)

E-BUSINESS IS HERE: NRC PREPARES TO ACCEPT ELECTRONIC SUBMITTALS FROM LICENSEES AND VENDORS

As part of the Nuclear Regulatory Commission's (NRC's) is continuing efforts to enhance electronic business processes, the Agency is developing a rulemaking to allow all individuals and organizations sending information to NRC to do so electronically, either through the Electronic Information Exchange (EIE) process at the Agency EIE Website (http://www.nrc.gov/NRC/EIE/index.html) or by mailing CD-ROM versions of their documents to NRC. The rulemaking will be comprehensive and address all 10 CFR Parts, including all holders of materials licenses. This rulemaking is anticipated in calendar year 2001.

In advance of the rulemaking, the Office of the Chief Information Officer (OCIO) is renewing an EIE pilot project for two NRC organizations—the Atomic Safety Licensing Board Panel (ASLBP) and the Office of the Secretary (SECY)—to test the submission and processing of documents sent to destinations other than the Document Processing Center (DPC). Traditionally, hearing documents have been submitted directly to SECY or ASLBP. ASLBP was part of the initial pilot until legal questions about digital signatures caused some of the participants to stop sending documents electronically. Recent legislation has clarified the use of digital signatures and the pilot will be restarted.

Most of the voluminous boxes of paper and three-ring binders from reactor licensees and vendors arriving at the loading dock of NRC

offices at One White Flint North are becoming a thing of the past. That's when NRC will permit reactor licensees and vendors licensed under 10 CFR Part 50 to submit documents to the Agency electronically, instead of in paper form. NRC's OCIO will notify the Agency by a Network Announcement when the electronic submittals officially begin.

These developments are the culmination of a process that began with a year-long pilot program between the Agency and licensees, for three nuclear power plants to work out technical and procedural bugs. The pilot recently ended successfully. Licensees participating in the EIE process first obtain *digital certificates* from NRC to submit their information via EIE over the Internet. The digital certificates provide the security that allows electronic documents to be digitally signed before submission. All documents sent in electronic format, whether via EIE or on a CD-ROM, are received by OCIO's DPC staff, for profiling and entry into NRC's Agencywide Documents Access and Management System. The DPC staff then electronically distributes them throughout the Agency, through the Electronic Regulatory Information Distribution System. One nice feature of the EIE system is that licensees and vendors submitting documents will be notified, via e-mail, of the time and date that NRC received the documents. Presently, unless documents are sent "Receipt Requested," licensees cannot verify that NRC received their packages until days later.

At this time, only documents submitted *to* NRC may be sent in electronic form; documents leaving the Agency cannot be sent electronically. The OCIO is exploring the requirements for a system that would permit the staff to electronically dispatch documents to Agency clients.

Additional information on either the Rulemaking or the EIE process may be obtained by contacting John Skoczlas at 301-415-7186.

(Contact: John Skoczlas, 301-415-7186, e-mail: jas1@nrc.gov)

COMPASS—COMPUTER CODE FOR IMPLEMENTATION OF MARSSIM

The Computerization Of the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) for Planning and Assessing Site Surveys (COMPASS) computer code is a tool for facilitating statistical calculations in planning of final status surveys, using the guidance in MARSSIM (NUREG-1575). COMPASS was developed by the Oak Ridge Institute for Science and Education-Environmental Survey and Site Assessment Program, with sponsorship of the U.S. Nuclear Regulatory Commission (NRC). The code is written in Visual Basic and runs on Windows and NT platforms.

COMPASS provides computerization of the MARSSIM survey and investigation process and includes functions to: (1) design surveys with multiple contaminants using the unity rule; (2) perform calculations of the modified derived concentration guideline levels (DCGLs) using the surrogate approach, gross-activity DCGLs using relative fractions, and the number of measurements and samples needed by the nonparametric statistical tests and the elevated measurement comparison test; (3) generate prospective and retrospective power curves to demonstrate the attributes of each MARSSIM survey unit design; and (4) determine whether residual radioactivity levels meet the release criteria, using a statistically based decision rule. Benefits of COMPASS include performing multiple analyses quickly with reduced calculation error, efficiently developing and implementing an effective survey design, and providing consistency of information.

NRC intends to issue the code as freeware.

COMPASS Beta version 0.9.1 was issued by NRC, as a download, for testing and evaluation by interested users on November 21, 2000, from NRC's Nuclear Facilities Decommissioning web site under "Special Projects" at: http://www.nrc.gov/NMSS/DWM/DECOM/decomm.htm.

Testing of the Beta code will end on December 22, 2000. Comments on testing of COMPASS Beta code version 0.9.1 should be forwarded to Dr. Richard Clement (Office of Nuclear Material Safety and Safeguards/Division of Waste Management/Decommissioning Branch).

(Contact: Dr. Richard Clement, 301-415-6625, e-mail: rsc1@nrc.gov)

MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

The U.S. Nuclear Regulatory Commission's (NRC's) Advisory Committee on the Medical Uses of Isotopes (ACMUI) held a meeting on November 8-9, 2000. The topics of discussion included: 1) status and implementation of the 10 CFR Part 35 rulemaking; 2) NRC initiatives: risk-informed and performance-based regulation;

3) intravascular brachytherapy and new radiation technology issues; 4) NRC lessons learned from Mallinckrodt exposure events; 5) NRC/Agreement State working group on event reporting; 6) update of other rulemaking activities; and 7) self-evaluation criteria for the ACMUI. Five new members, representing various specialities such as radiation oncology, nuclear pharmacy, therapy, medical physics, and radiation safety, began serving 3-year terms on the ACMUI.

Copies of the transcript and summary minutes for the meeting are available through the NRC Public Document Room (301-415-4737). The next meeting of the ACMUI will be noticed in the *Federal Register.*

(Contact: Betty Ann Torres, 301-415-0191, e-mail: bat@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.

MEDICAL

John M. Corboy, M.D., Wahiawa, HI EA-00-059. A Notice of Violation and Exercise of Enforcement Discretion was issued for a Severity Level II violation on July 25, 2000. The action was based on the failure of the licensee to account for radioactive decay of strontium-90 used in eye applicators. As a result, the incorrect source strength was used to determine treatment times, resulting in 71 misadministrations. A civil penalty was not proposed because the licensee voluntarily suspended use of the eye applicators, transferred the applicators, and requested termination of the license.

Roberto Buxeda-Dacri, M.D., Santurce, PR EA-00-141. A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2750 was issued July 14, 2000. The action was based on a violation involving the failure to test an eye applicator source, containing approximately 1147 megabequerels (31 millicuries) of Strontium-90, for leakage at proper intervals.

VA Medical Center, Philadelphia, PA EA-00-086. A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $5500 was issued July 19, 2000. The action was based on a violation involving the failure to comply with the requirements of 10 CFR 50.7, "Employee protection." The Merit Systems Protection Board substantiated that VA Medical Center, Philadelphia, had retaliated against a former research nurse, for whistle-blowing activity, when the individual was subjected to intolerable working conditions, and that this environment was created as a result of her raising safety issues.

OTHER

Spectrum Pharmacy, Inc., Mishawaka, IN EA-00-071. A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2750 was issued September 21, 2000. The action was based on the licensee's failure to ship radioactive material packages in accordance with NRC and Department of Transportation requirements, its failure to follow its emergency plan in response to a spill of radioactive material, and its failure to perform adequate surveys subsequent to the spill of radioactive material.

RADIOGRAPHY

Braun Intertec Corporation, Minneapolis, MN EA-00-147. A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $5500 was issued August 14, 2000. The action was based on a violation involving the willful failure to have two individuals present during radiography at a temporary job site.

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

SELECTED *FEDERAL REGISTER* NOTICES (September 1, 2000-September 30, 2000)

NOTE: U.S. Nuclear Regulatory Commission (NRC) contacts may be reached by mail at the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Only non-NMSS Office personnel will be identified by Office, in "Contact(s)," below.

FINAL RULES

"Licensing of Special Nuclear Material; Possession of a Critical Mass of Special Nuclear Material," 65 FR 56211, September 18, 2000.

Contacts: Theodore S. Sherr, 301-415-7218, e-mail: tss@nrc.gov.
Heather Astwood, 301-415-5819, e-mail: hma@nrc.gov.
Andrew Persinko, 301-415-6522, e-mail: axp1@nrc.gov.

OTHER NOTICES

"Relocation of the Nuclear Regulatory Commission's Public Document Room (completed September 26, 2000)," 65 FR 54865, September, 11, 2000.
Contact: Thomas Smith, OCIO, 301-415-7204, e-mail : tes@nrc.gov.

"Staff Meetings Open to the Public: Final Policy Statement," 65 FR 56964, September 20, 2000.
Contact: Rosetta O. Virgilio, OEDO, 301-415-2307, e-mail: rov@nrc.gov.

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

GENERIC COMMUNICATIONS ISSUED (September 1, 2000-November 30, 2000)

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 2000-12, "Potential Degradation of Firefighter Primary Protective Garments" was issued on September 21, 2000. This notice was issued to all holders of licenses for nuclear power, research, and test reactors, and fuel cycle facilities, to alert addressees to potential degradation of performance of firefighter primary protective garments (FFPPGs). Licensees were reminded that proper storage and regular thorough inspections of FFPPGs are important to ensure that these garments provide effective firefighter protection because their degradation may not be readily apparent.

Contacts: Christopher G. Cahill, Region I, 610-337-6916, e-mail: cgc@nrc.gov.
Paul W. Lain, NMSS, 301-415-6317, e-mail: pwl@nrc.gov.
Daniel M. Frumkin, NRR, 301-415-2280, e-mail: dxf1@nrc.gov.
Charles D. Petrone, NRR, 301-415-1027, e-mail: cdp@nrc.gov.
Mark H. Salley, NRR, 301-415-2840, e-mail: mxs3@nrc.gov.

IN 2000-15, "Recent Events Resulting in Whole-Body Exposures Exceeding Regulatory Limits" was issued on September 29, 2000. This notice was issued to all radiography licensees to alert addressees to recent events that resulted in radiographers receiving occupational whole body doses in excess of the 0.05-sievert (5-rem) total effective dose equivalent limit specified in 10 CFR 20.1201(a)(1).
Contact: Linda M. Psyk, NMSS, 301-415-0215, e-mail: lmp1@nrc.gov.

IN 2000-16, "Potential Hazards due to Volatilization of Radionuclides " was issued on October 5, 2000. This notice was issued to all NRC licensees that process unsealed byproduct material to alert addressees to the potential hazards associated with the volatilization of radiochemicals and/or radiopharmaceuticals if containment is breached during chemical or physical processing.
Contact: Kevin G. Null, Region III, 630-829-9854, e-mail: kgn@nrc.gov.

IN 2000-18, "Substandard Material Supplied by Chicago Bullet Proof Systems" was issued on November 29, 2000. This notice was issued to all 10 CFR Part 50 licensees and applicants, all category I fuel facilities, and all 10 CFR Part 72 licensees and applicants, to inform addressees of substandard material supplied by Chicago Bullet Proof Systems (CBPS) to Fort St. Vrain and Susquehanna nuclear power plants. CBPS supplied material that was not in conformance with specifications of the licensees' purchase orders and not in conformance with NRC guidance documents (e.g., NUREG-0908).

Contacts: Joseph Petrosino, NRR, 301-415-2979, e-mail: jjp1@nrc.gov.
Michael Warren, NMSS, 301-415-8098, e-mail: msw@nrc.gov.
Eric Benner, NRR, 301-415-1171, e-mail: ejb1@nrc.gov.
Robert Skelton, NRR, 301-415-3309, e-mail: rfs1@nrc.gov.

Regulatory Issue Summaries (RIS')

RIS 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media" was issued on October 23, 2000. This summary was issued to all holders of operating licenses for nuclear power plants, including licensees that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessels. This summary was also issued to those materials licensees, including certificate holders and vendors, that are required to have NRC-approved quality assurance programs, to

provide updated guidance on managing quality assurance records in electronic media.

Contacts: Michael T. Bugg, NRR, 301-415-3221, e-mail: mtb@nrc.gov.
James J. Pearson, NMSS, 301-415-1985, e-mail: jjp@nrc.gov.
Mark A. Sitek, NMSS, 301-415-5799, e-mail: mas3@nrc.gov.

RIS 2000-23, "Recent Changes to Uranium Recovery Policy," was issued on November 30, 2000. This summary was issued to all holders of materials licenses for uranium and thorium recovery facilities, to inform addressees of the Commission's decisions on four Commission Papers prepared by the Uranium Recovery staff and the Office of the General Counsel. All of the policy decisions will be codified in the new 10 CFR Part 41.
Contact: Kenneth R. Hooks, NMSS, 301-415-7777, e-mail: krh1@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: Misadministration involving an iodine-125 (I-125) permanent implant at Cumberland Medical Center, Crossville, Tennessee

Date and Place: August 14, 2000; Cumberland Medical Center, Crossville, Tennessee.

Nature and Probable Consequences: The licensee reported a therapeutic misadministration involving two patients being treated for prostate cancer with I-125 seed implants. The pre-treatment plan for patient No. 1 called for 78 seeds containing 12.06 megabecquerel (MBq) [0.326 millicurie (mCi)] per seed. The pre-treatment plan for patient No. 2 called for 123 seeds containing 8.47 MBq (0.229 mCi) per seed. During the post-plan review, it was discovered that an error had occurred when ordering the seeds. Patient No. 1 was treated with seeds containing 15.32 MBq (0.414 mCi) per seed and patient No. 2 was treated with seeds containing 10.77 MBq (0.291 mCi) per seed. Follow-up information indicates that only one patient received a reportable misadministration dose. The pre-treatment plan for patient No. 1 called for a dose of 10,800 to 11,000 centiGray (cGy) (10,800 to 11,000 rads) and the calculated dose was determined to be 13,000 to 13,500 cGy (13,000 to 13,500 rads), which exceeded the prescribed dose by approximately 23 percent. The dosage to patient No. 2 was calculated to have exceeded the prescribed dosage by approximately 17 percent. Both patients are being monitored for adverse reactions. The incident was caused by human error. The wrong seed activity was ordered from the source supplier, which resulted in the patients receiving more activity than was prescribed.

Actions Taken to Prevent Recurrence

Licensee: The licensee's corrective actions to prevent recurrence will include independent checks on the isotope type, activity, and number of seeds to be implanted. These checks will be performed by the radiation oncologist, the medical physicist, and the medical dosimetrist, before ordering, and again before patient implantation.

State Agency: The Tennessee Division of Radiological Health conducted interviews with licensee personnel and the medical physicist on August 31, 2000, to verify the circumstances of the event and the corrective actions taken by the licensee to prevent a recurrence.

Event 2: Misadministration involving the use of Yttrium-90 (Y-90) microspheres at the University of Pittsburgh's Presbyterian Hospital, Pittsburgh, Pennsylvania

Date and Place: August 15, 2000; University of Pittsburgh, Pittsburgh, Pennsylvania

Nature and Probable Consequences: On August 15, 2000, the licensee reported a possible misadministration, involving a patient undergoing treatment for liver cancer, using 2.96 gigabecquerels (80 millicuries) of Y-90 microspheres. The microspheres are manufactured and distributed by MDS Nordion under the product name TheraSphere. TheraSphere is administered to patients under a Humanitarian Device Exemption (HDE) issued by the Food and Drug Administration (FDA). TheraSphere is supplied with an administration set that facilitates the transfer of the microspheres from the product vial through an arterial catheter, which is inserted in the hepatic artery, and into the patient's liver. Before the treatment, technetium-99m labeled macroaggregated albumin (Tc-99m MAA), which mimics the transport of the microspheres through the hepatic artery and liver, was injected into the arterial catheter to verify that the microspheres would be

trapped in the vasculature of the liver and not travel to other areas of the body. A scan of the patient revealed that the Tc-99m MAA remained in the liver as required. During the subsequent administration of the TheraSphere, everything appeared to go well; however, surveys of the patient and the administration set showed that a significant quantity of the microspheres remained in the administration set and the arterial catheter. The University of Pittsburgh and MDS Nordion initiated an investigation and concluded that approximately 65 percent of the intended dose was administered to the patient. The University of Pittsburgh submitted a report of misadministration on September 12, 2000. Further investigation revealed that there was a significant problem with the design of the administration set, which resulted in the incomplete administration of the TheraSphere dose. MDS Nordion continues to evaluate the problem with the administration set. The FDA is aware of the problem and is working with MDS Nordion to amend the HDE. The University of Pittsburgh and MDS Nordion concluded that TheraSphere could be reliably administered to patients, using a larger volume of sterile, pyrogen-free water to transfer the microspheres in conjunction with careful surveys of the administration set during the administration. No one was contaminated or overexposed during this event.

Actions Taken to Prevent Recurrence

Licensee: The University of Pittsburgh postponed subsequent treatments pending the result of an investigation into the cause of this incident. The University of Pittsburgh worked with MDS Nordion to identify the cause of the administration. Patient treatments were resumed once it was determined that TheraSphere could be reliably administered using a larger volume of sterile, pyrogen-free water to transfer the microspheres, in conjunction with careful surveys of the administration set during the administration.

NRC: The State of Maryland was immediately notified of the event because NRC was aware that a Maryland licensee was intending to perform a TheraSphere treatment on August 16, 2000. NRC Region 1 and the Office of Nuclear Material Safety and Safeguards evaluated the circumstances leading to this event and are monitoring MDS Nordion's efforts, along with FDA, to redesign the administration set.

Event 3: High-Dose-Rate Remote Afterloader Misadministration at the University of Virginia, Charlottesville, Virginia

Date and Place: September 7, 2000; University of Virginia; Charlottesville, Virginia.

Nature and Probable Consequences: On September 13, 2000, the licensee notified the NRC Operations Center of a medical misadministration that occurred on September 7, 2000, regarding a patient who had undergone a high-dose-rate brachytherapy treatment (HDR treatment) for cervical cancer. The treatment was performed using a GammaMed HDR, Model No. 12i, and a tandem and ovoid applicator. The treatment plan was to give the patient a prescribed dose of 5 gray (Gy) [500 rads] in one single fraction. Instead, the patient received an unintended dose of 8 Gy (800 rads). The licensee discovered the error during a review of the patient's treatment plan late that same day.

The licensee investigated and determined that the radiation sources remained in the patient at the wrong locations because the positions in the treatment plan had been entered in the reverse order and the medical staff did not detect this error. From a review of the treatment and dose administered, the attending physician had determined that the patient would have no adverse effects from the unintended dose.

The cause of the event was operator error during the digitization of film data. In addition, the established second-check procedures were inadequate to detect the error. A contributory cause was that the software in the treatment planning system did not warn or prompt the user for confirmation that the most distal marker seed was used for the digitization of the first source-stopping position, and the fact that when the system draws the isodose curves, there are no graphical indications of the end of the treatment path, or numbering of the treatment positions, or any other indicator providing spatial orientation.

Actions Taken to Prevent Recurrence

Licensee: Corrective actions taken include:
1) modifying the annual retraining outline for physician and physicist users to include a discussion of the error for all future training;
2) modifying the procedure for the second physicist check to address the error; and
3) modifying the procedures for the physician check to address the error.

NRC: The NRC Region II conducted an inspection of the licensee during the week of September 18, 2000, to review the circumstances associated with the misadministration. NRC retained the services of a physician consultant to review the details of this event.

Event 4: Unexpected exposure to Iridium-192 sources at Mercy Hospital, Iowa City, Iowa

Date and Place: September 11, 2000; Mercy Hospital; Iowa City, Iowa.

Nature and Probable Consequences: Mercy Hospital reported an unexpected exposure to a radiation therapist, who was not a hospital employee, from iridium-192 (Ir-192) medical seed sources. The Iowa City Cancer Treatment Center employed the individual, who was acting on the hospital's behalf when the incident occurred. The individual, unfamiliar with the mechanics of the ordering process, thought that she had ordered a ribbon with six dummy seeds, and a ribbon with six Ir-192 seeds, when, in fact, the information that was retained by the supplier did not include the request for the dummy sources. A package containing seeds from the manufacturer was delivered to Mercy Hospital on September 11, 2000. The shipping papers for the package stated; "1 each leader," and on the next line "1 each ribbon with six seeds." The individual thought that the "1 each leader" was the dummy seeds and the "1 each ribbon with six seeds" was the Ir-192 seeds. The individual did not realize that the package shipping papers meant one each leader with one each ribbon with six seeds. The individual removed what she thought were the dummy sources and did not make a routine radiation survey, in an attempt to verify her assumption. The individual carried the ribbon of Ir-192 seeds in her hand to a room where a practice simulation of the upcoming procedure was to be performed using dummy seeds. The simulation was never performed because of some problems with loading the ribbon of seeds into a catheter. The ribbon of Ir-192 seeds was moved to various locations in the simulator room during the day and remained in that room until the next day. The next morning, the individual discovered that she had handled actual Ir-192 seeds. Total activity of the Ir-192 seeds was 0.69 gigabequerel (GBq) [18.54 millicurie (mCi)]. The State of Iowa calculated that the individual received 29 centisievert (cSv) (29 rem) to her right hand. The individual had the ribbon of Ir-192 seeds in her hand for about 20 minutes. Her whole body dose, as determined by her dosimeter reading, was 0.34 millisievert (mSv) [34 millirem (mrem)]. Several people who entered the simulator room were also exposed. The Radiation Safety Officer received a whole body dose of 0.48 mSv (48 mrem); an employee received a whole body dose of 0.13 mSv (13 mrem); and an oncologist received a whole body dose of 0.16 mSv (16 mrem).

Actions Taken to Prevent Recurrence

State Agency: The State of Iowa Department of Public Health (IDPH), Radioactive Materials Program, instructed Mercy Hospital that, as a licensee, it is responsible for all activities associated with its radioactive material license and that this responsibility extends to individuals outside the hospital if the individual is acting on the hospital's behalf. IDPH therefore concluded that it was Mercy's Hospital's responsibility to assure that all appropriate training is provided to such individuals, and in particular to employees of the Iowa City Treatment Center who interfaced with the radiological program. Iowa City Cancer Treatment Center functions as a separate entity and is not licensed by IDPH. IDPH issued Mercy Hospital with a Notice of Violation identifying five deficiencies. The deficiencies, which were indicative of a breakdown in the control of licensed activities and represented a lack of attention toward those activities, were collectively classified as an overall Severity Level III violation.

Event 5: Two potential misadministrations caused by calculation error involving iodine-125 (I-25) temporary implants at Sibley Memorial Hospital, Washington, District of Columbia

Date and Place: September 22, 2000; Sibley Memorial Hospital, Washington, District of Columbia.

Nature and Probable Consequences: The licensee reported a medical event in which two patients received greater radiation doses than prescribed, because of calculational errors. The licensee discovered that a mistake was made in ordering sources for the medical procedures. A change had been made to order sources in "air kerma strength" instead of megabequerels (millicuries) (mCi). The conversion is supposed to be the mCi divided by 1.27, but the licensee multiplied by 1.27 instead. Two patients received I-125 plaques to the eye for melanoma and were both prescribed to receive 7000 centigray (cGy) (7000 rad) to the apex of the tumor over 120 hours. However, the patients received 10,866 and 11,470 cGy (10,866 and 11,470 rads), respectively. The licensee does not expect any consequences beyond what was expected with the prescribed dose. The procedures were performed in an attempt to preserve the patients' eyes, as they would have been removed otherwise. The licensee ascribes the cause of the events to a calculation mistake, since the conversion equation was not performed properly. The licensee has determined that no other sources were ordered with the wrong calculation.

Actions Taken to Prevent Recurrence

Licensee: The licensee stated that treatments would be suspended until the quality assurance software was checked, training was provided to personnel, and written procedures were put in place to ensure the accuracy of the treatment calculation.

NRC: NRC Region I staff conducted an inspection and reviewed the circumstances surrounding the medical event and the potential causes. This inspection confirmed that an error in the calculation of dose from air kerma contributed to the event. NRC retained the services of a physician consultant to examine the events and effects on the patients.

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