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MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION OF SPECIALITY BOARDS; FINAL RULE

The U.S. Nuclear Regulatory Commission (NRC) published a final rule to amend its requirements for training and experience (T&E) for "Medical Use of Byproduct Material," 10 CFR Part 35, in the *Federal Register* (FR) on March 30, 2005 (70 FR 16335). The rule amends the regulations to change requirements for recognition of certain specialty boards' certification processes. These boards' certifications may be used for demonstrating the adequacy of the training and experience of individuals to serve as authorized users (AUs); authorized medical physicists (AMPs); authorized nuclear pharmacists (ANPs); or radiation safety officers (RSOs). The final rule also revises the requirements for demonstrating the adequacy of T&E for the educational pathway, other than the certification pathway, for achieving authorized status. The rule provides a more flexible and performance-based approach to specifying requirements for training and experience, using a graded approach to ensure that training in radiation protection is consistent with the need for adequate understanding and skills.

Background

The current regulations in Part 35 offer three pathways for individuals to satisfy T&E requirements to be approved as an RSO, AMP, ANP, or AU. These pathways are: (1) approval of an individual who is certified by a specialty board, whose certification process has been recognized by the NRC or an Agreement State as meeting NRC's requirements for training and experience; (2) approval based on an evaluation of an individual's training and experience; or (3) identification of an individual's approval on an existing NRC or Agreement State license. For this discussion, pathway 1 will be referred to as the "certification pathway" and pathway 2 as the "alternate pathway."

During development of proposed and final rules for the prior-to-recent-amendment medical use regulations in Part 35, August 13, 1998 (63 FR 43516) and April 24, 2002 (67 FR 20249), respectively, it was generally believed that the specialty boards, whose certification processes were recognized by the NRC, would meet, or could make adjustments to meet, the new requirements, established by that rulemaking, governing NRC recognition of specialty boards, and that they would continue to be recognized by NRC. However, when applications for recognition were received, NRC staff determined that, except for one board (the

Certification Board of Nuclear Cardiology), the boards did not meet all the requirements in the final rule. To address the potential that individuals would no longer satisfy requirements for T&E under the certification pathway, NRC modified the final rule by reinserting Subpart J of Part 35 for a 2-year transition period, during which NRC could work to ensure that appropriate requirements for T&E apply to recognition of specialty board certification processes. Subpart J provided for continuing recognition of the specialty boards, listed therein, during the transition period, which ended on October 24, 2004, as provided for in the revised rule published on April 24, 2002. NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) provided recommendations for an approach to revising requirements for T&E during the development of the current rule. In order to ensure an effective transition, the effective date of Subpart J was extended to October 24, 2005, under a separate rulemaking action (69 FR 55736, September 16, 2004).

In a SRM dated October 9, 2003, the Commission approved publication of a proposed rule to amend the requirements for T&E (SECY-03-0145, August 21, 2003). The proposed rule was published in the *Federal Register* (FR) on December 9, 2003 (68 FR 68549). The comment period on the proposed rule closed on February 23, 2004. Twenty-seven comments were received. The comments came from the Agreement States, the public, and the ACMUI, and are discussed in detail in the FR (70 FR 16335, March 30, 2005). In addition, the Organization of the Agreement States (OAS) filed a petition (PRM-35-17) requesting that 10 CFR 35.55, 35.190, 35.290, and 35.390 be amended to define and specify the minimum number of "didactic" training hours for AUs and ANPs identified in these sections.

Summary of Changes to Part 35

The principal changes in regulations in the final rule relate to revising the criteria that a certification board must meet for its certification process to be recognized by the NRC or an Agreement State. Changes have also been made to requirements for T&E in the alternate pathway. The NRC staff implemented the direction from the Commission, in an SRM dated October 9, 2003, related to SECY-03-0145, to make various changes to the proposed rule. In particular, the requirement for a preceptor statement was "decoupled" from the requirements for recognition of specialty board certification processes (placing the requirement on the individual to obtain the preceptor statement) in the proposed rule, published in the FR (68 FR 68549, December 9, 2003). This approach was followed in the final rule, as was the requirement for preceptor statements to be provided to NRC by licensees, for approval of applications for individuals to serve as RSOs, AMPs, ANPs, or AUs.

Significant amendments in the final rule are:

- The requirement, in 10 CFR 35.390(b)(1)(ii)(F), for experience with the elution of generators, testing, processing, and preparation of labeled radioactive drugs, is removed from 10 CFR 35.390.
- The requirements for experience with oral and parenteral administrations of byproduct material for which a written directive (WD) is required, currently in 10 CFR 35.390(b)(1)(ii)(G), are removed from the requirements for recognition of specialty board certification processes. However, the regulations continue to require this experience for individuals to qualify as AUs for uses of byproduct material for which a written directive is required under 10 CFR 35.300, for both the certification pathway and the alternate pathway.
- A new 10 CFR 35.396, entitled "Training for the parenteral administration of unsealed byproduct material requiring a written directive," is included in the final rule. This allows individuals who do not meet other requirements in 10 CFR 35.390(b)(1), to serve as AUs for parenteral administration of byproduct material for which a WD is required, if they meet the requirements in 10 CFR 35.396.
- Requirements for individuals to serve as RSOs were amended (10 CFR 35.50) to include medical physicists who meet the requirements specified therein.
- A requirement is added for AUs in 10 CFR 35.190, 35.290, and 35.390, and for ANPs in 10 CFR 35.55, that training in basic radionuclide handling techniques must include a minimum number of hours of classroom and laboratory training, for individuals to be approved as AUs and ANPs under the alternate pathway. Specifically, the final rule requires 8, 80, and 200 hours of classroom and laboratory training for 10 CFR 35.190, 35.290, 35.55 and 35.390, respectively, under the alternate pathway.

- "Attest" and "attestation" are used in place of "certify" and "certification," in requirements for the preceptor statements.
- The final rule grants, in part, OAS petition PRM-35-17, by incorporating requirements for certain minimum hours of classroom and laboratory training in basic radionuclide handling techniques, for ANPs and AUs, under the alternate pathway in 10 CFR 35.55, 35.190, 35.290, and 35.390.
- Agreement States are allowed up to 3 years to adopt the final rule.
- 10 CFR 35.10 provides for implementation of the requirements in 10 CFR 35.14(a) to provide the Commission with a copy of written attestation, signed by a preceptor, on or before October 25, 2005. Also, before October 25, 2005, a licensee shall satisfy the training requirements for an AU, AMP, ANP, or an RSO, by complying with either: (a) the training requirements in subpart J, or (b) the appropriate training requirements in subpart B or subparts D through H.

These and other changes to the rule are discussed in more detail in the FR (70 FR 16335, March 30, 2005).

NRC staff believes that the final rule provides requirements that are less prescriptive than those in the prior-to-recent-amendment medical use regulations and allows for more flexible approaches by specialty boards in setting up their certification processes and requirements. The changes will also permit more flexibility in training programs that lead to certification -- steps that will continue to ensure radiation safety while resulting in a reduction of regulatory burden.

Licensing guidance for medical uses of byproduct material, NUREG 1556, Volume 9, has been revised to conform to the revisions in the final rule.

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NATIONAL SOURCE TRACKING SYSTEM

The U.S. Nuclear Regulatory Commission (NRC) is developing a new National Source Tracking System (NSTS) for radioactive sources of concern. These sources will be called nationally tracked sources.

A nationally tracked source is a sealed source containing a quantity of radioactive material equal to or greater than the Category 2 levels listed in a new Appendix F to 10 CFR Part 20. A nationally tracked source may be either a Category 1 source (100 times the Category 2 threshold) or a Category 2 source. Nationally tracked sources do not include material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. The radioactive material and threshold values are from the International Atomic Energy Agency (IAEA) Code of Conduct. The NRC has adopted the Category 2 values, to allow alignment between domestic and international efforts to increase the safety and security of radioactive sources.

NSTS will eventually provide a life history of each nationally tracked source. The system will contain information on sources possessed by NRC and Agreement State licensees, as well as U.S. Department of Energy facilities. In order to implement the NSTS, NRC is conducting a rulemaking to require reporting of source transactions to the NSTS. These transactions include the manufacture of new sources, transfer of sources, receipt of sources, and disposal of sources. Licensees will be given the option of reporting by several mechanisms: (1) on-line to the NSTS; (2) batch load using electronic file submission; (3) mail; (4) facsimile; or (5) by telephone, with follow-up by facsimile or mail. Licensees will be required to make the report by the close of the next business day after the transaction.

The information to be reported for each source includes the manufacturer, model, serial number, radioactive material, source strength, and associated date. Also to be included in each report is the company name and license number. Transfer information would include the recipient, the shipping date, and the estimated arrival date. Receipt information would include the receipt date, the company name, and license number of the facility providing the source. Information for disposal would include the method and date of disposal, the waste manifest number, and the container identification of the container with the source.

Each licensee would be required to report its initial inventory of Category 1 sources by December 31, 2006, and its inventory of Category 2 sources by March 31, 2007. To ease the burden on licensees, NRC will use the information in the interim inventory database for the initial loading into the NSTS. Licensees will be asked to verify and/or

update the information by the same dates. Licensees would be required to begin reporting transactions for Category 1 sources by December 31, 2006. For Category 2 sources, the date to begin reporting would be March 31, 2007.

To maintain the accuracy and reliability of the information in the NSTS, the rule would also require licensees to reconcile their onsite inventory of nationally tracked sources with the information previously reported to the NSTS . The licensee would be required to verify that the inventory in the NSTS is correct. This reconciliation and verification process would occur in June of each year.

The proposed rule should be published for public comment in summer 2005. NRC plans to hold public meetings during the public comment period. The locations, dates, and times will be published in the *Federal Register*. The proposed rule, regulatory analysis, Office of Management and Budget supporting statements, and information on the public meetings will be available on the NRC rulemaking web site at http://ruleforum.llnl.gov. Before actual implementation of the system in December 2006, NRC will hold several workshops around the country to demonstrate the NSTS. These workshops will provide an opportunity for licensees to have hands-on access to the system. The format for the electronic submission should be available at the workshops.

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RADIATION SAFETY PROGRAM OVERSIGHT: TASKS MAY BE DELEGATED, BUT RESPONSIBILITIES MAY NOT

During a recent inspection at a facility that performs brachytherapy procedures, it was observed that the licensee exercised poor oversight of the brachytherapy radiation safety program. The licensee's poor oversight of the program was a contributing factor to a series of medical events.

The licensee delegated the responsibility for the day-to-day implementation of the brachytherapy radiation safety program to contract medical physicists. Additionally, the licensee also relied on them to monitor activities regarding the licensee's brachytherapy radiation safety program. Although the licensee relied on the contract medical physicists to audit the brachytherapy radiation safety program, the licensee did not take any steps to validate their audit findings. Also, the licensee relied on the contract medical physicists to interpret NRC regulations concerning identification and notification of medical events. The licensee accepted the contract medical physicists' misinterpretation of 10 CFR 35.3045. Furthermore, the licensee provided poor supervision of the contract medical physicists by expecting them to be familiar with the technical limitations of the applicator and to provide the authorized user with the aforementioned technical limitations. The authorized user was not familiar with the applicator instructions or the technical limitations regarding the use of the applicator and he did not provide these instructions and technical limitations to the contract medical physicist before the first use of the applicator. The licensee's poor management oversight of the brachytherapy radiation safety program resulted in missed opportunities to identify precursors associated with five medical events and failure to promptly identify and report those medical events.

In this instance, NRC is particularly concerned with the licensee's lack of management oversight of its radiation safety programs and the lack of supervisory and Radiation Safety Officer (RSO) oversight of its contract medical physicists. Certain duties may be assigned to others when adequate supervision is provided; however, the RSO is still responsible for implementing the radiation safety program, and the licensee is still responsible for regulatory compliance. NRC expects licensees to maintain adequate oversight of their radiation safety programs to ensure safe use of radioactive materials and the protection of public health and safety. Licensees are encouraged to refer to 10 CFR 35.24, "Authority and responsibilities for the radiation protection program", 10 CFR 35.27, "Supervision", and 10 CFR 35.2024, "Records of authority and responsibilities for the radiation protection program".

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DECOMMISSIONING WORKSHOP

The Decommissioning Directorate of the Division of Waste Management and Environmental Protection (DWMEP) held a workshop on April 20 and 21, 2005, at the Shady Grove Center in Rockville, Maryland. DWMEP held the workshop as part of the staff's initiatives to continually improve the process for decommissioning, and to solicit feedback on specific technical issues

concerning decommissioning. Approximately 180 people attended the workshop.

The first day of the workshop began with introductory talks by DWMEP Division Director, Larry Camper, and DWMEP Director of the Decommissioning Directorate, Dan Gillen. Staff then summarized the Integrated Decommissioning Improvement Plan (IDIP). The IDIP describes staff initiatives to improve the decommissioning process over the next 2 years.

The first day of the workshop was also devoted to obtaining feedback on issues that the staff evaluated as part of the License Termination Rule (LTR) Analysis. The LTR Analysis was conducted over a period of 2 years, resulting in staff obtaining direction from the Commission in two Staff Requirements Memoranda (SRM) (SRM-SECY-03-0069 and SRM-SECY-04-0035). Nine specific issues were evaluated in the LTR Analysis and staff recommended options for addressing the issues and providing paths forward regarding informing licensees and other stakeholders of the issues and resolutions. The staff identified several issues requiring further guidance for licensees and stakeholders, and the workshop was used as an initial opportunity for stakeholders to provide input into the guidance on these issues. To achieve this, individual breakout sessions were conducted with smaller groups of attendees, that addressed each of the LTR Analysis issues, and there were focused discussions on specific items and topics that staff intends to address in guidance.

Commissioner Jeffrey Merrifield presented the key-note speech on the morning of the second day of the workshop. His presentation on "Decommissioning Lessons Learned," provided the backdrop for the purpose of the second day of the workshop, which was dedicated to detailed discussions of lessons learned by the industry and NRC in decommissioning, and how best to use these lessons learned in future decommissioning projects. A panel comprised of NRC staff, an Agreement State representative, and industry representatives gave informative presentations on their perspectives of lessons learned in decommissioning.

After the panel presentations, the remainder of the second day of the workshop consisted of a facilitated discussion on lessons learned in decommissioning that focused on both the industry and NRC. A discussion was held to solicit feedback on the best ways for NRC to collect the lessons learned on decommissioning, to preserve those that should be used in future decommissioning projects, and to incorporate those lessons learned in documents or other communication methods, so they would be available to use for future decommissioning efforts.
Staff will post a draft summary report of the workshop on the Decommissioning Workshop Webpage (http://www.nrc.gov/public-involve/conference-symposia/decommissioning.html) for attendees to review and provide corrections and additions to the summary report before it is finalized. After the Summary Report is finalized, staff will begin evaluating and implementing some of the processes suggested at the workshop for identifying, preserving, and communicating decommissioning lessons learned.

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LICENSING IMPACT OF NEW URANIUM MAXIMUM CONTAMINANT LEVELS

In December 2000, The U.S. Environmental Protection Agency (EPA) published its final rule for radionuclides in drinking water using its authority under the Safe Drinking Water Act. The final rule included maximum contaminant levels (MCLs) for multiple classes of radionuclides, including uranium. For uranium, EPA adopted an MCL of 30 micrograms per liter (μg/l) in community water systems (CWS'). A CWS is a water system that serves at least 15 service connections or 25 residents regularly, year-round. The rule requires that CWS' comply with the new requirements by December 31, 2007. EPA has estimated that approximately 500 CWS' would be affected. Industry sources that have contacted NRC have estimated this number to be 1000 or higher.

The technologies that would be used to remove uranium from drinking water could have two results: (1) the CWS could be in possession of source material (uranium) exceeding 0.05 weight percent; and (2) the CWS could possess greater than 15 pounds of uranium in a very short period of time. Under these circumstances, these CWS' would require a specific license from NRC, or the corresponding Agreement State, to possess the source material.

Staff is preparing a Commission paper that will provide options and recommendations for the Commission's consideration. Until such time as any regulatory changes are made effective, the existing licensing requirements in 10 CFR Part 40 would apply.

Additional EPA information on this topic can be found at: http://www.epa.gov/safewater/rads/technicalfacts.html or http://www.epa.gov/safewater/radionuc.html

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CALIBRATION of DOSE CALIBRATORS FOR P-32 and OTHER BETA EMITTERS OR LOW- ENERGY PHOTON EMITTERS

During a recent inspection, a licensee was measuring and adjusting Phosphorous-32 (P-32) radiopharmaceutical dosages using a dose calibrator that had only been calibrated using high-energy gamma-emitting sources and had not been calibrated for P-32 use. 10 CFR 35.60, "Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material," requires the licensee to calibrate instruments used for direct measurement of dosages before medical use. In spite of this requirement, the licensee erroneously believed it was not required to calibrate the dose calibrator but to "only perform periodic test following a nationally recognized standard." The standard cited was American National Standards Institute (ANSI) N42.13, "American National Standard Calibration and Usage of 'Dose Calibrator' Ionization Chambers for the Assay of Radionuclides." This standard describes required calibration procedures (i.e., initial calibration with standard sources for each radionuclide of interest, dependence of the assay on geometric configuration and composition of the source container, and energy range) and advisory calibration recommendations to be applied when practical (i.e., cover complete activity ranges used) to achieve acceptable accuracy and reproducibility limits.

The licensee did not perform the procedures required in ANSI N42.13. Instead, the licensee used the dose calibrator manufacturer's radionuclide calibration setting for P-32 without performing the geometric dependency test. To properly calibrate the dose calibrator and accurately measure the activity of its P-32 dosages, the licensee needed, among other things, to perform the geometric dependency test for the actual containers and volumes routinely used at the licensee's facility and use the resulting data to obtain a site specific correction factor for P-32. This was important because the manufacturer's table of radionuclides and calibration settings included the disclaimer "no warranty of any kind can be made as to their (calibration numbers) accuracy, since there were many uncontrollable factors (as well as the accuracy of the published data) involved in the overall accuracy of an assay" and further warned that the P-32 data was for "estimation use only."

The U.S. Nuclear Regulatory Commission (NRC) recognizes the difficulties associated with measuring and calibrating dose calibrators for pure beta-emitting radionuclides and discussed some of these difficulties in Information Notice 2002-19, "Medical Misadministrations Caused by Failure to Properly Perform Test on Dose Calibrators for Beta-and-Low-Energy Photon-Emitting Radionuclides." An additional difficulty with beta calibrations is that lack of standard sources for certain radionuclides and, even if the standard sources were available, most medical use licensees do not have access to the National Institute of Standards and Technology prepared or traceable standard sources needed to perform the calibrations for beta-emitting radionuclides. All these difficulties contributed to NRC giving medical use licensees the option (in 10 CFR 35.63, "Determination of dosages of unsealed byproduct material for medical use") of determining the proper dosages by using a combination of volumetric measurements and mathematical calculations, based on the activity per unit volume determination made by the manufacturer or preparer licensed under 10 CFR 32.72, "Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35." This option gives licensees a better method of determining activities without depending on dose calibrator reading from instruments that are not calibrated for the radionuclides being administered to humans.

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WHAT'S NEW IN THE MEDICAL TOOLKIT

With the March 30 publication in the *Federal Register* (FR) of the 10 CFR Part 35 "Medical Use of Byproduct Material—Recognition of Specialty Boards; Final Rule," the U.S. Nuclear Regulatory Commission (NRC) updated its medical uses licensee toolkit (http://www.nrc.gov/materials/miau/med-use-toolkit.html) to: (1) include a link to the FR copy of the April 2002 revision of 10 CFR Part 35; (2) include a link to the FR copy of the new March 2005 rule; (3) add a red-line strike-out copy of sections of 10 CFR Part 35 changed by the final

rule; (4) include a link to NUREG-1556, Vol 9, Rev. 1, "Program-Specific Guidance About Medical Use Licenses;" (5) clarify that the "Guide for Diagnostic Nuclear Medicine," published in 2002 by the American College of Nuclear Physicians and the Society of Nuclear Medicine, has not been updated to conform to the changes to the training and experience requirements issued in the final rule; and (6) revise the link to the April 2005 NRC Form 313A, "Medical Use Training and Experience and Preceptor Attestation."

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UNDERSTANDING 10 CFR 35.3045(a)(3) WRONG TREATMENT-SITE REPORTABLE MEDICAL EVENT

A few medical use licensees have incorrectly interpreted the criteria in 10 CFR 35.3045(a)(3) for determining when a medical event involving the "wrong site" must be reported to the U.S. Nuclear Regulatory Commission (NRC). 10 CFR 35.3045(a)(3) requires a licensee to report any events, except for an event that results from patient intervention, if there is a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 sievert (Sv) (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site)."

Some licensees erroneously believed that if the "wrong site" received 0.5 Sv (50 rem) then it needed to receive at least 50 percent of the dose intended for the correct treatment site before the event met the criteria in 10 CFR 35.3045(a)(3). The correct interpretation is that once the "wrong site" receives 0.5 Sv (50 rem), the event is reportable if this site also receives a dose that is 50 percent more than anticipated at the "wrong site" if the administration had been delivered correctly (i.e., the right dose was delivered in accordance with the written directive to the correct treatment site).

When the written directive specifies the dose to the treatment site, it is understood that, even when the administration is delivered correctly, doses may be delivered to areas beyond the treatment site. For radiopharmaceuticals, tables may be used to identify the expected doses to other organs or tissues. When using sealed sources or the radiation from sealed sources, treatment planning systems are used to estimate and map expected dose curves at or near the correctly placed sources or correctly delivered radiation beam. When the dose or dosage is not given in accordance with the written directive, the licensee needs to determine the total dose delivered to the "wrong site" and compare it to the dose that would have been delivered to this "wrong site" if the administration had been given correctly.

If the "wrong site" were not expected to receive any dose during the correct administration, and it received .05 Sv (50 rem), the medical event needs to be reported. If the "wrong site" was suppose to receive .01 Sv (10 rem) during the correct administration but received .06 Sv (60 rem), the medical event would be reportable. In this case, the dose received by the "wrong site" exceeded by .05 Sv (50 rem) the dose it should have received, as well as more than 50 percent of what it should have received. If the "wrong site" was suppose to receive .01 Sv (10 rem) and it received .04 Sv (40 rem), the medical event would not be reportable because the dose to the "wrong site" was under .05 Sv (50 rem) even though the "wrong site" received more than 50 percent of what it should have. For permanent implants, NRC recognizes that the sources may migrate after being implanted in the correct site. This migration would not result in a reportable event under 35.3045(a)(3).

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SIGNIFICANT MEDICAL EVENTS

Event 1: Medical Event at St. Joseph Regional Medical Center

Date and Place: February 23, 2004, South Bend, Indiana

Nature and Probable Causes: The licensee reported that five patients who received brachytherapy treatments for endometrial cancer, received radiation doses to the wrong location. The first patient was treated in January 2004; the second and third patients in February 2004; and the fourth and fifth patients in March 2004.

A new Wang vaginal applicator was used during the procedures. The tandem device was loaded with Cesium-137 sources, and the sources were manufactured by Amersham. The tandem device was designed to use 3M brachytherapy sources; however, Amersham sources were used. The

Amersham sources were too small for use in the tandem device, causing the sources to slide out of position and irradiate the inner thigh, whenever the patients moved into a more up-right position. Approximately 2 weeks after treatment, the third, fourth and fifth patients developed ulcerations on the skin of the inner thigh. The licensee's initial calculations estimated the skin doses to be below 50 centisieverts (cSv) (rem). However, the third patient exhibited recurring skin ulcerations, prompting the licensee to reevaluate the calculated doses. The licensee's revised calculations determined that the third patient received an unintended dose to a small area of the skin on the upper thigh of approximately 2000 centigray (cGy) (rad). The fourth patient received an unintended dose to a similar area of the thigh of approximately 1500 to 2000 cGy (rad). Despite the unintended doses to the inner thigh, the licensee believed that the patients received the respective prescribed doses to the treatment areas, based on clinical observations. All patients were notified of the error. A NRC Region III inspection will review the circumstances surrounding the event and an NRC medical consultant will provide an independent medical evaluation of the probable deterministic effects of the radiation exposures.

Actions Taken to Prevent Recurrence

Licensee: The licensee retrained personnel and replaced the applicator with one that will accept both source sizes.

Event 2: Medical Event at Saddleback Memorial Hospital

Date and Place: January 24, 2005, Laguna Hills, California

Nature and Probable Causes: The licensee reported a medical event involving a breast cancer patient treated with a Varian Medical Systems remote high dose rate (HDR) afterloading unit (model VS2000) and Iridium -192 (Ir-192) source with an activity of 277.5 gigabecquerels (7.5 curies). Ten fractional treatments were administered from January 24 to January 28, 2005. The prescribed dose was 350 centigray (cGy) (350 rad) per fraction at 1 centimeter (cm) from the surface of the balloon, at two fractions per day, for a total of 3500 cGy (rad). The patient returned on March 18, 2005, complaining of pain on her breast. A moist desquamation was noted on the breast surface at the point the catheter had entered the breast. Re-evaluation of the treatment plan revealed that the wrong catheter length parameter (source travel distance) was used during the treatment. The Ir-192 source was implanted 8 cm short of its planned location, near the catheter breast entry point. Dosimetry reconstruction indicated that the maximum dose delivered to a tissue area of 2.5 by 2.1 by 0.5 cm, at the entrance port was 7000 cGy (rad).

Actions Taken to Prevent Recurrence

Licensee: Corrective actions included instituting a quality assurance checklist requiring two persons to verify and document treatment parameter determinations and correct treatment computer inputs, to include the catheter length parameter. Also, normal catheter length parameters for standard treatments will be documented and checked before treatments. Staff will be trained in these new procedures before using the HDR unit.

Event 3: Medical Event at St. Johns Mercy Hospital Center

Date and Place: March 9, 2005, St. Louis, Missouri

Nature and Probable Causes: The licensee reported that a 5 month-old infant was prescribed 18.5 megabecquerel (MBq) [0.5 millicuries (mCi)] of Technetium-99m (Tc-99m) myoview sulfur colloid, but instead received 429.2 MBq (11.6 mCi) of Tc-99m myoview sulfur colloid. Personnel did not look at the label when measuring the dose to be administered. The whole body dose to the infant was calculated to be between 5.2 and 10 centisieverts (rem). The physician has informed the infant's parents.

Actions Taken to Prevent Recurrence

Licensee: The licensee is determining corrective actions to prevent recurrence.

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GENERIC COMMUNICATIONS ISSUED (December 17, 2004 - May 20, 2005)

The following are 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: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html. Please note that this address is case-sensitive and

must be entered exactly as shown. If you have any questions or comments about generic communications in general, please contact Angela R. McIntosh, 301-415-5030; e-mail: arm@nrc.gov.

Bulletins (BL)

BL 2005-01, "Material Control and Accounting at Reactors and Wet Spent Fuel Storage Facilities," was issued on February 11, 2005. This BL was sent to all holders of operating licenses for nuclear power reactors, decommissioning nuclear power reactor sites storing spent fuel in a pool, and wet spent fuel storage sites. Note that this bulletin relates to material control and accounting programs and is, therefore, being withheld from public disclosure in accordance with 10 CFR 2.390. The bulletin is being provided only to those licensees needing to respond and addressees are requested to treat the information accordingly (i.e., similar to trade secrets and commercial or financial information).

(Technical Contacts: Martha Williams, NSIR, 301-415-7878; e-mail: msw2@nrc.gov; Dori Votolato, NSIR, 301-415-7633; e-mail: dxv1@nrc.gov; Glenn Tuttle, NSIR, 301-415-7644; e-mail: gwt@nrc.gov; Lead Project Manager: David Jaffe, NRR, 301-415-1439; e-mail: dhj@nrc.gov)

Information Notices (IN)

IN 2005-05, "Improving Material Control and Accountability Interface with Criticality Safety Activities at Fuel Cycle Facilities," was issued on March 10. 2005. This IN was sent to all licensees authorized to possess a critical mass of special nuclear material to inform them of a safety concern related to criticality safety at fuel fabrication and other facilities processing, storing, or handling critical masses of fissile material. The safety concern arises when licensees fail to establish and maintain a communication process between criticality safety staff and material control and accountability staff, so as to support timely identification of fissile material-related process upsets that challenge the criticality safety basis for the facility.

(Technical Contact: Dennis Morey, NMSS, 301-415-6107; e-mail: dcm@nrc.gov)

IN 2005-07, "Results of HEMYC Electrical Raceway Fire Barrier System Full Scale Fire Testing," was issued on April 1, 2005. This IN was sent to all holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel, and fuel facilities licensees. This IN was issued to inform addressees of the results of HEMYC electrical raceway fire barrier system (ERFBS) full-scale fire tests. The HEMYC ERFBS did not perform for one hour as designed because shrinkage of the HEMYC ERFBS occurred during the testing.

(Technical Contact: Daniel Frumkin, NRR, 301-415-2280, e-mail: dxf1@nrc.gov)

IN 2005-10, "Changes to 10 CFR Part 71 Packages," was issued on April 7, 2005. This IN was sent to all 10 CFR Part 71 licensees and certificate holders to remind them of the requirement to obtain NRC approval of all changes to NRC-approved Part 71 packages before use of the changed packages.

(Technical Contact: Frank Jacobs, NMSS, 301-415-3961; e-mail: fxj2@nrc.gov.)

Regulatory Issue Summaries (RIS)

RIS 2005-02, "Clarifying The Process for Making Emergency Plan Changes," was issued on February 14, 2005. This RIS was sent to all holders of operating licenses for nuclear power reactors, including research and test reactors and fuel facility licensees. This RIS was issued to: (1) clarify the meaning of "decrease in effectiveness (DIE)," as stated in 10 CFR 50.54(q); (2) clarify the process for making changes to emergency plans; and (3) provide some examples of changes that are not a DIE and some examples of a DIE emergency plan.

(Technical Contact: Kevin Williams, NSIR, 301-415-1104; e-mail: kxw@nrc.gov)

RIS 2005-03, "10 CFR Part 40 Exemptions for Uranium Contained in Aircraft Counterweights - Storage and Repair," was issued on February 28, 2005. This RIS was sent to all persons possessing aircraft counterweights containing uranium, under the exemption in 10 CFR 40.13(c)(5), to emphasize the scope and restrictions of the exemption from licensing requirements in 10 CFR 40.13(c)(5), as applied to counterweights containing uranium.

(Technical Contact: Gary Comfort, NMSS, 301-415-8106; e-mail: gcc1@nrc.gov.)

RIS 2005-04, "Guidance on the Protection of Unattended Openings That Intersect a Security Boundary or Area," was issued on April 14, 2005.

This RIS was sent to all holders of operating licenses or construction permits for nuclear power reactors, research and test reactors, decommissioning reactors with fuel on site, Category 1 fuel cycle facilities, critical mass facilities, uranium conversion facility, independent spent fuel storage installations, gaseous diffusion plants, and certain other material licensees. Note that the RIS contains physical security information and is, therefore, being withheld from public disclosure in accordance with 10 CFR 2.390.

(Technical Contact: Albert Tardiff, Office of Nuclear Security and Incident Response, 301-415-7015; e-mail: axt1@nrc.gov)

RIS 2005-06, "Reporting Requirements for Gauges Damaged at Temporary Job Sites," was issued on April 18, 2005. This RIS was sent to all material licensees possessing portable gauges, regulated under 10 CFR Part 30 to inform them of the reporting requirement associated with gauges damaged at temporary job sites.

(Technical Contact: Angela R. McIntosh, NMSS, 301-415-5030; e-mail: arm@nrc.gov)

(General Contact: Angela R. McIntosh, NMSS, 301-415-5030; e-mail: arm@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS

The NRC's enforcement program can be accessed via the U. S. Nuclear Regulatory Commission's (NRC's) homepage [http://www.nrc.gov/] under "What We Do." Documents related to cases can be accessed at [http://www.nrc.gov/], "Electronic Reading Room," "Documents in ADAMS." ADAMS is the Agency wide Document Access and Management System. Help in using ADAMS is available from the NRC Public Document Room, telephone: 301-415-4737 or 1-800-397-4209.

Gauges

R&M Engineering Consultants (EA-05-023)
On May 9, 2005, a Confirmatory Order Modifying License was issued to confirm recent commitments by R&M Engineering Consultants, to take in lieu of NRC pursuing escalated enforcement action. The commitments included leak testing and transferring two NRC-licensed gauges to an authorized recipient, providing copies of documents demonstrating that the transfer has taken place, and a request to terminate its NRC license.

Medical

Good Samaritan Regional Medical Center
(EA-04-234)
On March 31, 2005, a Notice of Violation was issued for a Severity Level III problem involving twelve violations indicating a lack of appropriate oversight and control of the brachytherapy program, including a programmatic weakness in the implementation of written directives.

Other

Soil Consultants (EA-04-103)
On April 27, 2005, an immediately effective Confirmatory Order was issued to confirm commitments made as part of a settlement agreement concerning an Order Imposing Civil Monetary Penalty in the amount of $9000 issued on February 1, 2005. The action was based on a Severity Level II violation for discrimination against an employee for engaging in certain protected activities (reporting safety concerns to his employer or to the NRC). In response to the Order, the licensee requested the use of NRC's alternative dispute resolution (ADR) process to resolve differences it had with NRC concerning the violation. As part of the settlement agreement that was reached through the ADR process, the licensee agreed to pay a civil penalty in the amount of $1200, and to take additional corrective actions to emphasize the importance of a Safety Conscious Work Environment at their facility.

Safety Light Corporation (EA-04-148)
On February 25, 2005, the NRC withdrew the December 10, 2004 Order. This decision was made after the Commission exercised its supervisory authority over licensing and enforcement proceedings, and by Order dated February 22, 2005, lifted the immediate effectiveness of the December 10, 2004 Order.

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

SELECTED *FEDERAL REGISTER* NOTICES (March 1, 2005 - May 31, 2005)

NUREG - 1814, "Status of Decommissioning Program – 2004 Annual Report," 70 FR 12248, March 11, 2005

(Contact: John T. Buckley, Decommissioning Directorate, Division of Waste Management and Environmental Protection, Office of Nuclear Material Safety and Safeguards, 301-415-6607; e-mail: jtb@nrc.gov)

Revision 2 of Regulatory Guide 7.9, "Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material," 70 FR 12755, March 15, 2005

(Contact: Nancy L. Osgood, Spent Fuel Project Office, 301-415-8513; e-mail: nlo@nrc.gov)

Revision 2 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material," 70 FR 12756, March 15, 2005

(Contact: James J. Pearson, Spent Fuel Project Office, NMSS, 301-415-1985; e-mail: jjp@nrc.gov)

10 CFR Part 35 "Medical Use of Byproduct Material--Recognition of Specialty Boards," 70 FR 16336, March 30, 2005

(Contact: Neelam Bhalla, Office of Nuclear Material Safety and Safeguards, 301-415-6843; e-mail: nxb@nrc.gov or Cindy Flannery, Office of Nuclear Material Safety and Safeguards, 301-415-0223; e-mail: cmf@nrc.gov)

10 CFR Part 2 [RIN 3150-AH71], "Model Milestones for NRC Adjudicatory Proceedings," 70 FR 20457, April 20, 2005

(Contact: Geary Mizuno, Office of the General Counsel, 301-415-1639; e-mail: gsm@nrc.gov)

10 CFR Part 71, "Regulations for the Safe Transport of Radioactive Material; Solicitation of Comments on Proposed Changes," 70 FR 21684, April 27, 2005

(Contact: John Cook, Office of Nuclear Material Safety and Safeguards, 301-415-8521; e-mail: jrc1@nrc.gov)

10 CFR Part 72 [RIN 3150-AH64], "List of Approved Spent Fuel Storage Casks: HI-STORM 100 Revision; Withdrawal of Direct Final Rule" 70 FR 24936, May 12, 2005

(Contact: Jayne M. McCausland, Office of Nuclear Material Safety and Safeguards, 301-415-6219; e-mail: jmm2@nrc.gov)

10 CFR Part 72 [RIN 3150-AH72], "List of Approved Spent Fuel Storage Casks: Standardized NUHOMS 24P, 52B, 61BT, 32PT, 24PHB, and 24PTH. Revision 8" 70 FR 29931, May 16, 2005

(Contact: Jayne M. McCausland, Office of Nuclear Material Safety and Safeguards, 301-415-6219; e-mail: jmm2@nrc.gov)

10 CFR Part 110 [RIN 3150-AH67], "Export and Import of Nuclear Equipment and Material; Exports to Syria Embargoed," 70 FR 29934, May 25, 2005

(Contact: Kirk Foggie, Office of International Programs, 301-415-2238; e-mail: kxf@nrc.gov, or Suzanne Schuyler-Hayes, Office of International Programs, 301-415-2333; e-mail: ssh@nrc.gov)

(General Contact: Michael K. Williamson, Office of Nuclear Material Safety and Safeguards, 301-415-6234; e-mail: mkw1@nrc.gov)

NOTE TO READERS: In an effort to keep the NMSS Quarterly Newsletter relevant, useful and informative, feedback regarding the content of the newsletter is welcomed. Readers desiring to contribute articles, self-explanatory diagrams, suggestions for future articles, bulletins, web-site postings, and other items of interest to the NMSS Licensee Newsletter readership, should contact Michael K. Williamson, from the Office of Nuclear Material Safety and Safeguards, Rulemaking and Guidance Branch. Mr. Williamson may be contacted at (301)415-6234 or mkw1@nrc.gov. In addition, to ensure proper delivery and non-interruption of subscription service, please report any address changes, additions, or deletions to Mr. Williamson.

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