U.S.NRC
United States Nuclear Regulatory Commission
*Protecting People and the Environment*

Office of Federal & State Materials & Environmental Management Programs

# LICENSEE NEWSLETTER

NUREG/BR-0117, No. 12-02 Summer 2012

## SAFETY CULTURE CASE STUDIES

The NRC has developed Safety Culture Case Studies to illustrate past events in which the presence or absence of a positive safety culture significantly contributed to the outcome of the event. The review of the circumstances and results of the investigations of these events are clear examples in which a positive safety culture helped to lessen consequences, and a weak safety culture contributed or exacerbated the causes and consequences of the event.

These case studies are learning tools. Those of us who are responsible for regulating or using radioactive material in a safe and secure manner should not become complacent and should be open to learning from the mistakes and problems others have faced in an effort to prevent recurrences. The case studies selected for this initiative represent a number of industries, including energy, construction, medical, and transportation.

The NRC has also developed a Safety Culture User Guide to help individuals and organizations apply lessons learned from the various case studies more effectively. The User Guide will provide readers with a better understanding of why a strong safety culture and safety-first focus are critically important. The NRC recommends that readers review the User Guide prior to reviewing the case studies.

Currently, the following four case studies are available on the NRC's Safety Culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html:

- Collision of Two Washington, D.C. Metropolitan Area Transit Authority Metrorail Trains
- US Airways Flight 1549: Forced Landing On the Hudson
- Partial Collapse of the Willow Island Cooling Tower
- Upper Big Branch Mine Explosion - 29 Lives Lost

Additional case studies are under development and will be added to the Web site as they are completed.

### INSIDE THIS ISSUE

Also, the NRC's Safety Culture Web site includes additional information about the safety culture policy statement including relevant background documents, safety culture brochure, *Federal Register* notices, and presentations made at public meetings, as well as other outreach activities.

(Contact: Cindy Flannery, FSME, 301-415-0223 or Cindy.Flannery@nrc.gov)


## THE 24TH ANNUAL REGULATORY INFORMATION CONFERENCE

On March 13-15, 2012, the NRC held the 24th Annual Regulatory Information Conference (RIC) at the Bethesda North Marriott Hotel and Conference Center in Rockville, MD. The NRC's Office of Nuclear Reactor Regulation (NRR) and Office of Nuclear Regulatory Research sponsored the 3-day conference. The RIC attracted more than 3,000 attendees from over 33 countries. The attendees included government, industry, international agencies and other interested stakeholders and members of the public who assembled to discuss nuclear safety and security initiatives and developments in the regulatory arena.

NRC Chairman Gregory B. Jaczko delivered the keynote address, "Moving Forward for Safety." NRC Commissioners Kristine L. Svinicki, George Apostolakis, William D. Magwood, and William C. Ostendorff also provided comments, along with Bill Borchardt, NRC's Executive Director for Operations, and Eric Leeds, Director of NRR.

The conference included sessions addressing the significant domestic and international issues associated with operating reactors, new and advanced reactors, fuel cycle facilities, nuclear security, safety research, and safety culture policies. One of the sessions discussed the Fukushima Dai-ichi accident and NRC's response to lessons learned such as seismic and station blackout events, flooding and ventilation issues, emergency preparedness and incident response, as well as research and regulation of spent fuel storage, handling, and safe disposition from nuclear power reactors. The agenda also offered a broad variety of technical poster and tabletop presentations.

## FSME STAFF MEMBER HELPING OTHERS

The FSME staff is making a difference in the community. Mr. Gregory Suber, FSME

Branch Chief, participated in a local high school's Senior Mock Interview Day. The purpose of the event was to provide graduating seniors with an authentic interview experience before they leave high school. For many of the students, this was their first time participating in a professional interview, so this was a very meaningful experience for them. The event was sponsored by the School to Career Transition program. It was designed to fulfill a Maryland State graduation requirement to help prepare students for success in college and the world of work.

## TRANSFER OF RADIOACTIVE BYPRODUCT MATERIALS

From recent inquiries, the FSME staff has developed a discussion on the circumstances under which radioactive byproduct materials may be transferred to unlicensed persons, specifically to persons who are exempt from licensing under the Title 10 Code of Federal Regulations

# FROM THE DESK OF THE DIRECTOR

Now that I am settled into this position, I have had the opportunity to experience firsthand and appreciate the broad range of issues and programmatic responsibilities that FSME faces on a daily basis. Since my start in October 2011, we have accomplished a lot. A few of these accomplishments include preparing the final rule for the physical protection of byproduct material (10 CFR Part 37), providing recommendations to the Commission for policy and technical direction to revise radiation protection regulations and guidance, and providing recommendations to the Commission on regulatory changes to the medical event definition for permanent implant brachytherapy programs.

In addition to providing recommendations to the Commission, in late April 2012, the staff briefed the Commission on its recommendations to make a regulatory change to the medical event definition for permanent implant brachytherapy programs. I would like to take this time to thank the Advisory Committee on the Medical Uses of Isotopes and the broader medical and stakeholder community for their help in developing these recommendations. The collaborative effort used to develop these recommendations is another example of how important it is to work with our State partners to achieve a common goal.

In early April 2012, the Organization of Agreement States and the Conference of Radiation Control Program Directors (CRCPD) briefed the Commission on several topics that are of great interest to the States. In late April 2012, I attended NRC's Agency Action Review Meeting (AARM); the AARM is an annual meeting where NRC senior managers meet to discuss NRC licensee performance and evaluate the process used by the agency to ensure the operational safety performance of nuclear licensees. Also, we just completed our annual assessment of the Agreement State program, and we appreciate the great work of our regulatory partners.

An open and collaborative relationship with our State partners is very important to me. As a reminder, the NRC, along with all Federal agencies, has implemented the Administration's Open Government (OG) initiative. The NRC has an OG section on its public Web site at http://www.nrc.gov/public-involve/open.html. As part of this initiative, the agency has expanded the number of datasets made publicly available to enhance the transparency of what we do. We hope that you will take a moment to visit the site and provide comments on how the NRC and FSME can continue to operate in an open and transparent manner.

Certainly, we appreciate the support we received from the States, Health Physics Society, and CRCPD regarding NRC's safety culture policy statement. We are pleased that these organizations have embraced this important initiative of outreach and education to emphasize safety over competing goals.

Thank you for all of your efforts to ensure the public health and safety and protection of the environment in all operations involving regulated nuclear materials.

Mark A. Satorius, Director

(10 CFR) 30.14, "Exempt Concentrations" and 10 CFR 30.18, "Exempt Quantities."

In 10 CFR Part 30, "Rules of General Applicability to Domestic Licenses of Byproduct Material," the regulation contains a number of provisions that exempt the end user from licensing requirements, which are called "exemptions." Among these are general materials exemptions which allow the use of many radionuclides in many chemical and physical forms subject to limits on activity, and which are specified in 10 CFR 30.14 and 10 CFR 30.18.

**Exempt Concentrations**

Section 30.14 of 10 CFR Part 30 provides an exemption from the requirements for a byproduct materials license to any person who receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in 10 CFR 30.70, "Schedule A--Exempt Concentrations." (Note, however, in paragraph (b) of this section, the exemption does not authorize the import of byproduct material or products containing byproduct material.)


Paragraph (c) of 10 CFR 30.14 provides that a manufacturer, processor, or producer of a product or material is exempt from the requirements for a license to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in 10 CFR 30.70 and which was introduced into the product or material by a licensee holding a specific license issued by the Commission expressly authorizing such introduction. However, the exemption does not allow the manufacturer to transfer the byproduct material if contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being. Paragraph (d) of 10 CFR 30.14 specifies that no person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued by NRC under 10 CFR 32.11, "Introduction of Byproduct Material in Exempt Concentrations into Products or Materials, and Transfer of Ownership or Possession: Requirements for License."

Section 32.11 of 10 CFR 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," prescribes the requirements for the issuance of specific licenses (i.e., an Exempt or E-distribution license) to persons who introduce byproduct material in exempt concentrations into a product or material owned by or in the possession of the licensee or another and specifies the regulations governing holders of such licenses. Applicants for a 10 CFR 32.11 license need to have a possession license for the byproduct material. In addition, they must provide a description of the product


or material; its intended use, method of introduction, initial concentration; control methods, estimated time interval between introduction and transfer, and estimated concentration at the time of transfer. Further, the applicant must provide reasonable assurance that the concentrations at the time of transfer will not exceed the limits, reconcentration is not likely, use of lower concentrations is not feasible, and the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for

ingestion or inhalation by, or application to, a human being. Sections 32.12, "Records and Material Transfer Reports," and 32.13, "Prohibition of Introduction," of 10 CFR Part 32 apply to distributors of these products.

An example of a situation in which these regulations might be applied would be if an oil refinery wishes to conduct a tracer study within certain equipment to identify potential process problems or determine other process characteristics. In this example, a licensee, who holds a NRC E-distribution license and an NRC or Agreement State possession license and is specifically authorized to conduct tracer studies, which may be the refinery or another specifically licensed company, introduces a quantity of labeled tracer into the process equipment, which is diluted by the large volume of product, and takes product samples downstream to analyze for process characteristics. The "contaminated" product, which the licensee has confirmed contains concentrations less than the limits specified in 10 CFR 30.70, may then be transferred, under 10 CFR 32.11, to unlicensed persons (exempt under 10 CFR 30.14). Any person who subsequently receives and transfers the product following the initial transfer is also exempt under 10 CFR 30.14.

**Exempt Quantities**

Section 30.18 of 10 CFR Part 30 provides an exemption from the requirements for a byproduct materials license to the extent that such person receives, possesses, uses, transfers, owns or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity set forth in 10 CFR 30.71, "Schedule B." (However, paragraph (e) of this section prohibits persons,

for purposes of producing an increased radiation level, from combining quantities of byproduct material covered under the exemption so that the aggregate quantity exceeds the limits.)

It is important to note that paragraph (c) of 10 CFR 30.18, "Manufacture, Distribution and Transfer of Exempt Quantities of Byproduct Material: Requirements for License," specifies that the exemption does not authorize, for purposes of commercial distribution, the production, packaging, repackaging, or transfer of byproduct material or the incorporation of byproduct material into products intended for commercial distribution. (The exemption in 10 CFR 30.14 does not include this prohibition.) Paragraph (d) of 10 CFR 30.18 prohibits persons, for purposes of commercial distribution, from transferring "exempt" quantities of byproduct material, knowing or having reason to believe that the byproduct material will be transferred to persons, except in accordance with a license issued by NRC under 10 CFR 32.18. Section 32.18 of 10 CFR Part 32 prescribes the requirements for the issuance of specific licenses (E-distribution licenses) to persons who wish to manufacture, process, produce, package, repackage, or transfer quantities of byproduct material for commercial distribution to persons exempt under 10 CFR 30.18 or the equivalent regulations of an Agreement State. Paragraph (a) of 10 CFR Part 32 requires applicants to have a possession license for the byproduct material. Paragraph (b) of 10 CFR Part 32 specifies that the byproduct material may not be contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being. Paragraph (c) of 10 CFR Part 32 specifies that the byproduct material must be in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and is intended to be used for its radioactive

properties. The paragraph further stipulates that the byproduct material may not be incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution. Paragraph (d) of 10 CFR Part 32 requires the applicant to submit copies of prototype labels and brochures that must be included with the byproduct material when transferred.

Sections 32.19, "Conditions of licenses," and 32.20, "Records and material transfer reports" of 10 CFR Part 32 also apply to commercial distributors of exempt quantities. Section 32.19 of 10 CFR Part 32 sets forth license conditions that specify limits on transfer and what may constitute an individual "quantity." This section also specifies container labeling criteria and other information that must accompany the product when transferred to an unlicensed person. Section 32.20 of 10 CFR Part 32 requires licensees to maintain the records and describes the type of information that must be included in the reports that are submitted annually to NRC.

The most common products authorized for distribution under 10 CFR 32.18 are plastic encapsulated "check" or calibration sources which are used to verify radiation detection instrument operability. Although the term "commercial distribution" is not defined in the regulations, the term has been interpreted in guidance such that commercial transfer of a product refers to the introduction of a material into the marketplace, whether or not a charge is assessed for that distribution. Commercial benefit does not necessarily include a monetary exchange. An important difference to note regarding commercial distribution of exempt quantities is that, while the regulations in of 10 CFR Part 30 for all other exempt products only require an NRC license for initial transfer of the products, (i.e., a license is not required for all subsequent transfers); all commercial transfers (including finished product retransfers) of exempt quantity products must be authorized by an NRC license.

While commercial distribution must be authorized under a specific NRC license, section 30.18 of 10 CFR 30 does allow licensees and others to make non-commercial transfers of byproduct material in individual quantities, each of which does not exceed the applicable quantity set forth in 10 CFR 30.71 to unlicensed individuals. The Statements of Considerations published in the *Federal Register* (35 FR 6426-6427; April 22, 1970), for the final rule established 10 CFR 30.18, which contains the following statement


to clarify this allowance: "Persons holding an Atomic Energy Commission or an Agreement State byproduct material license authorizing manufacture, processing, or production of byproduct material are authorized under the exemption to make transfers, on a noncommercial basis, of exempt quantities of byproduct material possessed under the license, on an exempt basis. This provision is designed to accommodate the occasional transfers between laboratories of small quantities of byproduct material in tissue samples, bioassay samples, tagged compounds, counting standards, etc., which involve a negligible risks." A typical example might be a hospital which transfers a tissue sample from a patient who had been treated for thyroid ablation with iodine-131 to an unlicensed pathology laboratory for testing after confirming that activity of iodine-131 in the tissue sample is less than the allowed limit.

Frequently, some confusion exists regarding exempt concentrations and quantities. Specifically, the misperception is that the limits create a "threshold" below which licensed material is no longer subject to licensing. This is an incorrect assumption. In addition, sections 30.11 and 30.18 of 10 CFR Part 30 do not provide an authorization for a licensee to transfer licensed material at or below the limits specified in the regulations

to an unlicensed person for disposal. Note that if a specific licensee receives an exempt quantity, product or material containing an exempt concentration, the license is subject to the requirements of 10 CFR Part 20, "Standards for Protection Against Radiation," (e.g., waste disposal). No exemption is allowed from the requirement of 10 CFR Part 20 in 10 CFR 30.14 or 10 CFR 30.18.

(Contact: Carrico, J Bruce, FSME, 301-415-7826 or JBruce.Carrico@nrc.gov)

## SIGNIFICANT ENFORCEMENT ACTIONS

The NRC issued significant enforcement actions for failure to comply with regulations.

### Humboldt Scientific, Inc.
(EA-11-138)

On March 8, 2012, the NRC issued a Notice of Violation to Humboldt Scientific, Inc. (HSI) for two Severity Level III problems. The problems involved a failure to obtain appropriate license authorization to export byproduct materials to restricted and embargoed destinations and a failure to submit annual reports of all americium shipments in accordance with 10 CFR 110.54(b). Specifically, on May 6, 2005, May 7, 2008, June 26, 2008, and July 31, 2008, HSI exported americium-241 and cesium-137 byproduct materials subject to NRC licensing jurisdiction, to embargoed destinations (i.e., Iraq and Sudan, respectively), without a specific license as required by 10 CFR 110.5. Even though americium exports were performed, HSI failed to make annual reports of americium exports for calendar years 2000-2009.

### S&R Engineering S.E.
(EA-11-098)

On January 13, 2012, the NRC issued a Notice of Violation and Proposed Imposition of a Civil Penalty in the amount of $14,000 to S&R Engineering (S&R) for a Severity Level (SL) III problem and two SL III violations. The SL III problem involved two violations: (1) S&R failed to comply with or respond to an NRC Order, as required by 10 CFR 2.202(b); and (2) S&R provided information to the NRC that was not complete nor accurate as required by 10 CFR 30.9(a). Specifically, as of January 13, 2012, S&R had not submitted an answer to the Order (which was required by November 28, 2009), had not paid the license fee, and had not disposed or transferred their licensed nuclear material to an authorized recipient. On August 3, 2010, the S&R president informed the NRC that S&R had transferred its portable moisture density gauge containing radioactive sources to another NRC licensee when S&R still possessed the gauge. The two additional SL III violations involved S&R's failure to afford the NRC an opportunity to inspect materials, activities, and records under the regulations as required by 10 CFR 19.14(a) and S&R's failure to use a minimum of two independent controls that formed tangible barriers to secure portable gauge from unauthorized removal, when the portable gauge was not under S&R's direct control and constant surveillance as required by 10 CFR 30.34(i). Specifically, on August 3, 2010, S&R provided inaccurate information to the NRC about the location of licensed material, thereby preventing inspection of its licensed activities. The gauge had been stored in its shipping case, which was located in an unlocked closet of a locked S&R office, providing only one barrier.

### Universal Product Concepts, Inc.
(EA-11-222)

On January 9, 2012, the NRC issued a Notice of Violation and Proposed Imposition of a Civil Penalty in the amount of $7,000.00 to Universal Product Concepts, Inc. (UPC) for a Severity Level III problem. The problem involved two violations: (1) a willful transfer of smoke detectors containing byproduct material

(americium-241) without an NRC license as required by 10 CFR 30.3(a); and (2) an import of material into the United States without having the required license for possession of the material as required by 10 CFR 110.5. Specifically, from May to July 2010, UPC imported and transferred approximately 19,423 smoke detectors containing byproduct material without the required NRC licenses authorizing such imports and transfers.

**Lincoln University of Missouri** (EA-11-219)

On December 19, 2011, the NRC issued a Notice of Violation to Lincoln University of Missouri for a Severity Level

III problem involving multiple violations of license conditions and NRC regulations. Specifically, the licensee failed to: (1) ensure that the individual named on the NRC license fulfilled the responsibilities of the radiation safety officer between May 2009 and August 18, 2011; (2) conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license between May 2009 and August 8, 2011; (3) notify the NRC in writing within 60 days of no longer conducting principal activities for a period of 24 months; (4) maintain records of receipt of radioactive materials for as long as the material was possessed as well as maintain disposal records until termination of the NRC license; and (5) comply with the applicable requirements for performing leak tests and inventories of generally licensed devices.

**International Cyclotron, Inc.** (EA-11-086)

On December 19, 2011, the NRC issued a Notice of Violation and Proposed

Imposition of a Civil Penalty in the amount of $7000, and an Order suspending licensed activities within 60 days to International Cyclotron, Inc. (ICI), for a Severity Level III violation of 10 CFR 30.35. The violation involved ICI's failure to provide a decommissioning funding plan. Specifically, on August 20, 2009, ICI was issued an NRC license authorizing the possession and use of unsealed byproduct material of applicable quantities set forth in Appendix B to 10 CFR Part 30. ICI has not provided a decommissioning funding plan that contains a signed original of the financial instrument obtained to provide financial assurance for decommissioning, as required by 10 CFR 30.35. Based on ICI's failure to fully and timely respond to requests for information, and compliance with NRC regulations, the NRC issued an Order Suspending Licensed Activities (Order). According to this Order, if ICI does not submit to the NRC an acceptable financial assurance instrument within 60 days of the date of the Order, ICI is required to suspend all activities authorized under its license. This Order will remain in effect until ICI submits a financial assurance instrument and the NRC informs ICI that the instrument is accepted.

## MEDICAL

**Cardinal Health PET Manufacturing Services, Inc.** (EA-11-146)

On November 9, 2011, the NRC issued a Notice of Violation to Cardinal Health PET Manufacturing Services, Inc., for a Severity Level III violation involving the failure to monitor the occupational exposure to an adult who was likely to receive, in 1 year from sources external to the body, an extremity dose in excess of 5 rem as required by 10 CFR 20.1502(a)(1). Specifically, on June 16, 2010, a Cardinal Health PET Manufacturing Services em-

ployee removed his extremity (ring) dosimetry on two separate occasions prior to handling a chemical cartridge containing approximately 4 curies of fluorine-18.

Information about the NRC's enforcement program can be accessed at http://www.nrc.gov/about-nrc/regulatory/enforcement/current.html. Documents related to cases can be accessed through the NRC's Agencywide Document Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html. Help in using ADAMS is available by contacting the NRC Public Document Room staff at 301-415-4737 or 1-800-397-4209 or by sending an e-mail to PDR.Resource@nrc.gov.

(Contact: Michele Burgess, FSME, 301-415-5868 or Michele.Burgess@nrc.gov)

## GENERIC COMMUNICATIONS ISSUED

The following are summaries of NRC generic communications issued by FSME. If any of these documents appears relevant to your needs and you have not received it, please call one of the technical contacts


listed below. The Web address for the NRC library of generic communications is http://www.nrc.gov/reading-rm/doc-collections/gen-comm.

## REGULATORY ISSUE SUMMARIES

The NRC provides regulatory issue summaries (RIS) as an


informational document used to communicate with the nuclear industry on a broad spectrum of matters.

On March 20, 2012, the NRC issued RIS 2012-04, "Notice of Revision to the Criteria for Identifying Materials Licensees for Discussion at the Agency Action Review Meeting," to all NRC materials licensees, including fuel cycle facilities and master material licensees, all Agreement State Radiation Control Program Directors, and State Liaison Officers. The RIS informed addressees that the NRC has revised the criteria for identifying nuclear material licensees, including Agreement State licensees, with significant performance problems for discussion at the NRC's Agency Action Review Meeting.

(Contact: Duane White, FSME, 301-415-6272 or Duane.White@nrc.gov)

On April 16, 2012, the NRC issued RIS 2012-06, "NRC Policy Regarding Submittal of Amendments for Processing of Equivalent Feed at Licensed Uranium Recovery Facilities," to all holders of NRC operating licenses for water treatment, companies that have submitted applications to construct all types of new uranium recovery facilities (conventional mills, heap leach facilities, and in situ recovery facilities), Radiation Control Program Directors, and State Liaison Officers. The RIS provided guidance on the impact that the processing of alternative feed may have for individual licensees.

(General Contact: Angela R. McIntosh, FSME, 301-415-5030 or Angela.McIntosh@nrc.gov)

## SIGNIFICANT EVENTS

### Misidentification of Source Location Resulting in Under Dose During HDR


Date and Place: January 5, 2012, Great Falls, Montana

Event Details:

During administration of high dose remote (HDR) afterloader brachytherapy using an Ir-192 (234.728 GBq (6.344 Ci) source, the patient received only about 10 percent of the prescribed 700 cGy (rad) dose for treatment of esophageal cancer. The location of the source was tracked by a radiographically opaque marker near the source. In this case, the end of the catheter also appeared somewhat radiographically opaque and was mistaken for the source location. When the nasogastric tube and the catheter were removed as a unit at the end of the procedure, it was discovered that the catheter was not advanced to the end of the nasogastric tube. As the result of an investigation, it was determined that the dose was delivered to a location 29 centimeters proximal to the end of the catheter and resulted in 1,000 cGy (rad) to a 4 centimeters length of tissue in the nasal and nasopharyngeal sinus area. The physician and patient were notified of the event. The patient was scheduled for an anatomical examination to assess the presence of adverse effects; however, no adverse health effects are anticipated. Corrective actions included procedure modification such that catheter length measurements are performed prior to treatment and the catheter and nasogastric tube are introduced to the patient as a unit. Also, the entire length of the catheter will be visible in computer tomography scans during all HDR procedures. An NRC-contracted medical consultant agreed with the hospital's analysis of this event.

**Erroneous Treatment Parameter Resulting in Under Dose During HDR**

Date and Place:
January 16, 2012,
Sioux Falls, South Dakota

Event Details: During administration of high dose remote (HDR) afterloader brachytherapy using a SenoRx Contura multi-catheter applicator, the patient received approximately 50 percent of the prescribed dose in 2 of the 10 fractions. The treatment parameter length entered was 10 cm less than calculated. The correct length was entered for the second fraction; however, after the third fraction on January 17, 2012, it was discovered that the original incorrect treatment plan had been inadvertently re-selected. Two additional fractions were added and the treatment plan was modified to achieve the total dose specified in the written directive. The licensee's medical consultant determined that the patient received approximately 2,720 cGy (rad) of unintended skin dose. Corrective actions included procedure revision, personnel training, and organizational changes.

**Patients Switched In Y-90 Microsphere Administration**

Date and Place:
January 19, 2012,
Philadelphia, Pennsylvania

Event Details: The licensee reported that two patients received different Y-90 microsphere (Sirtex Medical model SIR-Spheres) doses than prescribed. Both patients were scheduled to be treated on the same day, close in time. The worksheets were switched and each patient received the other patient's dose. The first patient reached stasis before receiving the full amount and received a dose 35 percent above the originally prescribed dose and was administered 513 MBq (13.86 mCi) instead of the prescribed 381.1 MBq (10.3 mCi). The second patient received 56% less than prescribed or 329.3 MBq (8.9 mCi) instead of the prescribed 751.1 MBq (20.3 mCi). The cause of the event was determined to be human error. To compensate for the error, the licensee administered a higher dose than planned to the second patient, during the next scheduled treatment. Written procedures were developed and implemented to both minimize the chance of errors

occurring in the microsphere dose preparation process and to identify and correct any such errors prior to administration.

**Patient Switch Results In Y-90 Under Dose**

Date and Place:
February 2, 2012, Murray, UT

Event Details: The licensee reported that a patient prescribed to receive 5.32 GBq (143.78 mCi) of Y-90 microspheres (MDS Nordion model Thera-Spheres) for a treatment dose of 12,000 cGy (rad) received another patient's microsphere treatment. Two patients were at the facility to receive microspheres at the same time. The first patient received the second patient's intended dose or 1.77 GBq (47.84 mCi). The error was identified prior to the second patient receiving treatment.

**Unintended Organs Dosed During Y-90 Microsphere Treatment**

Date and Place:
February 2, 2012,
Minneapolis, Minnesota

Event Details: The licensee reported that a patient received dose to unintended organs during a liver treatment that involved 1.55 GBq (41.89 mCi) of Y-90 microspheres (Sirtex Medical

model SIR-Spheres). The infusion procedure went according to plan. After accounting for normal loss within the delivery system, the final administered activity was 1.53 GBq (41.35 mCi). However, follow-up scans revealed that some of the microspheres were not in the liver. After investigation on February 6, 2012, it was determined that an estimated 10 to 15 percent of the microspheres were in the spleen, gastric fundus, and duodenum. The patient and the ordering physician were informed. From further investigation and the single-photon emission computed tomography (SPECT CT) imaging results, the following calculations of the administered activities and estimated doses were discovered: 83.9 percent to the liver for a dose of 53 Gy (5,300 rad); 5.8 percent to the gastric fundus for a dose of 44 Gy (4,400 rad); 9.3 percent to the spleen for a dose of 35 Gy (3,500 rad); and 1percent to the duodenum for a dose of 35 Gy (3,500 rad). These dose estimates have uncertainties of at least 20 percent with local concentrations and doses that may be significantly higher. Maximum concentrations per pixel in the SPECT images were as much as 50 percent higher than the average concentration. After a detailed investigation, the licensee was unable to identify any procedural failures or human errors that may have produced the event. This event may result in unintended, permanent functional damage and some form of medical intervention, which is likely. The patient was administered the radio-protective pharmaceutical Amifostine and will be monitored weekly to determine the extent of damage to the unintended organs. The RSO will provide periodic updates regarding the status of the patient to the State.

(General Contact: Angela R. McIntosh, FSME, 301-415-5030 or Angela.McIntosh@nrc.gov)


## SELECTED *FEDERAL REGISTER* NOTICES

| CITATION | SUBJECT | CONTACT | PUBLISHED |
|---|---|---|---|
| 77 FR 8078 | Unified Agenda of Federal Regulatory and Deregulatory Actions (Semiannual regulatory agenda) | Cindy Bladey, ADM, 301-492-3667 or Cindy.Bladey@nrc.gov | February 13, 2012 |
| 77 FR 8751 | Guidance for Decommissioning Planning During Operations (Draft regulatory guide; reopening of comment period) | James C. Shepherd, FSME, 301-492-6712 or James.Shepherd@nrc.gov. | February 15, 2012 |
| 77 FR 10401 | Low-Level Radioactive Waste Management Issues (Public meeting; request for comment) | Michael P. Lee, Ph.D., FSME, 301-415-6887 or Mike.Lee@nrc.gov; or<br><br>Tarsha Moon, FSME, 301-415-6745 or Tarsha.Moon@nrc.gov | February 22, 2012 |

# TO OUR READERS

In our attempt to keep the FSME Licensee Newsletter relevant, we welcome useful and informative feedback on the contents of the newsletter. If you would like to suggest topics, please contact Vanessa Cox or Gwendolyn Davis from FSME Rulemaking Branch A. Ms. Cox may be contacted at 301-415-8342 or Vanessa.Cox@nrc.gov. Ms. Davis may be contacted at 301-415-8165 or Gwendolyn.Davis@nrc.gov. In addition, to ensure proper delivery of the FSME Licensee Newsletter and to prevent any interruption of service, please report any address changes to Ms. Cox at FSME_Newsletter@nrc.gov.

Please send written correspondence to the following address:

Vanessa Cox, Editor FSME Licensee Newsletter
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
Two White Flint North, Mail Stop: T-8-F42
Washington, D.C. 20555-0001


Federal Recycling Program


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OFFICIAL BUSINESS