

NMSS Quarterly Newsletter



**U.S. Nuclear
Regulatory
Commission**

**Office of Nuclear
Material Safety
and Safeguards**

**NUREG/BR-0117
No. 06-01
March 2006**

<i>Contents</i>	<i>Page</i>
1. Regulatory Issue Summary 2005-31 – Control of Security-Related Sensitive Unclassified Non-Safeguards Information.....	1
2. Proposed Rule: Requirements for Expanded Definition of Byproduct Material	3
3. Performing the Surgical Procedures Associated With Sentinel Lymph Node Biopsy.....	4
4. Issuance of Order for Increased Controls for Certain Radioactive Materials Licensees	4
5. Significant Events (November 1, 2005 – January 31, 2006)	7
6. Generic Communications Issued (December 3, 2005 – February 28, 2006)	7
7. Significant Enforcement Actions.....	8
8. Selected Federal Register Notices.....	10

REGULATORY ISSUE SUMMARY 2005-31 – CONTROL OF SECURITY-RELATED SENSITIVE UNCLASSIFIED NON- SAFEGUARDS INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) traditionally has given the public access to a significant amount of information about the facilities and materials the Agency regulates. Openness has been and remains a cornerstone of NRC's regulatory philosophy. The Atomic Energy Act, subsequent legislation, and various NRC regulations have given the public the right to participate in the licensing and oversight process for NRC licensees. To participate in a meaningful way, the public must have access to information about the design and operation of regulated facilities and use of nuclear materials. However, NRC and other Government agencies have always withheld some information from public disclosure for reasons of security, personal privacy, or commercial or trade secret protection.

In the post-September 11, 2001 environment, NRC, like many other agencies, has found it necessary to be more judicious in determining what information to voluntarily release, so as not to inadvertently provide assistance to those who might use certain information for malevolent acts. NRC has issued orders and advisories and taken specific actions regarding the security of its licensed facilities and has also assessed and revised its policies and practices for making information available to the public. For example, one of the actions NRC took was to suspend public access to documents in its electronic Agency-wide Documents Access and Management System (ADAMS) on October 25, 2004. Subsequently, NRC screened those documents to determine whether they contained security-related sensitive information. Based on this screening, numerous documents were returned to public access in ADAMS. This screening process continues as requests for specific documents are received and as new documents are created by NRC and received from licensees and others.

To facilitate this screening process, NRC has developed screening criteria for conducting its reviews. In November 2005, NRC issued guidance [NRC Regulatory Issue Summary (RIS) 2005-26] for assessing whether documents associated with reactor licensees should be made publicly available. As part of the continuing efforts in this area, NRC has now developed the criteria for screening from public disclosure security-related sensitive information associated with various NRC-regulated activities of persons handling source, byproduct, and special nuclear material.

This RIS sets forth procedures that licensees and others are encouraged to follow when handling documents, and/or when submitting documents to the NRC that contain security-related sensitive information, other than classified or safeguards information, that could be useful, or could reasonably be expected to be useful, to a terrorist in a potential attack.

This RIS and its attachments do not apply to classified information or Safeguards Information. Classified information (Confidential, Secret, Top Secret) is withheld from the public by law. Safeguards Information is withheld because it provides details of security measures at nuclear facilities. Handling requirements for classified information and Safeguards Information are set forth in various NRC orders, regulations, and generic communications (e.g., requirements for the handling and protection of Safeguards Information are discussed in RIS-2003-08, "Protection of Safeguards Information from Unauthorized Disclosure," dated April 30, 2003). Sensitive (but unclassified, non-safeguards) information covers a range of information for which the loss, misuse, modification, or unauthorized access can reasonably be foreseen to harm the public interest, commercial or financial interests of an entity, the conduct of NRC and Federal Programs, or the personal privacy of individuals. As noted above, this RIS covers security related information that, if released, could cause harm to the public interest as it could be useful, or could reasonably be expected to be useful, to a terrorist in a potential attack.

SUMMARY OF ISSUE

This RIS: 1) informs licensees and others of the screening criteria that NRC uses to identify and protect Security-Related Sensitive Information in documents generated by the Agency and in documents received from licensees and others; 2) encourages licensees and others to identify security-related sensitive information contained in documents submitted to NRC, by using the screening criteria in Attachment 2 of this RIS and marking procedures; and 3) encourages licensees and others that may possess security-related sensitive information to control the information, to limit the risk that the information might fall into the hands of those who would use it for malevolent acts.

Specifically, protection of the information should be implemented in the following manner:

1. Screening of future documents submitted to NRC to assure that future submittals containing security-related sensitive information are not made publicly available in ADAMS, while still making other appropriate information available to the public. NRC is encouraging licensees and others to screen submittals. If practical, documents submitted to NRC should avoid including security-related sensitive information, so as to permit releasing the document to the public in its entirety.

2. Marking and submitting documents containing security-related sensitive information if it is necessary to include security-related sensitive information in a submitted document, the submittal should be marked to indicate the presence of such information as follows:

- a) The cover letter should clearly state that the attached documents contain security-related sensitive information. When separated from the attached documents, if the cover letter itself does not contain security-related sensitive information, the cover letter itself is uncontrolled.

- b) As shown in Attachment 1 of the RIS (Section A), the top of every page of a letter or document that contains security-related sensitive information should include the marking "Security-Related Information — Withhold Under 10 CFR 2.390" (note that NRC's procedure for these documents is to mark them as "Official Use Only - Security-Related Information). For the pages having security-related sensitive information, an additional marking (e.g., an editorial notebbox) should be included adjacent to the material meeting the screening criteria in Attachment 2 of the RIS. Information on suggested handling and methods of submittal of security-related sensitive information is also contained in Attachment 1 (Section B). Licensees and others can submit both a public and a non-public version of a document, when security-related documents need to be submitted. The public version could have the security-related sensitive information "marked out" or removed with a notation that the information was withheld on the basis that it is "Security-Related Information." This is similar to what is sometimes done to protect proprietary information under 10 CFR 2.390, except that an affidavit is not needed. Alternatively, security-related sensitive information could be segregated from the main body of the document and included only in attachments to the submittal. Only the attachments containing security-related sensitive information would be marked for withholding from public disclosure. Using this approach, the public version need not be marked as containing security-related sensitive information.

3. Protection of Security-Related Sensitive Information Documents that contain security-related sensitive information should be protected from public disclosure, using methods similar to that for protecting proprietary information. To the extent practicable, any existing documents containing security-related sensitive information that licensees or others have previously made available to the public should be withdrawn from public access. As with proprietary information, licensees and others

should have sufficient internal controls to prevent release of information. Possible methods to prevent the inadvertent release of security-related sensitive information include marking documents “Security-Related Information - Withhold Under 10 CFR 2.390,” restricting access to electronic recordkeeping systems that contain such information, and controlling the reproduction, distribution, and destruction of potentially sensitive records. Licensees and others should ensure that similar controls are in place when security-related sensitive information is provided to outside parties such as contractors or other Government agencies, and that the information is made available only to such parties who have a need to know the information to perform their jobs and who are made aware of the security-related nature of the information.

This RIS, the attached screening criteria, and additional explanatory material, as appropriate, are also posted on the NRC Website at <http://www.nrc.gov/reading-rm/sensitive-info.html> (note that the criteria for fuel cycle facilities in this website and in this RIS supersede information at <http://www.nrc.gov/materials/fuel-cycle-fac/review-criteria-fuel-cycle.html>). NRC staff will interact with licensees and others on a case-by-case basis to resolve questions about the application of the procedures and screening criteria set forth in this RIS and its attachments. NRC will continue to make as much information as possible available to the public. Much of NRC’s information is readily available to the public via the NRC Website (www.nrc.gov) and NRC’s ADAMS system (www.nrc.gov/reading-rm/adams.html). In addition, other information may be released to the public in response to formal and/or informal requests. Although the security-related sensitive information screening criteria were developed with the principles of the Freedom of Information Act (FOIA) in mind, a review for security-related sensitive information does not substitute for a FOIA review. FOIA requests will continue to be reviewed and processed independently from the security-related sensitive information review process.

(Contact: Frank Cardile, Division of Industrial and Medical Nuclear Safety, 301-415-6185, e-mail: fpc@nrc.gov)

PROPOSED RULE: REQUIREMENTS FOR EXPANDED DEFINITION OF BYPRODUCT MATERIAL

The Energy Policy Act of 2005 (EPAAct) was promulgated on August 8, 2005. Section 651(e) of the EPAAct expanded the definition of byproduct

material, as defined in Section 11e. of the Atomic Energy Act of 1954, to include certain discrete sources of radium, certain accelerator-produced radioactive material, and certain discrete sources of naturally occurring radioactive material, thereby placing these materials under U.S. Nuclear Regulatory Commission (NRC) jurisdiction. NRC is required under Section 651(e) of the EPAAct, to develop a regulatory framework for licensing and regulating this newly defined byproduct material.

As part of this regulatory framework, NRC took several initiatives in an effort to enhance stakeholder involvement and to improve efficiency during the rulemaking process. As part of this effort, NRC held a public roundtable meeting on November 9, 2005, and has established a Web page on the “Expanded Definition of Byproduct Material (NARM) Rulemaking.”

The November 9, 2005, public meeting was in a “roundtable” format to allow stakeholders an opportunity to discuss concerns, and to enhance interaction among all interested parties on the subject of the NRC regulating NARM. Representatives from other Federal agencies, States, and a broad spectrum of interest groups were invited to participate in the “roundtable” discussion.

During the public meeting, NRC provided an overview of the EPAAct, and discussed the rulemaking process and the role of the Nuclear Material Safety and Safeguards (NMSS) EPAAct Task Force established to help implement the requirements of the EPAAct. Other topics discussed included: (a) the role of State regulations; (b) potential implications regarding production of radiopharmaceuticals; (c) availability of radiopharmaceuticals to patients; (d) definition of discrete source; (e) the NRC jurisdiction over accelerator-produced radioactive material; and (f) waste and transportation issues.

The web page, “Expanded Definition of Byproduct Material (NARM) Rulemaking,” may be viewed via the rulemaking website at <http://ruleforum.llnl.gov> by going to the option “Other rulemaking-related comment requests.” Once the proposed rule is published, the web page will be moved to the “Proposed rules” option on the rulemaking website. The web page currently includes: (a) background information; (b) the EPAAct as it relates to this rulemaking; (c) transcript, meeting summary, and comments related to the November 9, 2005, public meeting; (d) and other related documents. The proposed rule will also be posted on the web page for public comment.

(Contact: Lydia Chang, Division of Industrial and Medical Nuclear Safety, 301-415-6319, e-mail: lwc1@nrc.gov)

PERFORMING THE SURGICAL PROCEDURES ASSOCIATED WITH SENTINEL LYMPH NODE BIOPSY

A U.S. Nuclear Regulatory Commission (NRC) licensee requested approval to perform a surgical biopsy of tissue containing Technetium 99m (Tc-99m) at one of its facilities without an NRC license. The procedure is called Sentinel Lymph Node Biopsy (SLNB).

The licensee stated that the first portion of the SLNB procedure - the injection of less than 37 megabecquerel (1 millicurie) of Tc-99m sulfur colloid - would be performed at a licensed facility under the supervision of an authorized user and, subsequently, the patient would be released. The next portion of the SLNB procedure, the surgical removal and biopsy of the tissue containing the technetium, would be performed at one of its facilities not licensed for radioactive material use.

The surgical removal of the radioactive tissue and its biopsy constitute the medical use of byproduct material in imaging and localization studies and must be performed at a licensed facility under the supervision of an authorized user. The licensed facility may have its own byproduct material license or, in this licensee's case, become an additional location of use listed on its existing medical use license after approval of a license amendment request to add the site where the surgical procedure is performed. The amendment must provide a description of the licensee's radiation safety oversight and day-to-day operating radiation safety program. NRC reviews this information in accordance with a risk-informed, performance-based approach.

The third portion of the SLNB procedure is the transfer of the surgically removed tissue to a pathology laboratory that may or may not be required to have an NRC license to receive the material. The licensee may transfer the tissue to a pathology laboratory exempt from licensing under the "exempt-quantity" provisions of 10 CFR 30.18, if the tissue contains an exempt quantity of radioactive material (in this case, 3.7 megabecquerel (100 microcuries) or less of Tc-99m). However, if the tissue contains greater than an exempt quantity, it must be transferred to a pathology laboratory with an NRC license. If the licensee does not have or use its own pathology laboratory, and the tissue exceeds

the exempt quantity criteria, then the licensee must verify that the recipient is authorized to receive the tissue containing the radioactive material. When shipping radioactive material, the licensee shipping the material and the shipper must meet Department of Transportation requirements.

In summary:

- The first portion of the procedure - the injection of the Tc-99m - must be performed under an NRC medical use license by, or under the supervision of, an authorized user who meets the imaging and localization training and experience qualifications, as stated in 10 CFR 35.290, "Training for imaging and localization."
- The second portion of the procedure - the surgical removal of the radioactive tissue - must also be performed under an NRC medical use license, and under the supervision of an authorized user meeting the requirements in CFR 35.290, "Training for imaging and localization."
- The third portion of the procedure - the pathology study of the radioactive tissue - may or may not have to be performed under an NRC license. Whether the radioactivity in the tissue contains an exempt quantity of radioactive material (in this case, 3.7 megabecquerel (100 microcuries) or less of Tc-99m) will determine if the pathology laboratory is exempt from licensing under the "exempt - quantity" provisions of 10 CFR 30.18.

(Contact: Donna-Beth Howe, Ph.D., Nuclear Material Safeguards and Safety, 301-415-7848, e-mail: dbh@nrc.gov)

ISSUANCE OF ORDER FOR INCREASED CONTROLS FOR CERTAIN RADIOACTIVE MATERIALS LICENSES

On December 1, 2005, the U.S. Nuclear Regulatory Commission (NRC) published, in the Federal Register (70 FR 72128), a notice regarding all licensees authorized to possess certain radioactive material, in quantities of concern (see attached table). This notice describes an Order (EA-05-090) imposing increased controls on licensees in possession of these radionuclides of concern, as well as on those who may possess them in the future. Copies of this notice can also be found on the NRC website in the Agencywide Documents Accession and Management System (ADAMS) at accession number ML053130405. In addition, the Order can be found at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/security/#8>.

Before the terrorist attacks of September 11, 2001, several national and international efforts were underway to address the potentially significant health and safety hazards posed by uncontrolled sources. These efforts recognized the need for increased control of risk-significant radioactive materials to prevent inadvertent and intentional unauthorized access, primarily because of the potential health and safety hazards posed by the uncontrolled material. After September 11, 2001, efforts shifted to include heightened oversight and awareness of the need to prevent intentional unauthorized access because of the possibility of potentially malicious acts. At the international level, the International Atomic Energy Agency (IAEA) published, in 2004, its "Code of Conduct on the Safety and Security of Radioactive Sources" (Code of Conduct), which focused on radionuclides that may pose a significant risk to individuals, society and the environment, and also focused on developing laws and regulations to achieve and maintain a high level of safety and security of these radioactive sources. The U.S. Government supports the IAEA's Code of Conduct and is taking actions to implement its recommended standards. The attached "Table of Radionuclides of Concern" is based on the IAEA Code of Conduct.

The loss of control of these risk-significant radionuclides has a potential to result in significant doses and adverse health effects to the public. Consequently, the Commission determined that licensees possessing such radionuclides must implement certain additional controls, to supplement the regulatory requirements. These supplemental controls are to ensure adequate protection of the public health and safety, and minimize the danger from malicious acts.

In November and December 2005, the NRC issued Order EA-05-090, which requires compliance with increased controls regarding the possession of the radioactive material quantities of concern listed in the attached table. The Order was sent to licensees authorized to possess these radioactive materials. The radionuclides of concern, and their corresponding quantities, are contained in the aforementioned table. To effect nationwide implementation, each Agreement State issued legally binding requirements to put essentially identical measures in place for licensees under their regulatory jurisdiction.

The Order was effective immediately and will remain in effect until the Commission incorporates similar measures into its regulations. Licensees have 180 days to come into compliance with the increased controls or on the first day that radionuclides of

concern are possessed which equal or exceed the quantity identified in the table, whatever is later. Licensees are to report to the Commission when they have achieved compliance with the requirements of the Order.

The purpose of the Order is to reduce the risk of unauthorized use of radioactive material, through access controls to aid prevention, as well as prompt detection, assessment, and response to mitigate potentially high consequences that would be detrimental to public health and safety. The increased controls provide enhanced security against unauthorized removal or access and list actions for the licensees to take in the following areas:

1. Controlling the access to radioactive material, and limiting access to only approved individuals who require access to perform their duties;
2. Developing and documenting a program to monitor and immediately detect, assess, and respond to unauthorized access to radioactive material quantities of concern, with enhanced monitoring during periods of source delivery or shipment;
3. Using specifically qualified carriers for transportation over highways and railways when the carrier is not the licensee. Additional security measures (ASMs) are required when shipping radioactive materials that equal or exceed 100 times the quantities in the table below (These ASMs were the subject of another NRC security Order issued on July 19, 2005);
4. Providing additional physical controls on portable or mobile devices; and,
5. Protecting detailed security information from unauthorized disclosure.

Licensees were also provided guidance for implementing the increased controls required by the Order. The guidance expands on the idea of: (a) access control; (b) detection and assessment; (c) coordination of radioactive material shipments; (d) physical barriers; (e) information protection; and (f) definitions of terminology used in the Order and guidance. The guidance also contains 201 questions and answers regarding issues of how licensees can implement these increased controls on these radioactive materials of concern. This guidance can also be found on the NRC website and in ADAMS, with accession number ML053130233.

It should be noted that the Order to implement the increased controls is applicable to licensees that

currently possess the radionuclides of concern in quantities of concern as listed in the aforementioned table. The Order is also applicable to licensees that do not currently possess these radionuclides but have near-term plans to possess the radionuclides at, or above the quantities of concern. In this case, licensees will need to implement the increased controls before they take possession of radioactive materials that exceed the threshold quantities listed in the table below.

To facilitate resolution of any issues or questions related to the Order or compliance with the requirements in the Order, contact Doug Broaddus at (301) 415-7197, or Frederick Sturz at (301) 415-6678. Questions about the Order and the increased controls can also be sent to ICSupport@nrc.gov. Additional guidance in response to licensee questions will be posted on the NRC website as supplemental questions and answers, and will be accessible through the web link referenced above. An NRC/Agreement State working group has also been established to ensure consistent implementation of the increased controls nationwide.

Table of Radionuclides of Concern

Radionuclide	Quantity of Concern1 (TBq)	Quantity of Concern2 (Ci)
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above ³	See Footnote Below ⁴	

¹ The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.

² The primary values used for compliance with this Order are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

³ Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

⁴ If several radionuclides are aggregated, the sum of the ratios of the activity of each source, i of radionuclide, n , $A_{(i,n)}$, to the quantity of concern for radionuclide n , $Q_{(n)}$, listed for that radionuclide equals or exceeds 1. [(aggregated source activity for radionuclide A) ÷ (quantity of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) ÷ (quantity of concern for radionuclide B)] + etc..... >1.

(Contact: Joe DeCicco, Office of Nuclear Material Safety and Safeguards, 301-415-7833, e-mail: jxd1@nrc.gov)

**SIGNIFICANT EVENTS
(November 1, 2005 – January 31, 2006)**

Event #1: Potential radiographer overexposure at a temporary job site

Date and Place: November 18, 2005,
Sand Springs, Oklahoma

Nature and Probable Causes: The licensee, located in Tulsa, Oklahoma, reported a potential overexposure to a radiographer at a temporary job site. The crew was using a SPEC exposure device (Model 150) with a 2.44 terabecquerel (66 curie) Iridium-192 source. The radiographer went to change the radiographic film, thinking that the assistant had fully retracted the source. While en route to change the film, the radiographer set down his radiation detection instrument to answer his cell phone. At the same time, the assistant was sending a text message on his cell phone. The radiographer was in front of the exposure device for approximately 3 minutes and his alarming rate meter was turned off. The calculated dose the radiographer received was 23 centisieverts (rem). The radiographers were taken to the hospital for blood tests as a precautionary measure and their dosimeters were sent for analyses. The Oklahoma Department of Environmental Quality investigated the event on November 21, 2005, and determined that the radiographer's thermoluminescent dosimeter (TLD) result was 4.4 centisieverts (rem), and the radiographer's total year-to-date whole-body exposure was 6.9 centisieverts (rem). The assistant radiographer's TLD result was 1.21 millisieverts (121 millirem). Both radiographers were suspended pending further investigation.

Update: The licensee contracted with the National Radiological Protection Board, in England, to perform cytogenetic testing on the radiographer. On December 20, 2005, the results of the test were received. The National Radiological Protection Board reported the whole-body exposure to be 4 centisieverts (rem). This result is in agreement with the results of the TLD.

Event #2: Extremity overexposure at radiopharmacy

Date and Place: December 31, 2005,
Houston, Texas

Nature and Probable Causes: The licensee reported that a nuclear pharmacy technician exceeded the annual extremity exposure limit with monitor readings reaching 53.44 centisieverts (rem) for

calendar year 2005. The technician was preparing Technetium-99m doses when he exceeded the extremity limit. The dose was being monitored, but management did not anticipate that the technician would exceed the limit. The technician experienced a heavy workload during the week of December 26, 2005 through, January 6, 2006, and his right hand received 3.12 centisieverts (rem). Corrective actions taken by the licensee included additional training, possible modification of technique, hiring new technicians, and having corporate health physics investigate the incident.

Event #3: Underdose at hospital

Date and Place: January 10, 2006,
Houston, Texas

Nature and Probable Causes: The licensee reported that a patient received an under treatment of Yttrium -90 microspheres during treatment for liver cancer. The nuclear medicine physician delivered the microspheres to the patient; however, after the treatment was presumed finished, he noted that some of the fluid remained in the vial. The retention fluid for the microspheres had become backed up from the site of injection (hepatic artery), and some spillage at the surface occurred, which was absorbed with gauze. The patient was prescribed to receive 0.41 gigabecquerel (11 millicuries), but there was 0.17 gigabecquerel (4.5 millicuries) left in the vial. The licensed medical physicist is evaluating the incident and making an effort to assess the dose delivered to the patient. Corrective actions taken by the licensee included modifying procedures.

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

**GENERIC COMMUNICATIONS ISSUED
(December 3, 2005 - February 28, 2006)**

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, or by e-mail: arm@nrc.gov.

Bulletins (BL)

None.

Information Notices (IN)

IN 2005-32, “Product Alert for Fire Hydrants,” was issued on December 23, 2005. This IN was issued to all holders of operating licenses for nuclear power reactors and fuel cycle facilities, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

(Technical contacts: Phil Qualls, 301-415-1849, e-mail: pmq@nrc.gov; and Rex Wescott, 301-415-6727, e-mail: rgw@nrc.gov)

IN 2006-02, “Use of Galvanized Supports and Cable Trays with Meggitt Si 2400 Stainless-Steel-Jacketed Electrical Cable” was issued January 19, 2006. This IN was issued to all holders of operating licenses for nuclear reactors except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel; and fuel cycle licensees and certificate holders.

(Technical contacts: Robert Wolfgang, 301-415-1624, e-mail: rjw1@nrc.gov; and Rex Wescott, 301-415-6727, e-mail: rgw@nrc.gov)

Regulatory Issue Summaries (RIS)

RIS 2005-31, “Control of Security-related Sensitive Unclassified Non-safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material,” was issued December 22, 2005. This RIS was issued to all licensees, certificate holders, applicants, and other entities subject to regulation by the U.S. Nuclear Regulatory Commission of the use of source, byproduct, and special nuclear material, except for those as covered by provisions of RIS 2005-26 for nuclear power reactors.

(Technical contacts: Materials Licensees may contact Paul Goldberg, 301-415-7842, e-mail: pfg@nrc.gov; Spent Fuel Storage and Transportation Licensees may contact Joe Sebrosky, 301-415-1131, e-mail: jms3@nrc.gov; Fuel Cycle Licensees may contact Patricia Silva, 301-415-8029, e-mail: pas6@nrc.gov; Waste Decommissioning Licensees may contact Ted Carter, 301-415-6668, e-mail: thc1@nrc.gov; High-Level Waste Licensees may contact Alexander Sapountzis, 301-415-7822, e-mail: aps@nrc.gov; Import/Export Licensees may contact Stephen Dembek, 301-415-2342, e-mail: sxd@nrc.gov)

RIS 2005-27, Rev.1, “NRC Regulatory Issue Summary 2005-27, Rev. 1, NRC Timeliness Goals, Prioritization of Incoming License Applications and Voluntary Submittal of Schedule for Future Actions for NRC Review,” was issued January 31, 2006. This RIS was issued to all 10 CFR Part 71 and Part 72 licensees and certificate holders.

(Technical contact: Jill Caverly, 301-415-6699, e-mail: jsc1@nrc.gov)

RIS 2006-01, “Expiration Date for NRC-Approved Spent Fuel Transportation Routes,” was issued January 24, 2006. This RIS was issued to U.S. Nuclear Regulatory Commission licensees that transport, or deliver to a carrier for transport, irradiated reactor fuel (spent nuclear fuel).

(Technical contacts: Susan H. Bagley, 301-415-5378, e-mail: shb@nrc.gov; and Kelly Riner 301-415-6623, e-mail: pkr@nrc.gov)

RIS 2002-15, Rev. 1, “NRC Approval of Commercial Data Encryption Products for the Electronic Transmission of Safeguards Information,” was issued January 26, 2006.

This RIS was issued to all authorized recipients and holders of sensitive unclassified safeguards information.

(Technical contact: Eric Lee, 301-415-8099, e-mail: ex1@nrc.gov)

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

SIGNIFICANT ENFORCEMENT ACTIONS

The U.S. Nuclear Regulatory Commission’s (NRC’s) enforcement program can be accessed via the 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.

Medical

Digirad Imaging Solutions, Inc. (EA-05-136)
On January 27, 2006, a Notice of Violation (NOV) for a Severity Level III violation with no civil penalty and an immediately effective Confirmatory Order was issued to confirm commitments made as part of a settlement agreement concerning submission of

inaccurate information to the NRC. The settlement agreement was reached as a result of an Alternative Dispute Resolution session, held at the request of the licensee. In addition to the NOV, the licensee has changed its procedures to ensure that any information it submits to NRC will be complete and accurate, and the Radiation Safety Officer will submit articles to various medical and health physics journals describing the incident to provide an opportunity for other licensees in the industry to learn from the incident.

Alfred C. Burris, Senior, M.D. (EA-05-110)

On January 27, 2006, a Notice of Violation (NOV) for a Severity Level III violation, with no civil penalty, and an immediately effective Confirmatory Order was issued to confirm commitments made as part of a settlement agreement concerning submission of false and/or inaccurate information. The settlement agreement was reached as a result of an Alternative Dispute Resolution session, held at the request of the applicant. In addition to the NOV, the applicant has agreed to correct the inaccurate information, and to submit an article to a cardiology journal and speak at training sessions for similar cardiology groups describing his experience and emphasizing the need to provide complete and accurate information to the NRC.

South Jersey Healthcare (EA-05-214)

On January 17, 2006, a Notice of Violation was issued for a Severity Level III violation involving the failure to secure from unauthorized removal, or limit access to, a package containing licensed material which was stored in a mail room (awaiting inter-office transfer). The mail room was an unrestricted area, and the licensee failed to control and maintain constant surveillance of this licensed material.

Danville Regional Medical Center (EA-05-201)

On December 13, 2005, a Notice of Violation was issued for a Severity Level III violation involving the failure to secure from unauthorized removal or access, and/or maintain constant surveillance of licensed material stored in a controlled or unrestricted area. Specifically, a High-Dose-Rate Remote Afterloader (HDR) unit was left unsecured and unattended in the HDR treatment room.

Lancaster General Hospital (EA-05-124)

On October 28, 2005, a Notice of Violation was issued for a Severity Level III problem composed of three violations. The violations involved: (1) a programmatic weakness in the licensee's gamma knife stereotactic radiosurgery program, which resulted in an overexposure to a patient; (2) the licensee's failure to notify the NRC that the frame of the gamma

knife unit, a basic component designed to prevent movement of the head during treatment, did not prevent the change of the treatment site coordinates; and (3) the licensee's failure to report the medical event within the required period.

Crozer-Chester Medical Center (EA-05-164)

On October 28, 2005, a Notice of Violation was issued for a Severity Level III violation involving the failure to secure from unauthorized removal or access, and/or maintain constant surveillance of licensed material stored in a controlled or unrestricted area. Specifically, an High-Dose-Rate Remote Afterloader (HDR) unit was left unsecured and unattended in the HDR treatment room.

Hershey Medical Center (EA-04-215)

On October 14, 2005, an immediately effective Confirmatory Order was issued to confirm commitments made as part of a settlement agreement concerning three separate occasions where the licensee's staff were injected with radiopharmaceuticals without the authorization of an Authorized User. The settlement agreement was reached as a result of an Alternative Dispute Resolution session, held at the request of the licensee. As part of the agreement reached, a Notice of Violation at a Severity Level III, with no civil penalty, was issued on October 14, 2005. In addition, the licensee has expanded its training program addressing NRC regulatory requirements, and the Chief of Nuclear Medicine, the Radiation Safety Officer, and the Chief Technologist will prepare articles, for various medical and health physics journals, that address, among other topics, the need to establish an environment and culture that promote regulatory compliance through the implementation of controls and procedures.

Gauges

Dickinson County Road Commission (EA-05-266)

On January 24, 2006, a Notice of Violation was issued for a Severity Level III violation involving the failure to secure, or maintain constant surveillance of, NRC-licensed material contained in a portable moisture/density gauge. Specifically, during a routine safety inspection, an NRC inspector entered the licensee's offices in an unlocked public building and found the gauge unsecured.

Foundation Engineering Science, Inc. (EA-05-146)

On November 22, 2005, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$3250, was issued for a Severity Level III problem involving the failure to secure from unauthorized removal, or limit access to, a nuclear gauge located

in a company vehicle parked in a public parking lot. As a result, a nuclear gauge was stolen, and remained uncontrolled in the public domain. In addition, the licensee did not immediately report the theft of the licensed material as required.

U.S. Engineering Laboratories, Inc. (EA-05-152)
On December 2, 2005, a Notice of Violation was issued for a Severity Level III violation involving the failure to maintain direct and constant surveillance of a portable gauge containing licensed material at a temporary job site, and to properly store a portable nuclear gauge at a different temporary job site.

Miscellaneous

Sabia, Inc. (EA-05-204)

On November 22, 2005, as part of an Alternative Dispute Resolution settlement agreement, as documented in a Confirmatory Order, Sabia, Inc., acknowledged two violations of NRC requirements involving its failure to comply with 10 CFR 150.20 compliance and transfer of licensed material to individuals not authorized to receive it. As part of the settlement agreement, Sabia also agreed to provide additional training to its employees and to conduct additional audits. NRC has agreed not to draw any conclusions on whether willfulness was involved or to pursue further enforcement actions related to these specific issues.

Safety Light Corporation (EA-03-219)

On November 18, 2005, a Notice of Violation (NOV) was issued as part of the terms of a settlement agreement reached between the Safety Light Corporation (SLC), the Pennsylvania Department of Environmental Protection, and the Nuclear Regulatory Commission. The NOV was issued for a Severity Level III problem involving: (1) the willful failure to make payments to the decommissioning trust fund in accordance with the schedules defined in SLC's license conditions; and (2) the failure to dispose of pre-2000 tritium wastes, in accordance with SLC's license conditions.

Ledoux Company (EA-05-135)

On November 01, 2005, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$3250, was issued for a Severity Level III problem involving the failures to adequately survey, secure and dispose of licensed material, in accordance with NRC requirements. Specifically, the licensee received a package containing seven analytical samples of Uranium-235, identified six of the seven samples shipped, and performed an unsuccessful cursory search for the seventh sample. After initiating a more thorough search, the licensee

concluded that the seventh sample had been disposed of with the packaging as normal trash.

Pacific Gas and Electric Company, Humboldt Bay Power Plant, Unit 3 (EA-05-166)

On December 20, 2005, a Severity Level II Notice of Violation, with a proposed \$96,000 Civil Penalty, was issued to the Pacific Gas and Electric Company (PG&E) as a result of the licensee's failure to: (1) keep adequate records of special nuclear material (SNM) inventory, transfer or disposal; (2) establish adequate procedures for control and accounting of SNM; and (3) conduct adequate physical inventories of SNM at the Humboldt Bay Power Plant. PG&E's records failed to account for the whereabouts of three 45.72 centimeter (18-inch) fuel rod segments after they were cut from a single fuel rod in 1968. Likewise, PG&E's records failed to account for in-core detectors, after some were cut in 1973.

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

SELECTED FEDERAL REGISTER NOTICES (December 1, 2005 – February 28, 2006)

10 CFR Part 31 [PRM-31-5], "Organization of Agreement States; Petition for Rulemaking," 70 FR 75423, December 20, 2005.

(Contact: Michael T. Lesar, Office of Administration, 301-415-7163 or Toll-free: 1-800-368-5642, e-mail: mtl@nrc.gov)

10 CFR Part 35 [PRM-35-18], "Peter G. Crane; Receipt of Petition for Rulemaking," 70 FR 75752, December 21, 2005.

(Contact: Michael T. Lesar, Office of Administration, 301-415-7163 or Toll-Free: 1-800-368-5642, e-mail: mtl@nrc.gov)

10 CFR Parts 20, 30, 31, 32, 33, and 35, "Expanded Definition of Byproduct Material (NARM Rulemaking), Availability of Web Page," 71 FR 29, January 3, 2006.

(Contact: Jayne M. McCausland, Office of Nuclear Material Safety and Safeguards, 301-415-6219, e-mail: jmm2@nrc.gov. For questions related to the NARM rulemaking, contact Lydia Chang, Office of Nuclear Material Safety and Safeguards, 301-415-6319, e-mail: lwc1@nrc.gov)

10 CFR Parts 30, 31, 32, and 150 [RIN 3150-AH41],

“Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,” 71 FR 275, January 4, 2006.

(Contact: Catherine R. Mattsen, Office of Nuclear Material Safety and Safeguards, 301-415-6264, e-mail: crm@nrc.gov)

10 CFR Part 35 [RIN 3150-AH19], “Medical Use of Byproduct Material--Recognition of Specialty Boards; Correction,” 71 FR 1926, January 12, 2006.

(Contact: Dr. Anthony N. Tse, Office of Nuclear Material Safety and Safeguards, 301-415-6233, e-mail: ant@nrc.gov)

10 CFR Parts 30, 40, 50, 60, 61, 63, 70, 71, 72, and 76 [RIN 3150-AH59], “Clarification of NRC Civil Penalty Authority Over Contractors and Subcontractors Who Discriminate Against Employees for Engaging in Protected Activities,” 71 FR 5015, January 31, 2006.

(Contact: Doug Starkey, Office of Enforcement, 301-415-3456, e-mail: drs@nrc.gov)

10 CFR Parts 170 and 171 [RIN 3150-AH83], “Revision of Fee Schedules; Fee Recovery for FY 2006,” 71 FR 7349, February 10, 2006.

(Contact: Tammy Croote, Office of the Chief Financial Officer, 301-415-6041; e-mail: txc1@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 on the contents of the newsletter is welcome. Readers desiring to contribute articles, self-explanatory diagrams, suggestions for future articles, bulletins, website postings, and other items of interest to the NMSS Quarterly 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 him.

Please send written correspondence and requests to:
Michael K. Williamson, Editor
NMSS Quarterly Newsletter
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Two White Flint North
Mail Stop: T8F-3
Washington D.C. 20555-0001



Federal Recycling Program