

NMSS News

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OFFICE OF NUCLEAR MATERIAL
SAFETY AND SAFEGUARDS

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SUCCESSFUL COLLABORATIONS

Collectively, the U.S. Nuclear Regulatory Commission (NRC) and the 37 Agreement States make up what is referred to as the National Materials Program. The National Materials Program is responsible for ensuring the protection of public health and safety and the environment for medical, academic, industrial, and general uses of radioactive materials in the United States. The NRC and the Agreement States work together to accomplish this important goal. For example, the NRC and Agreement States form working groups to develop licensing guidance documents for emerging medical technologies that are licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material," Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material." Emerging medical technologies that cannot meet all of the requirements in a category, have unique components or features that would need additional radiation safety precautions, or would require an exemption from the existing regulatory requirements are licensed under Subpart K (10 CFR 35.1000).

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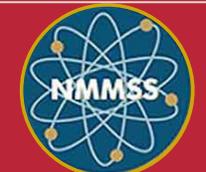
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In calendar year 2016, the NRC issued four guidance documents for licensing under 10 CFR 35.1000. Each document was developed through a joint NRC/ Agreement States Working Group:

- On February 12, 2016, the NRC published Revision 9 of the "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR Spheres® Licensing Guidance." The working group included members from NRC Headquarters, NRC Region I, and New Mexico.
- On May 25, 2016, the NRC published the "Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance." The working group included members from NRC Headquarters, NRC Region IV, Kentucky, and California.
- On September 28, 2016, the NRC published the "Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance." The working group included members from NRC Headquarters, NRC Region III, North Carolina, and Washington State.
- On October 7, 2016, the NRC published Revision 1 of the "Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes Licensing Guidance." The working group included members from NRC Headquarters, NRC Region I, New York, and Utah.

Two active NRC/Agreement States working groups are currently developing two additional licensing guidance documents. This includes Revision 10 of the “Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance,” and the “NorthStar Molybdenum-99/Techneium-99m Generator (RadioGenix™) Licensing Guidance.” These guidance documents are expected to be issued in 2017. When the NRC or an Agreement State finds out about an emerging medical technology that may fall under 10 CFR 35.1000, another joint working group will be formed to address the needs of the medical community.

(Contact: Sophie Holiday, NMSS, 301-415-7865 or Sophie.Holiday@nrc.gov)

DECOMMISSIONING FUNDING PLAN EXEMPTION

Under Title 10 of the *Code of Federal Regulations* (10 CFR) 30.35(a)(1), licensees are required to submit a decommissioning funding plan (DFP) if they possess and use unsealed byproduct material that has a half-life of greater than 120 days and that is in quantities exceeding 10^5 times the applicable quantities set forth in 10 CFR Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” Appendix B, “Quantities of Licensed Material Requiring Labeling.” This specific regulation ensures that licensees have adequate funding in place to fully decommission the licensee’s facility. In accordance with 10 CFR 30.111, “Specific Exemptions,” licensees can request an exemption from the requirements of the regulations in 10 CFR Parts 30 through 36 and 39 if the exemption would not endanger life or property or the common defense and security and is otherwise in the public interest.

The U.S. Nuclear Regulatory Commission (NRC) Advisory Committee on the Medical Uses of Isotopes (ACMUI) formed a subcommittee to review and evaluate the impacts of the DFP requirement for medical germanium-68 (Ge-68)/ galium-68 Ga-68 generators. A new Ge-68/Ga-68 generator contains 50 mCi at its calibration date;

under the NRC regulations, the possession of a single generator triggers the need for a DFP. Moreover, these Ge-68/Ga-68 generators have a 12-month expiration date and would most likely be returned to the manufacturer or distributor for final disposal to ensure that no Ge-68 would remain at the licensee’s site. Because of this, the requirements to develop, fund, update, and submit detailed cost estimates for NRC review are unnecessary for the decommissioning of sites licensed for the use of Ge-68/Ga-68 generators. The NRC staff independently verified ACMUI’s safety basis and assumptions in its report and concluded that the DFP requirements could be an impediment and may limit patient access to the radiopharmaceuticals developed from these generators. The radiation safety risks associated with decommissioning a site with Ge-68/Ga-68 generators are diminished when the generators are returned to the manufacturer or distributor.

Therefore, the NRC determined that granting an exemption to the DFP requirement for possession of these medical use generators, provided that certain conditions are met (i.e., a legally binding agreement to ensure that the device will be returned to the manufacturer



or distributor at the end of use), is commensurate with ensuring public health and safety while not limiting access to promising Ga-68 diagnostic imaging agents for patients. On July 29, 2016, the Director of the Office of Nuclear Material Safety and Safeguards sent a memorandum (Agencywide Documents Access and Management System (ADAMS) Accession No. MLI6082A415) to the NRC Regional Administrators to delegate authority to the regions to issue, when requested, an exemption to 10 CFR 30.35(a)(1) for medical Ge-68/Ga-68 generators. This exemption will only be granted when specific financial assurance requirements are met and if a legally binding agreement is in place for the licensee to return the generators to the manufacturer or distributor when the generators expire and are no longer used to prepare Ga-68 radiopharmaceuticals for patients, or if the licensee ceases its preparation of Ga-68 radiopharmaceuticals.



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SOURCE SECURITY AND ACCOUNTABILITY

Since the events of September 11, 2001, the U.S. Nuclear Regulatory Commission (NRC) has been enhancing the security and accountability of radioactive sources that pose a threat to the public. These enhancements have been focused on the most dangerous sources, those with International Atomic Energy Agency (IAEA) Category 1 and 2 quantities of radioactive materials. The NRC has considered expanding these enhancements to Category 3 sources in the past, most recently in 2009, but determined that the existing requirements provide adequate protection. As a result of recent events involving the NRC and the Agreement States as described below. In October 2016, the Commission directed the NRC staff to re-evaluate Category 3 source security and accountability. This article summarizes audits involving the NRC and Agreement States that were considered by the Commission in determining its direction to staff.

Accountability First Audit

In 2007, the Government Accountability Office (GAO) conducted an investigation (GAO-07-1038T) into the licensing program of the NRC. Using a fictitious company, GAO attempted to obtain radioactive materials licenses from one NRC regional office and one Agreement State. GAO succeeded in one of two attempts to obtain a radioactive materials license and used the license to place orders for radioactive material. The investigation demonstrated that GAO could have acquired an aggregated Category 3 quantity of material, although at no point in the investigation were radioactive materials actually shipped to the fictitious company. After the 2007 investigation, the NRC and the Agreement States made a number of significant changes to strengthen the licensing and regulatory processes to prevent individuals who have malevolent intent from obtaining a radioactive material license. The NRC staff submitted an Action Plan (Enclosure to SECY-07-0147, "Response to U.S. Government Accountability Office Recommendations and Other Recommendations to Address Security Issues in the NRC Materials Program, dated August 25, 2007) to the Commission to address recommendations for enhancing NRC and Agreement State inspection and licensing programs with respect to source security oversight. The Commission approved the staff's Action Plan in a Staff Requirements Memorandum (SRM-SECY-07-0147) dated September 18, 2007.





National Source Tracking System

In January 2009, licensees began reporting Category 1 and 2 source information to the NSTS as part of enhanced security measures that were enacted following the terrorist attacks of September 11, 2001. The NRC staff asked to defer further expansion of the NSTS (i.e., to include Category 3 sources) to allow staff to monitor the operation of the NSTS for 1 year and to apply insights gained to inform the decision on system expansion (SECY-09-0011, "Deferral of Rulemaking: Expansion of National Source Tracking System (RIN 3150-A129)," dated January 15, 2009). The Commission did not approve this request for deferral, so in June 2009, the staff requested approval of the final rule amending 10 CFR Part 20, "Standards for Protection against Radiation," and 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," to expand reporting to the NSTS to include Category 3 sources (SECY-09-0086, "Final Rule: Expansion of the National Source Tracking System (RIN 3150-A129)," dated June 10, 2009). In June 2009, the Commission did not reach a decision on the proposed rulemaking (two to two split vote), and the final rule was not approved (SRM-SECY-09-0086, dated June 30, 2009). Some of the Commission votes indicated that further expansion of the NSTS should be based on a vulnerability assessment, built from an interagency risk study for sources, and that the original recommendation lacked a risk-informed foundation for the proposed regulatory action.

Accountability Second Audit

In 2014, GAO initiated another audit of the materials licensing program to determine whether the licensing vulnerabilities identified in the 2007 investigation had been addressed by the NRC and Agreement States. In 2015, as part of the audit, GAO conducted an investigation that again attempted to obtain radioactive materials licenses from one NRC regional office and two separate Agreement States using a fictitious company. The 2015 investigation went beyond the 2007 investigation in its sophistication and planning; GAO rented storefront/warehouse space to demonstrate the fictitious company's legitimacy during prelicensing visits. GAO was successful in one of three attempts and acquired a license for a Category 3 well logging source. GAO was subsequently able to place an order for one Category 3 source, then altered the license and placed an order for a second Category 3 source. The investigation demonstrated that GAO could have acquired an aggregated Category 2 quantity of material, although at no point in the investigation were radioactive materials actually shipped to the fictitious company. Once notified by GAO in October 2015, the NRC and Agreement States took a number of actions, one of which included forming two NRC/Agreement State working groups to evaluate vulnerabilities identified as a result of the 2015 GAO investigation. Specifically, one working group considered enhancements to the pre-licensing guidance, while the second working group evaluated the need for enhancements to existing requirements or guidance for license verification and source tracking beyond Category 1 and Category 2 thresholds. The working groups completed their reports and recommendations in November 2016, and a steering committee evaluated their recommendations.

Final Audit Report

On July 15, 2016, GAO published its final report for the material licensing audit and investigation, GAO-16-330, "Nuclear Security: NRC Has Enhanced the Controls of Dangerous Radioactive Materials, but Vulnerabilities Remain." The report made three recommendations:

- (1) Take steps needed to include Category 3 sources in the NSTS and add Agreement State Category 3 licenses to the Web-Based Licensing System as quickly as reasonably possible.
- (2) At least until such time as Category 3 licenses can be verified using the License Verification System, require that transferors of Category 3 quantities of radioactive materials confirm





the validity of a would-be purchaser's radioactive materials license with the appropriate regulatory authority before transferring any Category 3 quantities of licensed materials.

- (3) As part of the ongoing efforts of the NRC working groups that are meeting to develop enhancements to the pre-licensing requirements for Category 3 licenses, consider requiring conduct of an onsite security review for all unknown applicants for Category 3 licenses to verify that each applicant is prepared to implement the required security measures before taking possession of licensed radioactive materials.

The NRC's Response

The two NRC working groups that were tasked with evaluating the GAO final report completed their reports and recommendations in October 2016. A steering committee evaluated the recommendations made by the two working groups. The two reports produced by the working groups will play a key role in the Category 3 source accountability re-evaluation.

Given the agency's operating experience with higher risk sources and in response to GAO's findings, the Commission directed the staff to take specific actions to evaluate whether it is necessary to revise NRC regulations or processes governing source protection and accountability. On October 18, 2016, the Commission issued its SRM for COMJMB-16-0001, "Proposed Staff Re-Evaluation of Category 3 Source Accountability" (Agencywide Document and Management System (ADAMS) Accession No. MLI6292A812). The SRM required the staff to submit a notation vote paper to the Commission within 10 months that includes the following:

- an evaluation of the pros and cons of different methods of requiring transferors of Category 3 sources to verify the validity of a transferee's license before transfer
- an evaluation of the pros and cons of including Category 3 sources in the NSTS
- an assessment, based on these evaluations, of these and any additional options that the staff identifies for addressing the source accountability recommendations made by GAO
- a vulnerability assessment that identifies changes in the threat environment between 2009 and the present that argue in favor of or against expansion of the NSTS to include Category 3 sources
- a regulatory impact analysis of the accrued benefit and costs of the change, including impacts to the NRC, Agreement States, non-Agreement States, and regulated entities
- a discussion of potential regulatory actions that would not require changes to NRC regulations that arose from or were considered by the staff working groups, including changes to guidance, training, and other program improvements, such as more closely monitoring the implementation of the staff recommendations using the Integrated Materials Performance Evaluation Program process
- an assessment of the risks posed by the aggregation of Category 3 sources into Category 2 quantities
- a consideration of the results of the 10 CFR Part 37 program review
- a collaboration with Agreement and non-Agreement States, regulated entities, public interest groups, industry groups, and the reactor community to fully assess the regulatory impact for any recommendations made in the notation vote paper
- any other factors arising from the staff's currently ongoing assessment that the staff concludes would bear on the Commission's deliberation on the proposed change.



The SRM also directed the staff to assess the risks posed by the aggregation of Category 3 sources into Category 2 quantities and to collaborate with its Agreement State partners, non-Agreement States, regulated entities, public interest groups, industry groups, and the reactor community in order to fully assess the regulatory impact for any recommendations made in the notation vote paper.

Security Assessment Needed

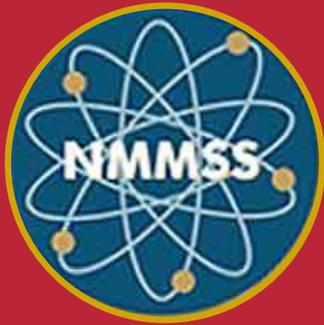
Additionally, the SRM directed the staff to consider the results of the assessment of the security requirements in 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," as required by Public Law 113-235, Consolidated and Further Continuing Appropriations Act, 2015, as a means to inform the staff's evaluation. This assessment, referred to as the "program review" of 10 CFR Part 37, encompassed an evaluation of nine review areas related to implementation of the security requirements in the rule. These areas included the results of inspections conducted of NRC licensees in the first 2 years of rule implementation as well as an evaluation of events reported under the provisions of the rule. The program review also included consideration of the definition of aggregation as it applies to well logging sources and an evaluation of enhanced tracking and accounting of radioactive sources. The results of the program review were documented in a Commission paper and sent to Congress on December 24, 2016. (ADAMS Accession No. MLI6348A230)

The staff has not considered enhancing Category 3 source security and accountability since 2009. The reevaluation is different from past efforts in its scope, because the reevaluation builds off the efforts resulting from the 2015 GAO investigation and integrates the recently completed comprehensive review of Part 37 and the current threat landscape. The Commission's inclusion of the language in the last bullet of the previous section speaks to its desire for a broad assessment.

Evaluation of the Need to Revise Regulations

To conduct the reevaluation of Category 3 source security and accountability as required by SRM-COMJMB-16-0001, the Office of Nuclear Material Safety and Safeguards established an NRC/Agreement State working group to evaluate and make recommendations on whether it is necessary to revise NRC regulations or processes governing source protection and accountability to continue to ensure adequate protection of public health and safety. The working group has begun its evaluations, and its recommendations will be documented in a notation vote paper to be provided to the Commission in August 2017. The number of NRC and Agreement State licensees that could be affected by this effort exceeds 5,000. Consequently, an important part of NRC's evaluation is to solicit input from the affected regulatory community, many of whom have not been subject to enhanced security and accountability requirements. The NRC published a *Federal Register* notice, 82 FR 2399, that contained specific questions for stakeholders to consider regarding Category 3 sources. A corrected FRN, 82 FR 4938, was published to remove erroneous text from the Public Comments Process section, that did not impact the questions or comment period. The working group will hold public meetings and webinars to facilitate feedback on the FRN along with providing presentations to industry groups and professional organizations to solicit feedback from a wide range of affected stakeholders. Additional information on this effort can be found at <https://www.nrc.gov/security/byproduct/category-3-source-security-accountability-reevaluation.html>. The input on this reevaluation is important to fully assess the regulatory impact for any recommendations that might be made regarding security and accountability of Category 3 sources. Stakeholders should consider responding to the specific questions in the *Federal Register* notice.

(Contact: Duncan White, NMSS, 301-415-2598 or Duncan.White@nrc.gov)



MEETING ANNOUNCEMENT

The Nuclear Materials Management and Safeguards System (NMMSS) is a nuclear materials tracking database jointly managed by the U.S Nuclear Regulatory Commission (NRC) and the U.S. Department of Energy/National Nuclear Security Agency. The NMMSS Annual Users Training Meeting is scheduled for May 15–18, 2017, in Las Vegas, NV. Registration and preliminary agenda information about the 2017 training event became available in December 2016. Recommendations or suggested topics for training, presentations, or breakout sessions for the annual training event should be provided to Mirabelle Shoemaker. Past training agendas and presentations are available via the NMMSS Web site at <https://nnsa.energy.gov/about/us/ourprograms/nuclearsecurity/nmmsshome>.

(Contact: Mirabelle Shoemaker; NMSS, 301–415–7363 or Mirabelle.Shoemaker@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS

The following is a listing of the NRC significant actions for failures to comply with regulations issued between May 1 and September 30, 2016.

Consumers Energy (EA-16-115)

On September 14, 2016, the NRC issued a Notice of Violation to Consumers Energy for a Severity Level III violation. The violation involves Consumers Energy's failure to have each individual who acts as a radiographer or a radiographer's assistant wear a direct reading dosimeter; an operating alarm rate meter; and a personnel dosimeter at all times during radiographic operations, as required by paragraph (a) of Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR 34.47, "Personal Monitoring." Specifically, on April 7, 2016, the individuals wore a single device to perform the functions of both a direct reading dosimeter and an alarming ratemeter simultaneously.

International Cyclotron, Inc. (EA-16-055)

On August 30, 2016, the NRC issued a Notice of Violation and Proposed Imposition of a Civil Penalty in the amount of \$14,000 to International Cyclotron, Inc. (International Cyclotron), for a Severity Level III violation. The violation involved International Cyclotron's failure to begin and complete decommissioning of its site in accordance with 10 CFR 30.36, "Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas." Specifically, on March 22, 2014, International Cyclotron notified the NRC that no principal activities under the license had been conducted for a period of 24 months and decommissioning would begin as soon as possible, before April 18, 2014. As of August 30, 2016, International Cyclotron had neither begun decommissioning nor submitted a decommissioning plan and had not completed the decommissioning of its site.

Plus, LLC. (EA-13-190)

On August 8, 2016, the NRC issued an Order Imposing Civil Monetary Penalty to Plus, LLC (Plus), in the amount of \$21,000. On May 3, 2016, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$42,000 to Plus for three willful Severity Level III violations. The violations involved the firm's failure to have NRC licenses to distribute, possess, and import byproduct materials. Plus requested mitigation of the significance of the violations and the proposed civil penalty amount because of its classification status as a small entity. After considering Plus's response, the NRC decided to retain the significance of the violations as stated in the Notice and to reduce the civil penalty amount to \$21,000.



City of Muskegon, City Hall—Engineering Department (EA-16-100)

On August 8, 2016, the NRC issued a Notice of Violation to the City of Muskegon, MI, City Hall—Engineering Department, for a Severity Level III violation. The violation involved the department's failure to have the individual specifically named on the license fulfill the duties of the Radiation Safety Officer (RSO) as required by NRC License Condition No. 12. Specifically, on April 18, 2014, the individual listed as RSO on the license was no longer employed by the department and thus could not fulfill the duties and responsibilities of the RSO.

Tetra Tech EC, Inc. (EA-15-230)

On July 28, 2016, the NRC issued a Notice of Violation and Proposed Imposition of a Civil Penalty in the amount of \$7,000 to Tetra Tech EC, Inc. (Tetra Tech), for a Severity Level III violation. The violation involved Tetra Tech's deliberate failure to obtain soil sample surveys in accordance with paragraph (a) of 10 CFR 20.1501, "General," by employees of Tetra Tech at the U.S. Navy's Hunter's Point Naval Shipyard site in San Francisco, CA. Specifically, on several occasions between November 18, 2011, and June 4, 2012, when obtaining soil samples to ascertain the amount of residual radioactivity in specific locations within Parcel C at Hunter's Point Naval Shipyard, Tetra Tech employees deliberately obtained soil samples from other areas that were suspected to be less contaminated and represented that the samples had been obtained from within the specified locations.

Applied Technical Services, Inc. (EA-16-046)

On July 28, 2016, the NRC issued a Notice of Violation and Proposed Imposition of a Civil Penalty in the amount of \$7,000 to Applied Technical Services, Inc. (ATS), for a Severity Level III problem for three related violations. The violations involved the following:

- (1) a failure to conduct a survey of the camera guide tube after taking an image of a pipe weld in accordance with 10 CFR 34.49, "Radiation Surveys"
- (2) a deliberate failure to post an area where industrial radiography was being performed with conspicuous radiation or high radiation signs that established a radiological boundary as required by 10 CFR 34.53, "Posting," and 10 CFR 20.1902, "Posting Requirements"
- (3) a failure to comply with a condition on the ATS license from the State of Georgia to ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area, as required by paragraph (b)(5) of 10 CFR 150.20, "Recognition of Agreement State Licenses."

Specifically, on October 20, 2015, while conducting industrial radiography at the National Aeronautics and Space Administration's Langley Research Center in Hampton, VA, after completing an exposure of a pipe weld, a radiographer approached the camera and the guide tube without a survey meter and did not conduct a survey of the camera to ensure that the source had been retracted. The radiographer did not post accessible portions of the radiation area with "radiation area" or "high-radiation area" signs, and the radiographer did not comply with provisions of the State of Georgia license to ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or high-radiation area. As a result, an NRC inspector unknowingly was able to walk unnoticed and unimpeded into the radiation area while radiographic operations were being performed.



QHG of Indiana, Inc. (EA-16-074)

On July 23, 2016, the NRC issued a Notice of Violation to QHG of Indiana, Inc. (QHG), for a Severity Level III violation. The violation involved QHG's failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive as required by paragraph (a) of 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive." Specifically, on January 7, 2016, during two separate medical administrations, the licensee used an instrument that was not capable of measuring with high confidence the amount of yttrium 90 remaining in the equipment used to deliver the dose. Therefore, the licensee could not determine that the two administrations were in accordance with the written directive. The licensee's procedures did not specify the instrumentation needed to provide high confidence that the administration would be performed in accordance with the written directive.



7NT Enterprises, LLC (EA-16-098)

On July 1, 2016, the NRC issued a Notice of Violation to 7NT Enterprises, LLC (7NT Enterprises), for a Severity Level III violation. The violation involved 7NT Enterprises' failure to use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal when the portable gauges were not under the control and constant surveillance of the licensee as required by paragraph (i) of 10 CFR 30.34, "Terms and Conditions of Licenses." Specifically, on multiple occasions, and most recently on March 22, 2016, the licensee stored portable gauges with only a single physical barrier, and they were not under the control and constant surveillance of the licensee.

Wayne County Well Surveys, Inc. (EA-16-031)

On May 19, 2016, the NRC issued a Notice of Violation to Wayne County Well Surveys, Inc., for a Severity Level III violation. The violation involved the failure to file, at least 3 days before engaging in the activity for the first time in a calendar year, a submittal containing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States," a copy of the Agreement State specific license, and the appropriate fee as required by 10 CFR 150.20, "Recognition of Agreement State Licenses." However, on several occasions between January 18, 2013, and October 16, 2015, the Agreement State licensee possessed and used licensed materials at temporary job sites in Indiana, a non-Agreement State, without first filing the required documentation with the NRC.



MEDICAL

MedStar Washington Hospital Center (EA-16-109)

On July 19, 2016, the NRC issued a Notice of Violation to MedStar Washington Hospital Center (MWHC) for a Severity Level III violation. The violation involved MWHC's failure to transfer licensed material to an authorized recipient in accordance with paragraph (a)(1) of 10 CFR 20.2001, "General Requirements." Specifically, on May 15, 2015, MWHC transferred radioactive waste containing iodine-131 to Stericycle, Inc., in Curtis Bay, MD, a waste processing company that was not authorized to receive the radioactive waste.



INDIVIDUALS

Mr. Justin Hubbard (IA-15-081)

On July 28, 2016, the NRC issued a Notice of Violation to Mr. Justin Hubbard for a Severity Level III violation of paragraph (a) of 10 CFR 30.10, "Deliberate Misconduct," involving deliberate misconduct that caused his employer, Tetra Tech, to be in violation of 10 CFR 20.1501(a) by deliberately submitting to Tetra Tech information that he knew to be incomplete or inaccurate in some respect material to the NRC. Specifically, on several occasions between November 18, 2011, and June 4, 2012, Mr. Hubbard, working as a radiation task supervisor for Tetra Tech at the U.S. Navy's Hunter's Point Naval Shipyard Parcel C location, in San Francisco, CA, directed his staff to take soil samples from other areas that were suspected to be less contaminated. As a result, it could have appeared that residual radioactivity within the specific locations in Parcel C was lower than it actually was. Mr. Hubbard also documented on related chain-of-custody forms that the samples had been obtained from the specified locations.

Mr. Martin Ferenc (IA-16-040)

On July 28, 2016, the NRC issued a Notice of Violation to Mr. Martin Ferenc for a Severity Level III violation of 10 CFR 30.10(a)(1) involving deliberate misconduct that caused his employer, Applied Technical Services, Inc., to be in violation of NRC requirements. Specifically, on October 20, 2015, while conducting industrial radiography at the National Aeronautics and Space Administration's Langley Research Center in Hampton, VA, Mr. Ferenc did not conspicuously post the area where industrial radiography was being performed with "radiation area" or "high-radiation area" signs to establish a radiological boundary, as required by 10 CFR 34.53 and 10 CFR 20.1902.

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 Agencywide Documents 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: Sophie Holiday, NMSS, 301-415-7865 or Sophie.Holiday@nrc.gov)

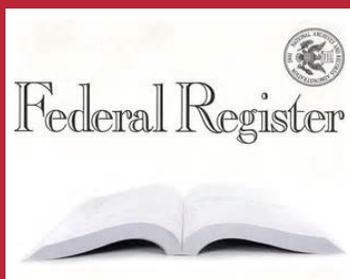
SELECTED FEDERAL REGISTER NOTICE

September 19, 2016

Federal Register (FR) Notice 81 FR 64209, "Environmental Properties Management; Cimarron Facility; Decommissioning Plan" (License amendment application; Notice of Opportunity to Request a hearing and to petition for leave to intervene)

The U.S. Nuclear Regulatory Commission has received a license amendment application from Environmental Properties Management (licensee) for the Cimarron Facility, located near Crescent, OK. The licensee is requesting an amendment to its source and byproduct materials license, SNM 928, to authorize decommissioning of the Cimarron Facility for unrestricted release.

(Contact: Kenneth Kalman, NMSS, 301-415-6664 or Kenneth.Kalman@nrc.gov)



September 19, 2016

FR Notice 81 FR 64207, "Issuance of Updates to NUREG-1556 (Consolidated Guidance About Materials Licenses), Volumes 1 (Portable Gauges), 2 (Industrial Radiography), 3 (Sealed Sources and Devices), 4 (Fixed Gauges), 10 (Master Material Licenses), 15 (Changes of Control and Bankruptcy), and 19 (Reciprocity)" (NUREG; Issuance)

The U.S. Nuclear Regulatory Commission (NRC) has issued Revision 2 to NUREG 1556, Volumes 1 and 3, and Revision 1 to NUREG-1556, Volumes 2, 4, 10, 15, and 19, revising licensing guidance for various materials licenses. The NRC has updated these documents to include information on updated regulatory requirements, safety culture, security of radioactive materials, protection of sensitive information, and changes in regulatory policies and practices. The documents are intended for use by applicants, licensees, and the NRC staff.

(Contact: Anthony McMurtray, NMSS, 301-415-2746 or Anthony.McMurtray@nrc.gov)

September 21, 2016

FR Notice 81 FR 64207, "Shipping, Receiving, and Internal Transfer of Special Nuclear Material" (Draft Regulatory Guide; Request for Comment)

The NRC is issuing for public comment Draft Regulatory Guide (DG) DG-5051, "Shipping, Receiving, and Internal Transfer of Special Nuclear Material." This DG would consolidate in one document NRC guidance concerning the material control and accounting requirements pertaining to shipments, receipts, and internal transfers of special nuclear material. The DG is part of the NRC's "Regulatory Guide" series, which was developed to describe and make available to the public information on methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific issues or postulated events, and data that the staff needs in its review of applications for permits and licenses.

(Contacts: Glenn Tuttle, NMSS, 301-415-7230 or Glenn.Tuttle@nrc.gov, or Mekonen Bayssie, Office of Nuclear Regulatory Research, 301-415-1699 or Mekonen.Bayssie@nrc.gov)

November 9, 2016

FR Notice 81 FR 78732, "Individual Monitoring Devices for Industrial Radiographic Personnel" (Petition for rulemaking; notice of docketing and request for comment)

The NRC has received a petition for rulemaking (PRM), dated July 14, 2016, from Dr. Army Bereson of the Nondestructive Testing Management Association and Mr. Walt Cofer of the American Society for Nondestructive Testing. The petitioners request that the NRC amend its regulations to authorize use of improved individual monitoring devices for industrial radiographic personnel. The NRC docketed the PRM on August 12, 2016, and assigned it Docket No. PRM-34-7. The NRC is examining the issues raised in PRM-34-7 to determine whether they should be considered in rulemaking.

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ONGOING RULEMAKINGS

RULEMAKING	DESCRIPTION	STATUS
PROPOSED RULES		
<p>10 CFR Parts 30 and 32, "Items Containing Byproduct Material Incidental to Production (formerly Polymer (Polycarbonate or Polyester) Track Etched (PCTE) Membranes)"</p>	<p>The proposed rulemaking would amend requirements for track etched membranes that have been irradiated with mixed fission products as part of the membrane production process. The proposed rulemaking would also accommodate the licensing and distribution of other irradiated products (e.g., gemstones) without the need for a specific exemption for each distributor.</p>	<p>The U.S. Nuclear Regulatory Commission (NRC) is currently drafting the regulatory basis for the rulemaking and expects to release it for public comment in August 2017.</p>
<p>10 CFR Part 73, "Enhanced Security for Special Nuclear Material"</p>	<p>The proposed rule would update security regulations, including portions of 10 CFR Part 73, related to physical protection of special nuclear material at NRC licensed facilities and in transit.</p>	<p>On February 3, 2015, the Office of Nuclear Security and Incident Response submitted a user need request (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14317A037) to NMSS to initiate a rulemaking to update the security regulations in 10 CFR Part 73. NMSS accepted the regulatory basis (ADAMS Accession No. ML14321A007) on February 25, 2015. On April 22, 2015, the NRC published the final regulatory basis in the <i>Federal Register</i> (80 FR 22434). A working group met and began developing the proposed rule. The due date for the proposed rule is to be determined.</p>

10 CFR Part 73, "Cyber Security at Fuel Cycle Facilities"

The proposed rulemaking would revise 10 CFR Part 73 to add new cyber security requirements for fuel cycle facilities.

On September 4, 2015, the NRC published the draft regulatory basis and asked for comments in the *Federal Register* (80 FR 53478). The NRC working group revised the document and completed the final regulatory basis on March 22, 2016. The notice appeared in the *Federal Register* on April 12, 2016 (81 FR 21449). The NRC has held ten public meetings on the rulemaking. The agency provided draft preliminary proposed rule language public review in May 2016 and discussed the rule at a public meeting on May 19, 2016. During an all-day meeting on August 25, 2016, those attending discussed the language of the revised draft of the preliminary proposed rule and the draft of the preliminary proposed guidance document. On November 2, 2016, staff briefed the Advisory Committee on Reactor Safeguards (ACRS) subcommittee on Digital Instrumentation and Control Systems (DI&C). Additional briefings of ACRS are scheduled in February and March 2017. The draft proposed rule package is being developed, and staff is continuing to work on various aspects of the package.

FINAL RULE

10 CFR Part 35, "Medical Use of Byproduct Material"; "Medical Event Definitions, Training and Experience and Clarifying Amendments"

The rule amends the reporting and notification requirements for medical events for permanent brachytherapy, amends training and experience requirements to remove attestation requirements for certain individuals, and makes changes, as requested, in Petition for Rulemaking (PRM)-35-20 and clarifying amendments.

The NRC published the proposed rule and draft guidance in the *Federal Register* (79 FR 42224) for public comments on July 21, 2014. The comment period closed on November 18, 2014. The NRC received 69 comment letters, each containing many individual comments. The comments are posted at <http://www.regulations.gov> under Docket ID NRC-2008-0175. The final rule, SECY-16-0080, "Final Rule: Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-A163; NRC 2008 0175)," went to the Commission for review on June 17, 2016.

10 CFR Part 61, "Low-Level Radioactive Waste (LLRW) Disposal"

The proposed rule would revise 10 CFR Part 61 to require LLRW disposal licensees and license applicants to conduct updated and new site-specific analyses and to permit the development of criteria for future LLRW acceptance based on the results of these analyses.

The NRC published the proposed rule and notice of availability of the draft guidance in the *Federal Register* (80 FR 16082 and 80 FR 15930) on March 26, 2015. The agency extended the comment period to September 21, 2015. The staff is reviewing the comments received. The final rule, SECY 16-0106, "Final Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61) (RIN 3150-A192)," went to the Commission for review and affirmation on September 16, 2016.

10 CFR Part 74, "Material Control and Accounting of Special Nuclear Material"

This rule would revise and consolidate the current material control and accounting (MC&A) requirements into 10 CFR Part 74. The rule would also clarify and strengthen the MC&A requirements, in part, by removing existing exemptions in the item control provisions.

The staff is resolving the public comments and preparing the final package for the rulemaking.

10 CFR Part 40, "Domestic Licensing of Source Material"; 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"; and 10 CFR Part 75, "Safeguards on Nuclear Material—Implementation of US/IAEA Agreement"; "Small Quantities Protocol"

This rulemaking implements the requirements of the agreement between the United States and the International Atomic Energy Agency (IAEA) for the application of safeguards in connection with the Treaty for the Prohibition of Nuclear Weapons in Latin America. In addition, this rulemaking implements the modifications to this agreement's small quantities protocol under the U.S. and IAEA Caribbean Territories safeguards agreement.

On May 25, 2016, the staff submitted SECY-16-0066, "Rulemaking Plan for Implementing the Modified Small Quantities Protocol to the United States International Atomic Energy Agency Caribbean Territories Safeguards Agreement," requesting Commission approval to initiate rulemaking. On July 21, 2016, the Commission approved initiation of the rulemaking. Specifically, the Commission provided its clearance for the Circular 175 memorandum authorizing the U.S. Department of State to negotiate and conclude a modified Small Quantities Protocol between the United States and IAEA with the Treaty for the Prohibition of Nuclear Weapons in Latin America. This rulemaking will go directly to a final rule as it has a foreign policy exclusion.

PETITIONS

PRM-20-28, PRM-20-29 and PRM-20-30, "Linear No Threshold Model and Standards for Protection against Radiation"

The NRC received three PRMs requesting that it amend 10 CFR Part 20, "Standards for Protection against Radiation," and change the basis of those regulations from the linear no threshold model of radiation protection to the radiation hormesis model.

On June 23, 2015, the NRC published in the *Federal Register* (80 FR 35870) the receipt of the PRM and Notice of Docketing and requested public comment on three PRMs: PRM-20-28, PRM-20-29, and PRM-20-30. The public comment period was scheduled to end on September 8, 2015, but on August 21, 2015, the NRC published in the *Federal Register* (80 FR 50804) the receipt of the PRM; Notice of Docketing, and extension of comment period. The NRC extended the public comment period until November 19, 2015, to allow more time for members of the public to develop and submit their comments. The staff is examining the issues raised in the PRMs to determine whether they should be considered in rulemaking.

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Thank you for your interest in this newsletter from the Office of Nuclear Material Safety and Safeguards. In our attempt to keep *The NMSS News Link* relevant to licensees, we welcome feedback on its contents. If you would like to suggest topics for the newsletter, please contact Vanessa Cox, NMSS Rulemaking and Project Management Branch, by telephone at 301-415-8342 or by e-mail at Vanessa.Cox@nrc.gov. In addition, to ensure proper delivery of *The NMSS News Link* and to prevent any interruption of service, please report e-mail address changes to Ms. Cox.

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