

NMSS
News

Link

**OFFICE OF NUCLEAR MATERIAL
SAFETY AND SAFEGUARDS**

**PURPOSE OF MEDICAL
EVENT REPORTING**

PAGE 1



**ANNUAL USERS
TRAINING MEETING**

PAGE 2



**INTERNATIONAL
SAFEGUARDS
REPORTING
REQUIREMENTS**

PAGE 2



**SIGNIFICANT
ENFORCEMENT
ACTIONS**

PAGE 4



**GENERIC
COMMUNICATIONS
ISSUED**

PAGE 7



**SELECTED FEDERAL
REGISTER NOTICES**

PAGE 9



**ONGOING
RULEMAKINGS**

PAGE 10



TO OUR READERS

PAGE 13



**PURPOSE OF MEDICAL
EVENT REPORTING**

The U.S. Nuclear Regulatory Commission (NRC) regulations aim to ensure radioactive materials are used safely in medical diagnosis, therapy and research. The rules exist to ensure the safety of medical workers, the public, and patients, and to protect the environment.



The term "medical event" may sound alarming when it applies to nuclear medicine and radiation therapy, but it rarely means that a patient has been harmed. Rather, a medical event refers to a potential problem with how a medical facility administered radioactive materials or radiation from radioactive materials. The provisions in Title 10 of the *Code of Federal Regulations* (10 CFR) 35.3045, "Report and Notification of a Medical Event," identifies the requirements for reporting a medical event.

The purpose of medical event reporting is to allow the NRC to follow up on incidents and determine if other licensees might be making the same or similar mistakes, or experiencing the same or similar challenges. When staff members identify similarities in the problems reported from multiple facilities, they can provide, with the help of the agency's Agreement State partners, information that could help prevent additional similar incidents. The NRC requires reporting, because a medical event indicates that there were problems administering the radioactive material or radiation in accordance with the physician's (authorized user's) directions (prescription). The NRC analyzes each medical event to see if further action is needed. A medical event may not result in a violation, but the failure to report a medical event is a violation.

The physician also needs to analyze the event to determine if a patient is actually harmed, whether from too high a dose or inadequate treatment when a dose is too low. In some cases, the NRC may ask a medical consultant (physician) to independently assess the medical consequences to the patient.

In summary, NRC regulations require that licensees report instances in which mistakes were made in the administration of radiation or radioactive materials that meet the criteria in 10 CFR 35.3045. Medical events may not result in

violations, but not reporting them is a violation. The purpose of these regulations is to allow the NRC and the Agreement States to gather data, look for trends and communicate with the medical facilities that the agencies regulate to prevent, when possible, similar problems from being repeated.

(Contact: Said Daibes, NMSS, 301-415-6863 or Said.Daibes@nrc.gov)

ANNUAL USERS TRAINING MEETING



The Nuclear Materials Management and Safeguards System (NMMSS) 2016 Annual Users Training Meeting will be May 9–12, 2016, in New Orleans, LA. This 4-day event offers unique learning and networking opportunities for the NRC licensees and the U.S. Department of Energy (DOE)/ National Nuclear Security Administration, along with other Federal agencies and contractor organizations involved in management of nuclear materials. A limited block of rooms has been reserved at the government per diem rate of \$122 per night on a first-come, first-served basis for the nights of May 8–12, 2016. Please register for the training event as well as review the draft agenda and reserve your hotel accommodations at <http://108.31.8.56/nmmss2016/>. There is no registration fee to participate in this valuable training opportunity. A training certificate will be provided.

(Contact: Mirabelle Shoemaker, NRC NMMSS Project Manager, 301-415-7363 or Mirabelle.Shoemaker@nrc.gov)

INTERNATIONAL SAFEGUARDS REPORTING REQUIREMENTS



The U.S. Government has negotiated and brought into force agreements with the International Atomic Energy Agency (IAEA) related to the implementation of international safeguards in the United States and its territories in the Caribbean. Under the safeguards agreements, a nuclear facility is a reactor, a fuel cycle installation, or any other type of installation possessing more than 1 effective kilogram of nuclear material. One aspect of these agreements is a requirement for the United States to report information to the IAEA. This information includes an eligible facilities list, design information questionnaires, material accounting reports, information on imports and exports of source and special nuclear materials, and information activities related to nuclear fuel cycles. The International Safeguards Team of the Material Control and Accounting Branch (MCAB) in the Division

of Fuel Cycle Safety, Safeguards, and Environmental Review is responsible for ensuring that accurate and complete information is collected regarding the installations licensed by the NRC and Agreement States and is properly reported. The NRC also responds to the IAEA, through the U.S. Department of State, to resolve any questions on information received by the IAEA concerning installations licensed by the NRC or Agreement States.

The U.S. and IAEA Safeguards Agreement requires the United States to provide the IAEA a list (eligible facilities list) of all U.S. nuclear facilities that do not have activities of direct national security significance. The IAEA may select any facility on that list for (a) reporting, design



information verification, and inspection, or (b) reporting and design information verification only. Since the agreements entered into force, nine NRC-licensed nuclear facilities have been selected for inspections (however, none is currently being inspected) and four (three fuel fabrication facilities and one enrichment facility) are currently selected for reporting and design information verification. The NRC's portion of the eligible facilities list has 269 facilities. DOE facilities are also on the list, and one is currently selected from the list for inspection.

When the IAEA selects a facility for inspection from the list, the United States is required to prepare and submit to the IAEA a design information questionnaire for the facility. This document follows a prescribed format and provides the IAEA with information necessary for the IAEA to design an effective international safeguards approach for the facility and to understand the accuracy and precision of the reported material accounting data. After the receipt of the design information questionnaire, the IAEA will typically confirm the accuracy of the information stated in the questionnaire through a design information verification site visit. After the site visit, the design information questionnaire will typically be changed to add or revise information to address the IAEA's questions. As facility design or operations change, the IAEA requires that the design information questionnaire for a facility be updated. MCAB staff is currently working with the four selected facilities to make sure that their responsible facility staff members are aware of the requirement and are updating the design information questionnaires to reflect the current facility status. During 2015, the IAEA conducted a design information verification visit at the Louisiana Enrichment Services gas centrifuge enrichment plant in Eunice, NM.

When the IAEA selects a facility from the eligible facilities list, the United States is also required to submit an initial inventory declaration for the facility regarding all source and special nuclear material at the facility, and to subsequently report all inventory changes that occur. Annually, the United States is also required to submit a physical inventory list for the facility and to submit a material balance report that assesses all of the inventory changes for the year and compares that book inventory value with the value obtained from the physical inventory taking. The reporting of inventory changes occurs monthly.

The United States is also required to report to the IAEA all U.S. imports and exports of source and special nuclear material. These reports are necessary for the IAEA to establish matches for import and export reports generated in other countries. Where the IAEA cannot match a U.S. import or export with an export or import of another country, MCAB works with the IAEA and other Federal agencies to resolve the issue. On average, the U.S. makes 26,000 nuclear material accounting reports to the IAEA annually. These reports are made through the U.S. Nuclear Materials Management and Safeguards System, which is jointly funded and managed by the NRC and DOE.

The United States also negotiated and brought into force the Protocol Additional to the US IAEA Safeguards Agreement (Additional Protocol) in 2009. The Additional Protocol requires the United States to report on certain activities related to the nuclear fuel cycle. These activities include, among others: research and development, manufacturing of nuclear-related equipment, imports and exports of such equipment, uranium and thorium mining, storage of uranium and thorium ore concentrates, activities on the sites of nuclear facilities, and nuclear fuel cycle development plans. On average, the NRC makes 200 declarations (quarterly and annually) per year. The primary annual information collection and reporting occurs in the first 2 months of each year.

(Contact: Bruce Moran, NMSS, 301-415-7269 or Bruce.Moran@nrc.gov)



SIGNIFICANT ENFORCEMENT ACTIONS

The NRC issued significant actions for failure to comply with a regulation.

Northern States Power Company (Monticello Nuclear Generating Plant, Unit 1) (EA-14-193)

On December 21, 2015, the NRC issued a Confirmatory Order to Northern States Power Company, Minnesota (licensee) to formalize commitments made as a result of an Alternative Dispute Resolution mediation session. The licensee made the commitments as part of a settlement agreement with the NRC regarding apparent violations of NRC requirements. The agreement resolves the licensee's failure to ensure nondestructive examinations (NDE) on spent fuel dry shielded canisters (DSC) that were performed in accordance with procedural requirements. The agreement also resolves the falsification of records when recording the NDE results, contrary to the requirements of the following:

- 10 CFR 72.158, "Control of Special Processes"
- 10 CFR 72.111, "Completeness and Accuracy of Information"
- paragraph (c) of 10 CFR 72.154, "Control of Purchased Material, Equipment, and Services"

The licensee agreed to a number of corrective actions, including: (1) restore compliance for all affected DSCs, (2) revise applicable procedures, (3) present at an industry forum, (4) submit an article to an industry publication, and (5) assess the effectiveness of improvements. In consideration of these commitments, the NRC agreed to refrain from issuing a Notice of Violation and a proposed imposition of a Civil Penalty.

JOMA Shop, LLC (EA-15-196)

On December 21, 2015, the NRC issued a Notice of Violation to JOMA Shop (JOMA) for a Severity Level III problem for two related violations. The violations involved JOMA's transfer of watches containing byproduct material without an NRC license as required by paragraph (a) of 10 CFR 30.3, "Activities Requiring License," and an import of byproduct material into United States without having the required license for possession of the byproduct material as required by 10 CFR 110.5, "Licensing Requirements." Specifically, beginning on or around May 2013, JOMA initially transferred (distributed/sold), 7,617 tritium watches to persons without obtaining a specific license authorizing such transfers and before April 2012. JOMA imported these watches without having a possession license issued by the State of New York, without first obtaining a specific import license from the NRC, and without obtaining a license to distribute the watches from the NRC.

ECS Mid-Atlantic, LLC (EA-15-148)

On December 14, 2015, the NRC issued a Notice of Violation to ECS Mid-Atlantic, LLC (ECS), for a Severity Level-III violation. The violation involved ECS's failure to control and maintain constant surveillance or failure to use two independent physical controls that form tangible barriers to secure a portable gauge from unauthorized removal as required by 10 CFR 20.1802, "Control of Material Not in Storage," and paragraph (i) of 10 CFR 30.34, "Terms and Conditions of Licenses." Specifically, on June 8, 2015, a portable gauge was left unattended and uncontrolled at a job site at the U.S. Naval Academy, and it was not secured with any physical controls that form tangible barriers to secure it from unauthorized removal.



CTI and Associates, Inc. (EA-15-157)

On November 23, 2015, the NRC issued a Notice of Violation to CTI and Associates, Inc., for a Severity Level III violation of both 10 CFR 20.1801, "Security of Stored Material," and paragraph (i) of 10 CFR 30.34, Terms and Conditions of Licenses." The violation involved CTI's failure to secure licensed material in a portable gauge from unauthorized removal or access, with a minimum of two independent physical controls that form tangible barriers, while the gauge was stored in a controlled or unrestricted area and not under the control and constant surveillance of the licensee. Specifically, the licensee left an unattended gauge inside an unlocked shipping container that was accessible to the public.

Testing Engineers & Consultants, Inc. (EA-15-141)

On October 23, 2015, the NRC issued a Notice of Violation to Testing Engineers & Consultants (TEC) Inc., for a Severity Level III violation. The violation involved TEC's 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, from 2011 until June 19, 2015, during off-duty hours, non-licensee building tenants had access to the storage room's locked door, which resulted in a only single physical barrier securing the gauges from unauthorized removal.

Cal Testing Services, Inc. (EA-15-117)

On October 9, 2015, the NRC issued a Notice of Violation to Cal Testing Services (CTS), Inc., for a Severity Level III violation. The violation involved CTS's failure to ensure each individual who acts as a radiographer or a radiographer's assistant wears 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 10 CFR 34.47, "Personnel Monitoring." Specifically, on March 20, 2015, a radiographer's assistant wore an inoperable alarm rate meter while performing radiographic operations.



MEDICAL

McLaren Medical Center Bay Region (EA-15-111)

On August 27, 2015, the NRC issued a Notice of Violation to McLaren Medical Center Bay Region (McLaren) for a Severity Level III violation. The violation involved McLaren'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, as of February 6, 2015, the licensee failed to include specific steps in its procedure for verifying the catheter position to ensure the administration was in accordance with the written directive. As a result, a medical event occurred because the patient received an unintended dose of approximately 2.6 gray (260 rad) to the skin of the right thigh.



INDIVIDUALS

Mr. Larry Yeates (IA-15-029)

On December 28, 2015, the NRC issued a Notice of Violation to Mr. Larry Yeates for Severity Level III violations of paragraphs (a)(1) and (a)(2) of 10 CFR Part 72.12, "Deliberate Misconduct." These violations involved the deliberate failures of Mr. Yeates to ensure that liquid penetrant nondestructive tests, a special process, were conducted in accordance with the Monticello Nuclear Generating Plant procedure. Specifically, from September 5, 2013 through October 17, 2013, Mr. Yeates deliberately failed to comply with procedure steps involving the developing time before the final interpretation of 38 welds on the six separate spent fuel storage dry shielded canisters that he examined. Additionally, Mr. Yeates failed to accurately record the nondestructive evaluation results. The information was not accurate, because the developer dwell times were over-reported.

Mr. Mickey Lovell (IA-15-028)

On December 28, 2015, the NRC issued a Notice of Violation to Mr. Mickey Lovell for Severity Level III violations of paragraphs (a)(1) and (a)(2) of 10 CFR Part 72.12, "Deliberate Misconduct." These violations involved Mr. Lovell's deliberate failures to ensure that liquid penetrant nondestructive tests, a special process, were conducted in accordance with the Monticello Nuclear Generating Plant procedure. Specifically, from September 5, 2013 through October 17, 2013, Mr. Lovell deliberately failed to comply with procedural steps involving the developing time before the final interpretation of 28 welds on the six separate spent fuel storage dry shielded canisters he examined. Additionally, Mr. Lovell failed to accurately record the nondestructive evaluation results. The information was not accurate, because the developer dwell times were over-reported.

Mr. Mawuena Gnamavo (IA-15-061)

On October 30, 2015, the NRC issued a Notice of Violation to Mr. Mawuena Gnamavo for a Severity Level IV violation of paragraph (b)(2) of 10 CFR 71.8, "Deliberate Misconduct." The violation involved Mr. Gnamavo's deliberate misconduct, which caused his employer, Columbian Hi-Tech (CHT), a certificate holder, to be in violation of paragraph (a) of 10 CFR 71.7, "Completeness and Accuracy of Information," requirement for knowingly submitting inaccurate quality and nondestructive examination inspector training and experience documents to CHT. Specifically, shortly after Mr. Gnamavo's initial hire date of January 30, 2012, he provided falsified documents to CHT, consisting of a letter of recommendation and a training certificate. CHT used these documents as part of the basis to certify Mr. Gnamavo as a qualified inspector in both visual examination and dye penetrant examination. Mr. Gnamavo then inspected and approved important safety welds on 10 CFR Part 71, "Packing and Transportation of Radioactive Material," and 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste," equipment and components without the required qualifications.

Dr. Bradley D. Bastow (IA-14-039)

On August 4, 2015, the NRC issued a Confirmatory Order to Dr. Bradley D. Bastow, radiation safety officer (RSO) for Cardiology II, P.C. The Order prohibits Dr. Bastow from serving as an RSO, including an assistant or associate RSO, while in NRC jurisdiction, until he demonstrates his completion of specific trainings and commits to comply with regulatory requirements. The NRC identified violations that were attributable to Dr. Bastow's activities as the RSO. For example, the violations involved Dr. Bastow's failure to repair or replace





radiation detection instrumentation and to ensure that the instrumentation was calibrated and operable. He also failed to shadow a radiation safety officer and to maintain complete and accurate documents. The violations continued to indicate that Dr. Bastow was not adequately fulfilling his duties as the RSO. This Order does not prevent Dr. Bastow from serving as an authorized user.

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 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: Michele Burgess, NMSS, 301-415-5868 or Michele.Burgess@nrc.gov)

GENERIC COMMUNICATIONS ISSUED

The following items summarize NRC generic communications issued by NMSS. If any of these documents appear relevant to your needs and you have not received a copy, 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 informational documents used to communicate with the nuclear industry on a broad spectrum of matters.

On November 12, 2015, the NRC issued **RIS-15-13**, "Seismic Stability Analysis Methodologies for Spent Fuel Dry Cask" (ADAMS Accession No. MLI3353A710). The agency issued the RIS to share information regarding acceptable seismic stability analysis methodologies with addressees to determine seismic stability of spent fuel dry cask loading stack-up configurations.

On December 4, 2015, the NRC issued **RIS-15-15**, "Information Regarding a Specific Exemption in the Requirements for the Physical Protection on Category 1 and Category 2 Quantities of Radioactive Material" (ADAMS Accession No. MLI5092A432). The agency issued the RIS to provide addressees with information regarding the guidance in NUREG-2155, Revision 1, "Implementation Guidance for 10 CFR Part 37, 'Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,'" and in the questions and answers concerning the application of 10 CFR Part 37 to licensees with 10 CFR Part 73, "Physical Protection of Plants and Materials," security plans, which can be found on the NRC's public Web site at <http://www.nrc.gov/security/byproduct/10-cfr-part-37.html>. Specifically, paragraph (b) of 10 CFR 37.11, "Specific exemptions," states,

Any licensee's NRC-licensed activities are exempt from the requirements of subparts B and C of this part to the extent that its activities are included in a security plan required by part 73 of this chapter.

This RIS is being issued to provide information on the activities that should be included within the licensee's security plan relative to this specific exemption from the requirements of Subparts B and C of 10 CFR Part 37.

On December 23, 2015, the NRC issued **RIS-15-17**, "Review and Submission of Updates to Final Safety Analysis Reports, Emergency Preparedness Documents, and Fire Protection Documents"



(ADAMS Accession No. MLI5321A400). The agency issued the RIS to remind licensees of the review and submission requirements of 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," regarding information that may be withheld from public disclosure, as well as to recommend that the updates to final safety analysis reports (FSARs) required by paragraph (e) of 10 CFR 50.71, "Maintenance of Records, Making of Reports," be made electronically on a total FSAR replacement basis, as described in paragraph (b)(6) of 10 CFR 50.4, "Written Communications." This RIS does not transmit or imply any new or changed requirements or staff positions, or require any specific action or written response. However, licensee review of FSAR updates and emergency preparedness and fire protection documents for physical protection information or Safeguards Information to be withheld from public disclosure, and submission of updates electronically on a total FSAR replacement basis, will enable the agency to more efficiently and effectively carry out its regulatory functions in an open and transparent manner.

On December 14, 2015, the NRC issued **RIS-15-18**, "Sodium Iodide-131 (I-131) Patient Release Information Collection" (ADAMS Accession No. MLI5321A391). The agency issued the RIS to all NRC medical use licensees and NRC Master Materials License (MML) medical use permittees administering sodium iodine I-131 to patients under a written directive to inform physicians, licensees, and permittees of an opportunity to voluntarily submit information requested in the NRC's November 16, 2015, *Federal Register* notice (FR) information request titled, "Sodium Iodide-131 (I-131) Patient Release Information Collection" (80 FR 70843). No specific action or any written response is required. The RIS is provided to the NRC MMLs for their information and for distribution to their appropriate medical use permittees. The NRC is providing this RIS to the Agreement States for their information and for distribution to their licensees, as appropriate.

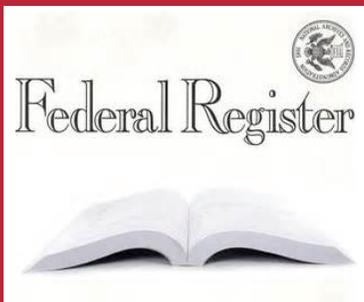
On December 21, 2015, the NRC issued **RIS-15-19**, "Decommissioning Timeliness Rule Implementation and Associated Regulatory Relief" (ADAMS Accession No. MLI5321A391). The agency issued the RIS to achieve the following:

- Provide clarity to licensees on the Decommissioning Timeliness Rule's (DTR's) requirements to notify the NRC to begin and complete decommissioning after certain criteria are met.
- Highlight opportunities for licensees to request alternatives to the DTR's requirements.
- Remind licensees that there are situations where they can request an alternative to the DTR's timeliness requirements for both beginning and completing decommissioning if adequately justified.
- Clarify when the DTR applies to licensees whose only location of use are temporary job sites.
- Clarify when the NRC considers that the licensee has transitioned from an "operational" to a "decommissioning" status.

This RIS informs licensees of requirements regarding the DTR under the following:

- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- 10 CFR Part 40, "Domestic Licensing of Source Material"
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"
- 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor- Related Greater than Class C Waste"

This RIS is supplemental guidance for decommissioning and does not contradict information presented in Administrative Letter 96-05, Revision 1, "Compliance with the Rule, 'Timeliness in Decommissioning of Material Facilities'" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML081570203) or NUREG-1757, Volume 3, Revision 1, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness, Final Report" (ADAMS Accession No. ML12048A683). This RIS does not apply to power reactors that have specific regulations concerning decommissioning (e.g., 10 CFR 50.82, "Termination of License," and 10 CFR 50.83, "Release of Part of a Power Reactor Facility or Site for Unrestricted use"). This RIS requires no action or written response beyond that already required by regulations. The NRC is providing this RIS to the Agreement States for their information and for distribution to their licensees, as appropriate.



SELECTED FEDERAL REGISTER NOTICES

January 27, 2016

Federal Register (FR) notice 81 FR 4680, "Draft NUREG/CR-7209, A Compendium of Spent Fuel Transportation Package Response Analyses to Severe Fire Accident Scenarios" (Draft NUREG/CR; Request for Comment)

Summary: The NRC is issuing for public comment draft NUREG/CR-7209, "A Compendium of Spent Fuel Transportation Package Response Analyses to Severe Fire Accident Scenarios." This report summarizes studies of rail and truck transport accidents involving fires, relative to regulatory requirements for shipment of commercial spent nuclear fuel (SNF). Comments were due by March 28, 2016.

(Contact: Jimmy Chang, NMSS, 301-415-7427 or Jimmy.Chang@nrc.gov)

October 28, 2015

FR notice 80 FR 66056, "Strata Energy, Inc." (Temporary Exemption)

Summary: The NRC is issuing a temporary exemption from certain NRC financial assurance requirements to Strata Energy, Inc. (Strata), in response to its annual financial assurance update for its Ross In-Situ Recovery (ISR) project. Issuance of this temporary exemption will not remove the requirement for Strata to provide adequate financial assurance through an approved mechanism, but will allow the NRC staff to further evaluate whether the State of Wyoming's separate account provision for financial assurance instruments it holds is consistent with the NRC's requirement for a standby trust agreement.

(Contact: John L. Saxton, NMSS, 301-415-0697 or John.Saxton@nrc.gov)



ONGOING RULEMAKINGS

| RULEMAKING | DESCRIPTION | STATUS |
|--|---|--|
| PROPOSED RULES | | |
| 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 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 <i>Federal Register</i> (80 FR 16082 and 80 FR 15930) on March 26, 2015. The comment period was extended until and closed on September 21, 2015. The comments received are under NRC review. The final rule package is due to the Commission in May 2016. |
| 10 CFR Parts 30 and 32, "Items Containing Byproduct Material Incidental to Production (formerly Polymer (Polycarbonate or Polyester) Track Etched (PCTE) Membranes)" | 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. | The NRC is currently drafting the regulatory basis for the rulemaking and expects to release it for public comment in December 2016. |
| 10 CFR Part 73, "Enhanced Security of Special Nuclear Material" | The proposed rule would update security regulations, including portions of 10 CFR Part 73, relating to physical protection of special nuclear material at NRC licensed facilities and in transit. | On February 3, 2015, the Office of Nuclear Security and Incident Response (NSIR) submitted a user need request (ADAMS Accession No. ML14317A037) to NMSS to initiate a rulemaking to update the security regulations within 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 was formed and is working on the proposed rule. |

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 working group is reviewing the comments.

FINAL RULE

10 CFR Part 35,
“Medical Use of
Byproduct Material
– Medical Event
Definitions, Training
and Experience
and Clarifying
Amendments”

The rule would amend the reporting and notification requirements for medical events for permanent brachytherapy, amend training and experience requirements to remove attestation requirements for certain individuals, make changes as requested in PRM-35-20, petition for rulemaking, and clarifying amendments.

The NRC published the proposed rule and draft guidance in the *Federal Register* (79 FR 42224) for public comments. The comment period closed November 18, 2014. The NRC received 48 comment letters, each containing numerous individual comments. The comments are posted at <http://www.regulations.gov> under Docket ID NRC-2008-0175. On October 8, 2014, the NRC held a public meeting to promote better understanding of the proposed amendments. The comments received are under NRC review. The final rule package is due to the Commission in Spring/early Summer 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, and would clarify and strengthen the MC&A requirements, in part, by removing existing exemptions in the item control provisions.

Staff is resolving the public comments and preparing the final package for the rulemaking. The final rule package is due to the Commission in November 2016.

PETITIONS

PRM-72-6, "Petition for Rulemaking (PRM-72-6), C-10 Research and Education Foundation, Inc."

The petitioner submitted 12 requests for the NRC to amend its regulations concerning dry cask safety, security, transferability, and longevity. In a *Federal Register* notice dated October 16, 2012, the NRC denied nine of the petitioner's 12 requests (Requests 1, 2, 3, 5-8, 10 & 12), accepted for consideration Request 11 as part of the ongoing independent spent fuel storage installation (ISFSI) security rulemaking effort (RIN 3150-A178; Docket ID NRC-2009-558), and reserved two requests for future rulemaking determination (Requests 4 and 9).

The package was sent to the Office of the Executive Director for Operation for their review in March 2016.

PRM-28, PRM-29 and PRM-30, "Linear No-Threshold Model and Standards for Projection Against Radiation"

The NRC received three petitions for rulemaking (PRM) requesting that the NRC amend its "Standards for Protection against Radiation" regulations and change the basis of those regulations from the Linear No-Threshold (LNT) 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 Petition For Rulemaking; 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 September 8, 2015. But on August 21, 2015, the NRC published in the *Federal Register*, 80 FR 50804, the receipt of the Petition for rulemaking; 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. Staff is examining the issues raised in the PRMs to determine whether they should be considered in rulemaking.

POLICY STATEMENT

Tribal Policy Statement The Tribal Policy Statement development will describe the Commission's policy for consulting and coordination with Native American tribes.

The proposed Tribal Policy Statement was published in the *Federal Register* (79 FR 71136) on December 1, 2014, and the public comment period closed on May 31, 2015. Staff is in the process of reviewing comments.

PRE-RULEMAKING

10 CFR Part 20, "Standards for Protection against Radiation, International Commission on Radiological Protection (ICRP) Recommendations" The rulemaking would incorporate recommendations from the ICRP to revise 10 CFR Part 20.

The NRC published an advance notice of proposed rulemaking in the *Federal Register* (79 FR 43284) on July 25, 2014, and the public comment period closed on June 22, 2015. Staff is reviewing comments.



TO OUR READERS

Thank you for your interest in our newsletter. In our attempt to keep the NMSS licensee newsletter—The *NMSS News Link*—relevant, 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.

Please send written correspondence to the following address:

Vanessa Cox, Editor, NMSS Licensee Newsletter
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Two White Flint North, Mail Stop: T-8-D36
Washington, DC 20555-0001



NUREG/BR-0117 No.16-02
March 2016



@NRCgov

