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Protecting People and the Environment

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FSME News Link

OFFICE OF FEDERAL & STATE MATERIALS & ENVIRONMENTAL MANAGEMENT PROGRAMS

Medical Use of Byproduct Material Proposed Rule

The U.S. Nuclear Regulatory Commission (NRC) has regulatory authority over the medical use of byproduct material. The NRC has issued regulations to provide for the radiation safety of workers, the general public, patients, and human research subjects when byproduct material is used for medical purposes. These regulations are contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material."

BACKGROUND

The NRC revised Part 35 in its entirety in 2002 (67 FR 20250), and further revised the training and experience (T&E) requirements in 2005 (70 FR 16336). In implementing the current regulations, the NRC staff, stakeholders, and the Advisory Committee on the Medical Uses of Isotopes identified issues that need to be addressed through the rulemaking process. These issues will be addressed in a proposed rule.

SUMMARY

The proposed rule will address three ongoing rulemaking projects and several other related topics. First, this rule proposes amendments to the reporting and notification requirements for a medical event for permanent implant brachytherapy. Second, the rule proposes changes to: (1) the T&E requirements for authorized users, medical physicists, radiation safety officers, and nuclear pharmacists; (2) the requirements for measuring molybdenum contamination and reporting of failed technetium and rubidium generators; and (3) allow associate radiation safety officers to be named on a medical license and several clarifying amendments. Third, the rule proposes changes to address a request in a petition for rulemaking (PRM 35 20) to exempt certain board certified individuals from certain T&E requirements (i.e., "grandfather" these individuals). This exemption would allow certain board certified individuals to be identified on a license or permit for materials and uses that they performed on or before October 24, 2005, the expiration date of the former Subpart J of 10 CFR Part 35 which contained the prior T&E requirements.

STATUS

In August 2013, the NRC staff sent the 10 CFR Part 35 proposed rule package (SECY 13 0084, available in NRC's Agencywide Documents Access and Management System

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(ADAMS) Accession No. ML13178A124) to the Commission for review and approval to publish the proposed rule in the *Federal Register* for public comment. In a staff requirements memorandum (SRM) dated January 6, 2014, the Commission approved publication of the proposed rule, subject to some changes, as noted in the SRM (ADAMS Accession No. ML14007A044).

After the NRC staff incorporates the Commission directed changes, the proposed rule will be published in the *ederal Register* for a 120 day comment period. Concurrent with the publication of the proposed rule, the draft guidance conforming to the proposed rulemaking will also be available for public comment. The NRC is anticipating publication of the proposed rule and the conforming draft guidance for public comment in mid May 2014.

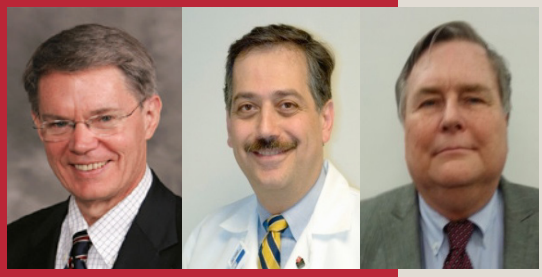
(Contact: Neelam Bhalla, FSME, 301-415-6843, or Neelam.Bhalla@nrc.gov, or; Edward Lohr, FSME, 301-415-0253, Edward.Lohr@nrc.gov)

COMPLIANCE BEGINS FOR THE PHYSICAL PROTECTION OF BYPRODUCT MATERIAL

On March 19, 2013, the NRC published a final rule that added a new part—Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"—to the NRC regulations in 10 CFR and made conforming changes to other regulations. The new requirements establish security requirements for the most risk significant radioactive materials, based on their quantities (i.e., category 1 quantities or category 2 quantities of these radioactive materials as determined in Appendix A, "General Provisions," to 10 CFR Part 37). The new rule became effective on May 20, 2013, and required compliance by NRC licensees by March 19, 2014, one year after publication. The NRC issued Regulatory Issue Summary (RIS) 2014 03, "Notice of 10 CFR Part 37 Implementation Deadline for NRC Licensees" (ADAMS Accession No. ML14052A157), to provide information to assist licensees in their compliance with the new requirements. Agreement States have until March 19, 2016, to issue compatible requirements for their licensees.

For more information on 10 CFR Part 37, please visit http://www.nrc.gov/security/byproduct/10 cfr part 37.html. The NRC welcomes comments and questions from anyone interested in the new regulations and their implementation. You can use the dedicated e-mail resource Part37.Resource@nrc.gov to ask questions and provide comments to the NRC regarding 10 CFR Part 37 and its implementation.

(Contact: Paul Goldberg, FSME, 301-415-7842, or Paul.Goldberg@nrc.gov)



(from left to right: Dr. Philip Alderson, Dr. Vasken Dilsizian, and Mr. Francis Costello)

NEW MEMBERS TO THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

The Acting Director of FSME, in consultation with the Commission, has selected three new members to the Advisory Committee on the Medical Uses of Isotopes (ACMUI). The new members are Dr. Philip Alderson, Dr. Vasken Dilsizian, and Mr. Francis Costello. These individuals will fill the existing vacancies on the ACMUI for the positions of the Health Care Administrator, Nuclear Cardiologist, and Agreement State Representative, respectively. The appointments are for 4 years.

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FROM THE DESK OF THE DIRECTOR

OFSME understands that interacting with our external stakeholders is one of the cornerstones of what makes a National Materials Program work. Recently, I reviewed a list of our external meetings and conferences. I was pleasantly surprised by not only the extensive list, but also by the level of involvement and interactions between the States and the NRC. The importance of these meetings is not lost on the NRC's senior leaders, as Chairman Allison M. Macfarlane, Commissioner William C. Ostendorff, and Deputy Executive Director of Operations (EDO) Michael F. Weber have participated in or are scheduled to participate in significant materials meetings and conferences.

The NRC continues to change and adapt to the shifting demands of our budgetary and regulatory framework, and FSME is no exception. Over the past year, FSME and the Office of Nuclear Materials Safety and Safeguards (NMSS) established a working group to evaluate a potential merge of offices. After careful consideration of the working group's recommendation and additional information provided by the staff, we have recommended to the EDO and the Commission that NMSS and FSME merge. A Commission paper was prepared that included the reason for the proposed merger and a short discussion on the alternatives considered in arriving at the staff's recommendation. Should the Commission approve the staff's recommendation, we will continue to communicate with both internal and external stakeholders as we move forward with implementing the Commission's direction. (Note: The staff proposed merging the two offices beginning October 1, 2014).

The regulation of radioactive materials is accomplished nationally by the NRC and 37 Agreement States. Since the NRC discontinues its authority when it enters into an agreement with a State, each Agreement State establishes legislations and regulations to protect public health and safety within its borders. To ensure that the regulations of radioactive material are conducted in a consistent manner nationally, each Agreement State's regulations must be compatible with NRC regulations. Compatibility regulations require that some regulations are identical between the NRC and States, but it also allows the Agreement States flexibility with other regulations. Compatibility has been an important topic in FSME for the last several months—there has been discussion on the amount of flexibility that should be afforded the Agreement States due to three significant projects currently underway. Two significant amendments to NRC regulations with important compatibility implications that will impact Agreement States have been the subject of discussion and direction by the NRC Commission. In addition to 10 CFR Part 35, "Medical Use of Byproduct Material," regulations that cover the medical use of radioactive material, FSME is amending the NRC regulations for low level waste disposal (10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste") where all the Nation's low level waste disposal facilities are licensed and regulated by Agreement States. FSME staff is also preparing a Commission paper to propose the final version of the agency's policy statement on compatibility, a process that started in 2011. In the coming months, the topic of compatibility and the amount of flexibility provided to Agreement States will continue to be an important topic in FSME.

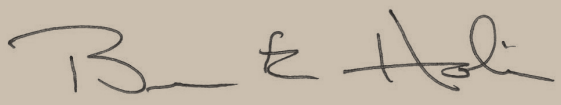
In March 2014, Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," became effective. This new rule codifies the orders that were put in place following 9/11. It is important to note that the rule also has some additional criteria that were gained from inspections and lessons learned. FSME recently issued a Regulatory Issue Summary (RIS 2014 03, "Notice of 10 CFR Part 37 Implementation Deadline for NRC Licensees") that highlighted this rule. I encourage you to distribute that RIS to your staff and licensees.

Also, in March 2014, we published the revised draft of the interim staff guidance (ISG) on "Evaluations of Uranium Recovery Facility Surveys of Radon and Radon Progeny in Air and Demonstrations of Compliance with 10 CFR 20.1301," for public comment. On April 2, 2014, a public meeting was held to discuss the revisions to the draft report and to solicit additional comments. Staff prepared the ISG on radon and radon progeny surveys and certain aspects of dose determinations for uranium recovery facilities to assist in evaluating compliance with the 10 CFR Part 20, "Standards for Protection against Radiation," public dose limit. The new revision to the draft was developed with the assistance of the many comments provided by all of our internal and external stakeholders. I trust that with the revised draft, and the additional comments you provided, we will be able to publish a final version in the near future that will assist us in dealing with this issue.

Radium is another topic of interest that I'd like to highlight. Recently, the Hunters Point Naval Shipyard (HPS) site in San Francisco, CA, has been of interest to the public. The Navy is the land owner and responsible for the cleanup of the HPS site under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, also known as the Superfund Act). However, the Navy uses various civilian contractors to perform aspects of remediation work at this site. The NRC's role at this site involves staying informed of the site's CERCLA activities and providing oversight to the Navy's contractors with NRC licenses. The NRC is drafting a Commission paper dealing with this topic. The paper will summarize the NRC's ongoing actions for what we expect to be a couple dozen military sites needing actions. Additionally, just as the Agreement States have wrestled with radium contamination at commercial sites, the NRC is expending effort to identify any potential additional sites that may need attention in NRC States.

I look forward to seeing many of you at the Conference of Radiation Control Program Directors (CRCPD) annual meeting in Atlanta this year.

Best wishes for some warmer spring weather!



Brian Holian, Acting Director

Dr. Alderson currently serves as Dean of the School of Medicine and as Vice President for Medical Affairs at Saint Louis University, located in St. Louis, MO.

Dr. Dilsizian currently serves as Chief of the Nuclear Medicine Division (PET Cardiovascular Imaging) at the University of Maryland Medical Center located in Baltimore, MD. He is also Professor of Radiology and Medicine at the University of Maryland School of Medicine, which is also located in Baltimore.

Mr. Costello is a Radiation Health Physicist with the Pennsylvania Bureau of Radiation Protection, located in Norristown, PA.

The ACMUI advises the NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy. The ACMUI membership includes health care professionals from various disciplines who comment on changes to NRC regulations and guidance; evaluate certain non routine uses of radioactive material; and bring key issues to the attention of the NRC staff for appropriate action. Additional information about the ACMUI can be found at http://www.nrc.gov/about nrc/regulatory/advisory/acmui.html.

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

APPOINTMENT TO THE CERTIFICATION REVIEW BOARD

DIn March 2014, Larry W. Camper, Director, Division of Waste Management and Environmental Protection of FSME, was appointed as a member of the Certification Review Board (CRB) for the Academy of Board Certified Environmental Professionals (ABCEP). The CRB is responsible for managing the ABCEP certification process. Members of the CRB represent many fields of professional effort (i.e., consulting, academia, private industry, government). The CRB is responsible for determining the qualifications of each applicant and grants or denies certification based upon the information provided. All CRB members are appointed by the ABCEP Board of Directors and must be certified by the ABCEP. As part of this process, Mr. Camper will serve as a member of a seven person team consisting of ABCEP certified professionals reviewing the credentials and application packages for individuals seeking certification by the ABCEP.

Mr. Camper was certified by the ABCEP in 2012 with a specialty in environmental assessment and he currently serves as the Chairman of the NRC National Environmental Policy Act Executive Steering Committee.

The FSME staff congratulates Mr. Larry Camper on his new appointment!!!

FUKUSHIMA LESSONS LEARNED

Background

On March 11, 2011, a 9.0 magnitude earthquake struck Japan and was followed by a 45 foot tsunami, resulting in extensive damage to the nuclear power reactors at the Fukushima Dai ichi facility.

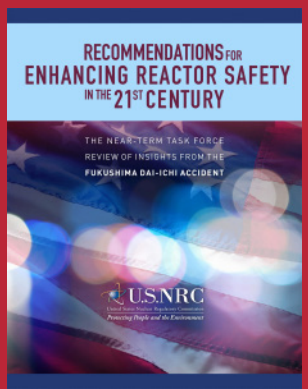
What is NTTF?

Following the Fukushima accident, the Commission directed staff to establish a Near Term Task Force (NTTF) to conduct a systematic and methodical review of NRC processes and regulations to determine whether the agency should make additional improvements to its regulatory system, and to make recommendations to the Commission for its policy development (tasking memorandum dated March 23, 2011). The NTTF conducted a review of insights from the Fukushima accident and developed near term recommendations described in a report entitled, "Recommendations for Enhancing Reactor Safety in the 21st Century," which was submitted to the Commission (SECY–11–0093, dated July 12, 2011). In brief, the NTTF developed 12 overarching recommendations, limited to radiological health and safety considerations for nuclear power reactors.

Recommendation 1 was the most significant overarching recommendation, which consisted of an overall recommendation, and four specific sub recommendations. This recommendation called for the establishment of a *logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense in depth and risk considerations.* The NTTF sub recommendations were to:

- 1.1 Draft a Commission policy statement that articulates a risk informed defense in depth framework.
- 1.2 Initiate rulemaking to implement a risk informed, defense in depth framework consistent with the above recommended Commission policy statement.
- 1.3 Modify the Regulatory Analysis Guidelines to more effectively implement the defense in depth philosophy in balance with the current emphasis on risk based guidelines.
- 1.4 Evaluate the insights from the Individual Plant Examination (IPE), and Individual Plant Examination for External Event (IPEEE) efforts, to identify potential generic regulations or plant specific regulatory requirements.

The remaining overarching recommendations pertain to system design for seismic and flooding and strengthening station blackout mitigation, vent design in boiling water reactors facilities, and additional aspects of emergency planning enhancements.



What is RMRF?

In a memorandum dated February 11, 2011, the NRC Chairman created a Risk Management Task Force (RMTF) headed by Commissioner George Apostolakis. The task force was chartered to develop a strategic vision and options for adopting a more comprehensive and holistic risk informed performance based regulatory approach for reactors, materials, waste, fuel cycle, and transportation that would continue to ensure the safe and secure use of nuclear material. In April 2012, the RMTF issued NUREG–2150, "A Proposed Risk Management Regulatory Framework (RMRF)." NUREG–2150 addressed agency mission, objective, risk management goal, and a decision making process in consideration of RMTF findings. More importantly, NUREG–2150 proposed over 50 recommendations for all NRC programs or business lines. Considering FSME programs, a total of 11 recommendations were proposed including 5 recommendations for materials uses; 3 recommendations for low-level waste, and 3 recommendations for uranium recovery program. The task force did not propose any recommendations for decommissioning.

What is the relationship between NTTF and RMRF?

The Commission linked the timeframe for developing an RMRF paper on policy statement within 6 months of issuing the SRM on NTTF Recommendation 1. In addition, the RMRF proposed framework for agency mission, objective, risk management goal, as well as

several recommendations are similar to NTTF Recommendation 1 and its sub-recommendations. For example, defense-in-depth concept is a common feature among NTTF and RMRF recommendations.

Why and how is FSME involved in NTTF and RMRF activities, and what is the potential future impact on FSME programs/business lines?

The NTTF Recommendation 1 and its sub recommendations apply to all NRC programs including FSME. Further, certain recommendations regarding safety and security apply to material uses and other FSME business lines. FSME is also involved in addressing material safety and security to ensure depth of analysis of potential incidents or accidents, including use of the defense-in-depth concept in equipment design, operational activities including human factors, as well as analysis of lessons learned based on NRC and international experience gained in licensing and control of radioactive material uses. Currently, FSME is also participating in Japan Lessons Learned Project Directorate (JLD) reviews, addressing lessons learned and potential needs for additional features to enhance safety and security.

With regard to RMRF, FSME staff participates in all RMRF work group (RMRF WG) activities focusing on development of a conceptual policy statement and addressing issues pertaining to FSME NUREG–1250 eleven recommendations. The FSME Deputy Office Director is continually involved in the RMRF Executive Steering Committee (ESC) meetings and discussion of implementation and stakeholder feedback issues. FSME staff also coordinates with Agreement States Liaison Officers to keep Agreement States informed of the ongoing RMRF activities, public meetings, and progress made on development of a policy statement.

Updates:

NTTF:

- FSME staff provided a summary of key activities to JLD that may be related to the ongoing JLD reviews such as regulations and/or regulatory guides that may need to be looked at in the context of JLD review activities.
- On June 14, 2012, the NRC Chairman issued a tasking memorandum entitled, "Evaluating Options Proposed for a More Holistic Risk Informed, Performance Based Regulatory Approach."
- NTTF WG developed a detailed paper addressing staff recommendations for disposition of Recommendation 1 of the NTTF (SECY–13–0132, December 6, 2013).
- NTTF WG briefed the Commission on approaches for disposition of NTTF Recommendation 1 (January 10, 2014).
- NTTF WG is awaiting Commission decision regarding options for disposition of Recommendation 1.

RMRF:

- FSME staff participated in RMRF WG meetings and contributed to development of a conceptual policy statement briefly addressing RMRF recommendations applicable to FSME business lines.

- RMRF developed a draft policy statement on July 12, 2013 and FSME staff provided a comment report (ADAMS Numbers ML13210A180 and ML13210A214) on the July 2013. FSME comments focused on format, content, and issues pertaining to implementation as applicable to its business lines.
- RMRF WG conducted a public meeting on July 30, 2013, to discuss NUREG–2150 recommendations and how to address such recommendations.
- RMRF conducted a meeting, open to the public, with ACRS for discussion of NUREG–2150 recommendations, conceptual policy statement, and alternative approaches to disposition of NUREG–2150 recommendations.
- RMRF WG re directed its activity to develop a white paper addressing a conceptual RMRF policy statement and soliciting public comments.
- On November 25, 2013, the (NRC published, "Conceptual Example of a Proposed Risk Management Regulatory Framework Policy Statement," in the *Federal Register* (FRN) and requested public comments (78 FR 70354; November 25, 2013); and a white paper on the topic (ADAMS No. ML13273A5179).
- The original FRN provided a closing date of January 10, 2014, for the public review and comment period. The NRC extended the closing date for public comments until February 28, 2014. In addition, a public meeting on this topic was conducted on January 30, 2014, at NRC Headquarters in Rockville, Maryland.
- Currently, NRC staff is reviewing and addressing in detail public comments and comments submitted by NRC offices.
- The timeframe for developing and submitting an RMRF policy statement to the Commission is six months from the date of issuance of Commission SRM on disposition of NTTF Recommendation 1 (see NTTF status above).

(Contact: Boby Abu Eid, FSME, 301-415-5811 or Boby.abu-Eid@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS

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

Canberra Industries, Inc. (EA–13–184)

On November 1, 2013, the NRC issued a Notice of Violation to Canberra Industries, Inc., (Canberra) for a Severity Level III violation. The violation involved the licensee's failure to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas as required by 10 CFR 20.1801, "Security of Stored Material." Specifically, Canberra stored an americium 241/ beryllium source in a locked calibration room in which there was a pass through window to an unlocked outer room that was open and accessible. Also, the source was inside a shielded drum that was not secured to the floor and the motorized device that is used to expose the source could have been operated by unauthorized individuals through an unlocked switch located in the outer room.

ADCO Services, Inc. (EA–13–131)

On October 30, 2013, the NRC issued a Notice of Violation to ADCO Services, Inc., for a Severity Level III violation. The violation involved the failure to have an individual specifically named on the

license to fulfill the duties of the radiation safety officer (RSO) as required by License Condition 11.A of the NRC License. Specifically, the RSO left the company on June 30, 2012, and the licensee did not hire a new qualified RSO. Also, the company did not submit an amendment request to the NRC until February 1, 2013.

Nordlund and Associates (EA–13–053)

On June 27, 2013, the NRC issued a Notice of Violation to Nordlund and Associates for Severity Level III violations. One of the violations involved the failure of Nordlund to confine possession and use of byproduct materials to the locations and purposes authorized by the license as required by 10 CFR 30.3(c)(2), "Activities Requiring License," and 10 CFR 30.34(c), "Terms and Conditions of Licenses." From August 7, 2009, to April 3, 2013, the licensee possessed four radium 226 gauges that were not on its NRC license and used one of these gauges for density measurements at a temporary job site on July 3 and 5, 2012. The licensee was not authorized to possess the gauges and did not submit a license amendment until February 19, 2013, which is more than 6 months from the waiver expiration date. The second violation involved the failure of the company to use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee as required by 10 CFR 30.34(i). Even while the radium gauges were locked within the shed, the company did not have a second physical barrier to prevent their removal. Another violation involved the failure of Nordlund to conduct operations so that the dose in any unrestricted area from external sources would not exceed 2 millirem in any one hour as required by 10 CFR 20.1301(a)(2), "Dose Limits for Individual Members of the Public." Specifically, as of January 16, 2013, the licensee stored its radium gauges in an outdoor shed in an unrestricted area in a manner would result in a dose of approximately 4.5 millirem per hour external to the shed.

MEDICAL

Centro de Medicina Nuclear (EA–13–059)

On November 5, 2013, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $7,000 to Centro de Medicina Nuclear (CDM) for a Severity Level III violation. The violation involved the failure of CDM to comply with an order issued on August 7, 2012, after CDM failed to pay the NRC licensing fee. Specifically, as of November 5, 2013, CDM had not submitted an answer to the order, paid the license fee, or submitted the required written report regarding the amount, condition, and status of its licensed material by August 27, 2012; or begun decommissioning its site by October 26, 2012.

Jackson Cardiology Associates, P.C. (EA–13–134)

On October 30, 2013, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $3,500 to Jackson Cardiology Associates, P.C. (Jackson), for a Severity Level III problem involving two violations. The first violation involved the failure of Jackson to supply and require the use of individual monitoring devices by adults likely to receive a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a), "Occupational Dose Limits for Adults," as required by 10 CFR 20.1502(a)(1), "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose." The second violation involved the failure of Jackson to ensure that information provided to the NRC was complete and accurate in all material

respects as required by 10 CFR 30.9, "Completeness and Accuracy of Information." Specifically, on August 20, 2012, a nuclear medicine technologist informed an NRC inspector that dosimetry had been left at home although it had been misplaced at the end of June 2012. The technologist neglected to inform the inspector that payments were not made to the vendor to continue the contract nor were the services of a replacement vendor obtained.

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 ADAMS at http://www.nrc.gov/reading rm/adams.html. Help in using ADAMS is available by contacting the NRC Public Document Room staff at 301-415-4737 or 1-800-397-4209 or by sending an e-mail to PDR.Resource@nrc.gov.

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

GENERIC COMMUNICATIONS ISSUED

The following are summaries of NRC generic communications issued by FSME. If any of these documents appears relevant to your needs and you have not received it, please call one of the technical contacts listed below. The Web address for the NRC library of generic communications is http://www.nrc.gov/reading rm/doc collections/gen comm.

Information Notice

The NRC issued an Information Notice (IN) to addressees to provide significant recently identified information about safety, safeguards, or environmental issues. Addressees are expected to review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems.

On November 15, 2013, the NRC issued IN 2013–22, "Recent Licensing Submittals Containing Personally Identifiable Information." The IN was issued to remind licensees to refrain from submitting personally identifiable information (PII) in licensing applications and other correspondence when the PII is not necessary to support NRC review of the submitted information. (Contact: Katie Wagner, FSME, 301-415-6202, or Katie.Wagner@nrc.gov)

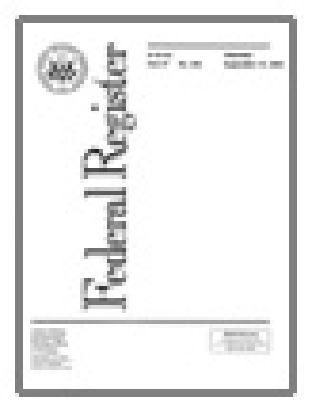
Regulatory Issue Summary

The NRC provides a regulatory issue summary (RIS) as an informational document used to communicate with the nuclear industry on a broad spectrum of matters.

On March 13, 2014, the NRC issued RIS 2014–03, "Notice of 10 CFR Part 37 Implementation Deadline for NRC Licensees." This RIS was issued to remind licensees required to implement the new 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material" that the compliance date of this rule is March 19, 2014, and to identify sources of reference information available to assist in compliance.

On January 10, 2014, the NRC issued RIS 2014–01, "Regulatory Requirements for Withholding of Proprietary Information from Public Disclosure." This RIS was issued to inform addressees how to request withholding of proprietary information from public disclosure under 10 CFR 2.390(b), "Public Inspections, Exemptions, Requests for Withholding," and how to submit proprietary information to the NRC.

(Contact: Hector Rodriguez Luccioni, FSME, 301-415-6004 or Hector.Rodriguez Luccioni@nrc.gov)



SELECTED *FEDERAL REGISTER* NOTICES

January 16, 2014

79 FR 2907 Consumer Product Policy Statement (Policy Statement; Revision)

Summary: The NRC is updating its policy statement on products intended for use by the general public (consumer products). The update reflects the NRC's current approach to radiation protection, legislation that has been enacted since the policy was published in 1965, and subsequent approaches taken in the NRC's regulatory framework for exemptions.

Contact: Shirley Xu, FSME, 301-415-7640 or Shirley.Xu@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 and new site specific analyses and to permit the development of criteria for future LLRW acceptance based on the results of these analyses.	The rulemaking package (SECY–13–0075 dated July 18, 2013) was sent to the NRC Commission for review. The SRM was issued February 12, 2014. A revised proposed rule is due to SECY in 12 months (February 2015).
10 CFR Part 35 – Medical Use of Byproduct Material – Medical event Definitions, Training and Experience and Clarifying Amendments	The proposed rule would amend the reporting and notification requirements for a medical event, training and experience requirements, and changes to address a request filed in a petition for rulemaking.	The rulemaking package (SECY–13–0084, dated August 8, 2013 was sent to the NRC Commission for review. On January 6, 2014, the SRM was issued approving the proposed rule with some modest changes. The proposed and draft guidance will likely be published for public comment in May 2014.
FINAL RULE		
10 CFR Part 71 – Compatibility with Transportation Standards	The rule would amend the transportation safety requirements in 10 CFR Part 71 to make changes to the NRC regulations for the packaging and transportation of radioactive material.	The NRC published the proposed rule in the *Federal Register* on May 16, 2013 (78 FR 28988). A final rule will likely be sent the Commission in September 2014.

DIRECT FINAL RULE		
10 CFR Part 70 – Appendix A Direct Final Rule, Reportable Safety Events	The direct final rule and companion proposed rule would modify the event reporting requirements In Part 70, Appendix A.	The Commission approved staff to move forward with rulemaking (COMSE-CY–13 –0005). The direct final rule and companion proposed rule may be published for public comment in October 2014.
10 CFR Part 73 – Safeguard Information – Modified Handling (SGI–M) Categorization Change for Materials Facilities	The direct final rule and companion proposed rule would remove the SGI M designation of the security related information for large irradiators, M&D licensees, and for any licensee that transports category 1 quantities of radioactive material or transports small quantities of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel. The security related information for these facilities and transportation will be protected under the requirements of the new 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."	The staff sent the Commission a rulemaking package on April 24, 2013 (SECY–13–0045), which the Commission approved. The SRM was issued on August 12, 2013. The direct final rule and companion proposed rule will likely be published for public comment in June 2014.
PETITIONS		
PRM-72-7 - NEI Petition – CoC Format and Content	The petition, submitted by Anthony Pietrangelo, on behalf of the Nuclear Energy Institute, requested that the NRC amend its 10 CFR Part 72 regulations to add a new rule governing spent nuclear fuel storage cask Certificate of Compliance (CoC) format and content, extend the applicability of the backfit rule to CoCs, and make other changes. The petitioner raised six issues to improve the efficiency of the licensing and oversight of spent fuel dry cask storage.	The receipt and request of the petition was published in the *Federal Register* on February 5, 2013 for 75-days of public comments.
PRM 32-8 – Campco Petition	CampCo submitted a petition for rulemaking (PRM 32 8) requesting the NRC to amend regulations to allow commercial distribution of tritium markers.	The receipt and request of the petition was published in the *Federal Register* on July 11, 2013, for 75 days of public comments.

POLICY STATEMENT		
Tribal Policy Statement	The tribal policy statement development will describe how to interact effectively with Native American tribes.	The staff sent the Commission a Tibal Policy Statement in January 2014 (SECY–14–0006). The policy statement will likely be published for public comment in June 2014.

PRE-RULEMAKING		
10 CFR Part 20 – ICRP Recommendations	The rulemaking would revise 10 CFR Part 20.	FSME is developing technical issue papers and will publish for stakeholder comment in mid-2014.

TO OUR READERS

Thank you for your interest in our newsletter. In our attempt to keep the FSME News Link relevant, we welcome feedback on its contents. If you would like to suggest topics for the newsletter, please contact Vanessa Cox, FSME 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 FSME News Link and to prevent any interruption of service, please report e-mail address changes to Ms. Cox at FSME_Newsletter@nrc.gov.

Please send written correspondence to the following address:
Vanessa Cox, Editor, FSME Licensee Newsletter
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
Two White Flint North, Mail Stop: T 8 F42
Washington, DC 20555 0001