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RULEMAKING ISSUE **(Notation Vote)**

December 19, 2022

SECY-22-0112

FOR: The Commissioners

FROM: Daniel H. Dorman
Executive Director for Operations

SUBJECT: PROPOSED RULE: RADIOACTIVE SOURCE SECURITY AND
ACCOUNTABILITY (3150-AK83; NRC-2022-0103)

PURPOSE:

The purpose of this paper is to obtain Commission approval to publish in the *Federal Register* the enclosed proposed rule (Enclosure 1) that would amend regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) to further ensure validity of license applicants. The proposed rule also would require licensees transferring category 3 quantities of radioactive material¹ to verify licenses through the U.S. Nuclear Regulatory Commission's (NRC) License Verification System (LVS) or by contacting the license-issuing authority to confirm that the recipient licensee is authorized to receive the type, form, and quantity of radioactive material to be transferred. In addition, the proposed rule would require that generally licensed devices containing category 3 quantities of byproduct material can only be transferred to licensees possessing a specific NRC or Agreement State license.

BACKGROUND:

In the staff requirements memorandum (SRM) for SECY-17-0083, dated December 21, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21355A290), the Commission approved the staff's recommendation to pursue rulemaking to amend 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct

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Enclosures 2 and 3 transmitted herewith contain Official Use Only - Sensitive Internal Information. When separated from Enclosures 2 and 3 this transmittal document is decontrolled.

¹ As defined in the United Nations' International Atomic Energy Agency *Code of Conduct on the Safety and Security of Radioactive Sources*, Annex I (2004) (<https://www.iaea.org/topics/codes-of-conduct>), category 3 sources, "if not safely managed or securely protected, could cause permanent injury to a person who handled them, or was otherwise in contact with them, for some hours." Category 3 sources are considered to be less dangerous than category 1 and category 2 sources.

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Material,” 10 CFR Part 40, “Domestic Licensing of Source Material,” and 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” to address security concerns with category 3 quantities of radioactive material.

Specifically, the Commission approved rulemaking to (1) require that applicants have safety and security equipment in place before granting a license for an unknown entity in order to address the concern related to obtaining a valid license using a fictitious company or by providing false information; (2) require that licensees transferring category 3 quantities of radioactive material verify that the recipient is authorized under its license to receive the type, form, and quantity of the radioactive material to be transferred, either through LVS or by contacting the license-issuing authority; and (3) clarify license verification methods for transfers involving quantities of radioactive material that are below category 2 thresholds in order to (a) update the oral certification method to require that the certification be followed up with confirmation by the use of one of the other acceptable verification methods in those parts, and (b) remove the obsolete method of obtaining other sources of information compiled by a reporting service from official records.

In addition, in SECY-22-0065, “Evaluation of the U.S. Nuclear Regulatory Commission's General License Program for Devices Containing Radioactive Materials in Response to SRM-SECY-17-0083,” dated July 8, 2022 (ADAMS Accession No. ML22103A248), the staff identified that some generally licensed devices containing category 3 quantities of radioactive materials are used in accordance with 10 CFR 31.5, “Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.” The staff indicated in that paper that it would use this rulemaking to address the license verification requirement for the transfer of all category 3 quantities of radioactive material, including those category 3 quantities contained in generally licensed devices.

The staff accelerated the development of this proposed rule because the scope and objectives were clearly defined and did not require additional outreach or research to develop the regulatory basis. The acceleration also responds promptly to Commission direction and recent recommendations in U.S. Government Accountability Office (GAO) reports.² To do so, the staff used collaborative approaches for stakeholder engagement consistent with the NRC’s strategic goal of inspiring stakeholder confidence.

DISCUSSION:

Overview of Proposed Changes to NRC Regulations – Major provisions of this proposed rule include changes to 10 CFR Parts 30, 31, 32, 40, and 70, in the following areas:

1. Validity of license applicants:

In SRM-SECY-17-0083, the Commission approved rulemaking that would require “unknown applicants” to have safety and security equipment in place before the NRC would issue a license. The purpose of such a rulemaking would be to more effectively and efficiently ensure the validity and non-malicious intent of license applicants. The staff is proposing to amend 10 CFR 30.33(a)(3), 40.32(d), and 70.23(a)(5) to state that specific licenses for byproduct material,

² GAO-16-330, “Nuclear Security: NRC Has Enhanced the Controls of Dangerous Radioactive Materials, but Vulnerabilities Remain,” dated July 2016 and GAO-22-103441, “Preventing a Dirty Bomb: Vulnerabilities Persist in NRC’s Controls for Purchases of High-Risk Radioactive Materials,” dated July 2022.

source material, and special nuclear material will only be issued if the applicant has demonstrated that it will use the requested material for the purposes stated in its license application. The rule text provides example methods of such demonstration (e.g., through installing safety and security equipment, establishing facilities, or developing procedures) that are consistent with pre-licensing guidance that is currently used by NRC and Agreement States. The guidance is not publicly available because the detailed considerations constitute security-related information. This provision would address the concern raised by the 2016 GAO report that a person could obtain a valid license using a fictitious company or by providing false information.

2. License Verification for Transfer of Category 3 Quantities of Radioactive Material:

The staff is proposing to add requirements in 10 CFR 30.41(d)(1)(i), 40.51(d), and 70.42(d)(1)(i), and make conforming changes to other regulations to require licensees transferring category 3 quantities of radioactive material to verify licenses through LVS or by contacting the license-issuing authority for the recipient licensee. This provision would address the concern raised by the 2022 GAO report related to an individual either altering a valid license to obtain more or different radioactive material than authorized or using a counterfeit license to obtain category 3 quantities of radioactive materials. As proposed, this verification would need to be conducted no earlier than 7 days prior to the transfer.

The proposed rule package includes a question to obtain insights on whether there are any routine transactions involving established licensees to which the enhanced license verification requirement (i.e., requiring license verification for category 3 transfers through use of the LVS or by the license-issuing authority) should not apply or should apply but with reduced frequency. The public comments on this question would be used to determine whether the final rule should exclude certain transactions.

The staff also is proposing to revise 10 CFR Parts 31 and 32 to address devices containing category 3 quantities of radioactive material that are possessed under a general license. The proposed rule would prohibit a manufacturer or distributor from transferring devices containing category 3 quantities of radioactive material to general licensees. In addition, general licensees would no longer be permitted to obtain devices that contain category 3 quantities of radioactive material under this proposed rule. This provision would also require that future transfers or disposals of devices with category 3 quantities of radioactive material, currently authorized under a general license, be subject to license verification under the new provisions. These changes would ensure that license verification is conducted for all transfers of category 3 quantities of radioactive material, providing enhanced controls and consistent treatment across the National Materials Program. Current holders of general licenses for devices containing category 3 quantities of radioactive material could continue to possess and use these devices under their general licenses, and they would continue to complete annual registrations as required. Requiring the current users of these devices to obtain specific licenses is unwarranted to address the intent of the license verification provision.

Stakeholder Engagement – The staff coordinated with the Agreement States and considered their feedback during the development of the proposed rule. An Organization of Agreement States representative participated on the rulemaking working group. On September 20, 2022, and on October 25, 2022, the staff held government-to-government meetings with Agreement States to discuss preliminary rule language for the Radioactive Source Security and Accountability proposed rule. The staff also met with the Standing Committee on Compatibility

(SCC) on November 3, 2022, to discuss the compatibility categories of the proposed requirements as well as the implementation timeframe.

The rulemaking would impact some medical licensees. Accordingly, the staff consulted with selected members of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the staff presented the rulemaking at the December 5, 2022, ACMUI public meeting. However, to facilitate the accelerated schedule for this rulemaking, and given the expected small impact on medical licensees, the staff has not requested formal comment by ACMUI.

A summary of the feedback received from the ACMUI members, the SCC, and the Agreement States is provided in Enclosure 2.

The Advisory Committee on Reactor Safeguards determined that it did not need to review this proposed rule.

Guidance – The staff expects to update NUREG-1556 series “Consolidated Guidance About Materials Licenses” to make changes to conform with this rulemaking effort. To support an accelerated development schedule for this proposed rule, the updates will be made in the next regularly scheduled update of each NUREG-1556 volumes, rather than a separately initiated update. Interim guidance, in the form of frequently asked questions (FAQs), will be added to the NRC's public website. The draft FAQs are available in ADAMS under Accession No. ML22334A029 and in the docket for the proposed rule (NRC-2022-0103).

Costs and Benefits – The NRC's analysis demonstrates that the proposed requirements, if issued by final rule, would result in a net cost of approximately \$23.1 million. The staff is recommending proceeding with rulemaking based on qualitative factors because, if issued, the final rule would address the concern related to an applicant using a fictitious company or providing false information to obtain a valid license or radioactive materials and would prevent individuals without valid licenses from receiving category 3 quantities of radioactive material.

Backfitting and Issue Finality Considerations – The staff has determined that the backfitting provisions in 10 CFR 50.109, 70.76, and 72.62, all entitled “Backfitting,” and the issue finality provisions in 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” do not apply to the changes proposed to 10 CFR Parts 30, 31, 32, and 40. The staff has also determined that the proposed changes to 10 CFR Part 70 would not constitute backfitting because they do not require a modification of, or addition to, a facility's systems, structures, or components or to the procedures or organization required to operate a facility.

Implementation – The NRC licensees who are the subject of this rule would be required to comply with the requirements within 30 days from the effective date of the final rule. The proposed rule seeks comments on the implementation time. Consistent with Management Directive 5.9, “Adequacy and Compatibility of Program Elements for Agreement State Programs,” the Agreement States would be required to adopt compatible regulations within 3 years from the effective date of the final rule.

RECOMMENDATION:

The staff recommends that the Commission approve the enclosed proposed rule for publication in the *Federal Register*. If the Commission approves publication of the proposed rule:

1. The staff will publish the proposed rule in the *Federal Register* for a 75-day public comment period.
2. The staff will submit information collection requirements to the Office of Management and Budget for its review and approval on or immediately after the date of publication of the proposed rule in the *Federal Register*.
3. The Office of Congressional Affairs will inform appropriate congressional committees.
4. The staff will work with the Office of Public Affairs on an appropriate public communication when NRC publishes the proposed rule in the *Federal Register* and will hold a public meeting during the comment period for the proposed rule.

COORDINATION:

The Office of the General Counsel reviewed this package and has no legal objection to the publication of the proposed rule. The Office of the Chief Financial Officer reviewed this package and has no concerns with the estimated resources in Enclosure 3.

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Dorman

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Daniel H. Dorman
Executive Director
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Enclosures:

1. Proposed Rule FRN for Radioactive Source Security and Accountability Rulemaking (Docket ID No. NRC-2022-0103, RIN No. 3120-AK83)
2. Proposed Rule: Radioactive Source Security and Accountability (3150-AK83, NRC-2022-0103) (non-public)
3. Proposed Rule: Radioactive Source Security and Accountability (3150-AK83, NRC-2022-0103) (non-public)

SUBJECT: PROPOSED RULE: RADIOACTIVE SOURCE SECURITY AND ACCOUNTABILITY
 (3150-AK83; NRC-2022-0103) DATED: December 19, 2022

**ADAMS Accession Number: Package ML22277A809, Commission Paper: ML22278A035
 Enclosure 1: ML22278A611, Enclosure 2: ML22277A804, Enclosure 3: ML22277A808**

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