

POLICY ISSUE

(Notation Vote)

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SECY-17-0083

FOR: The Commissioners

FROM: Victor M. McCree
Executive Director for Operations

SUBJECT: RE-EVALUATION OF CATEGORY 3 SOURCE SECURITY AND
ACCOUNTABILITY IN RESPONSE TO SRM-COMJMB-16-0001

PURPOSE:

This paper provides the results of the staff's re-evaluation of Category 3 source security and accountability (re-evaluation) in response to the Staff Requirements Memorandum (SRM) for COMJMB-16-0001, "Proposed Staff Re-Evaluation of Category 3 Source Accountability," dated October 18, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16292A812). This paper describes options developed by the Category 3 Source Security and Accountability Working Group (C3WG) and the U.S. Nuclear Regulatory Commission (NRC) staff's assessment of those options. The NRC staff seeks Commission approval of the resultant staff recommendations for source security and accountability of Category 3 quantities of radioactive material. The recommendations provided in this paper are informed by an analysis of the current threat environment related to radioactive materials, vulnerability and consequence data related to the use of Category 3 quantities of radioactive material, feedback received from extensive stakeholder outreach, and evaluation of the cost and benefit of potential changes.

In accordance with the SRM for SECY-15-0129, "Commission Involvement in Early Stages of Rulemaking," dated February 3, 2016 (ADAMS Accession No. ML15267A716), proposed rule changes identified as a result of this assessment will be provided to the Commission for approval in a rulemaking plan. As discussed in SECY-17-0025, "Update on Source Security

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When separated from Enclosures 4, 6, and 7, this transmittal document is decontrolled.

and Accountability Activities,” dated February 17, 2017 (ADAMS Accession No. ML16344A108), in order to maximize efficiency and minimize the cumulative effects of regulatory changes on radioactive materials licensees, the NRC staff plans to prepare an integrated rulemaking plan following receipt of Commission direction on the recommendations in this paper.

SUMMARY:

In conducting its re-evaluation, the C3WG expanded upon the analysis conducted by two previous NRC/Agreement State working groups (the Enhancements to the Pre-Licensing Guidance Working Group (PLWG), and the License Verification and Transfer of Category 3 Sources Working Group (LVWG)) that were formed to address the vulnerabilities identified by the Government Accountability Office (GAO) in 2016. The C3WG also conducted extensive analysis and outreach to fully assess the regulatory impacts of options considered in this paper. The details of the C3WG re-evaluation activities are provided in the following seven enclosures to this paper: (1) summary of background information that informed the Category 3 re-evaluation and analysis; (2) description of options and associated pros/cons; (3) summary of stakeholder outreach and comments; (4) threat, consequence, and vulnerability assessment (non-public); (5) regulatory impact analysis of the accrued costs and benefits of options; (6) the C3WG’s recommendations and the outcome of Steering Committee and NRC staff deliberations on the C3WG’s recommendations (non-public);¹ and (7) Fiscal Year (FY) 2017, 2018, and 2019 resources (non-public).

After considering the options presented by the C3WG, the NRC staff developed the recommendations presented in this paper, including pursuing rulemaking to revise Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 40, and 70 to require safety and security equipment to be in place for all unknown applicants² prior to issuing a license. The purpose of such a rulemaking would be to help ensure the validity and non-malicious intent of license applicants while presenting a negligible burden to the regulated community. The NRC staff also recommends pursuing rulemaking to clarify the methods for license verification of transfers involving quantities of radioactive material below the Category 2 threshold. Specifically, the NRC staff recommends pursuing revision of 10 CFR Parts 30, 40, and 70 to: (1) require that the oral certification license verification method be confirmed by the use of one of the other acceptable methods in those parts (e.g., copy of license, verification through the regulatory authority); and (2) remove the reporting service license verification method. If approved by the Commission, these changes would be included in the integrated rulemaking effort described in SECY-17-0025.

The NRC staff determined that the threat, vulnerability, and consequence data do not justify the cost associated with certain other regulatory changes described below, and as a result, does not recommend changes to: (a) require license verification through the License Verification System (LVS) or the regulator for transfers of Category 3 quantities of radioactive material; (b) require inclusion of Category 3 sources in the National Source Tracking System (NSTS);

¹ It should be noted that some of the NRC staff recommendations presented in this paper differ from those recommended by the C3WG. Enclosure 6 provides a full discussion of the decision-making process applied in this re-evaluation.

² As used in the “Checklist to Provide a Basis for Confidence that Radioactive Materials will be Used as Specified on the License” (non-public) and the enclosure to SECY-17-0025, an unknown applicant is an entity in which the regulatory agency does not have confidence based on previous regulatory engagement with the applicant, that it will use radioactive materials as specified on a radioactive materials license. The term “unknown applicant” is not, however, currently defined in NRC regulations. Any proposed rulemaking definition would be subject to change during the rulemaking process, if this recommendation to pursue rulemaking is approved by the Commission.

(c) amend security requirements related to aggregation of Category 3 sources to a Category 2 quantity of radioactive material; or (d) limit the quantity of byproduct material in a generally licensed device to ensure the security of radioactive materials. Notwithstanding the NRC staff determination that there is not a cost-justified security basis for limiting the quantity of byproduct material in a generally licensed device, and based on the feedback from external stakeholders and consideration of historical information, the NRC staff intends to conduct further evaluation to ensure that the general license (GL) program continues to provide reasonable assurance that public health and safety will be protected in the current environment. The NRC staff will inform the Commission of the results of this evaluation in FY 2018.

BACKGROUND:

On October 18, 2016, the Commission issued SRM-COMJMB-16-0001, directing the staff to evaluate whether it is necessary to revise NRC regulations or processes governing source protection and accountability with a focus on Category 3 sources.³ The SRM directed the staff to submit a notation vote paper that included the following nine tasks:⁴

- 1) 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 prior to transfer (See Enclosure 2);
- 2) An evaluation of the pros and cons of including Category 3 sources in the NSTS (See Enclosure 2);
- 3) An assessment, based on these evaluations, of these and any additional options that the staff identifies for addressing the source accountability recommendations made by the GAO (See discussion in this paper, Enclosure 2, and Enclosure 6);
- 4) A vulnerability assessment which identifies changes in the threat environment between 2009 and today that argue in favor of or against expansion of the NSTS to include Category 3 sources (See Enclosure 4);
- 5) A regulatory impact analysis of the accrued benefit and costs of the change, to include impacts to the NRC, Agreement States, non-Agreement States, and regulated entities (See Enclosure 5);
- 6) A discussion of potential regulatory actions that would not require changes to NRC regulations that arose from or were considered by the NRC staff working groups, to include changes to guidance, training, or other program improvements such as more closely monitoring the implementation of the NRC staff recommendations using the

³ The International Atomic Energy Agency defines a dangerous source as "a source that could, if not under control, give rise to exposure sufficient to cause severe deterministic [health] effects." A Category 3 source could be considered dangerous if not safely managed or securely protected. However, although improper use of a Category 3 source could lead to permanent injury if a person were in close proximity for longer periods of time, it is unlikely to lead to fatalities. See International Atomic Energy Agency, *Code of Conduct on the Safety and Security of Radioactive Sources* (http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004_web.pdf).

⁴ SRM-COMJMB-16-0001 included a list of tasks numbered from 1 to 7. In subsequent paragraphs of the SRM, direction was given to conduct activities such as considering the risks of aggregation of Category 3 sources into Category 2 quantities of radioactive material and soliciting feedback from stakeholders. In order to ensure appropriate tracking of these activities, the NRC staff numbered them sequentially, with the assessment of aggregation being identified as Task 8 and the solicitation of stakeholder feedback being identified as Task 9.

Integrated Materials Performance Evaluation Program process (See discussion in this paper and SECY-17-0025);

- 7) Any other factors that the NRC staff concludes would bear on the Commission's deliberation on the proposed change (See discussion in this paper and Enclosures 1 through 6);
- 8) An assessment of the risks posed by the aggregation of Category 3 sources into Category 2 quantities when conducting the above evaluations, and consideration of the current views of Agreement State partners (See Enclosures 2, 3, 4, and 6); and
- 9) A collaboration with Agreement State partners, non-Agreement States, regulated entities, public interest groups, industry groups such as those in the medical and industrial fields, and the reactor community, to fully assess the regulatory impact for recommendations (See Enclosure 3).

The SRM also directed staff to use the Congressionally-mandated review of 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," which was completed in December 2016 (ADAMS Accession No. ML16347A398), to inform the staff's evaluation.

The C3WG was formed to conduct the evaluation prescribed in the SRM and included representatives from the Office of Nuclear Material Safety and Safeguards (NMSS), the Office of Nuclear Security and Incident Response (NSIR), the Office of Nuclear Reactor Regulation (NRR), the Office of the General Counsel (OGC), NRC Region I, and Agreement States. The C3WG's charter can be found in ADAMS (Accession No. ML17010A017). The C3WG received direction from a Steering Committee comprised of senior leaders from NMSS, NSIR, NRR, OGC, NRC Region III, and Agreement States. The NRC staff informed the Commission of the formation of the C3WG in SECY-17-0025.

The C3WG's activities expanded upon the analysis conducted by the PLWG and the LVWG,⁵ both of which were formed to address the vulnerabilities identified by the GAO in materials licensing audit GAO-16-330, entitled "NRC Has Enhanced the Controls of Dangerous Radioactive Materials, but Vulnerabilities Remain."

DISCUSSION:

Based on the information obtained from performing the nine SRM tasks, paired with historical information described in Enclosure 1, the C3WG identified four overarching concerns related to the security and accountability of Category 3 quantities of radioactive material:

- **Concern 1:** *The ability to obtain a valid license using a fictitious company or by providing false information;*
- **Concern 2:** *The ability to alter a valid license to obtain more or different radioactive material than authorized or to counterfeit a license to obtain radioactive materials illicitly;*

⁵ A summary of the recommendations made by the PLWG and LVWG, and the results of the Steering Committee's deliberation on these recommendations, was provided in SECY-17-0025.

- **Concern 3:** *The ability to accumulate or aggregate Category 3 sources to a Category 2 quantity of radioactive material requiring enhanced security; and*
- **Concern 4:** *The limited accountability, lack of pre-licensing evaluations, and lack of routine oversight of Category 3 sources contained within generally licensed devices.*

As described below, the C3WG and the NRC staff determined that Concern 1 was fully addressed by the recommendations of the PLWG. As such, the C3WG focused its efforts on developing options to address Concerns 2 through 4.⁶ For each of those concerns, the options considered by the C3WG to address the concern, and the resulting NRC staff recommendations are summarized below. Those factors that the NRC staff concludes would bear on the Commission's deliberation on recommendations presented in this paper are summarized in the discussion of each concern presented below. Detailed discussions related to the factors considered by C3WG and NRC staff in this re-evaluation are provided in the seven Enclosures to this paper.

Concern 1: The ability to obtain a valid license using a fictitious company or by providing false information

Concern 1 is germane to licensing processes used to ensure the validity of license applicants and their intent to use radioactive materials as specified on the license application. The PLWG evaluated this concern and developed both rulemaking and non-rulemaking-related recommendations to improve NRC and Agreement State licensing processes. Specifically, the PLWG recommended rulemaking to amend 10 CFR Parts 30, 40, and 70 to require safety and security equipment to be in place before granting a license for an unknown entity. This requirement would apply to all unknown entities applying for a radioactive material license regardless of the quantity of licensed material requested (i.e., all quantities and types of radioactive material). The PLWG also identified several non-rulemaking-related recommendations to enhance licensing guidance (including guidance on pre-licensing evaluations⁷) and processes; these recommendations are described in an action plan (non-public) that is currently being implemented by the NRC staff.

The C3WG determined that the rulemaking and non-rulemaking-related recommendations made by the PLWG, and endorsed by its Steering Committee, fully addressed Concern 1. The non-rulemaking-related recommendations – which include enhancements to pre-licensing site visits, licensing guidance, and inspector and license reviewer training – would enhance the NRC's and Agreement States' ability to prevent individuals with malevolent intent from obtaining radioactive material through the licensing process. This view was endorsed by the C3WG

⁶ For Concerns 2 through 4, the C3WG considered a risk-informed, graded approach to the security and accountability of Category 3 sources, because the regulatory thresholds of risk significance are at the Category 1 and Category 2 levels. Exposure to Category 1 and Category 2 radioactive sources could lead to deterministic health effects including death or permanent injury of an individual; the key difference between these categories is the timeframe for the endpoint (minutes to hours for Category 1 versus hours to days for Category 2). Improper use of Category 3 sources is unlikely to lead to fatalities, but could lead to permanent injury if a person were in close proximity for longer periods of time. Therefore, increased vigilance and regulatory control are necessary to prevent exposure from a Category 1 and/or 2 source/quantity of radioactive material, and a risk-informed, graded approach to ensure safety of Category 3 sources/quantities of radioactive material is appropriate.

⁷ A pre-licensing evaluation entails the conduct of a pre-licensing assessment and site visit.

Steering Committee, and subsequently received support from the NRC staff.⁸ The non-rulemaking-related recommendations are being pursued through an action plan, and their implementation will be incorporated into the Integrated Materials Performance Evaluation Program (IMPEP) to ensure implementation throughout the National Materials Program. Further specificity regarding the non-rulemaking-related recommendations is contained in SECY-17-0025.

The rationale supporting the NRC staff's recommendation to pursue potential rulemaking to require safety and security equipment to be in place before granting a license for an unknown entity is:

- 1) An applicant's willingness and up-front investment to acquire the necessary equipment and construct the necessary facilities to implement a safe and secure radiation protection program would provide increased confidence that the applicant will use the radioactive materials as intended; and
- 2) While the NRC does not require it, a majority of Agreement States already require new applicants to acquire the necessary equipment and construct the necessary facilities prior to receiving a radioactive material license. Therefore, implementing this recommendation would ensure consistency from a national materials program perspective and would only affect those Agreement States that do not currently require that safety and security equipment be in place.

In estimating the costs for the recommended change, the C3WG assumed that applicants would not incur any additional costs beyond those that would already be required to conduct licensed activities (e.g., purchase of equipment for source storage). However, applicants would incur costs sooner because the safety and security equipment would have to be in place earlier in the process. As stated in Footnote 8, if rulemaking is approved by the Commission, staff would consider specific aspects associated with requiring the completion of facilities and acquisition of equipment prior to license issuance as part of the rulemaking process.

The C3WG also assumed that the NRC and Agreement States would incur initial costs to perform rulemaking and update guidance, and recurring costs to perform additional pre-licensing visits to ensure that safety and security equipment is in place before granting a license to an unknown applicant (see Enclosure 5 for specific cost estimates). The substantial benefits of implementing this recommendation were determined to be cost-justified by the NRC staff because, if implemented, the rulemaking would provide additional assurance of the validity of unknown applicants prior to authorizing them to possess any quantity of licensed radioactive material and would eliminate the acceptance of written and oral assurances regarding facility completeness and required security and safety equipment. The changes would also align the

⁸ In response to the direction in SRM-COMJMB-16-0001 to provide a notation vote paper to the Commission providing the results of the NRC staff's evaluation of whether it is necessary to revise regulations or processes governing source protection and accountability to continue to ensure adequate protection of public health and safety, the NRC staff is including recommendations related to pursuing potential rulemakings. If the Commission approves these recommendations, then the NRC staff, in accordance with SRM-SECY-15-0129, will submit a rulemaking plan to the Commission for approval to initiate these rulemakings. Specifics regarding these potential rulemakings would be further evaluated in the rulemaking process. For example, if rulemaking is approved by the Commission, staff would consider the definition for "unknown applicant," as noted above, as well as NRC policies and decisions that have not previously required completion of facilities and acquisition of equipment prior to license issuance. As part of this effort, the staff may also consider the need to establish mechanisms for applicants to demonstrate that they meet the requirements for a license prior to license issuance in order to obtain financing to purchase or lease facilities and safety and security equipment.

NRC with the majority of Agreement States which do not issue a license prior to facility completion.

Concern 2: The ability to alter a valid license to obtain more or different radioactive material than authorized or to counterfeit a license to obtain radioactive materials illicitly

To address this concern, the C3WG considered options for license verification, not only for Category 3 quantities of radioactive material, but also for all licenses authorizing possession of radioactive material. The C3WG considered licenses for all quantities of radioactive material because in past investigations and audits, GAO was able to demonstrate that licenses not subject to verification through regulatory authority are vulnerable to alteration or counterfeiting. The C3WG also reviewed the existing methods of license verification for transfers of radioactive material below the Category 2 threshold. These methods include use of: (1) a current copy of the transferee's specific license or registration certificate; (2) a written certification provided by the transferee; (3) oral certification from the transferee (for emergency shipments); (4) information compiled by a reporting service; or (5) confirmation from the Commission or the licensing agency of an Agreement State that the transferee is licensed to receive the radioactive material. The C3WG developed and considered the following six options to address this concern:

Option 1: No action

Licensees transferring any quantity of radioactive materials below the Category 2 threshold will continue to use the verification methods listed in 10 CFR 30.41, 40.51, and 70.42 before transferring any materials.

Option 2: Require verification of licenses authorizing possession of Category 3 quantities of radioactive material through LVS or the regulatory authority

Licensees transferring Category 3 quantities of radioactive material would be required to verify licenses through LVS or the regulatory authority. Agreement States that do not use the Web-Based Licensing (WBL) System as their license tracking system would need to either voluntarily provide their licenses authorizing Category 3 quantities of radioactive material to the NRC to facilitate verification through LVS, or perform manual license verification.

Option 3: Require only manufacturers and distributors to verify licenses authorizing possession of Category 3 quantities of radioactive material through LVS or the regulatory authority

License verification through LVS or the regulatory authority would only be required for transfers of Category 3 quantities of radioactive material from manufacturers and distributors (M&Ds) to customer licensees. Agreement States that do not use WBL as their license tracking system would need to either voluntarily provide their licenses authorizing Category 3 quantities of radioactive material to the NRC to facilitate verification through LVS, or perform manual license verification.

Option 4: Require verification of all licenses through LVS or the regulatory authority

Licensees transferring any quantity of radioactive material would be required to verify licenses through LVS or the regulatory authority. Agreement States that do not use WBL as their license tracking system would need to either voluntarily provide all of their licenses to the NRC to facilitate verification through LVS, or perform manual license verification.

Option 5: Require verification of licenses authorizing possession of Category 3 quantities of radioactive material through LVS or the regulatory authority and authenticate⁹ all licenses authorizing limits below the Category 3 threshold through a new system or the regulatory authority

Licensees transferring Category 3 quantities of radioactive material would be required to verify licenses through LVS or the regulatory authority. Licensees transferring any quantities of radioactive material below the Category 3 threshold would be required to authenticate certain information on a recipient's license through a new system or through the regulatory authority. Agreement States that do not use WBL as their license tracking system would need to either voluntarily provide all of their licenses to the NRC to facilitate verification through LVS and authentication through the new system, or perform manual license verification/authentication.

Option 6: Authenticate all licenses authorizing possession limits below the Category 2 threshold through a new system or the regulatory authority

Licensees transferring any quantity of radioactive material below the Category 2 threshold would be required to authenticate certain information on a recipient's license through a new system or the regulatory authority. Agreement States that do not use WBL as their license tracking system would need to either voluntarily provide all of their licenses to the NRC to facilitate license authentication through the new system, or perform manual license authentication.

For Options 2, 4, 5, and 6, the C3WG considered reducing the license verification/authentication frequency for transfers to established licensees (i.e., M&Ds, reactors, fuel cycle facilities, waste disposal facilities) as a result of stakeholder feedback (see Enclosure 3). With a reduced frequency, licensees transferring any quantity of radioactive material to an established licensee would only have to verify/authenticate a license once a year at the most or before transferring the material if transfers occur less frequently than once per year. Less frequent license verifications/authentications for transfers to established entities would result in reduced annual operating costs for industry. For more information on estimated costs for industry, see Enclosure 5.

Stakeholder Feedback and Historical Considerations Related to Concern 2

Two stakeholders stated they could see a benefit to license verification through LVS or the regulatory authority. However, most stakeholders commented that in spite of GAO's findings, the NRC has not provided a clear safety and security basis for an expansion of the LVS, beyond Category 1 and Category 2 quantities of radioactive material. Several stakeholders within the medical community commented that such an expansion would only add administrative burden (thus increasing medical care costs) with no real benefit to security. One Agreement State commented that the root concern is the ability of a licensee with nefarious intent to perform illegal license alterations so that they could acquire radioactive material for which they are not authorized, not that the current regulatory requirements are inadequate (see Enclosure 3). To address this challenge, the Agreement State recommended that the NRC consider options that will make licenses more difficult to alter or forge.

⁹ License authentication would be a process similar to license verification and would involve the review of limited license information before a transfer of radioactive material can occur. The review would be intended to provide reasonable assurance that a license is valid. The review would involve the corroboration of the licensee name, license address, license number, license amendment or issue date, and the address where the material is authorized to be stored. It would not involve the review of any isotopes or quantities.

In 2008, the Materials Program Working Group (MPWG) considered anti-counterfeiting measures to improve the security and authenticity of physical, paper licenses and concluded that there was little benefit to invest time and resources in developing methodologies to preclude the ability to counterfeit a physical, paper license. See Enclosure 1 for additional background on the MPWG's evaluation of anti-counterfeiting measures. The C3WG reconsidered the use of anti-counterfeiting measures for paper licenses and came to the same conclusion as the MPWG, and in addition, determined that anti-counterfeiting measures for paper licenses are not effective when using electronic means for license transmittal and/or verification. As such, the C3WG did not propose anti-counterfeiting measures as an option.

NRC Staff Evaluation of Options to Address Concern 2

After carefully considering all options described above, the NRC staff determined that there was insufficient basis to require license verification through LVS or the regulatory authority for transfers involving Category 3 quantities of radioactive material. The rationale supporting the NRC staff's recommendation to pursue Option 1 (no action) is:

- 1) Current threat, vulnerability, and consequence data do not support additional security and accountability controls for Category 3 sources covered under a specific license. (see Enclosure 4); and
- 2) The enhanced pre-licensing processes recommended by the PLWG provide appropriate controls to verify the identity of unknown applicants and assess their readiness to use radioactive material as intended.

As such, the NRC staff concluded that the costs to both the regulatory authorities and licensee population were not justified in the absence of current intelligence information and operating experience to demonstrate a need for a change to existing license verification requirements. See Enclosure 5 for specific cost estimates.

However, the NRC staff did determine that certain updates to existing license verification methods for transfers involving quantities of radioactive material below Category 2 thresholds may be warranted in order to ensure that available license verification methods are clear and provide an acceptable level of certainty that licensees requesting radioactive material are authorized to do so. In order to achieve this end, the NRC staff recommends pursuing amendments to 10 CFR Parts 30, 40 and 70 to: (1) update the oral certification method to require that the certification be followed up with confirmation by the use of one of the other acceptable methods in those parts, and (2) remove the unused method of obtaining other sources of information compiled by a reporting service from official records. The rationale for these recommendations is as follows:

- 1) The oral certification method for emergency shipments described in 10 CFR 30.41(d)(3), 40.51(d)(3), and 70.42(d)(3) currently allows the transferor to accept oral certification provided by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred; and specifying the license or registration certificate number, issuing agency, and expiration date. The regulations require the oral certification to be confirmed in writing within 10 days. The regulations do not require that the certification be confirmed by the use of one of the other acceptable verification methods in those parts (e.g., copy of license, verification through the regulatory authority). The NRC staff determined that requiring one of the other acceptable verification methods should be included within the

regulation to prevent misuse of this provision and make it consistent with the oral certification provision for license verification of transfers involving Category 1 and Category 2 quantities of radioactive material in 10 CFR 37.71(c).

- 2) The regulations in 10 CFR 30.41(d)(4), 40.51(d)(4), and 70.42(d)(4) currently allow the transferor to obtain other sources of information compiled by a reporting service from official records of the Commission or the licensing agency of an Agreement State to confirm the identity of licensees and the scope and expiration dates of licenses and registration. The C3WG was unable to identify any current reporting services in existence or previously existing reporting services that performed this function, and does not have reasonable assurance that such a service could adequately fulfill current safety or security requirements without having access to information that is restricted to regulatory authorities. Therefore, the NRC staff recommends the removal of this obsolete license verification method.

The NRC staff estimates that there would be negligible cost associated with making these administrative updates to existing license verification methods in 10 CFR Parts 30, 40 and 70, because the scope of the changes would be small and would be addressed in conjunction with the integrated rulemaking activities described in SECY-17-0025.

Finally, the NRC staff determined that increasing the number of Agreement States using WBL as their license tracking system would reduce the burden of providing the NRC staff with license updates for inclusion in WBL. This would benefit both the NRC, which is responsible for incorporating license images into the system upon receipt from Agreement States, and the Agreement States themselves, who submit the licenses. Increasing the use of WBL by Agreement States would enhance the accuracy of license data within the system and would eliminate the time and costs associated with providing license amendments to the NRC staff for the loading of those licenses into WBL. It would also reduce the use of a manual process for license verifications that cannot be completed through LVS (i.e., due to the latest license amendment not being readily available in the system) since licenses would be instantly available for license verification through LVS. As a result, the NRC staff plans to continue its efforts to encourage Agreement States to adopt WBL as their license tracking system. For instance, the NRC staff has, and continues to, implement system changes to WBL to provide features that better accommodate the needs of Agreement State users, such as the addition of customizable modules. The NRC staff also performs outreach to educate Agreement States on WBL and to ensure their awareness of available NRC staff support for those desiring to transition to full use of the system.

Concern 3: The ability to accumulate or aggregate Category 3 sources to a Category 2 quantity of radioactive material requiring enhanced security

In developing options to address this concern, the C3WG took into consideration both the results of the 10 CFR Part 37 program review and the recommendations made in GAO-16-330. First, the NRC staff in its 10 CFR Part 37 program review considered the definition of aggregation as it applies to lower category radioactive sources, including well logging sources, and concluded that the requirements of 10 CFR Parts 20 and 37 provide reasonable assurance of preventing the theft of lower category radioactive sources in storage and that the additional modality-specific requirements (e.g., those contained in 10 CFR Part 39 for well logging sources) add appropriate control for sources regardless of activity (see Enclosure 1). Second, in GAO-16-330, the GAO recommended that the NRC require the addition of all Category 3 sources to NSTS to facilitate oversight of the potential for aggregation of sources to a Category

2 quantity of radioactive material. With those considerations in mind, the C3WG developed and considered the following five options:

Option 1: No action

Category 3 sources would not be reported to the NSTS.

Option 2: Require licensees to report transactions involving Category 3 sources to the NSTS with the same reporting requirements as Category 1 and 2 sources

Transactions involving Category 3 sources would be reported to the NSTS with the same reporting requirements as Category 1 and Category 2 sources (by close of business the following day).

Option 3: Require licensees to report transactions involving Category 3 sources to the NSTS with changes to reporting requirements and changes to the NSTS

The reporting of all transactions involving Category 1, 2, or 3 sources would be required before radioactive material is physically shipped. In addition, NSTS would be modified to interact with WBL to calculate whether the pending source transfer would put the receiving licensee over its possession limit. The pending source transfer would also count against the receiving licensee's inventory even before the shipment has been received to prevent additional shipments from occurring simultaneously and allowing a licensee to obtain more material than authorized. This modification to NSTS, if pursued, would require conforming changes to NSTS requirements for Category 1 and Category 2 sources.

Option 4: Require licensees to report inventories of Category 3 sources to the NSTS annually

Licensees possessing Category 3 sources would report their inventory to the NSTS annually, but would not report on a transactional basis. Requirements for reporting Category 1 and Category 2 sources to NSTS would not change.

Option 5: Require licensees that have the potential to aggregate Category 3 sources into a Category 2 quantity of radioactive material¹⁰ to implement Subpart B of 10 CFR Part 37

The licensee would be required to develop an access authorization program, including background checks on all individuals who would have unescorted access to radioactive materials, based upon license possession limits – not actual possession. This would ensure that personnel with unescorted access to the radioactive material are trustworthy and reliable in the case where the licensee inadvertently aggregates to a Category 2 quantity of radioactive material, generally through a failure of operational controls.

Stakeholder Feedback Related to Concern 3

The majority of entities who submitted comments opposed expanding NSTS and 10 CFR Part 37 to include Category 3 sources. Overall, commenters stated that the NRC has not provided a clear safety and security basis for an expansion of NSTS. See Enclosure 3 for additional details on stakeholder feedback on this concern.

¹⁰ The C3WG did not consider aggregation of below Category 3 sources to a Category 2 quantity because the C3WG determined that the likelihood of that occurring was low and it would take such a large number of Category 4 and 5 sources to aggregate to a Category 2 quantity of radioactive material that it would not be feasible to obtain them.

NRC Staff Evaluation of Options to Address Concern 3

After carefully considering the options described above, the NRC staff determined that no regulatory changes should be pursued (Option 1). This recommendation is based upon the following rationale:

- 1) Current threat, vulnerability, and consequence data do not support additional security and accountability controls for Category 3 sources covered under a specific license. (see Enclosure 4);
- 2) Operating experience does not include any instances of a licensee accumulating or aggregating Category 3 sources to a Category 2 quantity of radioactive material for malevolent purposes;
- 3) Based on the 10 CFR Part 37 program review, the NRC staff concluded that the requirements of 10 CFR Parts 20 and 37 provide reasonable assurance of preventing the theft of lower category radioactive sources in storage, and that the additional modality-specific requirements (e.g., those contained in 10 CFR Part 39 for well logging sources) add appropriate control for sources regardless of activity;
- 4) The NSTS was designed and deployed as a secure registry of risk-significant sources held nationally (see Enclosure 1), and consequently, does not provide real-time information or serve to control commerce;¹¹ and
- 5) Routine inspections of licensees provide a mechanism to ensure that security requirements are being met, regardless of the quantity of radioactive material possessed.

As such, the NRC staff concluded that the costs to both the regulatory authorities and licensee population were not justified in the absence of current intelligence information and operating experience to demonstrate a need for the inclusion of Category 3 sources in NSTS or the amendment of security requirements related to aggregation of Category 3 sources to a Category 2 quantity of radioactive material. See Enclosure 5 for specific cost estimates.

Concern 4: The limited accountability, lack of pre-licensing evaluations, and lack of routine oversight of Category 3 sources contained within generally licensed devices

The C3WG re-evaluated the security and accountability of generally licensed devices as part of the broader evaluation of source security and accountability of Category 3 quantities of radioactive material. The options considered by the C3WG to address this concern were limited

¹¹ Information is submitted by the licensee to NSTS after the transaction has occurred (i.e., in accordance with the requirements in 10 CFR Part 20, reports of transactions such as source manufacture, transfer, or receipt must be submitted by the close of the next business day after the transaction occurs). Therefore, in the absence of changes to reporting requirements and changes to NSTS (as described in Option 3 for this concern), NSTS does not have the capability to identify all shipments that may result in the accumulation of lower category sources that could be aggregated into a Category 2 or higher quantity of radioactive material, nor does NSTS have the ability to prevent the transfer of sources as part of the license verification process in these instances.

only to Category 3 sources. The C3WG developed and considered the following four options for this concern:

Option 1: No action

Category 3 generally licensed devices would continue to be subject to registration requirements in 10 CFR 31.5(c)(13) or compatible Agreement State regulations. This registration process includes an annual update of the devices in the possession of the general licensee. General licensees are required to conduct and maintain records of leak tests and shutter tests, report lost or stolen devices and incidents involving their devices to their regulatory authority, and transfer the device only to authorized entities. The NRC does not conduct routine inspections of general licensees, but will conduct reactive inspections as warranted. A minority of Agreement States have an inspection program for their general licensees.

Option 2: Require M&Ds to notify the regulator prior to initially transferring a Category 3 generally licensed device in order to allow for the performance of a pre-licensing evaluation¹²

The notification by the M&Ds to the regulator would change from reporting quarterly (after the fact) to prior to the initial transfer of the Category 3 generally licensed device. The timeframe for reporting would allow for the NRC and Agreement States to perform a pre-licensing evaluation.

Option 3: Require M&Ds to notify the regulator prior to initially transferring a Category 3 generally licensed device in order to allow for the performance of a pre-licensing evaluation and implementation of an inspection program

In addition to the notification and timeframe changes discussed in Option 2, the NRC and Agreement States would inspect facilities possessing Category 3 generally licensed devices once every 5 years.

Option 4: Require general licensees possessing devices containing Category 3 sources to be specifically licensed

Generally licensed devices containing Category 3 sources would be converted to specific licenses. The NRC regulations would be amended to limit the quantity of certain byproduct material allowed in a generally licensed device to below Category 3 thresholds; facilities with devices containing byproduct material at or above this limit would be required to obtain a specific license. These licensees would be required to implement and maintain a radiation protection program with a radiation safety officer and authorized users. The NRC and Agreement States would perform a pre-licensing evaluation of unknown applicants and then inspect them on a regular basis.

Stakeholder Feedback Related to Concern 4

The majority of stakeholders commented that if the NRC were to expand LVS, NSTS, and 10 CFR Part 37 to include Category 3 sources, then all Category 3 devices should be specifically licensed. States also commented that it is difficult to conduct oversight activities on

¹² While a pre-licensing evaluation (i.e., assessment and site visit) would be conducted as part of the application review process for a specific license, a different approach would be applied to general licensees. Because a customer who orders a device from an M&D becomes a general licensee by possession of the device, the GL process does not include a formal application review. Consistent with this framework, an M&D would notify the regulatory authority 90 days prior to the initial transfer of a Category 3 generally licensed device to a customer. This time would allow the regulatory authority to conduct a pre-licensing evaluation.

general licensees under the current regulatory infrastructure. In particular, States expressed concern that instituting a new regulatory framework that does not include specifically licensing Category 3 devices (i.e., Options 2 and 3 above) would result in increased costs to the Agreement State programs without an ability to offset the costs through fees. See Enclosure 3 for additional details on stakeholder feedback related to this concern.

NRC Staff Evaluation of Options to Address Concern 4

After carefully considering the options described above, the NRC staff determined that no regulatory changes should be pursued at this time (Option 1).¹³ This recommendation is based upon the following rationale:

- 1) Current threat, vulnerability, and consequence data do not indicate the need for regulatory changes to ensure the security of these materials. Specifically, there has been no appreciable change in the threat environment that would warrant additional security and accountability controls for these sources since the NRC staff last proposed that specific licensing requirements be imposed on generally licensed devices in 2010;¹⁴ and
- 2) Operating experience does not include any instances of a licensee accumulating or aggregating Category 3 generally licensed devices/sources to a Category 2 quantity of radioactive material for malevolent purposes.

The NRC staff determined that changes to the provisions of the GL program were not warranted on the basis of security and accountability. However, as a result of: (1) potential health and safety bases for changes to the GL program that were identified by the NRC staff; (2) feedback received from external stakeholders; and (3) the historical information described in Enclosure 1 (which includes previous Commission direction to consider the possible need for modest changes to the program, such as implementation of inspection attributes), the NRC staff intends to conduct further evaluation to verify that the existing GL program continues to ensure the protection of public health and safety in the current environment. The NRC staff will inform the Commission of the results of this evaluation in FY 2018.

Coordination with Agreement States

The C3WG and its Steering Committee included representatives from the Agreement States. Additionally, 13 Agreement States and the Organization of Agreement States (OAS) provided written responses to the NRC's January 9, 2017, *Federal Register* Notice (82 FR 2399). A number of Agreement States also provided comments during webinars, including three Agreement States that had not provided written comments. A summary of the Agreement State and OAS comments can be found in Enclosure 3. The C3WG also provided the Agreement States with a briefing on the status of its activities on May 10, 2017. This briefing included a discussion of the concerns, options, and proposed recommendations. In addition, the C3WG provided updates on the status of the C3WG activities to the Agreement States during monthly conference calls.

¹³ The recommendation to maintain the status quo (i.e., take no action (Option 1)) is based on an evaluation of the need for regulatory changes to ensure the security and accountability of Category 3 generally licensed devices. A full evaluation of the safety basis for potential program changes was not completed by the C3WG due to time and scope constraints.

¹⁴ SECY-10-0105, "Final Rule: Limiting the Quantity of Byproduct Material in a Generally Licensed Device" (ADAMS Accession No. ML100690238)

CONCLUSION:

The NRC staff considered options to address four overarching concerns related to the security and accountability of Category 3 quantities of radioactive material.

- For Concern 1 (*The ability to obtain a valid license using a fictitious company or by providing false information*), the NRC staff determined that the rulemaking and non-rulemaking-related recommendations made by the PLWG adequately address the concern and should be pursued. Specifically, the NRC staff determined that the recommendation to require safety and security equipment to be in place prior to granting a license to an unknown entity was cost-justified based on the substantial benefit provided to security - namely that the rulemaking would provide greater assurance of the validity of unknown applicants prior to them receiving authorization to possess radioactive materials. In addition, the NRC staff has implemented an action plan for the PLWG's non-rulemaking-related recommendations, and will monitor implementation of program changes through the IMPEP.
- For Concern 2 (*The ability to alter a valid license to obtain more or different radioactive material than authorized or to counterfeit a license to obtain radioactive materials illicitly*), the NRC staff determined that the results of the threat assessment, vulnerability evaluation, and consequence analysis, as well as the review of actual reported incidents do not provide a basis to require license verification through LVS or the regulatory authority for Category 3 quantities of radioactive material, or to require license authentication for all quantities of material. Furthermore, the NRC staff concluded that the enhanced pre-licensing processes recommended by the PLWG would provide appropriate controls to verify the identity of unknown applicants and assess their readiness to use radioactive material as intended.
- For Concern 3 (*The ability to accumulate or aggregate Category 3 sources to a Category 2 quantity of radioactive material requiring enhanced security*), the NRC staff concluded that there is no threat, vulnerability, or consequence information that would justify the costs associated with the inclusion of Category 3 sources in the NSTS or through imposing additional physical security measures on licensees possessing Category 3 sources.
- Finally, for Concern 4 (*The limited accountability, lack of pre-licensing evaluations, and lack of routine oversight of Category 3 sources contained within generally licensed devices*), the NRC staff determined that changes to the provisions of the GL program were not warranted on the basis of security and accountability at this time; however, further evaluation of the existing GL program will be conducted by the NRC staff to ensure that it continues to provide protection of public health and safety in the current environment.

In its assessment of options to address Concern 2, the NRC staff determined that efforts to encourage the Agreement States to adopt WBL are beneficial for the purposes of minimizing burden to the regulatory authorities and enabling license verification through LVS, and as such, will continue to be pursued. The NRC staff concluded that some of the existing methods for license verification for transfers involving Category 3 and lower quantities of radioactive material in 10 CFR 30, 40, and 70 lack the needed specificity or are outdated. As a result, the NRC staff determined that rulemaking should be pursued to ensure that available license verification

methods are clear and provide an acceptable level of certainty that licensees requesting radioactive material are authorized to do so.

COMMITMENTS:

Listed below are the commitments made by the NRC staff in conjunction with this paper.

1. If approved by the Commission, the NRC staff will include changes listed in the Recommendations section below in the integrated rulemaking plan described in SECY-17-0025.
2. Conduct additional technical evaluation to verify that the existing GL program continues to provide protection of public health and safety in the current environment, and report the results of the evaluation to the Commission in FY 2018. Should the evaluation result in a determination that regulatory changes to the GL program are needed to provide reasonable assurance that public health and safety will be maintained, the NRC staff will include such rulemaking recommendations as part of the integrated rulemaking plan described in SECY-17-0025. In that SECY paper, the NRC staff anticipated that it would submit the subject rulemaking plan for Commission consideration 3 months following receipt of Commission direction on this paper. In order to allow for the potential to include any regulatory changes that may be identified as part of the GL safety basis re-evaluation initiative in the integrated rulemaking effort, staff now anticipates that it will submit the integrated rulemaking plan 5 months following receipt of Commission direction on this paper.

RECOMMENDATIONS:

In response to the Commission's direction to provide a notation vote paper that provides the results of the NRC staff's evaluation of whether it is necessary to revise regulations or processes governing source protection and accountability to continue to ensure adequate protection of public health and safety, the NRC staff recommends that the Commission:

1. Approve pursuing potential rulemaking to amend 10 CFR Parts 30, 40, and 70 to require safety and security equipment to be 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. Not direct the NRC staff to amend regulations to: (a) require license verification through LVS or regulatory authorities for transfers of Category 3 quantities of radioactive material; (b) require inclusion of Category 3 sources in NSTS; (c) impose security requirements to prevent aggregation of Category 3 sources to a Category 2 quantity of radioactive material; or (d) limit the quantity of byproduct material in a generally licensed device to ensure the security of radioactive materials.
3. Approve pursuing potential rulemaking for 10 CFR Parts 30, 40, and 70 to 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.

If approved by the Commission, recommendations 1 and 3 would be included in the integrated rulemaking plan described in SECY-17-0025, which would be provided to the Commission 5 months following receipt of Commission direction on this paper. In accordance with SRM-SECY-15-0129, the rulemaking plan will be submitted to the Commission for approval to initiate these rulemakings.

RESOURCES:

If approved by the Commission, implementation of the recommendations and commitments identified in this paper will entail the expenditure of resources allocated to the “Integrated Source Security and Accountability Rulemaking,” which is a planned rulemaking activity.¹⁵ Estimated resources for this rulemaking are included in Enclosure 7.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections. The Office of the Chief Financial Officer has also reviewed this paper for resource implications and has no objections.

/RA/

Victor M. McCree
Executive Director
for Operations

Enclosures:

1. Summary of Background Information that Informed Category 3 Re-Evaluation and Analysis
2. Description of Options and Associated Pros/Cons
3. Summary of Stakeholder Outreach and Comments
4. Threat, Consequence, and Vulnerability Assessment (non-public)
5. Regulatory Impact Analysis of the Accrued Costs and Benefits of Options
6. Category 3 Source Security and Accountability Working Group Recommendations and the Outcome of Steering Committee and NRC Staff Deliberations on the Working Group’s Recommendations (non-public)
7. Fiscal Year 2017, 2018, and 2019 Resources (non-public)

¹⁵ <https://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/active/RuleIndex.html>

RE-EVALUATION OF CATEGORY 3 SOURCE SECURITY AND ACCOUNTABILITY IN
RESPONSE TO SRM-COMJMB-16-0001, DATED AUGUST 18, 2017.

SRM-CMJMB16-0001-1 ADAMS Accession No.: ML17188A249 (P)

OFFICE	MSTR/SMPB	MSTR/ ASPB	MSTR/SMPB	NMSS/MSTR	NSIR	NRR	RI
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DATE	7/10/17	7/10/17	7/10/17	7/10/17	7/20/17	7/20/17	7/14/17
OFFICE	RIII	RIV	CFO	OGC	Tech Ed	NMSS	EDO
NAME	JGiessner for CPederson	SMorris for KKennedy	CNelson-Wilson for MWylie	LBaer for MDoane	WMoore	MDapas	VMcCree
DATE	7/19/17	7/18/17	7/17/17	7/28/17	7/31/17	8/15/17	8/18/17

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