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MEMORANDUM TO: Kevin Williams, Director
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

David Crowley, Chair
Organization of Agreement States

FROM: Tomas Herrera, Co-Chair *Tomas Herrera* Signed by Herrera, Tomas
on 04/30/21
Materials Safety and Tribal Liaison Branch
Office of Nuclear Material Safety
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General License Re-Evaluation Working Group
and General License Modernization Working Group

SUBJECT: SUMMARY OF THE EVALUATION OF THE NRC'S GENERAL
LICENSE PROGRAM BY THE GENERAL LICENSE RE-
EVALUATION WORKING GROUP AND GENERAL LICENSE
MODERNIZATION WORKING GROUP

PURPOSE

The General License Re-Evaluation Working Group (GLWG) and General License Modernization Working Groups (GLMWG) were established to review the U.S Nuclear Regulatory Commission's (NRC's) General License (GL) Program. The GLWG was established to ensure that the NRC's GL program continues to provide reasonable assurance that public health and safety will be protected in the current environment. The GLMWG was established to determine (1) should the National Materials Program continue to have a GL program, and if yes, (2) evaluate potential changes to the GL program based on a risk-informed, transformative approach. The charters for the working groups are in the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession Nos. ML18039A443 and ML20002C258 respectively. This memorandum summarizes the areas reviewed by the working

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groups and the recommendations. The memorandum also documents the Office of Nuclear Materials Safety and Safeguards (NMSS) position on the recommendations made by the working groups.

BACKGROUND

In SECY-17-0083, "Re-Evaluation of Category 3 Source Security and Accountability in Response to SRM-COMJMB-16-000-1," dated August 18, 2017 (ADAMS ML17188A249), the NRC staff committed to conduct a further evaluation to ensure the GL program continues to provide reasonable assurance that public health and safety will be protected in the current environment.

In response, the staff formed two working groups, in succession to one another, to conduct the evaluation as stated in SECY-17-0083. The working groups included representatives from NMSS, NRC Regions, the Office of General Counsel, and Agreement States. The working groups' charters can be found in ADAMS (Accession Nos. ML18039A443 and ML20002C258).

The working groups evaluated the GL program in order to determine whether public health and safety were being met in the current environment and to determine whether the efficiency or effectiveness of the GL program could be improved using a risk-informed approach. The first working group, the GLWG, convened to focus on public health and safety issues and identified that there was no available information to indicate that public health and safety was not being maintained through current program activities. However, the GLWG did identify potential areas where the GL program could be improved with regard to accountability for certain devices, while potentially reducing regulatory burden by alleviating reporting requirements for lower risk uses of generally licensed devices.

RECENT HISTORY OF THE GENERAL LICENSE PROGRAM

The GL program has remained relatively unchanged since the implementation of the annual registration program in 2001. The working groups did review the most recent activity in the GL program.

The current regulatory requirements for higher risk, generally licensed devices in § 31.5 of Title 10 of the *Code of Federal Regulations* (10 CFR) is based on the final rule published on December 18, 2000 (65 FR 79162). The rule was issued so that the NRC could better track general licensees and the generally licensed devices they possess that present a higher risk of exposure to the public or property damage in the case of loss of control (compared to other generally licensed devices), and to better ensure that these general licensees are aware of and understand the requirements for the possession of devices containing byproduct material. This rule was informed by NUREG-1551, "Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices" published in October 1996 (ADAMS Accession No. ML20134N331).

In 1997, NMSS formed the Nuclear Byproduct Material Risk Review Group (Risk Task Group) to focus on byproduct materials with two major goals. First, to develop and document a technical basis for a risk-informed approach to the regulation of nuclear byproduct materials that resulted in the development and implementation of a risk analysis methodology appropriate to the various byproduct materials systems, this was published in a non-public report. The second goal was to develop plans for a graded approach to nuclear byproduct material regulation based on risk information. The Risk Task Group, along with Brookhaven National Laboratory,

produced a report in February 2002 that looked at eight case studies and related risk assessment to risk inform the materials and waste arenas (ADAMS Accession No. ML022130067). The report concluded, as a result of integrating the results of the eight case studies along with the other risk-informing activities and studies, that risk information can be valuable and beneficial to the regulatory process and informs the need for methods, data, and guidance in this area. Of particular note to the work of the GLWG and GLMWG was the case study of gas chromatographs (GCs), a device generally licensed and viewed as low risk. The GC case study demonstrated that adequate risk studies have been performed to allow a risk-informed regulatory approach to be used with GCs.

Relative to radioactive materials and activities, the NRC previously evaluated the threshold for generally licensed devices and considered whether to limit the quantity of certain byproduct material allowable in these devices. This effort was first included in the action plan developed in response to the 2003 GAO audit. In SECY-06-0094, the NRC staff informed the Commission of the results of its analysis and recommended rulemaking to change certain regulations governing the possession, use and distribution of generally licensed devices. In the Staff Requirements Memorandum (SRM) for SECY-06-0094, the Commission approved the NRC staff's recommendation to amend certain generally licensed device and associated manufacturer requirements. On August 3, 2009, the NRC published a proposed rule "Limiting the Quantity of Byproduct Material in a Generally Licensed Device" (74 FR 28372). The proposed rule would have amended the regulations to limit the quantity of certain byproduct material allowed in a generally licensed device to below one-tenth of the International Atomic Energy Agency's Category 3 thresholds, and to require licensees with devices containing byproduct material at or above this limit to obtain a specific license. On August 10, 2010, the NRC staff provided SECY-10-0105, "Final Rule: Limiting the Quantity of Byproduct Material in a Generally Licensed Device" (ADAMS Accession No. ML100690242), to the Commission for consideration. In the SRM for SECY-10-0105 (ADAMS Accession No. ML103360262), the Commission disapproved publication of the final rule limiting the activity level allowed in generally licensed devices, but approved revision of the compatibility categories of 10 CFR 31.5 and 31.6 from B to C.

The NRC also evaluated a request to evaluate the regulations for exit signs containing tritium. By letter dated November 6, 2009, the Association of State and Territorial Solid Waste Management Officials submitted PRM-32-6 requesting the NRC amend its regulations to improve the labeling and accountability of tritium exit signs (ML093380129). The petitioner requested that the NRC revise its regulations and/or guidance to require that: the labeling be in several locations on the sign and printed with larger font; an expiration date should be distinctly legible to a fire or building inspector without taking down the sign; and the radiation trefoil should be displayed on the front and back of advertisements. The petitioner, after an evaluation of a case history of landfill leachate sampling, made the assertion that most unaccounted-for tritium exit signs are disposed of in solid waste landfills where they become potential sources of groundwater and surface water contamination. The petitioner claimed that a minority of tritium exit signs are returned to the manufacturer for recycling or disposed of as low-level radioactive waste.

The NRC staff recommended denying the petition for rulemaking because the NRC's current regulations in this area are adequate to protect public health and safety in SECY-11-0097 "Denial of Petition for Rulemaking (PRM-32-6) Association of State and Territorial Solid Waste Management Officials". The petitioner did not submit any new information that warranted rulemaking or called into question the existing regulatory requirements. In addition, while the NRC does not regulate solid waste landfills, the NRC staff also concluded that current landfill practices would mitigate the impacts from tritium released from any exit signs that may be

disposed in landfills. These include: cover systems that minimize rainfall penetration and limit the migration of tritium due to erosion or interaction with animals; cell liners that prevent leachate from leaking into the groundwater; gaseous extraction wells that remove gases building up within the landfill; and leachate collection systems that collect, process, and treat leachate, as appropriate. In addition to reviewing these previously published reports and comparing tritium concentrations measured in leachate and drinking water to regulatory standards, the NRC performed an independent analysis of possible risks to landfill workers and the general public from exposure to tritium associated with landfill disposals. This analysis was based on the disposal scenario for gun sights containing tritium discussed in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," dated June 2001. Using this methodology, staff concluded that the individual likely to receive the greater dose (landfill worker) would receive an amount significantly lower than the doses set for members of the public. Existing NRC regulations provide reasonable assurance that common defense and security and public health and safety are adequately protected. On November 2, 2011, the Commission approved the staff's recommendation to deny PRM-32-6 in SRM-SECY-11-0097.

NRC staff reviewed the February 2008 NRC report titled "Risk-Informed Decisionmaking for Nuclear Material and Waste application," (ML080720238) and noted that the staff in that report evaluated the use of generally licensed devices that contained nickel-63, polonium-210, and americium-241. While there were no definitive conclusions in the report, the discussions of these byproduct materials can be used to further risk-inform the NRC's GL program.

SUMMARY

The GLWG met from January 2018 through June 2019 to evaluate whether the GL program continued to provide reasonable assurance that public health and safety is protected in the current environment. As part of its review the working group evaluated reports events involving generally licensed devices in the NRC's Nuclear Materials Events Database, surveyed the Agreement States, and consulted with manufacturers and distributors of generally licensed devices. Based on its evaluation the GLWG could not identify any information that indicated that NRC's GL program was not maintaining public health and safety in the current environment. The working group noted that devices that contained hydrogen-3, nickel-63, or polonium-210 were reported lost at a higher frequency and in most cases are never recovered, however the risk associated with these devices containing these types of radionuclides is of low relative concern. The GLWG did identify potential areas to improve the GL program with regard to accountability for certain devices, while reducing regulatory burden by alleviating reporting requirements for lower risk uses of generally licensed devices. The GLWG recommended performing a one-time reconciliation of the NRC's General License Tracking System in order to further determine the effectiveness of the NRC's GL program. A summary of the GLWG recommendations and analysis can be found in Enclosure 1.

Since the GLWG could not identify any specific evidence that public health and safety was not being maintained and because of the significant cost of a one-time reconciliation of the NRC's general licensees, this option was not supported by the director of NMSS. However, the staff were directed to proceed with a further evaluation of the NRC's GL program and a second work group, the GLMWG, was established to perform a broader review of the GL program to identify opportunities to risk inform changes for more effective and efficient program activities. The GLMWG held numerous meetings beginning in January 2020 through July 2020. The objective of the GLMWG was to review the current state of the GL program and determine whether it should continue in the current state as well as identify any recommendations for risk-informing

the GL program activities. As part of its evaluation the GLMWG considered the GLWG's previous review, considered how certain devices were regulated internationally, and considered how to improve the GL program such that accountability would be improved but regulatory burden could be reduced through risk-informed recommendations for lower risk devices containing byproduct material.

One consideration of the GLMWG was to cease the GL program entirely and direct the devices currently in the program to be covered by the specific licensing processes or determine whether they could qualify to be distributed as exempt products. The GLMWG did not recommend cessation of the GL program in its entirety, but did recommend reducing oversight of certain types of GL devices to better align program activities and focus with the relative risks. The GLMWG also recommended a rulemaking that would expand the annual registration to include all activity levels of the currently registerable isotopes and to require additional information on the annual registration as part of an effort to improve accountability. The proposed rulemaking recommendation would also include relief options related to reporting requirements for lower risk devices relative to submitting reports of disposal, loss or missing, or damaged devices. In addition, a recommendation to reduce burden on distributors was proposed that would only require submission of quarterly reports of distribution for those devices that require annual registration. A summary of the GLMWG recommendations and analysis can be found in Enclosure 2.

STATUS

On September 28, 2020, the staff briefed the NMSS Office and Deputy Directors on the GLMWG recommendation for rulemaking. It was determined by the NMSS Office director that the work groups had not demonstrated any current health or safety concerns and the proposed rulemaking would only have a negligible improvement in public health and safety, and therefore did not support the recommendation for rulemaking or advancement of any other workgroup recommendations at this time. Staff will revisit the GL program if directed by the Commission. Subsequently, the Organization of Agreement States (OAS), whose members supported the GLWG and GLMWG, and the Conference of Radiation Control Program Directors, Inc. (CRCPD) plan to review these work group activities and recommendations to identify opportunities for increased efficiency or effectiveness across their member state programs. NMSS has been invited to participate in this OAS/CRCPD effort.

Enclosures

1. Summary of the General Licensing Re-Evaluation Working Group (GLWG)
2. Summary of the General Licensing Modernization Working Group (GLMWG)

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SUBJECT: SUMMARY OF THE EVALUATION OF THE NRC'S GENERAL LICENSE PROGRAM BY THE GENERAL LICENSE RE-EVALUATION WORKING GROUP AND GENERAL LICENSE MODERNIZATION WORKING GROUP

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