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July 8, 2022

SECY-22-0065

FOR: The Commissioners

FROM: Daniel H. Dorman
Executive Director for Operations

SUBJECT: EVALUATION OF THE U.S. NUCLEAR REGULATORY COMMISSION'S
GENERAL LICENSE PROGRAM FOR DEVICES CONTAINING
RADIOACTIVE MATERIALS IN RESPONSE TO SRM-SECY-17-0083

PURPOSE:

The purpose of this paper is to provide the results of the staff's evaluations of the U.S. Nuclear Regulatory Commission's (NRC's) General License (GL) Program for devices containing radioactive materials on the continued provision of reasonable assurance of adequate protection of public health and safety in the current environment and to provide the Commission with options to improve accountability of GL devices.

SUMMARY:

The staff evaluated the NRC's GL Program for devices containing radioactive materials to determine whether the Program continues to provide reasonable assurance of adequate protection of public health and safety. In recent years, the agency established two joint NRC/Agreement State working groups (WGs) to evaluate the GL program, the General License Program Re-Evaluation Working Group (GLWG) in 2018, and in 2020, the General License Program Modernization Working Group (GLMWG). The staff considered the recommendations that the two joint NRC-Agreement State working groups developed and is now providing the

CONTACTS: Tomas Herrera, NMSS/MSST
301-415-7138

Duncan White, NMSS/MSST
301-415-2598

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Commission with five options for the GL program: (1) maintain the status quo, (2) modify the annual GL registration requirements, (3) issue simplified specific licenses, (4) combine Options 2 and 3, and (5) increase communications between regulators and the licensed community.

After considering the recommendations from the WGs, the NRC staff recommends Option 1, maintaining the current regulations and implementation framework. The staff finds the costs associated with expanding the annual registration of generally licensed devices in Option 2 are not justified by a significant increase in the protection of public health and safety, as discussed in more detail below.

BACKGROUND:

In Staff Requirements Memorandum (SRM)-SECY-17-0083, "Staff Requirements—SECY-17-0083—Re-Evaluation of Category 3 Source Security and Accountability in Response to SRM-COMJMB-16-0001," dated December 21, 2021, the Commission directed the staff to conduct an evaluation to ensure the NRC's GL Program continues to provide reasonable assurance of adequate protection of public health and safety. The Commission specifically requested a notation vote paper be provided with options based upon the staff's evaluation of the recommendations developed by the GLWG and the GLMWG (Agencywide Documents Access and Management System [ADAMS] Accession No. [ML21355A290](#)).

There are approximately 18,500 generally licensed devices under NRC jurisdiction, and approximately 533 of these devices require annual registration. Generally licensed devices under the jurisdiction of Agreement States are not centrally tracked and data on the location of these devices are not readily accessible. Generally licensed devices containing radioactive material are typically used to detect, measure, gauge, or control the thickness, density, level, or chemical composition of various items or to produce light or an ionized atmosphere. Examples of such devices are gas chromatographs (detector cells), density gauges, fill--level gauges, static elimination devices, and self-luminous exit signs containing tritium.

The NRC's regulations in Title 10 *Code of Federal Regulations* (10 CFR) paragraph 32.51(a) or the equivalent Agreement State regulations require an application for a specific license to manufacture, or initially transfer devices containing byproduct material to persons generally licensed under 10 CFR 31.5. The regulations in 10 CFR 32.51(a)(6) require these devices to be registered in the Sealed Source and Device Registry by the specific licensee (manufacturer or distributor) upon the initial transfer of the device to an end user. The sealed source and device registration certificate is issued by the NRC or an Agreement State if the requirements in 10 CFR 32.51(a)(1-6) (or equivalent) are met. The issuance of a sealed source and device registration certificate for a generally licensed device requires the preparation of a thorough safety evaluation by the NRC staff or the Agreement State staff. The safety evaluation evaluates the assembly methods and any tamper-resistant features in the device that prevent inadvertent access to the radioactive material. In the safety evaluation, the NRC or the Agreement State evaluates how the device will maintain its integrity to ensure that the radioactive material will not be released from the source holder or be otherwise dispersed during normal use and credible accident conditions. In seeking approval for a generally licensed device design, the manufacturer or distributor of a device must provide reasonable assurance of public health and safety by submitting the information detailed in 10 CFR Part 32.51(a)(2). This requires the demonstration that (1) the device can be safely operated by persons not having training in radiological protection, (2) the radioactive material contained in the device will not be released or inadvertently removed from the device under ordinary conditions of handling, storage, and use of the device, (3) during the normal operation of the device it is unlikely that any person will

receive in 1 year a dose in excess of 10 percent of the annual limits specified in 10 CFR 20.1201(a), and (4) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in column IV of the table in 10 CFR 32.24, "Same: Table of organ doses."

Currently, generally licensed devices that require annual registration are identified in 10 CFR 31.5(c)(13)(i). These are:

devices containing at least 370 megabecquerels (10 millicuries) of cesium-137, 3.7 megabecquerels (0.1 millicurie) of strontium-90, 37 megabecquerels (1 millicurie) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 megabecquerels (1 millicurie) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label.

The annual registration requirement facilitates the tracking of generally licensed devices that present a greater risk of exposure to the public because of their isotope and activity. The registration requires general licensees that use and possess these devices with higher activity to update their inventory annually and comply with the regulatory requirements 10 CFR 31.5(c)(13)(i) (or agreement state equivalent).

In 2018, a joint NRC/Agreement State WG, the GLWG, was established to assess whether the GL Program continues to provide reasonable assurance of adequate protection of public health and safety in its current environment. The GLWG established its charter detailing the activities within the scope of this evaluation. The activities included: 1) understand the program basis and conduct a historical review; 2) evaluate the effectiveness of the NRC and Agreement States registration programs; and 3) evaluate stakeholder feedback ([ML18039A443](#)). The GLWG evaluated inspection information and material events involving generally licensed devices and sought feedback from manufacturers and distributors of these devices and the Agreement States on the effectiveness of the current program. After concluding its work, the GLWG determined that the existing GL Program is protective of public health and safety. After reviewing the GLWG's evaluation, NRC staff management directed a broader evaluation of the GL program to determine whether the program could be further risk-informed ([ML21085A735](#)).

In 2020, the GLMWG, a new joint NRC/Agreement State WG, was established to expand the initial assessment of the GL Program and provide risk-informed recommendations for lower risk devices containing byproduct material to improve their accountability, while reducing the regulatory burden ([ML20002C258](#)). The GLMWG specifically recommended potential changes to the regulations governing manufacturers, distributors, vendors, and end users. The GLMWG also evaluated the regulation of generally licensed devices internationally. In summary, the GLMWG recommended rulemaking to change the annual registration requirements for generally licensed devices by removing the isotope activity thresholds in 10 CFR 31.5(c)(13)(i) and expanding the registration requirements to include devices containing cesium-137, strontium-90, cobalt-60, radium-226, americium-241, or any other transuranic radioisotope in any quantities.

The description of work, evaluations, and recommendations of the GLWG and the GLMWG are summarized in a memorandum dated April 30, 2021 ([ML21085A734](#)).

DISCUSSION:

The regulations in 10 CFR 31.5, “Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere,” are a matter of compatibility for the Agreement States. Currently, 10 CFR 31.5 is designated as compatibility Category C.¹ Regulations that are a compatibility Category C relate to regulatory areas that could create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis if not implemented by an Agreement State. Such Agreement State Program elements shall embody the essential objective of the corresponding NRC program element, and if not implemented, would result in an undesirable consequence. Most Agreement States follow the same registration process as the NRC. Some States have regulation that are more restrictive than the NRC and currently register generally licensed devices that have additional isotopes and lower levels of activity than those specified in 10 CFR 31.5(c)(13)(i). In some instances, Agreement States require certain generally licensed devices to be regulated under a specific license.

The recent evaluations conducted by the GLWG and the GLMWG determined the GL Program is protective of public health and safety, however, a key challenge facing the use of generally licensed devices is accountability for these devices². The Agreement State representatives sitting in the WGs identified a lack of consistency in regulatory requirements for certain generally licensed devices across jurisdictions in the National Materials Program³ (NMP), which encompasses the NRC and 39 Agreement States. The options discussed and evaluated below are based on the GLMWG’s recommendations and were identified for the purposes of improving accountability of generally licensed devices or to improve outreach in the implementation of the GL Program.

Option 1—Maintaining Regulatory Status Quo

Option 1 would make no changes to the NRC’s GL Program nor to its regulatory requirements. The NRC regulations in 10 CFR 31.5(c)(13)(i) would continue to require end users of generally licensed devices to annually register devices that meet the threshold for registration in the regulation.

Advantages

- This option would not require the NRC or Agreement States to expend additional budgetary and staff resources to revise the current GL Program and associated regulations. No additional registration requirements would be imposed on general licensees, which would in turn require oversight by the NRC or Agreement States. As reflected in the efficiency principle of the NRC’s Principles of Good Regulation, this option balances the NRC’s and Agreement State’s regulatory activities with the degree of risk reduction achieved.

¹ Management Directive 5.9, “Adequacy and Compatibility of Program Elements for Agreement State Programs,” dated April 26, 2018 ([ML18081A070](#)). Compatibility determinations for regulations are made by the Commission. The summary of compatibility categories are available in the NRC regulation toolbox: NRC-STP: [Regulation Toolbox-Review Summary Sheets for New Regulations](#)

² Memo to Kevin Williams dated April 30, 2021 ([ML21085A734](#))

³ SA-10, “Joint Oversight of the National Materials Program” ([ML19123A085](#))

- Outreach explaining and implementing new policies or guidance would not be needed.
- Disadvantages

- Because general licensees in possession of nonregistered generally licensed devices do not hold a specific radioactive materials license, do not have devices that must be registered with the NRC, or do not receive routine communications from the NRC, general licensees may be unfamiliar with their regulatory responsibilities under 10 CFR Part 31. This can and has led to low-safety-significance violations with the regulatory requirements for some generally licensed devices; for example, licensees have failed to report the loss or improper disposal of these devices to the NRC or appropriate Agreement State.

Option 2—Modifying Annual Registration Requirements

Option 2 would change the annual registration requirements for generally licensed devices by removing the isotope activity thresholds for the same isotopes currently listed in 10 CFR 31.5(c)(13)(i). This would result in the annual registration of any devices containing cesium-137, strontium-90, cobalt-60, radium-226, americium-241, or any other transuranic radioisotope. These isotopes continue to be among the isotopes of highest safety concern for use in generally licensed devices; therefore, these isotopes would be subject to expanded registration requirements under this option to improve their accountability.

Advantages

- Option 2 would improve accountability for any device containing cesium-137, strontium-90, cobalt-60, radium-226, americium-241, or any other transuranic radioisotope, because they would be subject to the annual registration requirement.
- The current implementation and oversight of the GL Program would not change as the existing systems, practices, and processes can accommodate an increase in registrations.
- Because 10 CFR 31.5 is designated as compatibility Category C, which allows Agreement States to impose more restrictive requirements on general licensees, some Agreement States would not need to amend their regulations because they already have annual registration at a lower isotope activity threshold than the NRC.

Disadvantages

- Option 2 would require rulemaking and would be resource intensive for NRC and some Agreement States, as well as licensees. In addition, the GLMWG did not identify health or safety concerns that necessitate a change to 10 CFR 31.5(c)(13)(i). In its evaluation of reported radioactive material events, the staff did not identify any significant safety or security concerns with generally licensed devices. For this reason, staff does not believe that expanded registration will significantly enhance safety or security associated with the use and disposition of radioactive material in generally licensed devices.
- The NRC and Agreement States would need to establish outreach programs to notify end users of generally licensed devices of the new regulatory requirements applicable to

general licensees, and to explain the revised registration requirements under the new rules.

- The manufacturer and distributor community will be affected when more users need to complete an annual registration. The additional requirements would apply to a larger number of general licensees that would be required to register their devices annually and pay an annual fee. The staff anticipates that a portion of this new subset of the general licensees that would be subject to the annual registration may choose alternatives to the GL devices they are using in lieu of paying a registration fee.

Option 3—Requiring a Simplified Specific Licenses

Option 3 would require a subset of end users of generally licensed devices to obtain a simplified specific NRC or Agreement State license authorizing the possession and use of the radioactive material in the GL device. This subset of generally licensed devices subject to new regulatory requirements would include GL devices that contain larger quantities of radioactive material. The subset would include fixed gauges, which typically use higher activity sources than other generally licensed devices. Portable devices would also be included given their higher risk for loss. The staff would need to go through rulemaking to establish the regulatory requirements for these devices that would require a simplified specific NRC license. Since GL devices pose lower risk to public health and safety than other radioactive material currently authorized under specific licenses, the staff anticipates the process to obtain a simplified specific NRC license would be administratively less burdensome for the licensee than a specific license, but more restrictive than the current GL program requirements. Corresponding updates to licensing guidance in the NUREG-1556 series: “Consolidated Guidance About Materials Licenses” would also be issued.

Advantages

- Option 3 would create greater device accountability for the highest risk subset of generally licensed devices, including fixed gauges and portable devices.
- A simplified application and licensing process would be less burdensome than the current specific license licensing requirements.
- Some manufacturers and distributors would no longer be required to provide quarterly distribution reports to the NRC or the applicable Agreement State since that information would be captured in the new licensing process.
- Option 3 would enhance consistency in the regulation of generally licensed devices across all jurisdictions in the NMP by requiring all users of this subset of generally licensed devices to obtain a simplified specific license to use and possess applicable GL devices, as opposed to the current regulatory structure, where some Agreement States require an end user of particular material to maintain a full specific license where others permit use of the material under a general license.

Disadvantages

- Option 3 would require rulemaking to identify the subset of generally licensed devices that would now require a simplified specific license in NRC's regulations. In addition, implementing Option 3 would be resource intensive for the NRC, Agreement States, and affected licensees. Modification of the sealed source and device registration regulatory requirements would be necessary. Also, the NRC and Agreement States would need to issue the new simplified licenses for affected current and future materials users. Importantly, the GLMWG did not identify health or safety concerns that necessitate a change to 10 CFR 31.5(c)(13)(i).
- In addition to the rulemaking costs, the NRC and the Agreement States would also incur implementation costs for the issuance and oversight of the simplified specific license.
- Option 3 would require significant outreach to ensure the general licensee community is aware of the revised licensing requirements, especially the requirement to obtain a simplified specific license to possess certain devices that were formerly generally licensed. Moreover, users of generally licensed devices would incur the cost of obtaining a simplified specific license. The NRC and Agreement States would need to identify the general licensees that would be subject to the simplified specific license in the rulemaking process. End users currently subject to the requirements of GLs would need to submit an application for a simplified specific license.

Option 4—Combination of Options 2 and 3—Modifying Annual Registration Requirements and Requiring a Simplified Specific License

Option 4 combines Options 2 and 3 to create a specific subset of general licensees that would transition from general licensee status to a simplified specific licensee. In addition, the requirement for end users to register devices annually as described in Option 2 would be imposed.

Advantages

- Option 4 would improve the accountability of generally licensed devices by expanding the annual registration program to include devices containing the isotopes cesium-137, strontium-90, cobalt-60, radium-226, americium-241, or any other transuranic radioisotope in any quantities.
- Option 4 would create greater device accountability for generally licensed devices that pose a greater risk of exposure to the public. This subset of generally licensed devices would include fixed gauges, which typically use higher activity sources than other generally licensed devices, and portable devices, which have a greater risk of becoming lost due to the portable nature of the device. Option 4 would require end users of these generally licensed devices containing higher activity sources to obtain a simplified specific license. This new simplified specific license would authorize the possession and use of the radioactive material in GL devices that poses larger quantities of radioactive material.
- Requiring some current GLs to obtain a simplified specific license under Option 4 would result in lesser regulatory burden to certain manufacturers and distributors of GL devices

since they would no longer be required to provide quarterly distribution reports to regulatory agencies for those devices, as the users of those devices would become specifically licensed.

- Option 4 would enhance consistency in the regulation of generally licensed devices across all jurisdictions in the NMP. Under this option, all Agreement States and the NRC would require this subset of generally licensed devices to obtain a simplified specific license to use and possess applicable GL devices. This would resolve current inconsistencies where some Agreement States require an end user of certain material to maintain a specific license and others require only a general license.

Disadvantages

- Option 4 would require rulemaking to modify the annual registration requirements for sealed sources and devices containing the isotopes cesium-137, strontium-90, cobalt-60, radium-226, americium-241, or any other transuranic radioisotope in any quantities. Option 4 would also require rulemaking to create a new class of specific license in NRC's regulations. The modification of the sealed source and device registration requirements and issuance of a simplified specific license by the NRC and Agreement States would also be necessary. Implementing Option 4 would be resource intensive for the NRC, Agreement States, and affected licensees where the GLMWG did not identify health or safety concerns that necessitate a change to 10 CFR 31.5(c)(13)(i).
- More general licensees would be subject to an annual registration fee and would also incur the cost for training on the new requirements, as well as the cost for completing the annual registration.
- Option 4 would require a significant outreach effort to implement the changes in the regulations to promote understanding and compliance with the new or revised regulatory requirements.

Option 5—Increase Communications with End Users of Generally Licensed Devices

Approximately 92 percent of NRC general licensees do not possess devices containing isotopes requiring registration and therefore do not receive routine communication from the NRC. Although generally licensed devices across the Agreement States are not centrally tracked and information on the location of these devices is not readily accessible, the staff estimates that the percentage of registered end users under Agreement State jurisdiction is similar to that of NRC's registered users of generally licensed devices. On rare occasions, general licensees receive generic communications, such as an information notice or a regulatory issue summary.

Option 5 would establish routine communications with the end users (approximately 18,500 general licensees) to increase their awareness of their regulatory responsibilities with respect to the generally licensed devices they possess. For this option, there would be a resource commitment from the NRC to undertake the effort of reaching out, gathering, and maintaining general licensees' contact information. The resource commitment would be sustained to provide for ongoing licensee awareness of the regulatory requirements for generally licensed devices. The regulated community, including manufacturers and distributors, supports some form of increased communication between the NRC and Agreement States and general licensees to

ensure general licensees are aware of the regulatory requirements associated with the generally licensed devices in their possession.

The staff anticipates the benefits from this option to be limited. It is anticipated a portion of the communications attempts would be unsuccessful to gather and maintain contact information and a portion of the routine communications would be unsuccessful if the end user does not keep the regulatory agency apprised of personnel or point of contact changes. The current regulatory framework does not require a general licensee to keep the NRC informed of these changes. Furthermore, the responsibility to comply with the regulatory requirements ultimately resides in the end user and this proactive information campaign cannot guarantee that generally licensed devices would not be lost or would be always disposed properly due to increased awareness of the applicable regulatory requirements.

Advantages

- This option would result in increased end user awareness of the regulatory requirements for generally licensed devices, which could increase compliance and reduce potential material losses and improper disposition of generally licensed devices.

Disadvantages

- The NRC only has contact information for a portion of general licensees under the NRC's jurisdiction, particularly those subject to the annual registration requirements. The NRC does not have points of contact or email addresses for the majority of general licensees under NRC jurisdiction. Thus, a significant number of such outreach attempts may be unsuccessful.
- Option 5 would commit significant NRC resources to collect contact information and contact approximately 18,500 general licensees.

Coordination with Current Rulemaking Activities

In SRM-SECY-17-0083, the Commission also directed the staff to require license verification for licensees transferring Category 3 quantities of radioactive material. There are generally licensed devices that contain Category 3⁴ quantities of radioactive material. Since general licensees do not receive a specific radioactive materials license from the NRC, there is currently no way to perform a license verification in a manner similar to that of licensees that receive a specific license for possession of radioactive materials. License verification for general licensees was not evaluated by the GLWG nor the GLMWG. The license verification requirement for the transfer of all Category 3 quantities, including generally licensed devices, is being addressed as part of the Integrated Source Security and Accountability Rulemaking Plan being developed in response to SRM-SECY-17-0083.

Coordination with Agreement States

The Agreement States provided significant support to both WGs. Through the involvement of the Agreement State representatives, the WGs obtained valuable feedback to evaluate the GL

⁴ Under the NRC's jurisdiction, 13 general licensees possess 24 devices containing Category 3 quantities of radioactive material.

Program. In addition to the direct efforts of the Agreement State WG representatives, the WG representatives made presentations at the Conference of Radiation Control Program Directors (CRCPD) and Organization of Agreement States (OAS) annual meetings from 2018 through 2021.

Through its efforts, the GLMWG determined that most Agreement States were supportive of Option 2, which proposes to expand the annual registration requirements. The number of additional general licensees that would be required to complete annual registration would vary from Agreement State to Agreement State. While a number of Agreement States expect the annual registration requirement would produce minimal change in their regulatory processes, other Agreement States anticipate the change would create a significant increase in the number of annual registrations. The Agreement States anticipated the proposed rulemaking would create staffing challenges if the annual registration requirements were expanded. Some Agreement States stated that because they are authorized to impose more restrictive requirements when implementing the general license program, the implementation of Option 2 would not necessarily eliminate inconsistency in the regulation of generally licensed devices across Agreement States because some Agreements States require the registration or specific licensing of generally licensed devices with greater activity.

The Agreement States have committed to further risk-inform and find efficiencies within their GL programs, with a goal of reaching agreement to apply consistent regulations across all Agreement State jurisdictions in the NMP. Further, the CRCPD and the OAS are initiating an Agreement State-led WG to identify and evaluate potential improvements to the Agreement State GL programs, building upon the recommendations of the NRC's WGs. The CRCPD and OAS WG will provide guidance to the Agreement States on how to most effectively manage their GL programs and how to create consistency in the licensing of those generally licensed devices with higher activity sources or portable applications. The NRC staff will be part of these efforts as well.

RECOMMENDATION:

After weighing the advantages and disadvantages of the five options, the NRC staff recommends that the Commission approve Option 1. Option 1 would continue the existing regulatory framework for the GL Program. The current GL Program requires that devices undergo a rigorous safety review to demonstrate the devices will maintain their integrity during normal use and credible accident conditions. Only after the demonstration that devices had met the rigorous safety review are the devices authorized for distribution as generally licensed devices. The safety review provides the NRC staff with reasonable assurance of adequate protection of the public health and safety for generally licensed devices in use.

The existing regulatory requirements currently provide a risk-informed approach, as only generally licensed devices with a greater risk due to higher radioactivity are required to be registered annually. In addition, the NRC's current regulations and corresponding Agreement State regulations require that manufacturers and distributors file quarterly reports that track all generally licensed devices that have been distributed or transferred for servicing, repair, or disposal.

While approximately 92 percent of the generally licensed devices in the U.S. are not required be registered annually by their generally licensed users, the NRC staff has not identified a risk of exposure to the public from radioactive materials in generally licensed devices from their improper disposition or loss.

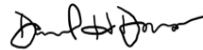
The staff bases its recommendation of Option 1 on the current environment and operational experience associated with the use of generally licensed devices across the NMP. The staff evaluated events involving GL devices, most of which involved device loss not associated with public or occupational exposure. The staff finds the current uses, disposition, manufacturing, and distribution of GL devices, and the current regulatory framework using a risk-informed approach for accountability of GL devices continues to be protective of public health and safety. The staff finds that the costs to the NRC, Agreement States, general licensees, and distributors associated with rulemaking and implementing changes to the GL Program as described in the options herein would be substantial and not supported by the potential benefits, and therefore the staff recommends the Commission select Option 1.

RESOURCES:

No additional resources beyond those already budgeted will be required to implement the staff's proposed recommendation. The enclosure includes an estimate of the NRC resources needed to implement each of the recommendations set forth in this paper.

COORDINATION:

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



Signed by Dorman, Dan
on 07/08/22

Daniel H. Dorman
Executive Director
for Operations

Enclosure:
Evaluation of the NRC's General
License Program for Devices
Containing Radioactive Materials:
Estimated Resources

SUBJECT: EVALUATION OF THE U.S. NUCLEAR REGULATORY COMMISSION'S
 GENERAL LICENSE PROGRAM FOR DEVICES CONTAINING RADIOACTIVE
 MATERIAL DATED: July 8, 2022

TICKET NO. SRM-S17-0083-2

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