

U.S. Nuclear Regulatory Commission/Agreement State Working Group

General License Program Modernization

Charter

**PURPOSE**

The General License Program Modernization Working Group (GLMWG) has been established to perform an evaluation of the existing General License (GL) program framework to determine its relevance for the current needs of the National Materials Program (NMP). The GLMWG will also identify areas where the GL program can be transformed into a risk-informed program that supports the needs of the regulatory agencies, manufacturers/distributors, and users of generally licensed devices with an appropriate risk focus, while maintaining safety.

**BACKGROUND**

The General License Program Re-Evaluation Working Group (GLWG) was established in 2018 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18039A443) to determine whether the current GL program provided reasonable assurance that public health and safety was being adequately protected in the current environment. The GLWG made several recommendations for further improving the GL program particularly to enhance accountability and to risk-inform the existing GL regulatory framework.

One of the suggestions made by the GLWG was to evaluate certain aspects of the GL program using a risk-informed approach. The NRC and Organization of Agreement States (OAS) identified an evaluation of the GL program as one of their regulatory priorities for 2019-2020 to determine if the program is relevant and appropriate and, if not, to suggest recommendations for change. Given the continued interest of the NMP on the GL program, NRC staff supported the need for a broader evaluation of the NRC's GL program. The formation of this working group continues the work of the GLWG and supports the regulatory priority identified by NRC and OAS.

**WORKING GROUP MEMBERSHIP**

The working group will operate as an NRC/Agreement State working group as described in MD 5.3, "Agreement State Participation in Working Groups." The working group will be co-chaired by an NRC staff member and an Agreement State representative, appointed by the OAS. There will be no steering committee for this working group.

<b>Organization</b>	<b>Working Group Members</b>
Office of Nuclear Materials Safety and Safeguards (NMSS) Division of Materials Safety, Security, State, and Tribal Programs	Tomas Herrera, Co-Chair Duncan White, Alternate Co-Chair Celimar Valentin-Rodriguez, Project Manager
NMSS Division of Rulemaking, Environmental, and Financial Support (Cost Analysis)	Mary Anderson, Cost Analyst
Agreement States	Angela Leek, Iowa/OAS Co-Chair Tyler Kruse, Minnesota Paul Schmidt, Wisconsin
Office of the General Counsel	Adam Gendelman, Attorney
Regional Offices	Michael Reichard, Region I

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Organization	Working Group Members
	Jason Draper, Region III Latischa Hanson, Region IV
Management Sponsor	David Alley, Division of Materials Safety, Security, State and Tribal Programs (MSST)

Other NMSS, Regional, and Agreement State staff may serve as resources to the working group at the request of the co-chairs and with the support of their management. The project manager will be responsible for the scheduling, tracking, and timely completion of the working group activities. Administrative support for the working group will be provided by MSST.

Additional support may be obtained from the Office of the Chief Financial Officer, Office of the Chief Human Capital Officer, Office of Enforcement, and any other NRC office at the request of the co-chairs and with the support of NRC management.

**ACTIVITIES AND SCHEDULE**

The table below describes the activities to be conducted:

Activity	Completion Date
<p><u>Activity 1:</u> Given the safety risk of GL devices, should the NMP continue to have a GL program, or should GLs be separated into specifically licensed and exempt devices?</p> <ul style="list-style-type: none"> <li>• The GL program was started in 1959 to save resources for the agency and reduce burden on the end users. If the agency was considering a program for similar devices in 2019, what would be the regulatory framework?</li> <li>• Evaluate the various categories of current GL devices and determine, based on safety implications associated with activity, device design, operational experience, and event data, whether the NMP should continue to recognize a generally licensed device framework?               <ul style="list-style-type: none"> <li>○ Consider implications/unintended consequences for manufacturers, distributors, and licensees,</li> <li>○ Consider international approaches,</li> <li>○ Consider implementation issues if GL program was discontinued,</li> <li>○ Determine costs/benefits,</li> <li>○ Determine pros/cons.</li> </ul> </li> </ul>	February 2020
<p><u>Activity 2:</u> If the working group determines that a GL program should continue, evaluate potential changes to the GL program based on a risk-informed, transformative approach.</p> <ul style="list-style-type: none"> <li>• Evaluate whether some generally licensed devices can meet the criteria of a product that can be distributed as an exempt product.</li> <li>• Evaluate whether some generally licensed devices should be specifically licensed.</li> </ul>	May 2020

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<ul style="list-style-type: none"> <li>• Should we continue to require that GL users report transfers, etc. to GLTS?</li> <li>• Should GL devices (or some subset) be registered using a similar process as we currently registered in-vitro kits (10 CFR 31.11) or depleted uranium shielding (10 CFR 40.25) ?</li> <li>• Are we currently requiring registration of the appropriate devices?                             <ul style="list-style-type: none"> <li>○ Should the regulatory program be tailored per device?</li> <li>○ Currently devices can be evaluated as a “B”, which allows them to either be distributed a generally licensed or specifically licensed – should this continue?</li> <li>○ Should the accountability of low-risk GL devices be of regulatory concern (i.e., reporting lost or stolen device or maintaining current or accurate information in GLTS)?</li> <li>○ Should we enhance communication with general licenses?</li> </ul> </li> </ul>	
<p><u>Activity 3:</u> Identify implementation steps to implement recommended option.</p> <ul style="list-style-type: none"> <li>• Identify changes to regulations.</li> <li>• Identify changes to policy statement on consumer products as appropriate.</li> <li>• Determine if NUREG-1717 must be revised and if the methodology is appropriate for a modern risk-informed GL product.</li> </ul>	May 2020
<p><u>Activity 4:</u> As appropriate, prepare memorandum or Commission Paper as directed by NRC management and OAS Board. Include options and recommendations.</p> <ul style="list-style-type: none"> <li>• Recommendations must include a cost benefit analysis.</li> <li>• Include pros and cons for each option.</li> </ul>	June 2020

The working group is encouraged to pursue any innovative or transformative idea to modernize the GL program.

The working group will conduct periodic alignment briefings with the MSST Director and the NMSS Office Director upon completion of key activities and recommendations. The OAS co-chair will keep the OAS Board informed of the working group's activities, products, and recommendations. The GLMWG's recommendations along with the findings from the GLWG will be included as part of a Commission Paper. MSST will be responsible for preparation of the paper.

The working group will sunset, once it has provided its recommendations to MSST management.

**LEVEL OF EFFORT EXPECTED OF PARTICIPANTS**

To support the schedule and activities listed above, the following level of effort is expected from the working group participants. The total duration of work will be 6 months:



GENERAL LICENSE PROGRAM MODERNIZATION WORKING GROUP CHARATER  
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\*concurrence via email

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