

NRC/Agreement State Working Group
Enhancements to Pre-Licensing Guidance

CHARTER

PURPOSE

The Enhancements to Pre-Licensing Guidance Working Group has been established as a Management Directive (MD) 5.3 working group to evaluate vulnerabilities identified as a result of 2015 Government Accountability Office (GAO) investigation and audit into the U.S. Nuclear Regulatory Commission (NRC) and Agreement State materials licensing programs. The working group will evaluate and make recommendations to the NRC management on strategies to mitigate the vulnerabilities.

BACKGROUND

In October 2015, the NRC staff was notified that GAO had conducted an investigation to determine if vulnerabilities identified in a 2007 GAO investigation were adequately addressed by the regulatory framework and other improvements implemented by the NRC and the Agreement States. The 2015 investigation was part of a larger audit of NRC and Agreement State materials licensing activities that began in 2014. The GAO is expected to publish the results of its investigation in early 2016.

After the 2007 investigation, the NRC and the Agreement States made a number of important changes to strengthen the licensing and regulatory processes to keep malevolent individuals from obtaining a radioactive material license. The 2015 investigation went beyond the 2007 investigation in its sophistication and planning, such that they obtained a license from an Agreement State. GAO demonstrated that they could have, but did not, acquire an aggregate category 2 quantity of material. In its first two out of three attempts to obtain a license, GAO was unsuccessful. The GAO investigation provides an important learning tool to identify which parts of the licensing process are adequate, and which parts require further strengthening.

The 2015 GAO investigation identified vulnerabilities in the National Materials Program (NMP) licensing process. The NRC and Agreement States all use a similar process to safely and securely license a wide range of radioactive materials for use in the medical, industrial and academic fields. It's important that all regulators implementing the NMP take steps to close any vulnerabilities in their licensing processes.

NRC considers the pre-licensing guidance and the Risk Significant Radioactive Material (RSRM) guidance an essential component for licensing under the NMP. The primary objectives of the existing pre-licensing guidance are to: 1) provide a basis of confidence that radioactive materials will be used as intended; 2) ensure that adequate site visits are conducted for "unknown" applicants (as defined in the pre-licensing guidance); and 3) ensure that suspicious applications are forwarded to the appropriate authority for follow-up.

In September 2008, NRC issued to the Agreement States the *Checklist to Provide a Basis for Confidence That Radioactive Materials Will be Used as Specified on the License and the Checklist for Risk-Significant Radioactive Materials (RCPD-08-020)*. The Materials Program Working Group issued this revised version of the Pre-licensing guidance which separated the *Checklist to Provide a Basis for Confidence that Radioactive Material will be Used as Specified on the License* (pre-licensing), and the *Checklist to Address Risk Significant Radioactive*

Material (RSRM). The RSRM guidance addresses licenses that are now subject to the requirements in 10 CFR Part 37.

Since the pre-licensing guidance is a matter of compatibility, the Agreement States were given six months to implement the guidance. Also in September 2008, a memorandum was issued by the program office to the NRC Regions directing immediate implementation of the checklist. Since 2009, Integrated Materials Performance Evaluation Program (IMPEP) reviews of the Agreement States and Regional programs have evaluated the implementation of this guidance.

The Enhancements to Pre-Licensing Guidance Working Group (EPLG) has been established to review the *Checklist to Provide a Basis for Confidence that Radioactive Material will be Used as Specified on the License* (pre-licensing) Guidance for enhancements.

WORKING GROUP AND STEERING COMMITTEE MEMBERSHIP

The EPLG and steering committee will operate as an NRC/Agreement State working group as described in Management Directive 5.3 *Agreement State Participation in Working Groups*. The working group and steering committee will be co-chaired by an NRC staff member and a representative from the Organization of Agreement States (OAS). Membership of the steering committee for the EPLG will be the same as the steering committee for the License Verification and Transfer of Category 3 sources working group.

Organization	Working Group	Steering Committee
NMSS	Lizette Roldán-Otero, Co-chair	Dan Collins/Pam Henderson, Co-Chair
NSIR	Gary Purdy	Melanie Galloway
OAS	Steve Mack, AR Co-chair	Alan Jacobson, MD Co-Chair
OGC	John Hull, Joan Olmstead, Alternate	Carrie Safford
Regional Offices	Scott Wilson, RI Sara Forster, RIII Roberto Torres, RIV	Member
Agreement State	Jennifer Granger, CA Louis Brayboy, NC	

Other Material Safety, State, Tribal, and Rulemaking (MSTR), Regional and Agreement State staff will serve as resources to the Working Group at the request of the Co-Chairs.

Administrative support for the working group will be provided by MSTR.

OBJECTIVES

The working group will focus on the lessons learned from the 2015 GAO investigation and audit to identify short term actions that can be taken within the months after the working group makes its recommendations.

1. Review information and evaluations including self-assessments prepared by either NRC or the Agreement States directly resulting from the 2015 GAO investigation and perform

a review of operational experience to ensure that licensing vulnerabilities are appropriately identified.

2. Review the current implementation of the pre-licensing guidance by NRC Regions and Agreement States to identify practices that minimize the likelihood that an individual with malevolent intent will obtain a radioactive material license. The working group should evaluate the following practices, take into account other identified practices and provide recommendations on strategies to mitigate the vulnerabilities in the NMP.
 - a. Evaluate handling the pre-license visit and delivery of license at the same time versus separately;
 - b. Review the licensing process and guidance to determine whether facilities approved for category 3 sources should have required security and safety¹ equipment in place before receiving license;
 - c. Consider the practicality of issuing a provisional license or documentation that would allow only for the possession and use of sources required for instrument calibration to allow applicant the opportunity to complete their facility once credibility is established as a result of the pre-licensing visit.
3. Review existing NRC pre-licensing guidance for NRC and Agreement State license reviewers/inspectors and make recommendations on strategies to improve its effectiveness.
4. Review existing NRC provided pre-licensing training for NRC and Agreement State license reviewers/inspectors and make recommendation on strategies to improve its effectiveness.
5. Review the 2016 GAO audit report and recommendations (when available). The working group shall recommend any strategies to mitigate the vulnerabilities based on the results of the GAO investigation and audit.
6. Provide the MSTR Division Director with a report summarizing the working group's activities and recommendations.

SCHEDULE

The Co-Chairs will determine the frequency and timing of working group meetings. The working group held its first meeting on January 22, 2016 and will deliver their report to the MSTR Division Director by July 1, 2016.

LEVEL OF EFFORT EXPECTED OF PARTICIPANTS

Given the importance of this review to the NMP, the working group participants should anticipate spending a substantive amount of their time, up to 50%, on working group activities.

MEETINGS

Meetings are pre-decisional and will be closed to the public.

¹ As required by 10 CFR Parts 20, 30, 31-36, 39, 40 and 70. This working group is not evaluating whether Part 37 should be extended to category 3 sources.

Working group members may delegate an alternative representative for a specific meeting. The working group may also invite individual(s) to participate in meetings as a resource to assist the working group with a particular issue. However, at least one of the named Co-Chairs must be present during any meeting.

Available technology will be used to facilitate interaction with the working group members, (e.g., conference calls, GoToMeeting and electronic mail). Face-to-face meetings, if necessary, will generally be held in the Washington, D.C., area unless alternate locations are agreed upon by working group members. If travel is necessary, travel and per diem expenses for Agreement State members of the working group will be covered by MSTR. Regions are responsible for the travel expenses of their staff.

APPROVED

/RA/

2/25/2016

Daniel S. Collins, Nuclear Regulatory Commission

Date

/RA/

3/3/2016

Sherrie Flaherty, Chair, Organization of Agreement States

Date

