

The National Materials Program

Standing Committee for Sealed Source and Device Expertise

PURPOSE

The Standing Committee for Sealed Source and Device (SS&D) Center of Expertise (CoE) has been established to serve as a resource for collaboration and to enhance the technical evaluations of sealed sources or devices containing a sealed source by relying on technical expertise from the NRC and the Agreement States. The committee will serve as a resource for all SS&D programs across the National Materials Program (NMP) to enhance the review and consistency of SS&Ds pursuant to NUREG-1556, Volume 3, *Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration*. This SS&D committee will rely on members' expertise to ensure SS&D programs across the NMP have the technical resources to ensure that safety evaluations are consistently across the NMP. The SS&D CoE will provide a forum to discuss methods and solutions acceptable to make the determinations needed to issue a registration certificate or continue the evaluation for a sealed source or device.

Furthermore, the committee will be made aware of those NRC reviews of devices (consumer products) requiring a safety evaluation and issuance of an SS&D certificate and authorized for exempt distribution following the guidance in NUREG-1556, Volume 8, *Consolidated Guidance About Materials Licenses: Program Specific Guidance About Exempt Distribution Licenses*. This will be usually for new devices to be licensed under 10 CFR 32.30 or those involving emergent technologies where applicable.

BACKGROUND

The information in NUREG-1556, Volume 3, Revision 2, it is designed to provide the SS&D reviewer with the guidance, information, and materials necessary to make a determination that the product is acceptable for licensing purposes. This guidance is used for all reviews across the NMP. SS&D registry sheets for specific, general, and exempt products containing radioactive material are incorporated into specific licenses issued by all Agreement States and the NRC. Since the mid-1990s, nearly 10 Agreement States have returned their SS&D programs to the NRC due to the challenges of maintaining specific expertise needed to conduct SS&D reviews due sometimes in part to the small number of manufacturers and distributors (M&D) in their jurisdiction. The expertise needed to evaluate SS&D applications often requires individuals with an engineering background. Agreement State with SS&D programs have been challenged to justify the necessary expertise due to the low number of amendments to existing SS&D registry sheets the State maintains or new applications. This has resulted in a disproportionate distribution of technical expertise across the NMP as only those SS&D programs with sufficient numbers of M&Ds and casework can maintain adequate resources and expertise. The rise in emergent technologies involving radiation materials, particularly in medical therapy, over the last 10 years has further amplified the disproportional distribution of expertise across the NMP. It is in the best interest of the NMP to identify SS&D technical resources into a standing committee to serve as resource for the entire NMP.

MEMBERSHIP

The SS&D Committee consists of staff from across the NMP including representatives from the

Agreement States and NRC programs with expertise in the evaluation of SS&Ds, event analysis and programmatic review. Terms of membership and size of the standing committee will be developed during this first meeting and determined by vote. Continued maintenance of the SS&D committee membership will be the role of the Co-chairs of the committee.

Initial members will be selected by the NRC and OAS Board based on availability, technical expertise, and peer recognition.

The standing committee will operate as an NRC/Agreement State steering committee as described in Management Directive 5.3, "Agreement State Participation in Working Groups." The standing committee will be made up of six members and will be co-chaired by an NRC staff member and an Agreement State representative from the Organization of Agreement States.

The following positions will serve on the standing committee:

1. NRC Co-Chair (Branch Chief of the Material Safety Licensing [MSLB] in the Division of Materials Safety, Security, State, and Tribal Programs [MSST] in the Office of Nuclear Material Safety and Safeguards [NMSS] or Senior Materials Technical Reviewer, MSLB or designee)
2. Agreement State Co-Chair (Organization of Agreement States [OAS] Director of Emerging Issues and Advocacy or designee)
3. NRC designated SS&D technical reviewer
4. OAS designated SS&D technical reviewer
5. NRC Co-Champion
6. OAS Co-Champion

The Co-Chairs will schedule meetings, determine the agenda, and provide support for documenting meetings and decisions made by the standing committee.

The Co-Champions will provide information from the committee meetings to the NMP, as necessary, at the Monthly NMP calls. This will mostly include only those items that will be of interest for all the participants. (e.g. good practices, emerging issues, special announcements)

The Agreement State Co-Chair would change when membership changes on the OAS Board (i.e., 3 years). The Agreement State and NRC technical reviewer representatives would have set term limits (i.e., 3 - 5 years), which would end at different times.

ROLE AND SCOPE

The primary responsibility of the Standing Committee of SS&D Center of Expertise is to aid the NMP in accomplishing its goal of enhance the technical evaluations of SS&Ds to provide reasonable assurance that they are protective of public health and safety and in compliance with regulatory requirements. The purpose of the committee is to provide technical assist with SS&D reviews, develop the knowledge and expertise within individual regulatory programs and to provide expert guidance to the NMP regarding issues associated with SS&Ds. Specifically, the Standing Committee of SS&D Expertise will support the NMP by:

1. Establishing membership criteria and maintaining membership.

2. Establish the role and responsibilities of the Standing Committee for SS&D Center of Expertise.
3. Developing procedures for the NMP to request technical assistance from the Standing Committee for SS&D Center of Expertise.
4. Providing technical assistance to the NMP on unique SS&D devices and uses, including emerging technologies.
5. Providing input to guidance for the IMPEP review process of SS&D programs.
6. Discuss training needs for SS&D qualification and refresher across the NMP.
7. Providing technical assistance on analyzing and corrective actions for SS&D events.
8. Continually reviewing the value of the SS&D committee to the NMP and implementing process improvements. (NMP metrics)
9. Keep the OAS Board, the CRCPD and the NRC informed of SS&D committee's activities and progress, as necessary. (NMP metrics)

LEVEL OF EFFORT EXPECTED OF PARTICIPANTS

The Standing Committee of SS&D CoE will meet at least quarterly or a more frequently as needed. Additional time to complete committee activities may be required by committee members in accordance with committee's scope outlined in this charter. The total level of effort for both the NRC and Agreement State participants is not expected to exceed 50 hours annually.

MEETINGS

Meetings will be scheduled by the Co-Chairs. Meetings will normally be closed to the public due to discussions on pre-decisional information not normally publicly disclosed. Attendance to meetings is open to any Agreement State or NRC staff member actively working in an SS&D Program or material licensing program involving distribution.

At least one of the co-chairs must be present during any meetings of the Standing Committee for SS&D Expertise and a minimum of 3 of the committee members must be present are required for a quorum.

Meetings will be held remotely using appropriate technology available to all members.

Administrative support will be provided by NRC's Division of Materials, Security, State and Tribal Programs.