

**Charter for the Joint
U.S. Nuclear Regulatory Commission/Agreement State
Standing Committee for Reviewing Emerging Medical
Technologies**

APPROVED

Kevin
Williams

Digitally signed by Kevin
Williams
Date: 2022.06.01
11:19:41 -04'00'

Director, NRC/NMSS/MSST

Date



Chair, OAS

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Date

PURPOSE

The purpose of this charter is to establish a standing committee to review licensing guidance documents developed that are related to emerging medical technologies. This standing committee will serve to help ensure consistency across all the licensing guidance documents, provide more flexibility, and help to prioritize the reviews by considering available resources, and consider the timeline of the U.S. Nuclear Regulatory Commission (NRC) review relative to the reviews by the U.S. Food and Drug Administration (FDA) and/or the Agreement States.

BACKGROUND

The NRC, under Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.1000, "Other medical uses of byproduct material or radiation from byproduct material," evaluates each application for an emerging technology on a case-by-case basis. The NRC evaluates each application in conjunction with the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), the medical community, and developers of the new technology to determine the risks associated with the technology, and the appropriate regulatory requirements, including the training and experience requirements for use of the technology. If the emerging technology was not specifically addressed in 10 CFR Part 35 Subparts D through H, the past method was to form a joint NRC/Agreement State working group to develop and issue licensing guidance for medical uses approved under 10 CFR 35.1000. Under this process, licensing guidance for emerging technologies took a year or more to complete. Also, NRC license reviewers could not approve a 10 CFR 35.1000 use without licensing guidance, which in some instances caused licensees to delay the ability to implement the new technology.

IMPROVED PROCESS

The NRC has developed a new process for reviewing emerging technologies that replaces individual working groups chartered in response to NRC licensing reviews specific to each emerging technology. The new process includes the creation of a new standing committee to ensure that stakeholder feedback is incorporated early in the process.

The licensing guidance will be developed by technical staff from the NRC's Medical Radiation Safety Team with support, as necessary, from a Sealed Source & Device (SS&D) reviewer or other technical staff from the NRC and Agreement States.

The new standing committee will review the licensing guidance documents, along with the ACMUI, Agreement States, and the NRC Regions, prior to the document proceeding through NRC's concurrence process. The benefits of this new process are that it:

1. Streamlines the review process and ensures consistency and a more uniform approach to licensing guidance development through the review by a single standing committee;
2. Provides a cost savings in both time and staff resources because the licensing guidance is being developed by an individual instead of by a working group; and
3. Remains inclusive of NRC regional, Agreement State, and ACMUI contributions to licensing guidance development.

For each emerging technology being reviewed, it is anticipated that it will take approximately eight months for the 35.1000 licensing guidance to be issued and the major activities are as follows:

1. The NRC's Medical Radiation Safety Team staff member will present to the standing committee its basis for developing 35.1000 licensing guidance for the emerging technology.
2. The NRC's Medical Radiation Safety Team staff member, with support from a SS&D reviewer or other technical staff as necessary, will develop the licensing guidance.
3. The standing committee, ACMUI, Agreement States, and NRC Regions will review and comment on the licensing guidance.
4. The NRC's Medical Radiation Safety Team staff member, with support from a SS&D reviewer or other technical staff as necessary, will resolve the comments on the draft licensing guidance.
5. The licensing guidance will go through NRC's concurrence process.
6. The licensing guidance will be issued.

MEMBERSHIP

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 staff will serve on the standing committee:

1. NRC Co-Chair (Branch Chief of the Medical Safety and Events Assessment Branch [MSEB] in the Division of Materials Safety, Security, State, and Tribal Programs [MSST] in the Office of Nuclear Material Safety and Safeguards [NMSS] or designee)
2. Agreement State Co-Chair (Organization of Agreement States [OAS] Director of Emerging Issues and Advocacy or designee)
3. Office of General Counsel (OGC) representative
4. NRC regional representative (staff or branch chief with knowledge and/or experience in medical licensing, inspection, and/or emerging medical technologies)
5. Agreement State representative (person appointed by the Agreement State Co-Chair)
6. Coordinator (a non-voting member from NMSS/MSST)

The coordinator will attend meetings to provide support for documenting decisions made by the standing committee. The standing committee may seek additional expertise on an as-needed basis.

The Agreement State Co-Chair would change when membership changes on the OAS Board (i.e., 3 years). The Agreement State and NRC regional representatives would have set term limits (i.e., 3 years), which would end at different times. The regional representative will rotate between Region I, III, and IV and will change at the end of each term limit. Both the Agreement State representative and the NRC regional representative should have alternates. These alternates may also attend meetings and serve in a non-voting advisory role when the primary representative is present.

If the standing committee needs management support to resolve issues that are more than minor, the co-chairs will bring the issues to the attention of the NRC/NMSS/MSST management, the OAS Executive Board, and OGC, as applicable.

OBJECTIVES

The standing committee has three main objectives:

1. Review the basis for the decision to proceed with developing 35.1000 licensing guidance;
2. Provide guidance and oversight to the NRC's Medical Radiation Safety Team staff member during development of the licensing guidance; and
3. Review and comment on the draft licensing guidance prior to the formal concurrence process.

If significant changes are made to the licensing guidance as it goes through the concurrence process, the standing committee may need to review the draft licensing guidance again.

MEETINGS

Standing committee meetings will be monthly or as needed depending upon workload. If there are no staff requests for committee input within the month, the co-chairs should discuss the need for a standing committee meeting. If the co-chairs determine that meetings are not needed at that time, the other members of the standing committee will be notified and a status of the emerging technologies under review will be provided.

Standing committee meetings are pre-decisional and will be closed to the public. Available technology will be used to facilitate interaction with the standing committee members (e.g., conference calls, e-mail, NRC BOX Enterprise and File Synchronization System, Microsoft Teams, WebEx services).

A quorum is established when a majority of the voting members are present, at least one of the named co-chairs, and either Agreement State representative. Standing committee members may delegate an alternative representative for a specific meeting. The standing committee may also invite individual(s) to a meeting to participate as a resource to assist the standing committee with an issue or in a training capacity.

LEVEL OF EFFORT

The level of effort will depend on the number of emerging technologies coming to the NRC for review. Historically, NRC has reviewed approximately three emerging technologies per year that may have resulted in the development of 10 CFR 35.1000 licensing guidance. For each emerging technology, the expected level of effort for committee members is approximately 1 to 2 hours for an initial meeting to review the basis for the decision to develop 35.1000 licensing guidance; approximately 4 to 5 hours to review and comment on the draft licensing guidance; and approximately 2 hours to meet as a committee to discuss feedback on the draft licensing guidance.