

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

October 4, 2022

ALL AGREEMENT STATES, CONNECTICUT, INDIANA, NRC NMSS, NRC REGIONS I, III, AND IV

NOTIFICATION OF ISSUANCE AND OPPORTUNITY TO COMMENT ON THE INTERIM STATE AGREEMENT (SA) PROCEDURE, SA-802, STANDING COMMITTEE FOR REVIEWING EMERGING MEDICAL TECHNOLOGIES (STC-22-059)

Purpose: To provide the National Materials Program (NMP) community an opportunity to comment on, and use the interim procedure, SA-802, *Standing Committee for Reviewing Emerging Medical Technologies*.

Background: On April 24, 2002, the U.S. Nuclear Regulatory Commission (NRC) amended Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 to add Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material" (67 FR 20249) and codify regulatory requirements for the use of new medical uses of byproduct material or radiation from byproduct material (i.e., an emerging technology) that is not specifically addressed in 10 CFR Part 35 Subparts D through H. The NRC evaluates each emerging technology on a case-bycase basis, in conjunction with the NRC's Advisory Committee on the Medical Uses of Isotopes, the medical community, and developers of the new technology, as appropriate, to determine the risks associated with the technology, and the appropriate regulatory requirements for use of the technology.

The NRC 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 and includes the creation of a new standing committee to ensure that stakeholder feedback is incorporated early in the process. On June 7, 2022, the final charter was established for the Standing Committee for Reviewing Emerging Medical Technologies (Agencywide Documents Access Management System Accession (ADAMS) No. ML22159A317). 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 composed of six members and will be cochaired by an NRC staff member and an Agreement State representative from the Organization of Agreement States.

Discussion: This letter notifies the NMP community that NMSS procedure SA-802 has been prepared and issued for use on an interim basis until April 4, 2023, to allow Agreement State and NRC staff to provide comments¹ based on their review of the procedure. The comment period was developed following consultation with the Organization of Agreement States. If there

_

¹ This information request has been approved by OMB 3150-0029 (expiration 1/31/2025). The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the FOIA, Library, and Information Collections Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to infocollects.resource@nrc.gov, and to OMB Office of Information and Regulatory Affairs (3150-0029), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e-mail: oira_submission@omb.eop.gov. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

STC-22-059 2

are no comments for this procedure, the procedure will be automatically finalized without any further action. Please provide comments to the contact person listed below.

This procedure has been uploaded to the NRC's public website for use, and for review and comment: https://www.nrc.gov/reading-rm/doc-collections/nmss-procedures/state-agreement.html. The procedure can be also found in ADAMS under Accession No. ML22269A546.

If you have any questions regarding this communication, please contact the individual named below:

POINT OF CONTACT: Celimar Valentin-Rodriguez

E-MAIL: Celimar.Valentin-Rodriguez@nrc.gov

TELEPHONE: 301-415-7124

Signed by Anderson, Brian on 09/27/22

Brian C. Anderson, Branch Chief State Agreement and Liaison Programs Branch Division of Materials Safety, Security, State, and Tribal Programs Office of Nuclear Material Safety and Safeguards STC-22-059 Notification of Issuance and Opportunity to Comment on Interim State Agreement Procedure SA-802 Standing Committee for Reviewing Emerging Medical Technologies DATE October 5, 2022

DISTRIBUTION:

ADAMS Accession No.: ML22269A547

OFFICE	NMSS/MSST	NMSS/MSST/MSEB	NMSS/MSST/SALB	
NAME	CValentin-Rodriguez <i>CV</i>	CEinberg <i>CE</i>	BAnderson <i>BA</i>	
DATE	Sep 27, 2022	Sep 27, 2022	Sep 27, 2022	

OFFICIAL RECORD COPY