WORKING GROUP CHARTER
Veterinary Release Rulemaking

PURPOSE

The purpose of this Working Group (WG) is to develop a rulemaking plan to request Commission approval to initiate a rulemaking to develop a regulatory framework that would authorize veterinary licensees to release animals containing byproduct material following veterinary procedures (e.g., diagnostic, therapeutic, and research) with appropriate instructions under certain circumstances. This charter describes the WG's composition and activities and provides an estimated schedule for developing the rulemaking plan.

SCOPE

Release of animals containing byproduct material has been authorized by the U.S. Nuclear Regulatory Commission (NRC) for over 20 years when public dose limits are unlikely to be exceeded. However, there is no specific regulatory framework in NRC regulations that allows veterinary licensees to release animals containing byproduct material. The staff will develop a clear and reliable risk-informed and performance-based regulatory framework, to ensure predictability and reliability of NRC actions with respect to regulating veterinary treatment of animals. This will ensure consistency in licensing actions in accordance with the agency's Principles of Good Regulation. The scope of this rulemaking would be to develop a regulatory framework to address this regulatory gap. This rulemaking would affect veterinary licensees or license applicants that are regulated by the NRC or the Agreement States.

OBJECTIVE

The objective of the WG is to develop a rulemaking plan for Commission consideration to initiate a Veterinary Release rulemaking. If approved, the WG would develop a regulatory basis, proposed rule, and potentially final rule and associated guidance. In developing the rulemaking plan, the WG will consider all alternatives to accomplish the outcome of the rulemaking, including non-rulemaking alternatives.

BACKGROUND

Appendix D to NUREG-1556, Volume 7, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18065A006), provides guidance to licensees on releasing animals containing byproduct material. This guidance states that licensees may release animals containing byproduct material after a veterinary procedure when the licensee ensures doses to members of the public will be below the 10 CFR Part 20, "Standard for Protection Against Radiation," dose limits. The guidance additionally states that licensees should provide written instructions to owners to reduce the dose to members of the public. The instructions should provide a margin for dose reduction but should not be relied upon as the primary way of keeping the dose to members of the public below the 10 CFR Part 20 dose limits. Historically, the most common veterinary uses of byproduct material are administrations of sodium iodide-131 (NaI-131) for therapeutic treatment of hyperthyroidism in cats. In such cases, owners are generally given instructions to follow for a short period of time. Due to the longer half-life of some emerging radionuclides

used in various veterinary medicine procedures, in order to control doses, pet owners and household members would need to follow instructions for a longer duration than what is required for NaI-131. Currently, the NRC does not have a specific regulatory framework to authorize licensees to release animals containing byproduct material following veterinarian procedures beyond the generic approach in 10 CFR Part 20. The NRC is contemplating a rulemaking to codify the authorization of veterinary licensees to release animals containing byproduct material with appropriate instructions under certain circumstances. This rule would be appropriately risk-informed and performance-based, while providing the needed clarity to veterinary licensees and license applicants that are regulated by the NRC or Agreement States.

MEMBERSHIP

Direct WG support is expected to come from the Division of Materials Safety, Security, State, and Tribal Programs (MSST) and the Division of Rulemaking, Environmental, and Financial Support (REFS), both within the Office of Nuclear Material Safety and Safeguards (NMSS); Organization of Agreement States, Inc. (OAS); NRC Region I; and the Office of the General Counsel (OGC). The project sponsor for this activity is Kevin Williams, Director, NMSS/MSST.

On January 16, 2019, NMSS issued NMSS Procedure State Agreement (SA)-801A, "Agreement State Participation in Rulemaking Working Groups" (ADAMS Accession No. ML18263A239). SA-801A details the procedure for NRC and Agreement State interactions during the entire rulemaking process and complements other NRC directives and guidance for rulemaking activities. In accordance with SA-801A, this is an NRC/OAS WG as described under NRC Management Directive 5.3, "Agreement State Participation in Working Groups," and chaired by an NRC staff member. The WG may seek additional expertise on an as-needed basis. The WG membership and responsibilities are depicted in the following table:

Organization	Working Group Members
NRC/NMSS/MSST	Andrew Carrera, Chair and Technical Lead Katie Tapp, Back Up and Technical Lead
OAS	Adam Gause (South Carolina), Agreement State Representative
NRC/NMSS/REFS	Caylee Kenny, Rulemaking Project Manager
NRC/NMSS/REFS/Regulatory Analysis and Support Branch (RASB)	Angella Love-Blair, Regulations Specialist
NRC/NMSS/REFS/RASB	Pamela Noto, Cost Analyst
NRC/Region I	Robin Elliott, Regional Representative
NRC/OGC	Adam Gendelman, Senior Attorney

If the WG needs management support to resolve issues that are significant or have policy implications, then a Steering Committee would be convened for this effort. The Steering Committee Chairperson would be the Director or Deputy Director of REFS, and the members would include the Director of MSST; the Director of the Division of Radiological Safety and Security (Region I); the OGC Assistant General Counsel for Reactors, Agreement States, and Fee Policy; and the OAS Director of Rulemaking appointed by the OAS Executive Board/Director of Emerging Issues and Advocacy, or their designees.

SCHEDULE

The high-level schedule below covers the rulemaking plan development process. The schedule is preliminary and may change. A more detailed schedule will be provided to WG members.

WG kickoff meeting	October 7, 2021
WG develops rulemaking plan (including problem statement, alternatives, and costs/benefits)	Mid October 2021 – March 2022
Government-to-government meeting with Agreement States to discuss alternatives considered by the WG[1]	December 2021
WG aligns with the divisions, office, and the Office of the Executive Director for Operations (OEDO) on the alternatives considered and path forward of the rulemaking plan	December 2021 – January 2022
Interdivision (REFS, MSST, and NRC Region) review and concurrence on the rulemaking plan package; OAS reviews and provides comments to NRC	March – April 2022
OGC No Legal Objection (NLO) review	May 2022
NMSS office reviews and concurs on rulemaking plan package	June – July 2022
OEDO reviews and concurs	July 2022
Rulemaking Plan Submittal to the Commission	Early August 2022

LEVEL OF EFFORT EXPECTED OF WG MEMBERS

To support the schedule and activities listed above, approximately 100 hours of effort is expected for WG members with no authoring responsibility to:

1. Attend and participate in weekly meetings on the development of the rulemaking plan package and review draft documents, from October 2021 – July 2022, approximately 2 hours each meeting.
2. Support three management alignment briefings during the rulemaking plan package development period, from December 2021 – January 2022, approximately 1 hour each meeting.
3. Review the rulemaking plan package and provide comments to management (if requested by the division management or OAS Director of Rulemaking) during the Agreement State review and NRC interdivision review and concurrence period, approximately 10 hours total.
4. Attend and support monthly Steering Committee meetings (if one is set up), from October 2021 – July 2022, approximately 1 hour each meeting.

Management briefings will be held, as needed, during the development of the rulemaking plan package. Members of the WG are invited to attend and support these briefings. WG members should keep their management appropriately apprised of WG activities throughout the development of the rulemaking plan. WG meeting dates and locations will be coordinated by the project managers in consultation with the WG, as appropriate. All WG meetings and briefings will be teleconference supported. Maximum use will be made of available electronic

[1] OAS representative on the rulemaking WG to lead the meeting.

communication options to facilitate interaction within the WG and among its members. Examples of these communications include conference calls, emails, and other options. This working group operates as an NRC/OAS working group with the roles and responsibilities described in Section IV of SA-801A and NRC Management Directive 5.3.

Signed by Tappert, John on 11/10/21

November 10, 2021

John R. Tappert, Director, NRC/NMSS/REFS — Date

Signed by Williams, Kevin on 11/10/21

November 10, 2021

Kevin Williams, Director, NRC/NMSS/MSST — Date

November 10, 2021

Auggie Ong, Chair, OAS — Date

SUBJECT: WORKING GROUP CHARTER – VETERINARY RELEASE RULEMAKING

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ADAMS Accession No.: ML21299A348

OFFICE	NMSS/MSST/MSEB	NMSS/MSST/MSEB	NMSS/REFS/MRPB
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