

WORKING GROUP CHARTER

Rulemaking on Exempt Quantities in Section 30.71, “Schedule B”

PURPOSE: The purpose of this working group (WG) is to develop a rulemaking plan to request Commission approval to initiate a rulemaking to revise Section 30.71, “Schedule B,” of Title 10 of the *Code of Federal Regulations* (10 CFR), to include additional radionuclides that are currently not listed in the table. This table is used along with 10 CFR 30.18, “Exempt Quantities,” in determining the need for a specific license. The staff also plans to revise certain sections in 10 CFR Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” related to exemptions to make clear when a license is required.

DISCUSSION: The regulation in 10 CFR 30.18(a) exempts persons from the requirements for a license for byproduct material if the quantity does not exceed the applicable quantity listed in Schedule B. On August 8, 2005, the President signed into law the Energy Policy Act. This law expanded the definition of byproduct material, which added additional byproduct material to the U.S. Nuclear Regulatory Commission’s (NRC) jurisdiction. Schedule B does not include all of the radionuclides that are now within the NRC’s jurisdiction. Many people use these radionuclides in research and as check sources. Because the radionuclides are not listed in Schedule B, a person must obtain a license for possession and use. The addition of radionuclides, including alpha emitters, for use by the medical, industrial, commercial, and academic communities will reduce regulatory burden for end users of these products which would be used under 10 CFR 30.18 “Exempt quantities.” Schedule B would be updated using the quantities that are in Appendix C, “Quantities of Licensed Material Requiring Labeling,” to 10 CFR Part 20, “Standards for Protection Against Radiation.”

MEMBERSHIP: This WG is sponsored by the Office of Nuclear Material Safety and Safeguards (NMSS), Division of Rulemaking, Environmental, and Financial Support (REFS) and Division of Materials Safety, Security, State and Tribal Programs (MSST). The rulemaking organization, REFS, will be the rulemaking lead organization, and MSST will be the principal technical lead organization. The management sponsors for this activity are Jill Shepherd, Branch Chief, NMSS/REFS/Materials Rulemaking and Project Management Branch (MRPB); Maria Arribas-Colon, Branch Chief, NMSS/MSST/Materials Safety and Tribal Liaison Branch (MSTB); and Christian Einberg, Branch Chief, NMSS/MSST/Medical Safety and Events Assessment Branch (MSEB). The WG will consist of NRC staff members and a representative from the Organization of Agreement States (OAS). The membership of the WG is provided in the table below. The WG may seek additional expertise as needed.

Name	Organization	Role
Shirley Xu	NMSS/MSST/MSTB/SSDT	Technical Lead
Torre Taylor	NMSS/REFS/MRPB	Rulemaking Project Manager
Helen Chang	NMSS/REFS/RASB	Regulations Specialist
Alexa Sieracki	NMSS/REFS/RASB	Cost Analyst
Daniel Dimarco	NMSS/MSST/MSEB	Working group member
Jeffery Lynch	NMSS/MSST/SALB	Working group member
Betsy Ullrich	RI/DRSS/CIRDA	Working group member
Brenda Miles	OCIO	Paperwork reduction act support
Brian Harris	OGC/LRAA/RASFP	Attorney
Frank Pepper	OAS	Working group member

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A Steering Committee will be convened if the WG needs management support to resolve issues that are more than minor. The Steering Committee Chairperson is the Director or Deputy Director of REFS, and the members include:

1. Chair, Director of REFS
2. Deputy Director of MSST
3. Director of Region I Division of Radiological Safety and Safeguards
3. OGC Assistant General Counsel for Rulemaking, Agreement States, and Fee Policy
4. OAS Director of Rulemaking or their designee

OBJECTIVES:

1. Develop a rulemaking plan to request Commission approval to initiate a rulemaking to revise 10 CFR 30.71, to include additional radionuclides that are currently not listed in the table, and revise certain sections in 10 CFR Part 30 related to exemptions, to make clear when a license is required. In developing the rulemaking plan, the WG will ensure that all options for accomplishing the objectives of the rulemaking have been appropriately considered. The WG will also evaluate the need for a regulatory basis before developing a proposed rule.
2. Develop proposed and final rule packages for Commission review and approval with consideration of associated public comments.

SCHEDULE: The estimated high-level schedule below covers development of the rulemaking plan document as well as the proposed and final rules. If staff determines that a regulatory basis is needed, the schedule will shift by about 1 year. The schedule is preliminary and may change. Detailed schedule information will be provided to WG members.

WG kick-off meeting	March 21, 2022
Develop rulemaking plan document	April–July 2022
Management and Agreement State review	October 2022–March 2023
Rulemaking plan due to Commission	April 2023
Proposed rule due to Commission	12 months after approval of initiation of rulemaking by Commission
Final rule due to Commission	14 months after end of public comment period

LEVEL OF EFFORT: The level of effort for each WG member is estimated to be approximately 50 hours and is listed below. The level of effort is subject to change.

1. During the development of the rulemaking plan, the level of effort will be approximately 2 hours per week for 16 weeks, which includes 1 hour of preparation time. Working group meetings will be scheduled each week for 1 hour. (32 hours total)
2. During the rulemaking plan and concurrence period, the level of effort will be approximately 3 hours to address comments from NRC management and the Agreement States at the five stages of review. The WG will meet after each review with 2 hours each to review and revise the rulemaking plan based on comments and 1-hour WG writing sessions. (15 hours total)

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3. Briefings with the steering committee will be held as needed during the development of the rulemaking plan. (2 hours total)

Management briefings will be held as needed during the development of the rulemaking plan and proposed and final rules. Members of the WG will support these briefings as needed. All WG meetings and briefings will be hybrid, with teleconference or Microsoft Teams available.

Maximum use will be made of available electronic communication to facilitate interaction within the WG. Examples of these include Microsoft Teams meetings, conference calls, e-mails, and other options. There is no travel anticipated with this rulemaking activity.

WORKING GROUP MEMBERS ROLES AND RESPONSIBILITIES

This WG operates as an NRC/Agreement State WG with the roles and responsibilities described in Section IV of [SA-801A](#), “Agreement State Participation in Rulemaking Working Groups,” (ADAMS Accession Number 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.

Responsibilities of the WG members depend on their areas of programmatic responsibility and expertise. The following points reflect the duties and responsibilities of the WG members. The responsibilities of the Agreement State representative(s) to the WG are specified in Section IV.I of SA-801A and includes keeping the OAS Board (i.e., Director of Rulemaking) informed of the status of the project. In general, WG members should:

1. Work with the rulemaking project manager or technical lead to assess the tasks needed to: prepare the rulemaking product package and any related guidance; review and comment on drafts; address comments; assist in estimating any information collection burden; assist in the development of cost estimates; assist in preparing briefing materials; and facilitate concurrence on the package.
2. Keep their branch, division, and office managers apprised of the status of the rulemaking action; obtain comments and input on policy decisions from their branch and division managers; and notify their BCs of potential problems or policy issues.
3. Ensure that their management’s opinion is understood and shared with the WG.
4. Review draft schedules and provide input reflecting their management’s views. Coordinate with the RM project manager (PM) to ensure a feasible and mutually acceptable schedule of deliverables.
5. Attend WG meetings and come prepared to participate.
6. Provide timely input.
7. Inform the RM PM and guidance PM, as appropriate, of conflicting priorities, previously unanticipated problems, and other potential sources of delay.

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8. Review contractor reports (where REFS has lead contractor responsibility) or monitor contractor efforts (where WG member's division or office has lead contractor responsibility).
9. Prepare associated licensing, inspection, and enforcement guidance, as appropriate (if the same WG is used for the guidance). The technical lead division is responsible for preparing guidance documents and coordinating with affected organizations. The technical lead should develop milestones for the guidance that ensure that the draft or final guidance will be available for office-level review and concurrence at the same time as the proposed or final rule package enters office-level review and concurrence. (Often the members of the WG for the rule will participate on the WG for the guidance.)
10. Keep their management on the steering committee informed.
11. Facilitate the rulemaking concurrence process by keeping their management informed of significant issues of concern and helping to develop an appropriate resolution of those issues. Clear and frequent WG member communication with their management during document development is essential to minimize the number of new issues identified during the concurrence process.
12. Support briefings, committee meetings, and public meetings, as necessary.
13. Prepare and present material related to the guidance or other areas for which they may have a lead at public meetings.
14. Follow SA-801A and the WG Charter.

Tara Inverso, Deputy Director, NRC/NMSS/REFS

Date

Theresa Clark, Deputy Director, NRC/NMSS/MSST

Date


Auggie Ong, Chair, Organization of Agreement States

Date

05/25/22

SUBJECT: WORKING GROUP CHARTER FOR RULEMAKING PLAN - RULEMAKING ON
EXEMPT QUANTITIES IN SECTION 30.71, "SCHEDULE B"
DATED: MAY 25, 2022

ADAMS Accession Number: ML22105A569

OFFICE	NMSS/REFS/ MRPB	NMSS/REFS/ MRPB	NMSS/MSST/ MSTB	NMSS/MSST/ MSTB:BC	NMSS/REFS/ MRPB:BC	NMSS/MSST/ SALB:BC
NAME	TTaylor	PCline-Thomas	SXu	MAribas	JShepherd	BAnderson
DATE	04/19/22	04/18/22	04/19/22	04/19/22	4/25/22	04/19/22
OFFICE	NMSS/MSST:DD	NMSS/REFS:DD				
NAME	TClark	TInverso				
DATE	5/11/22	5/11/22				