

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

May 10, 2019

William Irwin, Sc.D., CHP, Chief Office of Radiological Health Vermont Department of Health 108 Cherry Street P.O. Box 70 Burlington, VT 05402

Dear Dr. Irwin:

We have reviewed the final revisions to the Vermont regulations Chapter 6, Subchapter 5 "Radioactive Materials Rules," received by our office on April 11, 2019. These regulations were reviewed by comparison to the equivalent U.S. Nuclear Regulatory Commission (NRC) rules as identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Lillian Colasurdo (Assistant Attorney General for the Vermont Department of Health) on May 3, 2019.

As a result of our review, we have five comments related to compatibility that have been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. We have determined that if these regulations are revised, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements." We also have three editorial comments identified in the enclosure that are not necessary for compatibility but should be addressed in the State's next rulemaking.

In order to resolve these comments and ensure compatibility of the Vermont regulations, the NRC staff requests a letter from Vermont Department of Health, copying the Vermont Attorney General and Governor of Vermont, that commits to making the changes described in this letter as soon as practicable. This commitment letter needs to be provided to the NRC staff, addressed to Kevin Williams, Deputy Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, no later than 60 days from the date of this letter. However, the resolution of these comments does not interfere with NRC staff's processing of Vermont's agreement state application.

We request that when you revise your regulations to address our comments, a copy of the "as published" regulations be provided to us for review. As requested in NMSS Procedure SA-201, "Review of State Regulatory Requirements," please highlight the location of any changes made by Vermont, in response to our comments, and provide a copy to Kevin Williams, Deputy Director, Division of Materials Safety, Security, State, and Tribal Programs, NMSS. The SRS Data Sheet summarizes our knowledge of the status of other Vermont regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, will be posted on the NMSS State Communication Portal: https://scp.nrc.gov/rulemaking.html.

W. Irwin 2

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact Michelle Beardsley, State Regulation Review Coordinator, at (267) 884-2305 (Michelle.Beardsley@nrc.gov) or Monica Ford at (610) 337-5214 (Monica.Ford@nrc.gov).

Sincerely,

/RA/

Andrea L. Kock, Director Division of Materials Safety, Security, State and Tribal Programs Office of Nuclear Material Safety and Safeguards

Enclosures:

- 1. Compatibility Comments
- 2. Vermont SRS Data Sheet

CC:

L. Colasurdo, VT Dept. of Health Vermont Attorney General Governor of VT W. Irwin 2

SUBJECT: VERMONT DEPARTMENT OF HEALTH LETTER, DR. IRWIN

DATE: MAY 10, 2019

DISTRIBUTION: SP05 DIR RF 19-26 MFord, RSAO DWhite, SALB VT File

ADAMS Accession No.: ML19102A160 (Letter) ML19102A130 (Package) *via email

OFFICE	RI	ASPB	OGC	ASPB:BC	MSTR:D
NAME	MFord	MBeardsley	MSegarnick	PMichalak	AKock
DATE	4/25/19	5/2/19	5/3/19	05/7/19	05/10/19

OFFICIAL RECORD COPY

COMPATIBILITY COMMENTS ON VERMONT FINAL REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	1.3.8	20.1003 30.4 40.4 70.4	10 CFR 20, 30, 40, 70	[A]	Definition: Special Nuclear Material In section 1.1.8, VT omits the phrase, "but does not include source material" from section 1.3.8. This language should be included at the end of item (1) and the end of item (2). VT needs to make the above change to section 1.3.8 in order to meet the Compatibility Category [A] designation assigned to 10 CFR 20.1003 Definition of "Special Nuclear Material."
2	1.2.6.4 12.2.1	30.4 35.2 36.2 39.2	10 CFR 30, 35, 36, and 39	B [B] [B]	Definition: Sealed source VT adopts a definition of sealed source in section 1.2.6.4 that is not essentially identical to the definition of sealed source as stated in 10 CFR 30.4, 35.2, 36.2, and 39.2. Also, VT adopts the definition of sealed source by reference in Section 12.2.1. VT should delete the definition of sealed source from section 1.2.6.4 during its next rulemaking to meet the Compatibility Category B designation assigned to 10 CFR 30.4, and the Compatibility Category [B] designation assigned to 10 CFR 35.2, 36.2, and 39.2, Definitions of Sealed Source.
3	12.6.2	32.26	10 CFR 32	NRC	Gas and Aerosol Detectors containing byproduct material: Requirements for license to manufacture, process, produce or initially transfer VT states in Section 12.6.2 that it does not incorporate 10 CFR 32.26 by reference. 10 CFR 32.26 relates to Gas and Aerosol detectors

STATE SECTION NRC SECTION		RATS ID	CATEGORY	SUBJECT and COMMENTS	
					containing Byproduct Material. In VT's Section 1.2.6.5, VT states that Byproduct Material includes NARM. Therefore by adopting a regulation for the incorporation of NARM into a gas or aerosol detector, VT is regulating an activity delegated to the NRC under 10 CFR 32.26 which is a Compatibility Category NRC. VT needs to delete section 12.6.2 in order to meet the Compatibility Category NRC designation assigned to 10 CFR 32.26.
4	1.3 1.2.5 19.0	61.2	10 CFR 61	B, C	Definitions: Disposal, Waste, and Hazardous Waste VT adopts the definitions in 10 CFR Part 61 by reference in Section 1.3. However, they do not adopt definitions of "disposal", "waste", and "hazardous waste" in Sections 1.2.5 and 19.0. VT needs to adopt these three definitions in order to meet the Compatibility Category B designation assigned to 10 CFR 61.2, Definition of Waste, and the Compatibility Category C designation assigned to 10 CFR 61.2, Definitions of Disposal, and Hazardous Waste.
5	12.10.1	150.3	10 CFR 150	NRC	Definition: Foreign Obligations VT adopts all of 10 CFR 150.3 by reference in Section 12.10.1. Since this definition is a Compatibility Category NRC, VT cannot adopt it by reference. VT needs to not adopt by reference the Definition of "Foreign Obligations" in order to meet the Compatibility Category NRC designation assigned to 10 CFR 150.3 Definition of "Foreign Obligations".

Editorial Comments

State Section	NRC Section	Comment
1.3.6 1.3.11 7.2.1	19.3 Definition Regulated Entities	This regulation is a Compatibility Category D and therefore not required to be adopted. However, VT adopts a definition of "Regulated Entities" in 1.3.6; States that the definition of "regulated entity" as stated in 10 CFR 19.3 is not adopted by reference in 1.3.11; and adopts all of 10 CFR 19.3 (and thereby adopts the definition of "regulated entity") in 7.2.1. This may cause confusion. VT should add the definition of "regulated entities" as
		stated in 10 CFR 19.3 to Section 7.2.2 so that it is not adopted by reference.
12.8.2	40.13	VT says it does not adopt 10 CFR 40.13(j) and (m) by reference in section 12.8.2. There are no equivalent sections to 40.13(j) and (m) in the 10 CFR. VT should remove these references during its next rule update.
1.2.6.5 1.3.4 12.8.2	10 CFR 40.4	The definition of "byproduct material" in 10 CFR 40.4 is limited to the meaning of byproduct material as defined in the Atomic Energy Act § 11e.(2), and does not include naturally occurring or accelerator-produced material, which are types of byproduct material as defined in AEA §§ 11e.(3) and (4). Therefore, the following sentence is an incorrect interpretation of 10. CFR 40.4

and should be deleted where it appears (in similar form) throughout the state regulations:

"In 10 C.F.R. 40.4, the definition of "Byproduct Material" includes naturally occurring or accelerator-produced material (NARM)."

Also, note that the inclusion of NARM in the meaning of "byproduct material" as stated in Section 1.2.6.5 extends the meaning of byproduct material to include NARM, which is not otherwise included in the definition of byproduct material in 10 CFR 40.4. While this is not a compatibility issue because the definition is compatibility category "H&S," and meets the essential objectives of the regulation, the inclusion of NARM in byproduct material is broader than the definition in 10 CFR 40.4.

STATE REGULATION STATUS

State: Vermont

[The amendment(s) reviewed are identified by an "*" at the beginning of the equivalent NRC requirement.]

De	beginning of the equivalent NRC requirement.]					
RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes	
*NA	10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61.55¹, 61.66¹, 61.67¹, 70, 71, and 150 Vermont Radioactive Materials Rule	NA	ML17172A627 6/19/2017 Revised Proposed ML17331A820 11/22/2017 Revised Proposed ML18019A066 01/18/2018 Revised Proposed ML18268A249 09/24/2018 Final ML19102A160	Comments 10/25/2017 ML17172A626 Comments 01/09/2018 ML17331A819 No Comments 02/27/2018 ML18019A050 Comments 10/4/2018 ML18268A243 Comments 05/10/2019 ML19102A130	Vermont submitted regulations that incorporate NRC regulations by reference.	
2018-1	Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments, 10 CFR Parts 30, 32 and 35	01/14/2022			Vermont incorporates Parts 30, 32, and 35 by reference in their final regulations which were effective March 1, 2019. Therefore, the regulations in this RATS ID have been incorporated by reference.	
2018-2	Miscellaneous Corrections -	12/21/2021			Vermont incorporates Parts 30, 32, and	

Tracking Ticket Number: 19-26

Date: 05/10/2019

Organizational Changes 10 CFR Parts 37, 40. 70 and 71		35 by reference in their final regulations which were effective March 1, 2019. Therefore, the regulations in this RATS ID have been incorporated by reference.
---	--	--

¹ IMPEP review team: Vermont submitted Parts 61.55, 61.56 and 61.57 relating to classification, characterization, and labeling of radioactive waste only; please ensure that Vermont does not have licensees/plans for Part 61 facilities.