



UNITED STATES
NUCLEAR REGULATORY
COMMISSION
WASHINGTON, D.C. 20555-0001

March 11, 2022

Mr. Paul Schmidt, Chief
State of Wisconsin Department of Health Services
Radiation Protection Section
1 West Wilson Street
P.O. Box 2659
Madison, WI 53701-2659

SUBJECT: TECHNICAL ASSISTANCE REQUEST: WISCONSIN DEPARTMENT OF HEALTH SERVICES

Dear Mr. Schmidt:

This letter is in response to the Wisconsin Department of Health Services' (DHS) Technical Assistance Request (TAR), dated December 6, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML22027A510). The TAR requested that the U.S. Nuclear Regulatory Commission (NRC) respond to Wisconsin DHS's questions regarding jurisdiction over its licensees' Type B package quality assurance (QA) programs, as described in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71.17 and 10 CFR 71, subpart H.

Background:

Under 10 CFR 71.17, the NRC grants a general license to any NRC licensee to transport, or deliver for transport, licensed material in an NRC-approved package if the licensee has an approved QA program which meets the requirements of 10 CFR Part 71, subpart H. QA programs for Type B packages can be either "full-scope" (including design fabrication, and modification) or "user-only." Although the NRC is the sole regulatory authority for "full-scope" QA programs, the Agreement States regulate "user-only" Type B package QA programs for use within their jurisdiction (see STC-17-060 (ADAMS Accession No. ML17213A844) for additional information regarding this regulatory authority).

Wisconsin's Request for Assistance:

Starting in early 2022, the Missouri University Research Reactor (MURR) will be routinely shipping Type B quantities of molybdenum-99 and technetium-99m to a facility in Beloit, Wisconsin, operated by NorthStar Medical Technologies (NorthStar) and under the jurisdiction of Wisconsin DHS. The Type B package used for these shipments are owned by NorthStar, but will be packaged for shipment in Missouri, by MURR staff, under MURR's Part 50 research reactor license and provided to a carrier for shipment using the general license under 10 CFR 71.17. MURR will be the shipper of record on the shipping papers.

Wisconsin DHS has determined that, as the package owner, NorthStar bears responsibility for the maintenance of the packages. Wisconsin DHS believes that NorthStar has adequate

administrative infrastructure and technical expertise to support the proposed partial "user-only" Type B quality assurance program which are occurring in Wisconsin under NorthStar's authority.

Since MURR is the shipper, NRC would have oversight of the pre-shipment elements of the Type B quality assurance program, which are performed in Missouri by MURR staff. Wisconsin DHS therefore intends to approve and inspect the elements of a "user-only" Type B quality assurance program which are occurring in Wisconsin under NorthStar's authority.

Wisconsin's DHS requests clarification on the following questions:

Wisconsin DHS Question 1: Can an entity that is not a 10 CFR 71.17 general licensee bear regulatory responsibility for a "user-only" Type B quality assurance program? DHS has determined that NorthStar can assume responsibility for elements of a Type B quality assurance program even though they are not the shipper (i.e., because they are the cask owner). Does NRC concur with this assessment?

NRC Staff Response: The NRC concurs with the assessment. An entity who is not a general licensee of the Commission under 10 CFR 71.17 can hold a "user-only" QA program, so long as the entity is a licensee of the Commission.

A "user-only" QA program would be applicable to the procurement, maintenance, repair, and use activities conducted by NorthStar with regard to its transportation packages. Thus, when NorthStar sends those packages to an NRC licensee, such as MURR, NorthStar should include any documentation that MURR (pursuant to 10 CFR 71.17) would need to ensure that the package as fabricated and maintained will meet the certificate of compliance. The NRC Information Notice 2004-13 (ADAMS Accession No. ML041810535) may provide some further clarifying information.

Wisconsin DHS Question 2: Does NRC concur that oversight of the Type B QA program for these shipments can be split between NRC and Wisconsin DHS, with NRC overseeing the task being performed by MURR and Wisconsin DHS overseeing the tasks being performed by NorthStar?

NRC Staff Response: The NRC has oversight responsibility for operations at MURR, which includes transportation activities. The inspection program implemented at MURR for transportation activities and performed on an annual basis includes requirements for the review of the transportation QA program and associated quality activities pertaining to the use of packages, which includes pre-shipment quality activities such as inspection, loading, closing, and preparation of the package for shipment; as well as delivery of the package to the carrier, including the associated radiological surveys and hazardous material communications (e.g., shipping papers, package marking and labeling, placarding, etc.). The NRC concurs that the oversight of quality activities performed by NorthStar, which is planned to include, but not limited to, package storage and annual maintenance, are the responsibility of Wisconsin DHS as NorthStar is a licensee of the State of Wisconsin.

Wisconsin DHS Question 3: Wisconsin DHS notes that many of the regulations for quality assurance programs in 10 CFR 71, Subpart H, are currently designated as Compatibility Category "NRC". However, the Compatibility Category of 10 CFR 71.101(c) is "C," and in July 2017, the Standing Committee on Compatibility agreed that the Agreement States are the regulatory authority to regulate all aspects of a "user-only" QA programs. Does NRC agree that

Agreement States have the authority to regulate all aspects of a "user-only" QA program (including the program elements currently designated as Compatibility Category "NRC")?

NRC Staff Response: As you note, certain regulations in 10 CFR Part 71 that contain quality assurance program (QAP) review criteria (e.g., §§ 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125) are designated as Compatibility Category NRC, and cannot be adopted by the Agreement States. The NRC is proposing to address these compatibility issues in a current rulemaking so that the Agreement States can adopt compatible QAP regulations that would require their licensees to follow these QAP criteria, and allow Agreement States to approve, inspect, and enforce their licensees' QAPs. Regulatory Guide (RG) 7.10 contains specific guidance for reviewing QAPs based on the criteria in the above regulations. [REDACTED] until the Part 71 rulemaking is completed to change the compatibility categories, the Agreement States may review their licensees' QAPs using the guidance in RG 7.10. When an Agreement State approves a QAP that meets RG 7.10 guidance, the Agreement State may incorporate the QAP into the license, which would make the QAP enforceable by the Agreement State.

If you have any questions regarding this correspondence, please contact me at (817) 200-1180 or Tomeka Terry at (301) 415-1488 or Tomeka.Terry@nrc.gov.

Sincerely,

Geoffrey B.
Miller

Digitally signed by Geoffrey
B. Miller
Date: 2022.03.11 12:30:30
-05'00'

Geoffrey Miller, Acting Deputy Director
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

SUBJECT: TECHNICAL ASSISTANCE REQUEST: WISCONSIN DEPARTMENT OF HEALTH SERVICES DOCUMENT DATE: MARCH 11, 2022

DISTRIBUTION:

- BWhite, NMSS
- JTapp, NMSS
- YDiaz-Sanabria, NMSS
- MBeardsley, NMSS
- BAnderson, NMSS
- HGonzalez, NMSS
- SHelton, NMSS
- JMcManus, OGC
- CMcCann, OGC

ADAMS Accession No.:ML22024A138 *via e-mail

OFFICE	NMSS/DFM	NMSS/DFM	OGC	NMSS/DFM
NAME	TTerry*	SFiguroa*	JMcManus*	BWhite*
DATE	01/24/22	01/26/22	02/23/22	02/25/22
OFFICE	NMSS/DFM	NMSS/DFM	NMSS/MSST	NMSS/MSST/SALB
NAME	JTapp*	Chris Jacobs for/ YDiaz-Sanabria*	MBeardsley*	BAnderson*
DATE	02/28/22	03/01/22	02/28/22	02/28/22
OFFICE	NMSS/DFM	NMSS/DFM		
NAME	HGonzalez*	GMiller*		
DATE	03/01/22	03/11/22		

OFFICIAL OFFICE USE ONLY