Tony Evers
Governor

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Secretary

State of Wisconsin
Department of Health Services

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May 28, 2026

Kathryn Brock, Acting Deputy Director
Division of Materials Safety, Security, State and Tribal Programs
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
T8-E18
Washington, D.C. 20555-0001

Dear Ms. Brock:

Enclosed is a copy of the requirement that corresponds to the following equivalent amendments to NRC's regulations.

RATS-ID	Title	State Section
2023-1	Miscellaneous Corrections - 10 CFR Parts 1, 2, 26, 32, 40, 50, 51, 52, 72, and 73	See attached policy

Because the affected requirement applies only to applicants (not to licensees), we believe that adoption of this Program policy satisfies the compatibility and health and safety categories established in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200. Wisconsin Agreement State staff were instructed on this policy on May 13, 2026.

If you have any questions, please feel free to contact Mark Paulson of my staff at 608-264-6516 or mark.paulson@dhs.wisconsin.gov.

Sincerely,

Mark Werner
Director, Bureau of Environmental and Occupational Health
Executive Sponsor, Radioactive Materials Program

Enclosures:
As stated.

Enclosure 1: Wisconsin Department of Health Services Radioactive Materials Program Policy Memo

To: Mark Paulson
From: Megan Shober
Date: May 28, 2026

Re: RATS-ID 2023-1 and DHS 157.13(4)(i) 2.a.

Background: Entities such as pharmacies or drug manufacturers who apply for a radioactive materials license to manufacture, prepare, or transfer radioactive drugs for distribution for medical use are subject to the approval criteria in DHS 157.13(4)(i). For the purposes of this policy, these entities are referred to as "radiopharmacies."

DHS 157.13(4)(i) 2. gives the applicant several options for demonstrating that its production of drugs is licensed by another oversight body such as the US Food and Drug Administration (FDA), a state board of pharmacy, or another state agency. The option described in DHS 157.13(4)(i) 2.a. contains an incorrect regulatory reference to 21 CFR 207. Since the Wisconsin Radioactive Materials Program requires these entities to be licensed by the Wisconsin Board of Pharmacy, the compatibility concern is minimal.

Discussion:

1. Radioactive Materials Program Procedure 2.02 "Initial Applications, Renewals, or Requests to Amend a Radioactive Materials License" directs licensing staff to use DHS 157 as a technical basis for evaluating license applications.

   Compensatory action: When reviewing a new radiopharmacy license application where the applicant submits evidence that they are registered or licensed with the FDA as the owner or operator of a drug establishment, license reviewers will ensure that the entity is registered with the FDA under 21 CFR 207.17(a), instead of 21 CFR 207.20(a).

2. Radioactive Materials Program Procedure 2.06 "Receipt and Prioritization of Licensing Actions" directs administrative staff to inform applicants that their radioactive materials license application has been received.

   Compensatory action: After receiving a new license application for a radiopharmacy, the Radioactive Materials Program will inform the applicant of the error in DHS 157.13(4)(i)2.a. and will provide the correct regulatory reference of 21 CFR 207.17(a).

This policy will remain in place until the rule reference in DHS 157.13(4)(i) 2.a. is corrected.