



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

October 14, 2026

MEMORANDUM TO: Hossein Jadvar, M.D., Ph.D., Chair
Advisory Committee on the Medical Uses of Isotopes

FROM: Chris Einberg, Chief  Signed by Christian Einberg on 10/14/26
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, and State Programs
Office of Nuclear Material Safety and Safeguards

SUBJECT: RESPONSES TO THE ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES'S RECOMMENDATIONS ON
THE TARGETED ALPHA THERAPIES RADIOISOTOPE
LICENSING AND OVERSIGHT MEMORANDUM

Below are the U.S. Nuclear Regulatory Commission's (NRC) staff responses to the recommendations and comments from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on the Targeted Alpha Therapies Radioisotope Licensing and Oversight Memorandum. The ACMUI provided these recommendations and comments to the NRC staff on April 20, 2026, following review of the memorandum Agencywide Documents Access and Management System (ADAMS) Accession No. (ML26237A162). The full report from the ACMUI can be found at (ML26138A233).

Recommendations

1. **ACMUI Recommendation:** When referring to FDA approved radiopharmaceuticals, the generic name, brand name, manufacturer and indication should be used and not just the nuclide.

NRC Response: Accepted

2. **ACMUI Recommendation:** Make presented on editorial changes.

NRC Response: Accepted

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Dissenting Opinion

1. **Dissenting Opinion:** Encourage NRC to incorporate lessons learned from existing research and development licenses by providing additional information in this document on identification and management of radionuclidic impurities, dosage measurement and calibration for isotopes in decay chains, and internal dose monitoring for astatine-211.

NRC Response: Partially Accepted. NRC staff took into account what was written in the dissenting opinion and made some changes in the document to reflect adding additional information for dosage measurement and calibration for isotopes in decay chains, and internal dose monitoring. As this is just a general oversight and licensing memo, NRC staff made the decision to exclude some of the more specific recommendations that would provide new regulatory direction. The NRC is in the process of evaluating these items such as addressing identification and management of radionuclidic impurities

2. **Dissenting Opinion:** The spill procedures section should include a reference to 10 CFR 30.50(b) for unplanned contamination events.

NRC Response: Accepted

3. **Dissenting Opinion:** The actinium-225 decay scheme graphic should match the accompanying text. The graphic endpoint is thallium-205 but the text endpoint is “stable bismuth-209.”

NRC Response: Accepted