



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

December 7, 2022

MEMORANDUM TO:

Hruta Virkar
Assistant Inspector General for Audits
Office of the Inspector General

FROM:

John W. Lubinski, Director
Office of Nuclear Material Safety
and Safeguards

A handwritten signature in black ink, appearing to read "R. Lewis".

Lewis, Robert signing on behalf
of Lubinski, John
on 12/07/22

SUBJECT:

STATUS OF RECOMMENDATIONS: THE OFFICE OF THE
INSPECTOR GENERAL'S AUDIT OF THE U.S. NUCLEAR
REGULATORY COMMISSION'S PROCESS FOR
LICENSING EMERGING MEDICAL TECHNOLOGIES (OIG-
22-A-07)

Below is the U.S. Nuclear Regulatory Commission's (NRC) status of the recommendation from the Office of the Inspector General (OIG) Audit of U.S. Nuclear Regulatory Commission's Process for Licensing Emerging Medical Technologies (OIG-22-A-07), dated May 9, 2022. This audit report included a recommendation related to the NRC's process for licensing emerging medical technologies (EMTs). The NRC staff responded to this recommendation in a June 8, 2022, memorandum (Agencywide Documents Access and Management System Accession No. [ML22139A065](#)), and OIG responded on July 11, 2022 ([ML22192A101](#)), that the staff's proposed action would resolve the recommendation. This memorandum provides an update on this recommendation and recommends closure of the recommendation.

Recommendation:

Enhance the efficiency of the emerging medical technology licensing and guidance development processes by compiling a list of emerging medical technology-related guidance and information in a centralized location for NRC staff and Agreement State officials.

Status:

Completed. Staff created a [Nuclepedia page](#) with information related to emerging medical technologies. This page has up-to-date information about NRC activities related to EMTs, including a link to the NRC's SharePoint site for Emerging Medical Technologies. This SharePoint site is the repository for EMT-related information including activities of the Standing

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Committee for Reviewing Emerging Medical Technologies (current membership and working documents). The site also includes links to current list of EMTs, as well as links to other EMT-related resources including, ACMUI reports related to EMTs, and information about the ongoing rulemaking to establish requirements for rubidium-82 generators and EMTs.

Staff also updated the NRC's [public webpage for EMTs](#), located in the NRC's Medical Toolkit¹, including links to manufacturer's websites for each technology (when applicable) and the charter and State Agreements procedure for the Standing Committee for Reviewing Emerging Medical Technologies. The links to the guidance documents were reviewed and updated as needed, and more information about the ongoing rulemaking to establish requirements for rubidium-82 generators and EMTs added.

The NRC staff will continue to update these repositories of EMT-related information as needed.

Completion Date: December 2, 2022

Point of Contact: Celimar Valentin-Rodriguez

¹ The Medical Uses Toolkit does not include proprietary or confidential information shared with the NRC by vendors or by the U.S. Food and Drug Administration under its memorandum of understanding with the NRC. However, the staff has established internal processes to share information with the Agreement States as needed to complete reviews.

SUBJECT: STATUS OF RECOMMENDATIONS: THE OFFICE OF THE INSPECTOR GENERAL'S AUDIT OF THE U.S. NUCLEAR REGULATORY COMMISSION'S PROCESS FOR LICENSING EMERGING MEDICAL TECHNOLOGIES (OIG-22-A-07) DATED: DECEMBER 7, 2022

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