



MEMORANDUM

DATE: January 3, 2023

TO: Daniel H. Dorman
Executive Director for Operations

FROM: Hruta Virkar, CPA /*RA*/
Assistant Inspector General for Audits

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

REFERENCE: 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), DECEMBER 7, 2022.

Attached is the Office of the Inspector General's (OIG) analysis and status of recommendations as discussed in the agency's response dated December 7, 2022. Based on this response, recommendation one is now closed. All recommendations related to this audit report are now closed.

If you have questions or concerns, please call me at 301.415.1982 or Mike Blair, Team Leader, at 301.415.8399.

Attachment:
As stated

CC: M. Bailey, OEDO
M. Meyer, OEDO
J. Jolicoeur, OEDO
RidsEdoMailCenter Resource
OIG Liaison Resource
EDO_ACS Distribution

AUDIT REPORT
AUDIT OF THE U.S. NUCLEAR REGULATORY COMMISSION'S PROCESS
FOR LICENSING EMERGING MEDICAL TECHNOLOGIES
Status of Recommendations
(OIG-22-A-07)

Recommendation 1: 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.

Agency Response Dated
December 7, 2022:

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 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 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.

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Recommendation 1 (continued):

OIG Analysis: The OIG has reviewed the agency actions listed above and has determined the actions meet the intent of the recommendation. This recommendation is therefore closed.

Status: Closed.