

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

June 8, 2022

MEMORANDUM TO:

Eric Rivera

Acting Assistant Inspector General for Audits

Office of the Inspector General

FROM:

Catherine Hanev

Cathunic Hanny Signed by Hanney, Cathy

Deputy Executive Director for Materials, Waste, Research, State, Tribal, Compliance, Administration,

and Human Capital Programs

Office of the Executive Director for Operations

SUBJECT:

STAFF RESPONSE TO 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)

This memorandum responds to your May 9, 2022, memorandum transmitting the subject audit report. We appreciate the Office of the Inspector General's (OIG) audit of the U.S. Nuclear Regulatory Commission's (NRC) process for licensing emerging medical technologies (EMT) and the OIG's recommendation for enhancement of certain activities within that program.

In the audit report, the OIG makes one recommendation: that the NRC compile a list of EMTrelated information and guidance in a centralized location for NRC staff and Agreement State officials. The staff agrees that implementation of the recommendation, as described below, will improve the NRC's process for the licensing of EMTs. The staff intends to implement this recommendation by December 30, 2022. The OIG's recommendation and the staff's response are provided below.

CONTACT: Celimar Valentin-Rodriguez, NMSS/MSST

301-415-7124

E. Rivera - 2 -

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.

Response and Planned Action

Agree: As the OIG notes in the May 9, 2022, report, having a centralized location for EMT-related information will enhance the efficiency of capturing emergency medical technology related guidance. The staff has identified the following strategies to centralize EMT-related information and make it more accessible:

- Enhance the Emerging Medical Technologies website located in the Medical Uses
 Toolkit within the NRC's public website with applicable EMT-related information¹. These
 resources include guidance, videos on medical use regulations, and documents
 associated with the Standing Committee for the Review of Emerging Medical
 Technologies.
- 2. Leverage Nuclepedia to ensure the resources in the Medical Uses Toolkit, as well as other documents that are internally facing, are easily accessible to the NRC staff.

The staff will complete this action by December 30, 2022.

Point of Contact: Celimar Valentin-Rodriguez, NMSS/MSST

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: STAFF RESPONSE TO 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: JUNE 8, 2022

DISTRIBUTION: OEDO-22-00189

Public
JJolicoeur, OEDO
GButler, OIG
CEinberg, NMSS
CValentin-Rodriguez, NMSS
RidsEdoMailCenter Resource
RidsNmssOd Resource
RidsOigMailCenter Resource

ADAMS Accession No.: ML22139A065 (Memo) ML22136A067 (Pkg)

OFFICE	NMSS/MSST	NMSS/MSST	NMSS/MSST	OGC	NMSS/TechEditor
IINIAME	CValentin-	CEinberg	KWilliams	Illrvin	PMenefee-
	Rodriguez				Buzdygon
DATE	5/19/2022	5/19/2022	5/23/2022	5/24/2022	5/24/2022
OFFICE	NMSS/OD	DEDM			
NAME	JLubinski	CHaney			
DATE	6/1/2022	6/08/2022			

OFFICIAL RECORD COPY