



# Audit of the Nuclear Regulatory Commission's Process for Licensing Emerging Medical Technologies

OIG-22-A-07  
May 9, 2022



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## **MEMORANDUM**

**DATE:** May 9, 2022

**TO:** Daniel H. Dorman  
Executive Director for Operations

**FROM:** Eric Rivera /RA/  
Acting Assistant Inspector General for Audits

**SUBJECT:** AUDIT OF THE NRC'S PROCESS FOR LICENSING EMERGING  
MEDICAL TECHNOLOGIES  
(OIG-22-A-07)

Attached is the Office of the Inspector General's (OIG) audit report titled *Audit of the NRC's Process for Licensing Emerging Medical Technologies*.

The report presents the results of the subject audit. Following the April 20, 2022, exit conference, and a follow-up meeting held on April 25, 2022, NRC staff indicated that they had no formal comments for inclusion in this report.

Please provide information on actions taken or planned on the recommendation within 30 days of the date of this memorandum.

We appreciate the cooperation extended to us by members of your staff during the audit. If you have any questions or comments about our report, please contact me at (301) 415-5915 or Mike Blair, Team Leader, at (301) 415-8399.

Attachment: As stated



# Results in Brief

## Why We Did This Review

The NRC develops specific licensing guidance, reviews license applications, and issues decisions on the applications for the use of emerging medical technologies regulated under 10 CFR 35 Subpart K. Due to an anticipated growth in medical applications of radioisotopes and advancements in medical technologies, the NRC predicted that in fiscal years 2020-2023 there will be the potential need to evaluate up to 15 emerging medical technologies.

The audit objective was to determine the NRC's efficiency in licensing the use of emerging medical technologies, including developing technology specific guidance for licensing the use of emerging medical technologies under 10 CFR 35 Subpart K.

## *Audit of the NRC's Process for Licensing Emerging Medical Technologies*

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### What We Found

The OIG evaluated the NRC's efficiency in licensing the use of emerging medical technologies (EMTs), including its development of technology specific guidance for licensing the use of EMTs under 10 CFR 35 Subpart K. The OIG found that the NRC's licensing processes for EMTs are generally efficient, and the NRC's current effort to revise its guidance-development process is intended to improve the efficiency of these processes. However, the OIG also found that strengthening the NRC's knowledge management practices related to EMTs would further support the NRC's efforts to improve EMT processes.

Currently, the NRC does not systematically record the EMT knowledge its staff acquire informally as part of their job duties. Although the NRC would appear to have the means to retain this knowledge, such as by storing documents or video recordings in SharePoint, there is not a systematic process for recording such knowledge and making it available to employees.

### What We Recommend

This report contains a recommendation to enhance the efficiency of the emerging medical technology licensing and guidance development processes by compiling a list of EMT-related guidance and information in a centralized location for NRC staff and Agreement State officials.

# TABLE OF CONTENTS

<u>ABBREVIATIONS AND ACRONYMS</u> .....	iii
I. <u>BACKGROUND</u> .....	1
II. <u>OBJECTIVE</u> .....	6
III. <u>FINDING</u> .....	6
IV. <u>NRC COMMENTS</u> .....	10
<b>APPENDIX</b>	
A. <u>OBJECTIVE, SCOPE, AND METHODOLOGY</u> .....	11
<u>TO REPORT FRAUD, WASTE, OR ABUSE</u> .....	13
<u>COMMENTS AND SUGGESTIONS</u> .....	13

## ABBREVIATIONS AND ACRONYMS

ACMUI .....	Advisory Committee on the Medical Use of Isotopes
CFR.....	Code of Federal Regulations
EMT .....	Emerging Medical Technology
NMSS.....	The Office of Nuclear Material Safety and Safeguards
NRC .....	The Nuclear Regulatory Commission
OIG .....	The Office of the Inspector General

# I. BACKGROUND

The U.S. Nuclear Regulatory Commission (NRC) develops guidance and reviews license applications for the medical use of byproduct,<sup>1</sup> source,<sup>2</sup> and special nuclear material.<sup>3</sup> Specific to byproduct material, the NRC licenses the use of radiopharmaceuticals,<sup>4</sup> and radiation therapy,<sup>5</sup> which are both used for cancer treatments. Some of these therapies and radiopharmaceuticals may be emerging medical technologies (EMTs), which are new medical uses of byproduct material, or radiation from byproduct material, that are not addressed by specific NRC regulations.

## Emerging Medical Technology

One example of an EMT is Gamma Knife® technology. This is a system that uses highly focused radiation to target lesions and tumors in the brain. (Figure 1)

**Figure 1: Gamma Knife® Technology**



Source: NRC

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<sup>1</sup> Byproduct material refers to the tailings or waste produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes.

<sup>2</sup> Source material refers to uranium or thorium, or any combination thereof, in any physical or chemical form, or ores which contain greater than 0.05 percent by weight of uranium and/or thorium.

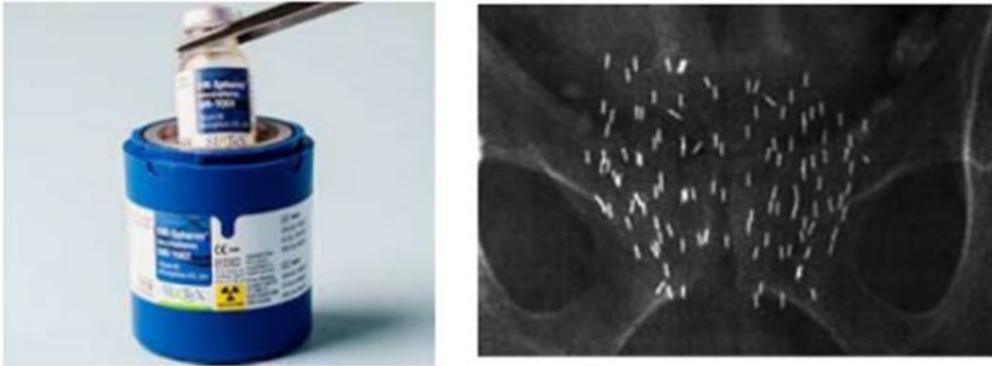
<sup>3</sup> Special nuclear material refers to plutonium, uranium-233, or uranium enriched in the isotopes uranium-233 or uranium-235.

<sup>4</sup> Radiopharmaceuticals are pharmaceutical drugs that emit radiation and are used in diagnostic or therapeutic medical procedures.

<sup>5</sup> Radiation therapy is the therapeutic use of ionizing radiation to treat disease in patients. Although most radiation therapy procedures are intended to kill cancerous tissue or reduce the size of a tumor, therapeutic doses may also be used to reduce pain or treat benign conditions.

Other types of EMTs include intravenous radiation treatments used to treat other types of cancers, and radioactive seed treatments for lymph node cancer. (Figure 2)

**Figure 2: Intravenous radiation treatment (left image) and applied seed treatment (right image).**



Source: NRC

Since 2006, the NRC has developed guidance for 11 EMTs that fall under Subpart K. The descriptions of the 11 EMTs are shown in Figure 3.

**Figure 3: Available EMTs and Guidance**

	Technology Name/Description
1	<i>Alpha Tau Alpha DaRT™</i> manual brachytherapy, a device used to treat tumors.
2	<i>Best Vascular, Inc. Beta-Cath Intravascular Brachytherapy (IVB) System</i> is used to treat the narrowing of coronary arteries.
3	<i>Germanium-68/Gallium-68 Pharmaceutical Grade Generators</i> are designed to prepare certain radiopharmaceuticals for clinical use, such as imaging, and for research and development.
4	<i>I-125 Iotrex Liquid Brachytherapy Source in Cytoc GliaSite Radiation Therapy System</i> is a type of radiation therapy that uses radioactive materials that are temporarily or permanently implanted to treat malignancies or certain benign conditions.
5	<i>Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes</i> consist of radioactive seeds that are used in the treatment of breast lesions or cancers.
6	<i>Leksell Gamma Knife® Perfexion™</i> and <i>Leksell Gamma Knife® Icon™</i> are tools used in intracranial surgery.
7	<i>NeoVista, Inc's Epi-Rad90 (Sr-90) Ophthalmic System</i> is an ophthalmic device that uses radioactive material to treat cancer type illnesses through the eyes.
8	<i>NorthStar Medical Radioisotopes, LLC RadioGenix™ Molybdenum-99/Technetium-99m Generator System</i> is a generator used to produce radioactive agents that can be used in the preparation of FDA-
9	<i>TheraSphere and SIRspheres Yttrium-90 Microspheres</i> are small spheres containing radioactive elements that are infused into the arterial system of the liver to treat cancer.
10	<i>ViewRay System for Radiation Therapy</i> uses a unique combination of magnetic resonance imaging and radiation therapy technology to provide high-contrast pretreatment images and continuous soft-tissue imaging during treatment.
11	<i>Xcision® GammaPod™ Licensing</i> treats breast cancer by delivering focused radiation.

Source: NRC

## Regulatory History of EMTs

In 2002, the NRC amended Title 10 of the Code of Federal Regulations (10 CFR) Part 35 to add generic requirements for new medical uses of byproduct material or radiation from byproduct material. Subpart K, “Other Medical Uses of Byproduct Material or Radiation from Byproduct Material,” or 10 CFR 35.1000, defines the process to obtain a license or license amendment for EMTs. In brief, Subpart K allows the NRC and the Agreement States, through their compatible regulations, to regulate medical uses that are not otherwise addressed in 10 CFR Part 35 on a case-by-case basis. Under Subpart K, the NRC can license EMTs using detailed licensing guidance that is specific to the EMT device model, vendor, and use. When sufficient operating experience is acquired and an EMT is no longer considered “emerging,” the NRC can establish regulations for the technology elsewhere in 10 CFR Part 35.

## Agreement State Program

Under certain conditions, as allowed in the *Atomic Energy Act of 1954*, as amended, the NRC enters into agreements with state governors. These agreements authorize individual states to regulate the use of specific radioactive materials within their borders. This includes radioisotopes used in medicine and industry. States that meet these conditions and agree to regulate materials using the same or compatible standards as the NRC are called Agreement States. See Figure 4 for a map of Agreement States and non-Agreement States. (Figure 4)

There are 39 Agreement States, with only 11 states<sup>6</sup> under the NRC’s jurisdiction. As a result, the Agreement States issue most of the EMT licenses. As of 2022, the NRC and the Agreement States have issued 18,227 licenses in the U.S. for medical, industrial, and academic uses of source, byproduct, and special nuclear materials. The NRC has administered approximately 2,187 active licenses, with 16,040 administered by the Agreement States. Approximately 88 of the 2,187 licenses administered by the NRC are for the use of EMTs.

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<sup>6</sup> Puerto Rico, Guam, American Samoa, the U.S. Virgin Islands, and Northern Marianas are also under the NRC’s jurisdiction.



## Resources

The NRC was unable to quantify the full extent of resources allocated for EMT licensing because these resources are under the overall umbrella of “Licensing Resources.” However, for EMT guidance development, the NRC has allocated 2 full-time equivalents for fiscal year 2020 through fiscal year 2023. There are also 15 qualified license reviewers in Regions I, III, and IV. These reviewers are responsible for issuing decisions on applications for medical licenses, including applications for the use of EMTs.

## Updated Guidance Development and Licensing Process

In July 2020, the NRC revised the process for reviewing and developing guidance for EMTs. Under this revised process, the time necessary to develop EMT guidance is intended to decrease the time from 1 year or longer, to 8 months. In addition, a proposed rulemaking will include already approved EMTs in other 10 CFR Part 35 subparts, thus decreasing the agency’s reliance on Subpart K and potentially speeding up the review process. Key elements of the NRC’s revised process include:

- *The Standing Committee.* Under its revision of the EMT process, the NRC created a new standing committee to ensure that stakeholders’ feedback is incorporated early in the process. The new process is intended to streamline the review of EMTs and ensure a more uniform approach to licensing guidance development through a single standing committee. The process will include the participation of the ACMUI, the Agreement States, and NRC regional staff. The standing committee is currently in the process of reviewing three EMTs. The timely completion of a review is intended to validate the efficiency of the revamped guidance development process.
- *Licensing Process.* Qualified license reviewers from Regions I, III, and IV review and issue decisions on applications for the use of EMTs. This process is similar to the process used to review other types of radioactive materials applications. However, in addition to using the NRC’s general guidance when reviewing EMT applications, reviewers also follow the guidance developed by the NRC for each different EMT. This guidance is publicly available on the NRC’s website.

- *Rulemaking.* On January 13, 2022, the Commission approved the NRC staff's proposal to initiate a rulemaking.<sup>7</sup> The rulemaking intends to expand Part 35 so that the approval of EMTs and EMT updates will be more performance-based, thus decreasing the agency's reliance on Subpart K and potentially speeding up the review process.

## II. OBJECTIVE

The audit objective was to determine the NRC's efficiency in licensing the use of emerging medical technologies, including developing technology specific guidance for licensing the use of emerging medical technologies covered under 10 CFR 35 Subpart K.

## III. FINDING

### A. The EMT knowledge management process could be strengthened.

The EMT knowledge management process could be strengthened. Management should maintain programs that capture organizational knowledge and promote learning to enable internal efficiencies; however, NRC management lacks a structured process to systematically capture EMT-related knowledge. As a result, the NRC risks duplication of effort, EMT process inefficiencies, and loss of information.

#### What Is Required

**Management should maintain programs that capture organizational knowledge and promote learning to enable internal efficiencies.**

According to the NRC's *Knowledge Management Program* guidance, knowledge management is the collection of methods relating to creating, sharing, using, and managing the knowledge and information of an organization. It is a multidisciplinary approach to achieve organizational objectives by making the best use of knowledge. In addition, industry, in general, recognizes knowledge management as a key enabler of internal efficiencies.

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<sup>7</sup> SRM SECY-21-0013: *Rulemaking Plan to Establish Requirements for Rubidium-82 Generators and Emerging Medical Technologies*, January 13, 2022.

Under the U.S. Government Accountability Office’s *Standards for Internal Control in the Federal Government*,<sup>8</sup> management processes should ensure that relevant data from reliable sources are retained as quality information within the entity’s information system. Management should use the quality information to make informed decisions and evaluate the entity’s performance in achieving key objectives and addressing risks.

## What We Found

### **The EMT knowledge management process can be strengthened.**

While NRC staff participate in knowledge management activities related to EMT, the NMSS process for retaining EMT knowledge can be strengthened. Staff stated that the EMT knowledge management process is very informal. For example, staff generally acquire EMT knowledge informally through the following means:

- **Staff Qualification Training:** Though overall staff qualification training is comprehensive, the availability of classes relating to EMTs is limited.
- **Standard “on-the-job” experience to gain familiarity with EMTs:** This includes employee participation in meetings and employees conducting their own independent research, such as reading EMT manufacturers’ technical brochures.
- **Communication with Agreement States:** Staff may also work closely with Agreement State counterparts; however, some EMT-related data is not always readily available. The NRC must obtain the Office of Management and Budget’s approval to acquire certain types of data/information, such as the number of EMT licensees from Agreement States, and this can be a lengthy process.

Staff involved with EMTs stated knowledge is generally acquired through participation in meetings and by reaching out to other experienced staff.

## Why This Occurred

### **NRC management lacks a structured process to capture EMT-related knowledge.**

The NMSS does not have an organized, structured knowledge management approach to comprehensively capture EMT-related knowledge. Knowledge acquired through oral means is not systematically preserved. NRC management stated there is no dedicated EMT repository. A few staff members mentioned that the NRC’s Nuclepedia website

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<sup>8</sup> Government Accountability Office, *Standards for Internal Control in the Federal Government*, GAO-14-704G, September 2014.

functions as the EMT knowledge repository, but it is not clear how Nuclepedia is being used and maintained for this purpose in a systematic way. Other staff were not certain if their office retains EMT-specific knowledge in SharePoint<sup>9</sup> or other repositories, or if EMT information in SharePoint was up to date. Staff further indicated that EMT-related knowledge management information may be captured in one region but not necessarily shared with other regions. NRC management acknowledged that a centralized location for EMT technology guidance/information would be beneficial for NRC staff and Agreement State officials.

## Why This Is Important

### **The NRC risks duplication of effort, EMT process inefficiencies, and loss of information.**

Without a systematic approach to capture knowledge related to EMTs, there is an increased risk of key historical information being lost. Less experienced staff will continue to rely on more senior staff members' informal knowledge sharing. This may affect the senior staff's efficiency as they take time to address questions. In addition, less experienced staff may also need more time to assess EMTs while developing guidance or reviewing license applications. This could lead to delays in guidance development and licensing reviews.

Further, capturing EMT-specific information informally may lead to a loss of information and knowledge transfer. This is especially true for the small group of NMSS employees who oversee EMTs. Since December 31, 2021, 2 of 17 staff members involved with EMT guidance development and licensing have retired. These two employees had a combined 75 years of experience. Without a strong EMT knowledge management program, the knowledge, and information resulting from this experience could easily be lost.

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<sup>9</sup> SharePoint is a collaboration platform that is closely integrated with Microsoft Office and Active Directory. SharePoint sites can be created and used to manage collaboration tools such as document libraries, discussion boards, shared task lists, shared calendars, blogs, wikis, and surveys. SharePoint can be used as a secure platform to store, organize, share, and access information.

## **Recommendation**

The OIG recommends that the Executive Director for Operations:

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.

## **IV. NRC COMMENTS**

An exit conference was held with the agency on April 20, 2022, and a follow-up meeting on April 25, 2022. After reviewing a discussion draft, agency management provided comments that have been incorporated into this report, as appropriate. As a result, agency management opted not to provide formal comments for inclusion in this report.

## OBJECTIVE, SCOPE, AND METHODOLOGY

### Objective

The audit objective was to determine the NRC's efficiency in licensing the use of emerging medical technologies, including developing technology specific guidance for licensing the use of emerging medical technologies covered under 10 CFR 35 Subpart K.

### Scope

This audit focused on determining whether the NRC's processes for licensing EMTs, including its development of EMT specific guidance, are efficient. We conducted this audit at NRC headquarters in Rockville, Maryland, from October 2021 to April 2022. Throughout the audit, auditors considered the possibility of fraud, waste, and abuse in the program.

Internal controls related to the audit objective were reviewed and analyzed. Specifically, the OIG reviewed the components of the control environment, risk assessments, control activities, information and communication, and monitoring. Within those components, the OIG reviewed the principles of exercising oversight responsibility; identifying, analyzing, and responding to risk; assessing fraud risk; identifying, analyzing, and responding to change; designing control activities; designing activities for the information system; implementing control activities through policies; using quality information; communicating internally; performing monitoring activities; and, evaluating issues and remediating deficiencies.

### Methodology

The OIG reviewed relevant criteria for this audit, including, but not limited to:

- Title 10 of the Code of Federal Regulations (10 CFR), Part 35, *Medical Use of Byproduct Material*.
- NUREG 1556, Volume 9, Revision 3, *Program-Specific Guidance About Medical Use Licenses*, Sep 2019.
- NUREG 1556, Volume 20, Revision 1, *Guidance About Administrative Licensing Procedures*, Nov 2020.
- Management Directive (MD) 5.3, *Agreement State Participation in Working Groups*, June 2016.

- *Standing Committee for Reviewing Emerging Medical Technologies, (Draft), undated.*
- *Rulemaking Plan to Establish Requirements for Rubidium-82 Generators and Emerging Medical Technologies, SECY-21-0013, February 2021.*
- *Inspection Manual Chapter (IMC) 1248, Appendix A, Materials Health Physics License Reviewer Qualification Journal, April 2013.*
- *Audit of NRC's Oversight of Medical Uses of Nuclear Material, OIG-16-A-02, October 8, 2015.*
- *U.S. Government Accountability Office, Standards for Internal Control in the Federal Government, GAO-14-704G, September 2014.*

The OIG conducted analyses of various documents and data to determine the efficiency of the NRC's EMT licensing processes. This included reviewing documentation relating to proposed rulemaking and ongoing revisions to how guidance is handled. The OIG interviewed NRC staff and management from the NMSS and Regions I, III, and IV to better understand how the NRC develops guidance for the use of EMTs and licenses such use. The OIG also interviewed staff from various Agreement State offices and a member of the ACMUI to obtain their views on the NRC's efficiency in licensing EMTs. In addition to other analyses, OIG auditors analyzed the NRC's enforcement actions, data on agency resources allocated to guidance development, and the number of EMT licensees in the NRC's jurisdiction.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Throughout the audit, auditors considered the possibility of fraud, waste, and abuse in the program.

The audit was conducted by Mike Blair, Team Leader; Timothy Wilson, Audit Manager; Roxana Hartsock, Senior Auditor; and Julie Corwin, Senior Management Analyst.

## TO REPORT FRAUD, WASTE, OR ABUSE

### Please Contact:

Email: [Online Form](#)

Telephone: 1-800-233-3497

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Address: U.S. Nuclear Regulatory Commission  
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Mail Stop O5-E13  
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Rockville, MD 20852

## COMMENTS AND SUGGESTIONS

If you wish to provide comments on this report, please email the OIG using this [link](#).

In addition, if you have suggestions for future OIG audits, please provide them using this [link](#).