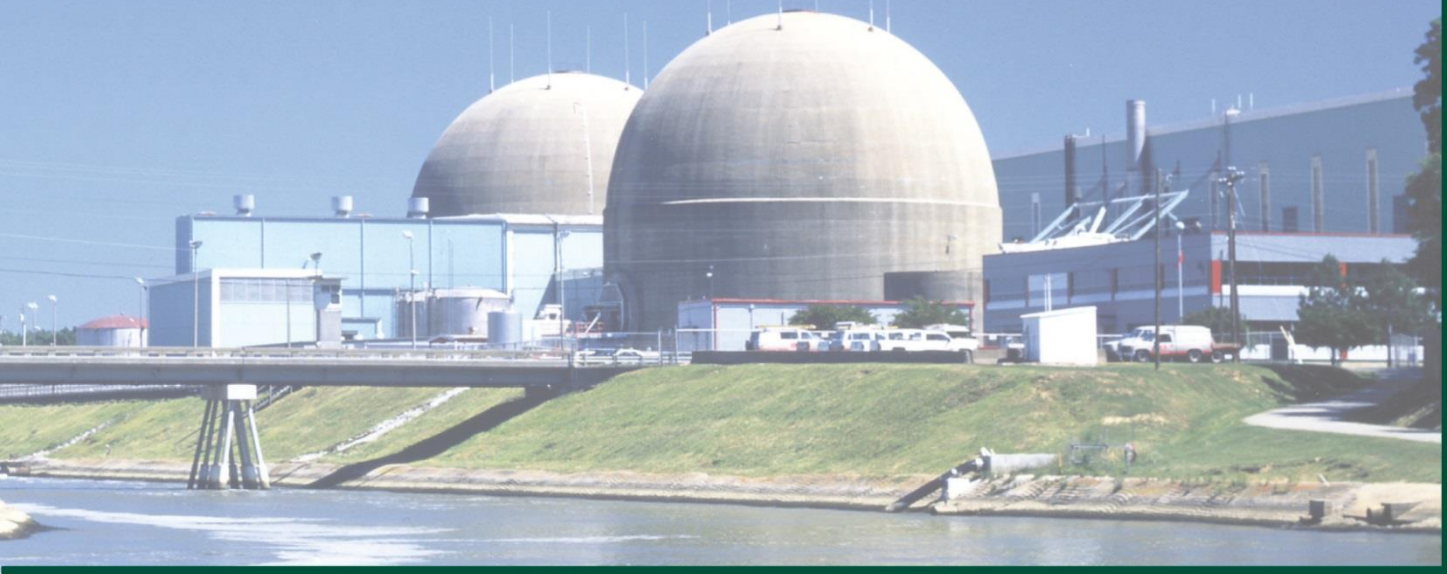
OFFICE OF THE INSPECTOR GENERAL

U.S. NUCLEAR REGULATORY COMMISSION
DEFENSE NUCLEAR FACILITIES SAFETY BOARD

# Audit of NRC's Oversight of Medical Uses of Nuclear Material

OIG-16-A-02
October 8, 2015



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

OFFICE OF THE
INSPECTOR GENERAL

October 8, 2015

MEMORANDUM TO: Mark A. Satorius
Executive Director for Operations

FROM: Stephen D. Dingbaum ***/RA/***
Assistant Inspector General for Audits

SUBJECT: AUDIT OF NRC'S OVERSIGHT OF MEDICAL USES OF NUCLEAR MATERIAL (OIG-16-A-02)

Attached is the Office of the Inspector General's (OIG) audit report titled *Audit of NRC's Oversight of Medical Uses of Nuclear Material*.

The report presents the results of the subject audit. Following the September 15, 2015, exit conference, agency staff indicated they had formal comments for inclusion in this report. These comments and OIG's analysis of the comments are included as report appendixes.

Please provide information on actions taken or planned on each of the recommendations within 30 days of the date of this memorandum. Actions taken or planned are subject to OIG followup as stated in Management Directive 6.1.

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 Sherri Miotla, Team Leader, at (301) 415-5914.

Attachment: As stated

# Office of the Inspector General

U.S. Nuclear Regulatory Commission
Defense Nuclear Facilities Safety Board

OIG-16-A-02

October 8, 2015

# Results in Brief

## *Audit of NRC's Oversight of Medical Uses of Nuclear Material*

### Why We Did This Review

The Nuclear Regulatory Commission (NRC) is responsible for overseeing the medical uses of nuclear material through its licensing, inspection, and enforcement programs. The types of medical uses regulated by NRC include diagnostic, therapeutic, and research. NRC issues medical use licenses to medical facilities, develops guidance and regulations for use by licensees, and maintains a committee of medical experts to obtain advice about the use of byproduct materials in medicine.

This committee, the Advisory Committee on the Medical Uses of Isotopes (ACMUI), is an independent committee established by the NRC for the express purpose of advising NRC staff. ACMUI provides NRC staff with advice, technical assistance, consulting, and key issues.

When a medical facility has a potential problem using radioactive material, it may meet NRC's criteria for a medical event. These events may involve doses to a patient of the wrong amount, the wrong radioactive drug, incorrect administration of a drug, or dose to the wrong patient or wrong part of the body. There are about 40 medical events ach year.

The audit objective was to determine if NRC's oversight of medical uses of radioactive isotopes adequately protects public health and safety.

### What We Found

NRC provides adequate oversight of the medical uses of radioactive isotopes to protect public health and safety; however, opportunities for improvement exist with regard to clarifying NRC's medical event policy, periodically assessing medical event reporting, and providing better feedback to ACMUI.

Medical event reporting requirements are inconsistently understood by licensees and NRC staff. This inconsistent understanding is due to a general lack of clarity surrounding NRC's requirements and purpose for reporting medical events. Furthermore, NRC provides insufficient medical event data to medical licensees. As a result, NRC is not effectively achieving all the possible benefits of medical event reporting.

NRC has not conducted a periodic self-assessment of its medical events reporting requirements to determine if they are effectively meeting their intended purpose. As a result, NRC is not in a position to make any informed conclusions regarding the effectiveness of its approach to collecting information on medical events.

NRC does not routinely provide sufficiently detailed feedback to ACMUI despite relying on it as a key advisory body. This lack of sufficiently detailed feedback is a result of NRC not having current, formalized policies and procedures that clearly articulate the expectations for providing feedback to ACMUI. As a result, the benefits of having the ACMUI provide expert advice may not be fully realized and the potential for miscommunication and misunderstanding remains.

### What We Recommend

This report makes recommendations to increase clarity in NRC's regulations, to conduct self-assessments of the medical program, and to increase feedback to ACMUI. Management stated their general agreement with two of the findings (A & C) but not with the third finding (B). The agency's comments are included in Appendix C of this report.

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## ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| 10 CFR | Title 10 of the *Code of Federal Regulations* |
| ACMUI | Advisory Committee on the Medical Uses of Isotopes |
| FSME | The Office of Federal and State Materials and Environmental Management Programs |
| NMED | Nuclear Materials Events Database |
| NMSS | Office of Nuclear Material Safety and Safeguards |
| NRC | U.S. Nuclear Regulatory Commission |
| OIG | Office of the Inspector General |
| rem | Roentgen equivalent man |
| Sv | Sievert |

# I. BACKGROUND

Nuclear medicine is the use of radioactive material to provide information about the functioning of a person's specific internal organs (diagnostic) or to treat a disease (therapeutic). Diagnostic procedures generally use small amounts of radioactive material to facilitate imaging of certain

**Gamma Knife uses beams of radiation to treat cancerous brain tumors.**

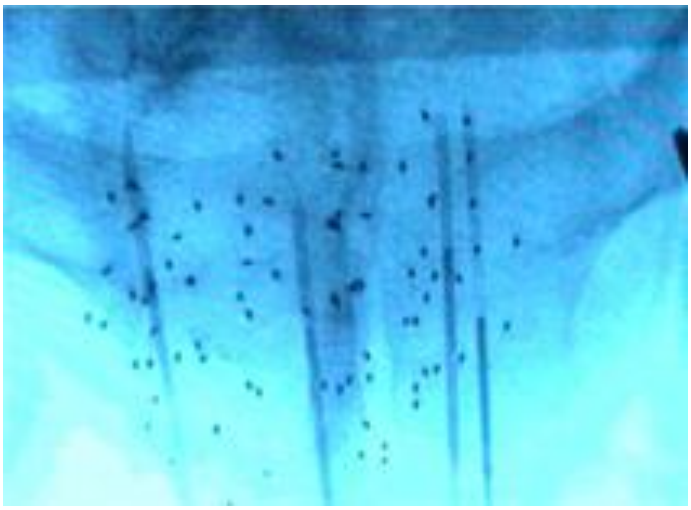
**Source: Nuclear Regulatory Commission (NRC)**

organs to help physicians locate and identify tumors, size anomalies, or other physiological or functional organ problems. Therapeutic uses of radioactive material are intended to kill cancerous tissue, reduce the size of a tumor, or reduce pain.

There are three main categories of radiation therapy: (1) External beam therapy is a beam of radiation directed to the target tissue. Several different types of machines provide external beam therapy. Some treatment machines contain high-activity radioactive sources that emit

photons to treat the target site; (2) Brachytherapy treatments use sealed radioactive sources[1] placed near or even directly in cancerous tissue. The radiation dose is delivered at a distance of up to an inch from the

**Post-operation image of a prostate brachytherapy patient**



**Source: NRC**

target area; and (3) Therapeutic radiopharmaceuticals deliver a large radiation dose inside the body. Different radioactive material can be given to patients and will concentrate in different regions or organ systems.

## Federal Regulations

The Atomic Energy Act of 1954 authorizes the Nuclear Regulatory Commission (NRC) to issue licenses for those using nuclear material for medical, commercial, industrial, and research and development purposes. The act also states the production and use of source,[2] byproduct,[3] and special nuclear material[4] must be regulated in order to protect the health and safety of the public.

[1] A sealed radioactive source (or sealed source) is any radioactive or byproduct material encased in a capsule designed to prevent leakage or escape of the material.

[2] Source material is natural uranium or thorium or depleted uranium that is not suitable for use as reactor fuel.

[3] Byproduct material, in general, is nuclear material (other than special nuclear material) that is produced or made radioactive in a nuclear reactor or a particle accelerator.

[4] Special nuclear material consists of uranium-233 or uranium-235, enriched uranium, or plutonium.

Title 10 of the *Code of Federal Regulations* (10 CFR), Part 35, contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects.

**NRC Oversight**

In addition to its regulatory authority over the medical use of radiation, NRC has authority over the possession and use of byproduct, source, and special nuclear material in medicine. NRC is responsible for overseeing the medical uses of nuclear material through its licensing, inspection, and enforcement programs. NRC issues medical use licenses to medical facilities, develops guidance and regulations for use by licensees, and maintains a committee of medical experts and health care professionals that provides advice about the use of byproduct material in medicine.

The Office of Nuclear Material Safety and Safeguards (NMSS), through the Medical Safety and Events Assessment Branch, is responsible for the programmatic direction and development of policy for the medical use of radioactive material. The Medical Safety and Events Assessment Branch also provides support and technical assistance to NRC's regional offices for licensing and inspection. The branch is responsible for maintaining, revising, and updating medical licensing guidance, inspection procedures, internal NRC guidance, regulations, and policy statements related to the medical use of radioactive material.

The NRC regional offices ensure protection of public health and safety and the environment through the licensing, inspection, event response, enforcement, and allegations activities for NRC-licensed medical users in the United States, Puerto Rico, and the Virgin Islands where NRC has jurisdiction.[5]

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

ACMUI is an independent committee established by the NRC for the express purpose of advising NRC staff. ACMUI provides advice that helps staff create medical regulations that are meant to be useful, realistic,

[5] Region I oversees Region II's materials program.

practical, not overly burdensome, and not intrusive in the practice of medicine. ACMUI further assists NRC staff by providing technical assistance in licensing, inspection, and enforcement cases; providing consulting services when necessary; and by bringing key issues to the attention of NRC staff for appropriate action.

ACMUI is a 13-member committee consisting of medical experts and health care professionals from various disciplines.[6] Membership in ACMUI is gained through a formal nomination and selection process. ACMUI members are appointed to 4-year terms and, with approval from NRC, may elect to serve up to two consecutive terms, for a maximum term of 8 years.

## Other Regulators

### Agreement States

NRC has relinquished its authority to regulate certain radioactive material, including some radioisotopes, to a majority of the States. These States,

**Figure 1: Map of NRC Agreement States**


**Source: NRC**

which have entered into an agreement assuming this regulatory authority

[6] ACMUI is composed of the following: a nuclear medicine physician, a nuclear cardiologist, a medical physicist in nuclear medicine unsealed byproduct material, a medical physicist in radiation therapy, a radiation safety officer, a nuclear pharmacist, two radiation oncologists, a patients' rights advocate, a Food and Drug Administration representative, an Agreement State representative, a health care administrator, and a diagnostic radiologist.

from NRC, are called Agreement States. Agreement States, like NRC, regulate reactor-produced radioisotopes within their borders and must provide at least as much health and safety protection as NRC. There are currently 37 Agreement States that have regulatory authority over medical licensees, and these States oversee approximately 86 percent of all medical licensees.

Food and Drug Administration

The NRC and the Food and Drug Administration have a Memorandum of Understanding that coordinates existing NRC and Food and Drug Administration regulatory programs for medical devices, drugs, and biological products utilizing byproduct, source, or special nuclear material. The Food and Drug Administration is responsible for regulating the manufacture and marketing of machines that generate radiation, such as x-rays, as well as devices, drugs, and biologics containing radioactive material. NRC has responsibility for overseeing the manufacture, distribution, and use of byproduct material and the machines that use this material.

**Medical Events**

NRC regulations aim to assure radioactive material is used properly in medical diagnosis, treatment, and research. The regulations are also meant to assure the safety of patients, medical workers, and the public, as well as to protect the environment. These regulations require licensees to report any event which fits the definition of a medical event.

Medical events refer to a potential problem with how a medical facility uses radioactive material. These events may involve doses to a patient of the wrong amount, the wrong radioactive drug, incorrect administration of a drug, or dose to the wrong patient or wrong part of the body. Appendix B of this report provides the complete medical event definition located in 10 CFR Part 35.3045.

Per 10 CFR Part 35.3045, licensees are required to report medical events within 1 calendar day, by telephone, to the NRC Operations Center. Licensees are also required to submit a written report to the appropriate NRC regional office within 15 calendar days of discovering the medical event.

NRC analyzes each event to see if further action is needed. If there is a violation, NRC may take enforcement action. NRC also searches for trends to see if something in NRC's regulations or guidance may need to be clarified. While a medical event may indicate a potential problem in a facility's use of radioactive material, it does not necessarily result in harm to a patient or a safety violation for the medical facility.

On average, there are approximately 40 reported medical events per year out of hundreds of thousands of medical procedures involving radioactive material.

## II. OBJECTIVE

The audit objective was to determine if NRC's oversight of medical uses of radioactive isotopes adequately protects public health and safety. Appendix A of this report contains information on the audit's scope and methodology.

## III. FINDINGS

NRC provides adequate oversight of the medical uses of radioactive isotopes to protect public health and safety; however, opportunities for improvement exist with regard to

- Clarification of NRC's medical event reporting requirements.
- Periodic self-assessment of medical event reporting.
- Providing better feedback to ACMUI.

### A. Medical Event Reporting Is Unclear

Medical event reporting requirements are inconsistently understood by licensees and NRC staff. According to NRC's Principles of Good Regulation, regulations should be readily understood and easily applied. However, this inconsistent understanding is due to a general lack of clarity surrounding NRC's requirements and purpose for reporting medical events. Furthermore, NRC provides insufficient access to medical event data to medical licensees. As a result, NRC is not effectively achieving all the possible benefits of medical event reporting.

## What Is Required

### NRC Requirements Should Be Clear

NRC's Principles of Good Regulation states that regulations should be coherent, logical, and practical. There should be a clear nexus between regulations and agency goals and objectives. Furthermore, agency positions should be readily understood and easily applied.

## What We Found

### Medical Event Reporting Requirements Inconsistently Understood

Medical event reporting requirements are inconsistently understood by licensees and NRC staff. Specifically, the Office of the Inspector General (OIG) learned that several licensees either underreported, or reported and later retracted, medical events. Furthermore, a specific interim guidance document had to be written to help address some of the confusion.

Inaccurate Reporting of Medical Events

According to several NRC staff, there is a belief that medical events are underreported. Although many inspectors agreed that finding medical events during safety inspections is difficult and is not the focus of the inspection, it is not uncommon for inspectors to discover medical events during inspections.[7] For example, one senior inspector estimated having identified roughly half of the medical events incurred by licensees that the inspector had inspected. Another senior inspector surmised having found approximately 10 medical events during the inspector's career. A former inspector claimed to have identified "a number of medical events" while working as an inspector.

In addition to NRC inspectors, an ACMUI member reported questioning the accuracy of medical event reporting when reviewing the annual

[7] This applies to routine safety inspections. In the case of "reactive" inspections, inspectors contact or visit licensees specifically to inspect a medical event.

medical events reports, as the events seemed to represent a "very, very, very, small number." An Agreement State representative questioned the number of medical events reported for a specific medical procedure. This representative said one of the expected risks of this procedure is that non-targeted organs could be affected, yet events associated with this procedure are rarely reported.

Conversely, some inspectors have stated that licensees often report events that are eventually retracted because the events do not meet the medical event criteria established in NRC regulations. For example, one inspector said that many licensees seem to take a conservative approach to reporting medical events. The inspector thinks that licensees may actually overreport events. Another inspector echoed this sentiment, saying most licensees would rather report an event and then later retract it, as opposed to having NRC discover it. Meanwhile, a regional inspection manager explained that while certain events seem to be obvious medical events, NRC headquarters may take the position that they are not actually medical events.

NRC does not keep official records of how a medical event was identified. Specifically, NRC does not track how many medical events were self-reported – and later retracted – by licensees, or if the medical event was discovered by an NRC or Agreement State inspector during an inspection. In an attempt to identify such data, OIG conducted general searches of NRC's public material events database and the Nuclear Material Events Database (NMED)[8] for the period of July 2005 to July 2015. Of approximately 600 medical events recorded in NMED, OIG identified 30 medical events that were not reported by licensees but were discovered by NRC or Agreement State inspectors.[9] Additionally, OIG identified 44 medical events self-reported by licensees that were eventually retracted because it was determined that the events did not meet the criteria of a medical event.[10]

[8] NMED contains records of all materials events reported to NRC by NRC licensees, Agreement States, and non-licensees. This database may be accessed only by NRC staff, Agreement State staff, and other users authorized by NRC.

[9] These figures indicate only what was discovered by inspectors. They do not represent the total number of events that may not have been reported by licensees.

[10] The events that are eventually retracted do not necessarily indicate confusion over medical event reporting requirements in all cases. In some cases, the retractions may be due to the complexity of treatment planning and the post-treatment assessment of the medical event against NRC reporting criteria.

Interim Enforcement

**Permanent brachytherapy "seeds" containing Iodine-125**

**Source: NRC**

Another example that illustrates the confusion surrounding medical events involved NRC's issuance of a medical event interim enforcement policy.[11] In July 2013, NRC issued an interim enforcement policy to provide regulatory relief and further clarification to the medical event reporting requirements for permanent implant brachytherapy. The regulation had previously required licensees to report medical events for this particular procedure even when the treatment may have been medically appropriate. Furthermore, the policy was created, in part, to offer clarification on reporting requirements that were being interpreted and enforced differently by two NRC regional offices. The interim enforcement policy will remain in place until the implementation of the new Part 35 rule.

Part 35 Rulemaking

The concerns surrounding medical events have been ongoing for several years and NRC has taken notice. The regulation that addresses the medical uses of radioactive material, Part 35, is currently in the rulemaking process. The proposed rule contains several regulatory changes including some regarding medical event reporting. NRC staff is currently reviewing all public comments and anticipates submitting the final proposed rule to the Commission in March 2016. In addition to the final rule, new guidance documents that correspond with the rule will be developed. An NMSS manager believes the proposed changes to medical event reporting will "help NRC tremendously."

[11] NRC-2013-0114, "Interim Enforcement Policy for Permanent Implant Brachytherapy Medical Event Reporting," July 3, 2013.

In summary, OIG identified several illustrative examples that support stakeholders' view that the medical event reporting requirements can be confusing. Specifically, the instances of underreporting and retracting medical events, NRC's issuance of an interim enforcement policy to address inconsistent application of regulatory requirements, and the substantive proposed revisions to Part 35 corroborate the confusion surrounding medical event reporting requirements.

## *Why This Occurred*

### Medical Event Reporting Requirements Unclear

There is a general lack of clarity to NRC's requirements and purpose for reporting medical events. Not only do medical events pose a challenge to licensees, but there is confusion surrounding the medical event reporting requirements from a regulatory and advisory perspective as reflected in the following comments:

- "NRC has incredibly complicated, contorted medical event regulations. Not only is it difficult for licensees to interpret, sometimes it is difficult for NRC." – NMSS staff member
- "It [medical event] is a complicated definition." – NMSS manager
- "Medical events can be confusing to me too, so I can see how it's confusing to a licensee." – NRC inspector
- "The medical event definition especially causes issues..." – Agreement State representative
- "Medical event criteria…[are] a bit ambiguous." – ACMUI member

Many NRC staff believe that the majority of unreported medical events are due to licensees not understanding they even incurred an event. As one NRC inspector summarized, the medical event reporting requirements can be effective only "if the licensees understand what they're supposed to report."

#### Purpose Not Stated for Licensees

The purpose of reporting medical events is not listed in NRC regulations or licensee guidance. Specifically, OIG was unable to locate an explanation for medical event reporting in Part 35 or any guidance

documentation. When questioned about the purpose of reporting medical events, several NRC staff provided various responses but could not identify where the purpose was located.

While performing documentary review for this audit, OIG was able to locate the importance of medical event reporting in an internal procedure document.[12] The document stated that medical event information "is invaluable in assessing trends or patterns, identifying generic issues or generic concerns, and recognizing any inadequacies or unreliability of specific equipment and procedures." Further, it stated that medical event information "will significantly aid in understanding why the event occurred and identifying any actions necessary to improve the effectiveness of NRC and Agreement State regulatory programs."

However, an explicit purpose for the reporting of medical events was not identified by OIG in any external, publicly available document that is readily accessible to licensees.[13] As one medical team member said, "It would make sense to have it in the regulations because that's what licensees read to see what they are required to do."

Limited Sharing of Medical Event Data

NRC does not proactively share the majority of medical event information with licensees. For example, NRC typically provides medical event information to licensees only if a trend is detected. When this occurs, NRC will send out a generic communication to licensees. This has occurred on two occasions over the past 5 years.

NRC conducts an annual trending analysis of medical events, but this report is only provided to ACMUI and Agreement States. There is also a publicly available annual report on material events provided by an NRC contractor. However, this report provides only limited information on a small number of medical events that are considered to be significant. Finally, there is an "events database" on NRC's public Web site, but this database provides very limited search functions.

[12] FSME Procedure Approval SA-300, *Reporting Material Events,* March 27, 2013.

[13] NRC management noted that the purpose of medical event reporting is located in Federal Register 45 FR 31701, published on May 14, 1980.

A licensee stated that they do not receive effective feedback on medical events from NRC. The licensee noted that it is the licensees who incur the medical events, yet they only have limited access to medical event data. An NRC regional manager opined that NRC could do a better job of sharing medical event information and that NRC expects licensees to take their own initiative in obtaining this information. The manager added that NRC should make sure licensees are getting the message of how other medical events could impact their programs.

## *Why This Is Important*

### NRC Not Achieving Possible Benefits of Reporting

NRC is not effectively achieving all the possible benefits of medical event reporting. As it currently stands, medical event reporting is unreliable due to the underreporting and retracting of events by licensees who do not consistently understand the requirements. In the cases where events are retracted, an extra burden is created as licensees must expend time and resources to complete paperwork and address the event with NRC and other parties. NRC must then send an inspector to the licensee site within 5 days to inspect the event, in addition to involving regional management and NRC headquarters staff to further assess the event.

There is an ongoing effort between the American Society for Radiation Oncology and the American Association of Physicists in Medicine to create a database that would allow the medical community to anonymously share information and learn from mistakes. A licensee suggested that it may be helpful if NRC approached the reporting of medical events in a similar manner. OIG concludes that if the purpose of medical event reporting is to collect data to prevent future events, the information collected could be used in a more effective way that enhances its benefit as a learning tool.

## Recommendations

OIG recommends that the Executive Director for Operations

1. Clearly define the purpose of medical event reporting in a publicly available document and clarify the reporting requirements.

2. Proactively provide all medical licensees with medical event tracking/trending information for lessons-learned purposes.

## B. Event Reporting Process Not Periodically Assessed

To date, NRC has not conducted a periodic self-assessment of its medical events reporting requirements to determine if they are effectively meeting their intended purpose. Conducting periodic self-assessments of a reporting process and associated requirements is a recognized best practice in the nuclear regulatory community. This programmatic deficiency exists because there is no requirement that a thorough and periodic review of the medical event reporting process be conducted. As a result, NRC is not in a position to make any informed conclusions regarding the effectiveness of its approach to collecting information on medical events.

### *What Is Required*

**Self-Assessment of Reporting Process Recognized Best Practice**

Conducting periodic self-assessments of a reporting process and associated requirements is a recognized best practice in the nuclear regulatory community. Self-assessments are intended to provide an opportunity to determine whether (1) the issues identified are being reported in a timely manner, (2) reporting is strongly encouraged, and (3) reporting activities are consistent among licensees. Furthermore, performing a self-assessment of a reporting process can identify significant weaknesses, recommend remedial measures to address those weaknesses, and provide an opportunity to measure current reporting requirements against licensee experience and recognized good practices.

## *What We Found*

### No Self-Assessment of Reporting Process

NRC's approach to medical event reporting requirements is found to be confusing and, therefore, controversial by some stakeholders. However, to date, NRC has not conducted an internal review or assessment of its medical event reporting requirements to determine if the requirements are appropriate or effective in meeting their intended purpose.

For example, there are industry concerns about the way NRC handles medical event reporting. Some stakeholders noted that NRC's approach to medical event reporting is perceived to be punitive in nature. Specifically, stakeholders opined that the associated reporting requirements are actually a deterrent to self-reporting medical events. Examples that support the stakeholders' perception of NRC's current approach to medical event reporting as punitive include the following:

- Licensees must report medical events to NRC, the referring physician, and the patient, even if the event had no negative effect on the patient.[14]
- A physician can perform a procedure perfectly, but if the results are different than what was intended due to the patient's unique physiology, NRC requirements may dictate that a medical event be reported despite there being no medical negligence.
- Medical events are public information and can adversely affect a medical practice.
- NRC inspectors may occasionally take a confrontational approach towards licensees that report medical events.

As one ACMUI member said,

> How do you ensure various medical facilities are honest in reporting medical events without having the fear that NRC will come down hard on them? It is a very delicate balance because you want everyone to report [medical events], but

[14] Per 10 CFR Part 35, the referring physician has the authority to inform the patient, or based on medical judgment, withhold the information if telling the patient would be considered harmful.

at the same time, if the people involved feel it will be a big deal and create a ruckus within their career or organization, maybe they won't report it.

## *Why This Occurred*

### No Policy Requiring Periodic Assessment

NRC has never conducted a self-assessment of its approach to reporting medical events. This programmatic deficiency exists because there is no requirement that a thorough and periodic review of the medical event reporting process be conducted to determine if

- The intended purpose of reporting requirements is being met.
- The thresholds of the reporting requirements are appropriate.

## *Why This Is Important*

### No Assurance That Medical Event Reporting Approach Is Effective

Confusion and contention will likely continue to surround NRC's approach to medical event reporting if the agency does not periodically assess and make appropriate improvements to its medical reporting requirements. Specifically, NRC is not in a position to draw any conclusions regarding the effectiveness of its approach to collecting information on medical events. Additionally, NRC is not able to proactively address programmatic weaknesses or stakeholder concerns in a timely manner.

There have also been some industry claims that medical event reporting may negatively affect the practice of medicine.[15] The reasoning is that some physicians do not want to perform specific procedures that tend to have a higher occurrence of medical events due to the perceived punitive nature of the reporting requirements. While there may be some truth to these claims, OIG was unable to obtain data from any sources that could

[15] NRC's Medical Policy Statement states that NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

support or verify the statement. However, several NRC staff agreed this consequence was theoretically possible and NRC must be cognizant of how it handles medical event reporting. An Agreement State representative said it is up to the regulators to treat medical events as they should be treated – that licensee event identification and reporting is "a good thing."

By establishing a periodic self-assessment of the medical events program, NRC can more readily address the program's weaknesses. This would also help solidify NRC's position that medical event reporting is about public safety and not about punishing licensees for their mistakes.

**Recommendation**

OIG recommends that the Executive Director for Operations

3. Develop and implement policy and procedures that require periodic assessments of NRC's approach to medical event reporting. These assessments should include whether

    i. The intended purpose of the reporting requirements is being met.
    ii. The thresholds of the reporting requirements are appropriate.

## C. Insufficient Feedback Provided to ACMUI

NRC does not routinely provide sufficiently detailed feedback to ACMUI despite relying on it as a key advisory body. This is inconsistent with NRC's Principles of Good Regulation as well as NRC's commitment to the Open Government initiative, both of which require transparency in decisionmaking. This lack of sufficiently detailed feedback is a result of NRC not having current, formalized policies and procedures that clearly articulate the expectations for providing feedback to ACMUI. As a result, the benefits of having ACMUI provide expert advice may not be fully realized and the potential for miscommunication and misunderstanding remains.

## *What Is Required*

### Independence, Openness, and Collaboration Required in NRC's Regulatory Process

NRC's Principles of Good Regulation identify key organizational values that guide the agency's regulatory actions. Among these values are independence and openness. Independence requires that final decisions be documented with the reasons explicitly stated while openness requires that NRC appropriately inform and involve stakeholders in the regulatory process. Additionally, NRC's Commitment to Open Government reinforces the need for transparency and collaboration in its operations so that stakeholders can participate meaningfully in the regulatory process.

## *What We Found*

### NRC Provides Insufficient Feedback to ACMUI

NRC does not provide sufficiently detailed feedback to ACMUI on proposed recommendations despite relying on it for expert advice and to inform regulatory decisionmaking. Currently, the agency provides ACMUI with marginal feedback on its proposed recommendations by means of a spreadsheet and corresponding memorandum that is provided to each Committee member during the semi-annual meetings held each year. The following table shows the type of information the spreadsheet provides concerning ACMUI recommendations submitted to NRC.

**Generic Example of ACMUI Recommendation Tracking Spreadsheet**

| Advisory Committee on the Medical Use of Isotopes Recommendations (2007 to Present) | | | | | | |
|---|---|---|---|---|---|---|
| **Date** | **Subject** | **Subcommittee Report (N, Y & title)** | **Discussion** | **Status[16]** | **Open vs. Closed** | **Additional Notes** |
| Date recommendation submitted by ACMUI. | Subject of recommendation. | Did ACMUI draft a subcommittee report on the recommendation? If yes, note title of report. | Did an ACMUI hold a discussion/ presentation on the recommendation? If yes, note title of discussion or presentation. | Is the recommendation "accepted," "partially accepted," "pending," "not accepted," or "acknowledged" by the NRC staff? | Is the recommendation "open" or "closed?" If "closed," note date of closure. | Notes on basis for the NRC's decision on the recommendation. |

**Source: OIG**

ACMUI receives feedback from NRC staff on recommendations and the regulatory basis for the staff's acceptance or denial of proposed recommendations via the spreadsheet and Response to Actions memorandum. However, the spreadsheet is designed primarily to be a tracking tool and therefore provides minimal information regarding the basis for the staff's decision on a particular recommendation. For example, some entries for recommendations that were "not accepted," or "partially accepted," state the basis for the staff's decision simply as, "This is outside of the scope of this rulemaking," "Current Expanded Rulemaking," or "Majority of comments were accepted." Other recommendations in "pending" or "acknowledged" status provide no basis or explanation for the staff's determination.

The Response to Actions memorandum is intended to be the formal method by which ACMUI recommendations and subsequent actions are reviewed and staff's response to them is recorded. However, like the spreadsheet, the memorandum provides only minimal information on what actions NRC is required to take in response to an ACMUI recommendation or activity. The memorandum does not provide feedback or a regulatory basis for any decisionmaking in response to ACMUI recommendations.

[16] Status of the recommendation refers to whether the recommendation was "accepted," "partially accepted," "pending," "not accepted," or "acknowledged" by the NRC staff. "Accepted" means the recommendation was accepted by NRC staff and forwarded for consideration. "Partially accepted" means that part of the recommendation was accepted. "Pending" means that the staff has not made a decision on the recommendation and is waiting for more information from ACMUI before making a determination. "Not accepted" means that the recommendation was not accepted and will not be forwarded for consideration. "Acknowledged" means that the staff is aware of the intended purpose of the recommendation but the recommendation pertains to a non-medical subject such as resource constraints.

Multiple ACMUI members opined that the current way they receive information on the Committee's proposed recommendations does not provide sufficient detail to clearly articulate or completely understand NRC's position. One ACMUI member cited two examples where the reason given for NRC staff's decisionmaking was "frustrating" and seemed "arbitrary." Another ACMUI member stated that NRC "is vague in its explanation" for not accepting an ACMUI recommendation. An additional ACMUI member opined that it would be helpful if ACMUI received more feedback from NRC on the decisions regarding proposed recommendations.

To learn how ACMUI understands and recognizes the method by which NRC provides feedback, OIG posed the following question to all ACMUI

**2014 ACMUI briefing with NRC Commission**

**Source: NRC**

members: "How is feedback given?" Of the seven responses received, none of the respondents identified the recommendation spreadsheet or Response to Actions memorandum as a means of receiving feedback. Additionally, none of the respondents identified a different method by which written feedback was provided. In fact, most respondents indicated that the feedback was verbal and provided informally during meetings with staff. The varied responses were indicative that ACMUI members have an inconsistent recognition of when and how NRC provides feedback.

Despite the lack of sufficient feedback and recognition of a common feedback process, ACMUI members stated that, in general, communication and coordination between NRC staff and the Committee has improved significantly in recent years. Committee members are provided the opportunity to ask questions and discuss any of the highlighted topics at their semiannual meetings with NRC. An ACMUI member noted, "Right now, there is a great sense of mutual respect between the ACMUI and NRC staff. There is a feeling of understanding of how each has work to do and we each appreciate the need to work together. The working relationship has been very effective in injecting ACMUI input into NRC regulations and guidance."

The expertise and commitment of NRC staff is also recognized by ACMUI. For example, one Committee member noted, "the staff ACMUI encounters is bright, professional, and well-intentioned… the staff is genuinely concerned with formulating rules that meet their mandate but are not intrusive to medical practice and are reasonable." Formalizing the feedback process between NRC and ACMUI will help develop a mutual understanding and expectation for feedback and therefore will further improve this valuable working relationship.

## *Why This Occurred*

### NRC Lacks Policy and Procedures Guiding Feedback

The lack of sufficient feedback is a result of not having a current, formalized policy and operating procedures that clearly articulate the expectations and process for providing feedback to ACMUI. In contrast to ACMUI, the Advisory Committee on Reactor Safeguards, another NRC Federal advisory committee, has a current, formalized Memorandum of Understanding with the agency that provides specific instructions to guide staff's provision of timely and appropriately detailed feedback.

While conducting fieldwork, the audit team identified two documents that addressed, in part, communication and coordination between NRC and ACMUI. However, these documents lack specific instructions on the provision of feedback and are outdated.

The first document, NUREG BR 0309, "Serving on the Advisory Committee on the Medical Use of Isotopes (ACMUI): A Members Guide," dated 2004, addresses the general methods of interaction among NRC, ACMUI, and the Commission. Specific information on the process and procedures for providing feedback to ACMUI on its recommendations is not provided. Rather, the NUREG simply states ACMUI recommendations will be reviewed and considered by NRC staff and that NRC staff will provide a basis for its decision.

The second document, "[Office of Federal and State Materials and Environmental Management Programs] FSME Policy and Procedures, 2-5, Revision 0," dated 2011, defines and documents staff guidance and procedures for interfacing with ACMUI during the development of major medical policy issues. However, this document does not provide specific instructions on the process for providing feedback to ACMUI. Rather the information is focused on what type of information should be included in staff correspondence to the Commission regarding ACMUI recommendations.

The agency is aware of the need to develop updated guidance that provides specific instructions for giving feedback to ACMUI. At present, the agency is in the process of drafting an internal policy and procedures document that outlines the roles, responsibilities, and administrative duties of NRC staff who support ACMUI. This document is expected to include detailed instructions on providing feedback to ACMUI, including how and when feedback is to be provided.

## *Why This Is Important*

### Benefits of Employing ACMUI Not Fully Realized

There are multiple effects of not having a current, formalized policy and subsequent operating procedures that clearly articulate the expectations and process for providing feedback to ACMUI. Generally, the benefits of having ACMUI provide expert advice to NRC may not be fully realized, and there is greater risk of miscommunication and misunderstanding between NRC and ACMUI. This can lead to a perception that NRC is not being transparent in its regulatory processes.

Since ACMUI members are not experts in regulatory matters, the committee members are at a disadvantage when trying to understand the NRC's regulatory approach to reviewing recommendations and the subsequent decisionmaking process. Having a consistent understanding of how recommendations are reviewed and considered by the agency and being provided detailed and timely feedback would help ACMUI be more effective in providing appropriate assistance to NRC.

Additionally, without a formalized, clearly understood process by which feedback is provided to ACMUI, there is potential for misunderstandings to occur between ACMUI and the agency. Such an instance occurred on ACMUI's proposed recommendation on medical event reporting compatibility.[17] Specifically, ACMUI recommended that current regulations be revised such that only medical event reporting for permanent implant brachytherapy be changed from Compatibility C to Compatibility B. ACMUI did not recommend any additional medical event reporting changes to Compatibility B. However, the Commission's notational vote indicated its support for changing medical event reporting for *all* medical procedures to Compatibility B. This issue was brought to the attention of ACMUI by a Committee member during the March 2015 semiannual meeting, 14 months after the Commission vote. An ACMUI member characterized this occurrence as "a significant process breakdown" among ACMUI, NRC staff, and the Commission.

A lack of regulatory knowledge, coupled with the potential for misunderstandings, further reinforces the desire by some ACMUI members that NRC conduct business more transparently. To maximize the benefits of employing an advisory committee, NRC must provide timely and sufficiently detailed feedback so that input provided by ACMUI continues to be useful, and the working relationship between ACMUI and NRC remains effective.

[17] An Agreement State radiation control program is compatible with NRC's regulatory program when its program does not create conflicts or gaps that would jeopardize orderly regulation of agreement-related material on a nationwide basis. Compatibility B signifies an NRC regulation that should be identically adopted by Agreement States; Compatibility C signifies an NRC regulation of which Agreement States should simply adopt the "essential objectives."

**Recommendation**

OIG recommends that the Executive Director for Operations

4. Develop and implement policy and procedures to guide provision of sufficiently detailed and timely feedback to ACMUI from NRC staff.

# IV. CONSOLIDATED LIST OF RECOMMENDATIONS

OIG recommends that the Executive Director for Operations

1. Clearly define the purpose of medical event reporting in a publicly available document and clarify the reporting requirements.

2. Proactively provide all medical licensees with medical event tracking/trending information for lessons-learned purposes.

3. Develop and implement policy and procedures that require periodic assessments of NRC's approach to medical event reporting. These assessments should include whether

    i. The intended purpose of reporting requirements is being met.
    ii. The thresholds of the reporting requirements are appropriate.

4. Develop and implement policy and procedures to guide provision of sufficiently detailed and timely feedback to ACMUI from NRC staff.

# V. AGENCY COMMENTS

On August 25, 2015, OIG provided the agency with a discussion draft of this report prior to the exit conference which has held on September 15, 2015. Subsequently, agency management provided supplemental information via informal written and verbal comments that have been incorporated into this report, as appropriate.

On September 30, 2015, agency management provided formal comments to the draft report that indicated general agreement with two findings and disagreement with one finding contained in the audit report. Appendix C contains a copy of the agency's formal comments. Appendix D contains OIG analysis of the agency's formal comments.

**Appendix A**

# OBJECTIVE, SCOPE, AND METHODOLOGY

## Objective

The audit objective was to determine if NRC's oversight of medical uses of radioactive isotopes adequately protects public health and safety.

## Scope

The audit focused on reviewing current NRC oversight processes for medical uses of radioactive isotopes. We conducted this performance audit at NRC headquarters (Rockville, MD) from February 2015 through July 2015. Internal controls related to the audit objective were reviewed and analyzed. Throughout the audit, auditors were aware of the possibility of fraud, waste, or abuse in the program.

## Methodology

OIG reviewed relevant criteria, such as Federal regulations including the Federal Advisory Committee Act, NRC's Medical Use of Byproduct Material Policy Statement, and Title 10 of the Code of Federal Regulations, particularly 10 CFR Part 35 *Medical Use of Byproduct Material*.

OIG also reviewed NRC guidance documents such as

- NUREGs.
  1. BR-0217 Rev. 1 "The Regulation and Use of Radioisotopes in Today's World" April 2000.
  2. 1556 Vol. 9 "Consolidated Guidance About Material Licenses, Program-Specific Guidance About Medical Use Licenses" January 2008.
  3. 1925 Rev. 2 "Research Activities FY 2012-2014" August 2013.
- Management Directives.
  1. 8.1 "Abnormal Occurrence (AO) Reporting Procedure" September 2011.

2. 8.10 "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility" March 2014.
3. 8.3 "NRC Incident Inspection Program" June 2014.

- Inspection Manual Chapters.
  1. 1360 "Use of Physician and Scientific Consultants in the Medical Consultant Program" November 2006.
  2. 2800 "Material Inspection Program" November 2010.
- Inspection Procedures.
  1. 87103 "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing" November 2000.
  2. 87130 "Nuclear Medicine Programs, Written Directive Not Required" October 2002.
  3. 87131 "Nuclear Medicine Programs, Written Directive Required" August 2011.
  4. 87132 "Brachytherapy Programs" April 2012.
  5. 87133 " Medical Gamma Stereostatic Radiosurgery and Teletherapy Programs " August 2011.
  6. 87134 "Medical Broad-Scope Programs" August 2011.

2. Previous OIG Investigations.
   1. "NRC Oversight of Requirements Pertaining to the Release of Patients Treated with Medical Isotopes" August 2011.
   2. "NRC Regulatory Oversight of the Pennsylvania Veterans Affairs Medical Center Brachytherapy Program" January 2014.

OIG conducted searches in NRC's material events public database as well as the Nuclear Material Events Database. OIG also reviewed the proposed Part 35 rule and each of the public comments.

OIG traveled to Region I, King of Prussia and also observed two medical inspections at licensee facilities located in Washington, D.C., including a broad scope licensee and a nuclear medicine office.

OIG conducted interviews with management and staff from the NMSS Medical Safety and Event Evaluation Branch, in addition to various safety inspectors and license reviewers from Regions I, III and IV during the course of this audit. OIG interviewed several ACMUI members, Agreement State representatives, and industry representatives/licensees. Finally, OIG attended a monthly NMSS/Regions Part 35 meeting and the semi-annual ACMUI/NMSS and ACMUI/NRC Commission meetings.

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.

The audit was conducted by Sherri Miotla, Team Leader; Mike Blair, Audit Manager; Jacki Storch, Audit Manager; Kevin Nietmann, Senior Technical Advisor; George Gusack, Auditor; Meredith Johnson, Management Analyst; and Connor McCune, Student Intern.

## § 35.3045 REPORT AND NOTIFICATION OF A MEDICAL EVENT

(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in—

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following—

(i) An administration of a wrong radioactive drug containing byproduct material;

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

**Appendix C**

# AGENCY FORMAL COMMENTS

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

September 30, 2015

MEMORANDUM TO: Stephen D. Dingbaum
Assistant Inspector General for Audits
Office of the Inspector General

FROM: Michael F. Weber ***/RA/***
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

SUBJECT: FORMAL COMMENTS ON OFFICE OF THE INSPECTOR GENERAL DRAFT REPORT "AUDIT OF NRC'S OVERSIGHT OF MEDICAL USES OF NUCLEAR MATERIAL"

This memorandum is in response to your September 23, 2015, e-mail transmitting the Office of the Inspector General's (OIG) draft report, "Audit of NRC's Oversight of Medical Uses of Nuclear Material." The enclosure includes the staff's comments.

In general, the U.S. Nuclear Regulatory Commission (NRC) staff agrees with two of the findings highlighting areas of improvement (Finding A and Finding C). However, the staff does not agree with some of the conclusions for why improvement is necessary, and similarly the recommendations resulting from them. Staff does not agree with Finding B, and has provided additional information on the recommendation from this finding in the enclosure. For the recommendation under Finding B, the staff has procedures and policies in place that provide what is asked for in the recommendation. Expansion of these efforts would require more resources with no increase in fulfilling NRC's public health and safety mission. For recommendations 1 and 4 that we do agree with, we will take actions to respond to the recommendations. These actions will be balanced with consideration of the current budgetary environment and limited availability of resources and the increased value to be achieved.

CONTACT: Douglas Bollock, NMSS/MSTR
301-415-6609

H. Bell

I appreciate OIG's audit of NRC's oversight of medical uses of nuclear material, as the NRC is committed to conduct its regulatory and licensing activities in an effective, efficient, open, and transparent manner.

Enclosure:
Staff's Comments on Draft Audit Report

cc: Chairman Burns
Commissioner Svinicki
Commissioner Ostendorff
Commissioner Baran
SECY

**STAFF'S COMMENTS ON THE OFFICE OF THE INSPECTOR GENERAL DRAFT REPORT: AUDIT OF THE U.S. NUCLEAR REGULATORY COMMISSION'S OVERSIGHT OF MEDICAL USES OF NUCLEAR MATERIAL**

**The Office of the Inspector General's (OIG's) Finding A: Clarification of the U.S. Nuclear Regulatory Commission's (NRC's) medical event reporting requirements**

The staff agrees with most aspects of this finding. The issue highlighted in this finding has existed for decades. Staff has been working with the medical community and other stakeholders to clarify what constitutes a medical event when it comes to permanent implant brachytherapy. To remedy this, as approved by the Commission, staff developed an Interim Enforcement policy to help licensees identify medical events for this particular medical procedure, and to maintain consistency in the enforcement of these events. This is an interim solution while the agency pursues a long-term solution. The proposed Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 rule changes, when finished, will address the confusion over the requirements that the medical community has shared with the NRC over the years. Staff worked with the Advisory Committee on the Medical Uses of Isotopes (ACMUI), the medical community, and other stakeholders, along with the Agreement States, on this proposed rule change, and it is generally understood that the changes will provide the clarity the medical community needs. Staff agrees that the purpose of medical event reporting has not been clearly and succinctly described. Thus, some clarification is needed. For these reasons staff agrees that we will take action on Recommendation 1, "Clearly define the purpose of medical event reporting in a publicly available document and clarify the reporting requirements."

Although the staff agrees with Finding A, the staff disagrees with Recommendation 2, "Proactively provide all medical licensees with medical event tracking/trending information for lessons learned purposes." The basis for this recommendation is that there is limited sharing of medical event data. However, as stated in the report, the frequency of medical events is very low when considered in the context of the magnitude of the procedures. The staff has not seen significant trends that haven't been already identified in the annual Nuclear Materials Event Database (NMED) reports. In addition, the staff does not have new information to share on any past trends or events to form the basis for more generic communications. When significant new situations or trends are identified, staff responds accordingly and develops a new generic communication. The NRC presents its annual trending analysis to ACMUI each year, and the ACMUI provides their analysis back to the NRC. This is done during the fall and spring ACMUI public meetings, and the slides and information presented are available on the NRC's public Web site. The NRC also publically shares the NMED annual report that identifies high level issues and trends in medical events. Staff devotes a reasonable and justified level of resources to accomplish these efforts, and openly shares this information with licensees and other stakeholders as requested. Finally, medical events involving NRC licensees are frequently followed up by NRC inspections, which result in publically available inspection reports. States update events in NMED, and if there are lessons to be learned from the causes, this information is then highlighted in presentations to ACMUI, and possibly incorporated in the NMED annual report.

For staff to take further action to provide proactively medical licensees with tracking/trending data would require significant resources, with a small benefit compared with the information

available publicly now. This would also be a burden on each State, because they may have to spend resources to redact information in accordance with applicable State law. Staff has also recently pursued the feasibility of making a version of NMED publically available. Staff solicited information from the states and members of the general public and held a public meeting in October 2014 (Agencywide Documents Access and Management System (ADAMS) Accession Number ML15036A526). There was no attendance from any medical licensees or medical community representatives at the public meeting. The high costs of creating and maintaining a public NMED coupled with the perceived lack of interest among stakeholders, does not support further efforts in this area. Staff recognizes the importance of ensuring information is accessible by members of the public. Additional efforts to address this recommendation would have minimal benefits but increase resource requirements during a period of flat or decreasing budgets.

**OIG Finding B: Periodic self-assessment of medical event reporting**

Though staff generally agrees that improvement in this area could be pursued, a process is already in place to assess event reporting on an annual basis. This process looks for trends to identify any abnormalities or discrepancies in event reporting. Staff conducts this annual trend review, which includes a 5 and 10-year trending analysis, as part of preparations for the Agency Action Review Meetings (AARM) each year. Event reporting has remained relatively consistent from year to year. No trends or indications have been identified that indicate concerns with reporting. This information is communicated to the Commission in the annual paper on the AARM (see SECY-15-0058). Staff also analyzes all medical events that are reported throughout the year on a real-time basis, to help identify any adverse trends or corrective actions that need to be shared immediately with the medical community through generic communications.

Recommendation 3 states that staff should "Develop and implement policy and procedures that require periodic assessments of NRC's approach to medical event reporting." These assessments should include whether: the intended purpose of reporting requirements is being met, and whether the thresholds of the reporting requirements are appropriate. As stated above, the NRC does assess medical events, along with all material events on a continuous basis and annually. The staff and ACMUI do this each year, and staff conducts another broader review to look at long term trends in support of the annual AARM meetings.

The intended purpose of reporting medical events is to identify causes in order to correct and prevent recurrence of significant and adverse events. Through generic communications, licensees and Agreement States are notified if there is a possibility or likelihood that the same errors could recur. In addition, the NRC did an evaluation of the appropriateness of the medical event reporting requirements with ACMUI assistance as a result of an ACMUI briefing to the Commission. This is documented in Staff Requirements Memorandum (SRM) - M04032B (ADAMS Accession Number ML040760566), dated March 16, 2004. The SRM directed the staff to provide the Commission with recommendations concerning the current definition of medical events. The staff involved ACMUI in the development of these recommendations. The result was to make changes to the rule involving medical events for permanent brachytherapy, changing the dose based criteria for reporting and defining medical events. These changes have been included in the proposed rule change to 10 CFR Part 35 published earlier this year. The underlying intent of this recommendation is already being accomplished through current

staff activities. Further analysis or assessment would require additional resources (both the NRC and Agreement State) with little benefit.

**OIG Finding C: Providing better feedback to ACMUI**

Staff agrees it can improve on the feedback to ACMUI. Recommendation 5 states "Develop and implement policy and procedures to guide provision of sufficiently detailed and timely feedback to ACMUI from NRC staff." Updated internal policies and procedures for staff who work with ACMUI are currently under revision. Some of the anticipated changes include adding additional requirements to provide feedback to ACMUI on what staff sends to the Commission, including the committee's unfettered opinions, as well as providing additional information to ACMUI with reasons why staff does not agree or does not plan to take action on their recommendations. These changes will help to better inform ACMUI members of the rationale behind staff's proposed actions and allow for greater dialogue between the NRC and ACMUI.

**Appendix D**

# OIG ANALYSIS OF AGENCY COMMENTS

**The Office of the Inspector General's (OIG's) Finding A: Clarification of the U.S. Nuclear Regulatory Commission's (NRC's) medical event reporting requirements**

Agency Comment

The staff agrees with most aspects of this finding. The issue highlighted in this finding has existed for decades. Staff has been working with the medical community and other stakeholders to clarify what constitutes a medical event when it comes to permanent implant brachytherapy. To remedy this, as approved by the Commission, staff developed an Interim Enforcement policy to help licensees identify medical events for this particular medical procedure, and to maintain consistency in the enforcement of these events. This is an interim solution while the agency pursues a long-term solution. The proposed Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 rule changes, when finished, will address the confusion over the requirements that the medical community has shared with the NRC over the years. Staff worked with the Advisory Committee on the Medical Uses of Isotopes (ACMUI), the medical community, and other stakeholders, along with the Agreement States, on this proposed rule change, and it is generally understood that the changes will provide the clarity the medical community needs. Staff agrees that the purpose of medical event reporting has not been clearly and succinctly described. Thus, some clarification is needed. For these reasons staff agrees that we will take action on Recommendation 1, "Clearly define the purpose of medical event reporting in a publicly available document and clarify the reporting requirements."

Although the staff agrees with Finding A, the staff disagrees with Recommendation 2, "Proactively provide all medical licensees with medical event tracking/trending information for lessons learned purposes." The basis for this recommendation is that there is limited sharing of medical event data. However, as stated in the report, the frequency of medical events is very low when considered in the context of the

magnitude of the procedures. The staff has not seen significant trends that haven't been already identified in the annual Nuclear Materials Event

Database (NMED) reports. In addition, the staff does not have new information to share on any past trends or events to form the basis for more generic communications. When significant new situations or trends are identified, staff responds accordingly and develops a new generic communication. The NRC presents its annual trending analysis to ACMUI each year, and the ACMUI provides their analysis back to the NRC. This is done during the fall and spring ACMUI public meetings, and the slides and information presented are available on the NRC's public Web site. The NRC also publically shares the NMED annual report that identifies high level issues and trends in medical events. Staff devotes a reasonable and justified level of resources to accomplish these efforts, and openly shares this information with licensees and other stakeholders as requested. Finally, medical events involving NRC licensees are frequently followed up by NRC inspections, which result in publically available inspection reports. States update events in NMED, and if there are lessons to be learned from the causes, this information is then highlighted in presentations to ACMUI, and possibly incorporated in the NMED annual report.

OIG Response

During the course of the audit, several individuals – both industry and NRC staff – agreed that medical event information was not always shared in a proactive, productive way. OIG maintains that medical event information should be openly shared with licensees, and this information should be shared ***before*** the events become a trend.

OIG is aware of the medical event report provided to ACMUI each year; however, the public meeting slides covering this report contain only general information on medical events and do not address the details of each medical event. Likewise, the annual NMED report addresses only Abnormal Occurrences, which compose a small number of medical events.

While OIG does not deny that medical event information is available to licensees, the only way to gain access to *all* medical event information is to conduct a tedious search in NRC's Event Notification Report Web page. With an extremely limited search function and the inability to run reports,

the Event Notification Report Web page limits accessibility and does not provide any guarantee that the appropriate medical event information will be identified. Therefore, NRC should proactively provide this information at regular intervals. If the intent of medical event reporting is to identify potential problems and prevent their reoccurrence, then licensees should have easier access to this information for their own lessons learned purposes.

Agency Comment

For staff to take further action to provide proactively medical licensees with tracking/trending data would require significant resources, with a small benefit compared with the information available publicly now. This would also be a burden on each State, because they may have to spend resources to redact information in accordance with applicable State law. Staff has also recently pursued the feasibility of making a version of NMED publically available. Staff solicited information from the states and members of the general public and held a public meeting in October 2014 (Agencywide Documents Access and Management System (ADAMS) Accession Number ML15036A526). There was no attendance from any medical licensees or medical community representatives at the public meeting. The high costs of creating and maintaining a public NMED coupled with the perceived lack of interest among stakeholders, does not support further efforts in this area. Staff recognizes the importance of ensuring information is accessible by members of the public. Additional efforts to address this recommendation would have minimal benefits but increase resource requirements during a period of flat or decreasing budgets.

OIG Response

OIG is not advocating for the creation of a public NMED with this recommendation. OIG believes sending licensees a report similar to what is provided annually to ACMUI, for example, would be more effective than NRC's current method of providing medical event information (as described above). This should also minimize the amount of resources needed since the annual report has already been generated by NRC. Furthermore, there should be little (if any) extra burden on States because the information is already available in the Event Notification Report.

**OIG Finding B: Periodic self-assessment of medical event reporting**

Agency Comment

Though staff generally agrees that improvement in this area could be pursued, a process is already in place to assess event reporting on an annual basis. This process looks for trends to identify any abnormalities or discrepancies in event reporting. Staff conducts this annual trend review, which includes a 5 and 10-year trending analysis, as part of preparations for the Agency Action Review Meetings (AARM) each year. Event reporting has remained relatively consistent from year to year. No trends or indications have been identified that indicate concerns with reporting. This information is communicated to the Commission in the annual paper on the AARM (see SECY-15-0058). Staff also analyzes all medical events that are reported throughout the year on a real-time basis, to help identify any adverse trends or corrective actions that need to be shared immediately with the medical community through generic communications.

OIG Response

The premise of this finding centers on the assessment of the overall medical event reporting program. In other words, keeping medical event reporting as-is and reviewing the results/trends does not fix any potential fundamental issues of the program itself.

Agency Comment

Recommendation 3 states that staff should "Develop and implement policy and procedures that require periodic assessments of NRC's approach to medical event reporting." These assessments should include whether: the intended purpose of reporting requirements is being met, and whether the thresholds of the reporting requirements are appropriate. As stated above, the NRC does assess medical events, along with all material events on a continuous basis and annually. The staff and ACMUI do this each year, and staff conducts another broader review to look at long term trends in support of the annual AARM meetings.

OIG Response

As mentioned above, the issue is not with the reported medical events – it is with the medical event reporting process as a whole. Specifically, the recommendation aims to address issues such as (A) how NRC

determines the effectiveness of medical event reporting, (B) if any of NRC's policies potentially discourage licensee event reporting, (C) if any of NRC's policies affect the practice of medicine, and (D) if the purpose of medical event reporting is truly being met, etc. A self-assessment of the program would help answer these types of questions.

It should be noted that OIG encountered a significant number of questions and complaints, from both industry and NRC staff, about medical event reporting. This served as an indication that an internal review of the program should be conducted.

Agency Comment

The intended purpose of reporting medical events is to identify causes in order to correct and prevent recurrence of significant and adverse events. Through generic communications, licensees and Agreement States are notified if there is a possibility or likelihood that the same errors could recur. In addition, the NRC did an evaluation of the appropriateness of the medical event reporting requirements with ACMUI assistance as a result of an ACMUI briefing to the Commission. This is documented in Staff Requirements Memorandum (SRM) - M04032B (ADAMS Accession Number ML040760566), dated March 16, 2004. The SRM directed the staff to provide the Commission with recommendations concerning the current definition of medical events. The staff involved ACMUI in the development of these recommendations. The result was to make changes to the rule involving medical events for permanent brachytherapy, changing the dose based criteria for reporting and defining medical events. These changes have been included in the proposed rule change to 10 CFR Part 35 published earlier this year. The underlying intent of this recommendation is already being accomplished through current staff activities. Further analysis or assessment would require additional resources (both the NRC and Agreement State) with little benefit.

OIG Response

While the rulemaking is a potentially positive step, the rulemaking primarily involves the medical event definition and changes to permanent brachytherapy medical event reporting. Further, this process was initiated over 11 years ago. The SRM did not address assessing NRC's medical event reporting requirements as a whole.

FSME Policy and Procedure 6-11, published in January 2014, states

> Self-assessments are designed to serve as a critical and diagnostic evaluation of an organization's processes and activities associated with the implementation of various programs. Periodic self-assessments are a proactive initiative to ensure compliance with applicable guidance and requirements. Specifically, self-assessments serve to identify strengths and weaknesses within FSME activities, processes, and programs, which will allow for improved efficiency and effectiveness.
>
> FSME plans to conduct self-assessments scheduled in an annual self-assessment plan. In addition, FSME will occasionally conduct reactive self-assessments in response to current issues, such as identifying reasons for out-of-standard performance, capture lessons-learned from a particular activity, prepare for an external assessment, or evaluate significant changes to a program.

While FSME has since merged with NMSS, NRC management informed OIG that FSME policy is still relevant and used by NMSS staff today.

OIG maintains that self-assessments should provide significant value as NRC has no comparable program currently in place. While this may require additional resources, NRC – not OIG – is ultimately responsible for determining the periodicity of the assessments. Therefore, resource limitations may be taken into account when determining the periodicity.

**OIG Finding C: Providing better feedback to ACMUI**

Agency Comment

Staff agrees it can improve on the feedback to ACMUI. Recommendation 5 states "Develop and implement policy and procedures to guide provision of sufficiently detailed and timely feedback to ACMUI from NRC staff." Updated internal policies and procedures for staff who work with ACMUI are currently under revision. Some of the anticipated changes include adding additional requirements to provide feedback to ACMUI on what staff sends to the Commission, including the committee's unfettered opinions, as well as providing additional information to ACMUI with

reasons why staff does not agree or does not plan to take action on their recommendations. These changes will help to better inform ACMUI members of the rationale behind staff's proposed actions and allow for greater dialogue between the NRC and ACMUI.

OIG Response

OIG looks forward to the agency's efforts in addressing the recommendations in this report.

## TO REPORT FRAUD, WASTE, OR ABUSE

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## COMMENTS AND SUGGESTIONS

If you wish to provide comments on this report, please email OIG using this link.

In addition, if you have suggestions for future OIG audits, please provide them using this link.