



OFFICE OF THE
INSPECTOR GENERAL

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

December 24, 2015

MEMORANDUM TO: Victor M. McCree
Executive Director for Operations

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

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

REFERENCE: DEPUTY EXECUTIVE DIRECTOR FOR MATERIALS,
WASTE, RESEARCH, STATE, TRIBAL, COMPLIANCE,
ADMINISTRATION, AND HUMAN CAPITAL
MEMORANDUM DATED NOVEMBER 30, 2015

Attached is the Office of the Inspector General's (OIG) analysis and status of recommendations 1, 2, 3, and 4 as discussed in the agency's response dated November 30, 2015. Based on this response, recommendations 1, 2, 3, and 4 are resolved. Please provide an updated status of the resolved recommendations by June 30, 2016. If you have questions or concerns, please call me at 415-5915, or Sherri Miotla, Team Leader, at 415-5914.

Attachment: As stated

cc: J. Jolicoeur, OEDO
F. Brown, OEDO
B. Pham, OEDO
J. Arildsen, OEDO
G. Tracy, OEDO
EDO_ACS Distribution Resource

Audit Report

AUDIT OF NRC'S OVERSIGHT OF MEDICAL USES OF NUCLEAR MATERIAL

OIG-16-A-02

Status of Recommendations

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

Agency Response Dated
November 30, 2015:

Staff agrees with Recommendation 1. Staff realizes that the purpose of medical event reporting is not well understood and has not been disseminated to the public in an official manner. Therefore, clarification is needed. Staff will take the following corrective actions to address Recommendation 1. Staff believes these will provide the clarity the medical community needs.

1. Staff will develop a statement that explains the purpose of medical event reporting and its utility to the NRC, including how the agency uses this information to maintain public health and safety. The staff will publish this statement on NRC's Web site and send it to the medical list server and the Agreement States in a State and Tribal Communication. Staff has set a target completion date of February 26, 2016.
2. Staff will incorporate the statement described above into the Title 10 of the *Code of Federal Regulations* Part 35 final rule statement of considerations. Staff has set a target completion date of June 24, 2016.

Point of Contact: Douglas Bollock, NMSS/MSTR, (301) 415-6609

OIG Analysis: The actions proposed by the agency meet the intent of the recommendation. This recommendation will be closed when NMSS issues its statement on the purpose of medical event reporting and publishes it on NRC's Web site, in addition to sending it to the medical list server and to Agreement States

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Status of Recommendations

Recommendation 1 (cont.):

via a State and Tribal Communication. Furthermore, NMSS is to incorporate the statement into the 10 CFR Part 35 final rule statement of considerations.

While not specifically mentioned in the agency response above, NMSS is also to clarify medical event reporting requirements in the 10 CFR Part 35 rulemaking. NMSS acknowledged this in its formal comments to the audit report.

Status: Resolved.

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Status of Recommendations

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

Agency Response Dated
November 30, 2015:

Staff agrees, in part, with Recommendation 2. The agency currently has multiple medical event tracking and trending initiatives that are used for lessons learned purposes. This information is shared with the public via annual reports, outreach activities, and public meetings. As stated in the OIG's audit report OIG-16-A-02, medical events have a low frequency of occurrence. When trends are identified, staff reacts accordingly and develops a new generic communication. The NRC presents its annual trending analysis to Advisory Committee on the Medical Uses of Isotopes (ACMUI) each year, and the ACMUI provides its 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 Nuclear Materials Event Database (NMED) annual report, which identifies high level issues and trends for medical events. Staff devotes a reasonable and justified level of resources for these efforts, and openly shares all this information with any licensee when requested. Finally, medical events at NRC licensees are frequently followed up by the 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 the ACMUI, and possibly incorporated into the NMED annual report. The NMED annual report covers all events for the previous year.

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Status of Recommendations

Recommendation 2 (cont.):

Staff recognizes the importance of ensuring information is accessible by members of the public, and will take additional steps to be proactive in getting medical event information out to licensees and the public.

The staff will provide a link on the medical toolkit to the medical event slides given at the ACMUI meetings twice a year. This will include both the presentation given by staff during the spring meeting, and the presentation given by the ACMUI during the fall meeting. These presentations include medical events from the past year, and the causes (if known). Staff will also alert licensees to the availability of this information in a notice in the Office of Nuclear Material Safety and Safeguards (NMSS) newsletter. "These actions will be reflected in the ACMUI Policy and Procedures (P&P) 6-15." The target completion date for inclusion in the P&P is February 26, 2016.

Point of Contact: Douglas Bollock, NMSS/MSTR, (301) 415-6609

OIG Analysis: The actions proposed by the agency meet the intent of the recommendation. This recommendation will be closed when NMSS provides a link on the medical toolkit Web page to the medical event slides presented at the ACMUI meetings. Additionally, NMSS is to describe these actions in its update of ACMUI P&P 6-15 and alert licensees of this change in the NMSS newsletter.

Status: Resolved.

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Status of Recommendations

- Recommendation 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.

Agency Response Dated
November 30, 2015:

Staff agrees with Recommendation 3. The staff in the NMSS Medical Safety and Events Assessment Branch (MSEB) annually reviews all medical event reports 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. Though the AARM analysis does not explicitly contain an assessment of the medical event reporting program itself, the AARM process requires a review of the current and previous year's information to assess whether the program is operating as intended. Because the AARM process does not explicitly analyze the overall event reporting program, staff will do the following:

Staff will conduct an annual self-assessment of the overall effectiveness of NRC's event reporting program. This assessment will include: 1) how the staff determines the effectiveness of reporting; 2) whether any policies potentially discourage licensee event reporting; 3) whether any policies affect the practice of medicine; and 4) whether the purpose of medical event reporting is being met. This assessment will be conducted by MSEB staff, and reviewed by the MSEB branch chief. It will be captured in an NMSS/MSTR

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Status of Recommendations

Recommendation 3 (cont.):

Division procedure (the division that oversees the AARM for materials). The target completion date is June 24, 2016.

Additionally, the ACMUI created a subcommittee during its October 2015 public meeting, to assess all medical event reporting. This assessment will be presented to the ACMUI full committee and the NRC staff during the ACMUI public meeting in March 2016. Staff will review and evaluate any recommendations and take appropriate actions at that time. Currently there are no set actions or due dates.

Point of Contact: Douglas Bollock, NMSS/MSTR, (301) 415-6609

OIG Analysis: The actions proposed by the agency meet the intent of the recommendation. This recommendation will be closed when NMSS completes its initial, revised medical event reporting self-assessment and includes these revisions to its Division procedure.

Status: Resolved.

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OIG-16-A-02

Status of Recommendations

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

Agency Response Dated
November 30, 2015:

Staff agrees with recommendation 4. Staff believes that 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 the ACMUI. The proposed corrective action in response to this recommendation will result in improved communication mechanisms to allow for more timely feedback to the ACMUI from the NRC staff.

Staff is updating NMSS P&P 2.5 and 6.15, which involve the administration of the ACMUI, to include additional requirements to provide feedback to the ACMUI on what staff sends to the Commission, including the ACMUI's unfettered opinions, and the reasons why staff does not agree with or will not take action on the ACMUI's recommendations. Staff has set a target completion date of February 26, 2016.

Point of Contact: Douglas Bollock, NMSS/MSTR, (301) 415-6609

OIG Analysis: The actions proposed by the agency meet the intent of the recommendation. This recommendation will be closed when NMSS completes its updates of NMSS P&P 2.5 and 6.15 to include additional requirements to provide feedback to ACMUI.

Status: Resolved.