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.