

Summary of Major Agreement State Comments and Staff Response

Criterion III.C: Medical Event Criteria

Comment- OAS and three states disagreed with the staff's recommended use of "a consultant physician deemed qualified by NRC or an Agreement State" in the determination of criterion I.A.3 and III.C.3 as some states do not currently use consultant physicians. OAS stated this could impose additional costs to agreement states or lead to inconsistent reporting across the states as states choosing not to employ consultant physicians will not have any medical event AOs.

Response- The staff modified its previously proposed AO criteria wording of "consultant physician" to "independent physician" in response to the states' comments as it agrees that the term consultant may be too stringent. However, the staff recommends that the medical event criterion be evaluated by a physician independent of the licensee or not directly involved in the care of the patient involved to avoid bias in the determination of whether the event is an AO.

Comment- OAS and one state requested determining factors for the terms "unintended" or "unexpected" when describing adverse side effects in the medical criteria should be given. One state commented that medical procedures have risks and side effects associated with them. A physician could easily argue a patient symptom/issue is a side effect of the medical procedure.

Response- No changes were made in response to these comments. The staff agrees that a patient could experience significant health effects following a medical event which meets the first two AO criteria but a physician determines that the medical procedure, and not the event, caused the patient side effect. As a physician is required to determine the cause and severity of symptoms, the staff does not recommend adding determining factors to these terms. However, these comments highlight the importance of having an independent physician make the determination to avoid the influence of bias on their determination.

Comment- OAS and two states provided comments regarding "death" in criterion III.C.3. Specifically, OAS and one state stated they disagreed with the staff's revised criterion III.C.3 as they did not agree with the new criteria being included as an "and" and recommended that a patient death should be standalone. Another state commented that death can be a consequence in the medical procedure unrelated to the medical procedure itself. Therefore, this state recommended that either the wording be changed to "Death directly related to the radiation dose received" or consider removing "death" as it would fall under the previous criteria of significant unexpected adverse health effect.

Response- No changes were made in response to these comments. Although death can be a consequence of medical procedures unrelated to the medical event, "death" is the most severe unintended and unexpected outcome of any kind of medical procedure (radiation or non-radiation). The staff believes the inclusion of events in which a death has occurred is appropriate. However, as death could be caused by the medical procedure itself, the staff thinks it would be inappropriate to report cases where death occurred with no associated medical event.

Comment- OAS recommended that criterion for unintended or unexpected permanent functional damage to an organ or a physiological system be combined into one criterion.

Response- The changes were made in the revised criterion III.C.3(a) as recommended.

Comment- OAS encourages the staff to review previous years of abnormal occurrence reports against the new draft criteria to see if the medical events that would qualify as AOs under the new criteria yield the type of information the NRC desires to collect. The Board reviewed medical event AOs published in fiscal years (FY) 2010-2012, and of the 50 medical AOs reported under Section III.C, it appears that only two would qualify under the proposed criteria.

Response- The staff reviewed FY 2010 to 2013 reports and agreed that the number of events would be significantly reduced; however, the staff could not determine a specific number as not all reports contained information by which they could be evaluated by the revised criteria and patient side effects were not provided by an unbiased, independent physician. The staff concluded that had this approach been utilized in the past, approximately half of the AOs reported in FY 2010 to 2013 would have been forwarded to a medical consultant, while the other half would have been appropriately screened out as not needing further evaluation for AO purposes. The staff realizes that most of the AO event descriptions in AOs reported in FY 2010 through FY 2013 stated that no adverse health effects from radiation exposure were expected and therefore would likely not have been reported under the proposed criteria. However, the staff's goal of using the recommended criteria is not to reduce the number of medical AOs, but to screen out medical events that are not health or safety significant to patients, and therefore do not meet the threshold of an AO.

Introduction: Addition of Agreement States

Comment- One state recommended the addition of the statement "or Agreement States" after "Commission" in the introduction paragraphs 1 and 3.

Response- The staff agreed with this comment and added "or Agreement States" to these paragraphs.

Criteria I.C.4 and I.C.5: Restructure

Comment- One state recommended moving the revised criteria I.C.4 and I.C.5 to section II as they thought these criterion are designed more for nuclear power plant/fuel cycle licensees and suggested material licensees would be covered by "radiological sabotage" in criterion I.C.2. However, if these criteria remain, further explanation is recommended for "substantial breakdown" in criterion I.C.4 and "significant" in I.C.5. OAS and an additional state also recommended further clarification for "substantial breakdown" if it applies to material licensees.

Response- No changes were made in response to these comments. Section I.C of the AO criteria is intended to provide security-related criteria for all licensees that possess radioactive material, which would include Agreement State, fuel cycle, and nuclear power plant licensees.