



Medical Event Abnormal Occurrence Criteria

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Outline

- **Abnormal Occurrence Background**
- **Current Commission Direction**
- **Current Medical Abnormal Occurrence Criteria**
- **Past ACMUI Recommendation**
- **Question for ACMUI**

Background

- **An abnormal occurrence (AO) is an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety.**
- **The NRC sends AOs to Congress in an Annual Report, NUREG-0090.**

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Background (cont.)

- **The AO criteria was changed in 2017.**
- **As directed by the Commission, the Medical AO Criteria was only changed slightly.**

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Current Commission Direction

The Commission requested the staff to evaluate whether the current abnormal occurrence criteria provides an appropriate threshold for determining if an incident or event is significant from the standpoint of public health and safety or whether the criteria should be revised.

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Current Medical AO Criteria

- **To be classified as an AO, a medical event must meet a dose threshold and incident criteria**
- **First, the event must meet the following dose threshold**
 - **Equal or greater than**
 - **1 Gy to bone marrow or lens of the eye**
 - **2.5 Gy to the gonads, or**
 - **Exceeds, by 10 Gy, the expected dose to any other tissue**

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Current Medical AO Criteria

- **In addition, the event must involve one of the following**
 - **A dose that is at least 50% greater than prescribed**
 - **The wrong radiopharmaceutical, route of administration, or treatment mode**
 - **A leaking source**
 - **Wrong patient or research subject**

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Reported Events

- **Since 2006, over 95% of AOs have been medically related.**
- **In most AOs reported, the event descriptions stated the patient experienced no significant harm.**
- **There were 9 medical AOs reported in FY 2018 using the updated criteria.**

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2015 ACMUI Recommendation

- **Current criteria leads to overreporting in the medical area.**
- **Current criteria is flawed as**
 - **dose thresholds can be met with very slight changes in beam location with no consequence to patients**
 - **can result in reporting of events to Congress which were known, inherit risks of the procedure, such as in Y-90 microsphere events**

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2015 ACMUI Recommendation

- **Specific criteria recommended:**
 - **Replace the current criteria with a medical event, as defined in 10 CFR 35.3045 or 35.3047, which results in a dose that, unintended permanent functional damage to an organ or a physiological system as determined by an independent physician deemed qualified by the NRC or an Agreement State.**

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Question for ACMUI

Does ACMUI believe the current medical AO criteria provides an appropriate threshold for determining if an incident or event is significant from the standpoint of public health and safety or does the ACMUI recommend the criteria be revised?