



MEDICAL ABNORMAL OCCURRENCE (AO) CRITERIA

Suggested Refinement to Proposed Criteria

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CURRENT ACMUI RECOMMENDED MEDICAL AO CRITERIA

For Medical Licensees

- A medical event that results in death; or
- A significant impact on patient health that would result in permanent functional damage or a significant adverse health effect that would not have been expected from the normal treatment regimen, as determined by an NRC or Agreement State – designated consultant physician(s).

NRC PROPOSED REFINEMENT

*Events Involving Patients or Human Research Subjects*¹⁷

- A medical event that results in a dose other than the dose to the intended target that is:
 - Greater than or equal to 1 Gy (100 rad) to a major portion of the bone marrow or to the lens of the eye; **or**
 - Greater than or equal to 2.5 Gy (250 rad) to the gonads; **or**
 - Greater than or equal to 10 Gy (1,000 rad) to any other unintended organ or tissues other than the treatment site; **and**

¹⁷ Criteria III.A.3 and III.A.4 also apply.

NRC PROPOSED REFINEMENT

- Results in a significant impact on patient health that would result in **one or more** of the following, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State:
 - Unintended permanent functional damage to an organ.
 - Unintended permanent functional damage to a physiological system.
 - A significant unexpected adverse health effect.
 - Death.

NRC PROPOSED REFINEMENT

~~For Medical Licensees~~ **Events Involving Patients or Human Research Subjects** ¹⁷

- A medical event that results in ~~death~~ **a dose other than the dose to the intended target that is:**
 - Greater than or equal to 1 Gy (100 rad) to a major portion of the bone marrow or to the lens of the eye; **or**
 - Greater than or equal to 2.5 Gy (250 rad) to the gonads; **or**
 - Greater than or equal to 10 Gy (1,000 rad) to any other unintended organ or tissues other than the treatment site;

and

Note: Blue font is indicative of language currently used to capture Medical AOs. NRC staff recommends retention of this language.

NRC PROPOSED REFINEMENT

- Results in a significant impact on patient health that would result in ~~permanent functional damage or a significant adverse health effect that would have not been expected from the normal treatment regimen, as determined by an NRC or Agreement State designated consultant physician(s)~~ **one or more** of the following, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State:
 - Unintended permanent functional damage to an organ.
 - Unintended permanent functional damage to a physiological system.
 - A significant unexpected adverse health effect.
 - Death.

NRC PROPOSED REFINEMENT

(Footnote 17 Reference)

III. Events at Facilities Other than Nuclear Power Plants and All Transportation Events

A. Events Involving Design, Analysis, Construction, Testing Operation, Transport, Use, or Disposal of Licensed Facilities or Regulated Materials

1. An accident criticality.
2. A major deficiency in design, construction...
- 3. A serious safety-significant deficiency in management or procedural controls.**

NRC PROPOSED REFINEMENT

III. Events at Facilities Other than Nuclear Power Plants and All Transportation Events (continued)

- 4. A series of events (in which the individual events in which individual events are not of major importance), recurring incidents, or incidents with implications for similar facilities (generic incidents that raise a major safety concern.**

SUMMARY OF REFINEMENTS

- **Dose Criteria Retained**

- *“Greater than or equal to 1 Gy (100 rad)...”*
- Useful to staff for the non-arbitrary, consistent identification of events that could be serious.
- Aids in efficient use of NRC staff resources.

- **Clarification:**

- Minimally only one of the second set of criteria need be met.
- **“...one or more** of the following, as determined by a consultant physician(s)...”

SUMMARY OF REFINEMENTS

- **Proposal to Apply Generic Trend Criteria to Medical Facilities**

- *“Serious safety-significant deficiency in management or procedural controls.”*
- *“A series of events (in which the individual events are not of major importance), recurring incidents, or incidents with implications for similar facilities (generic incidents) that raise a major safety concern.”*

NEXT STEPS

- Agreement State Early Comment
- Commission Review
- Publication in *Federal Register* (90 days)
- Staff Incorporation of Comments
- Commission Review/Final Approval
- Final AO Criteria in *Federal Register*

DISCUSSION

