

Summary of All Proposed Changes to the Abnormal Occurrence Criteria

INTRODUCTION

The introduction summarizes the types of incidents or events that will be considered abnormal occurrences (AOs). The staff proposes two changes to this portion. First, the staff proposes that events in examples 1 and 3 may include not only events involving radioactive material and facilities regulated by the Commission but also those organizations regulated by Agreement States. Second, the staff proposes adding as a fourth example of an AO, “substantiated case of actual loss, theft, or diversion of risk significant radioactive material licensed by or otherwise regulated by the Commission or Agreement States,” to include a security example to the AO criteria.

In presenting the criteria used to determine which events will be considered for reporting as AOs, the staff proposes to add language to indicate that the listing is “by types of events” and make additional editorial changes for clarity.

SECTION I: “ALL LICENSEES”

This section, entitled “All Licensees,” specifies criteria that are intended to capture significant safety events that pertain to all NRC and Agreement State licensees. In this section, the staff proposes to add footnote 1 to clarify that medical patients are excluded under this section. Medical patients are addressed in section III of the criteria, “Events at Facilities Other than Nuclear Power Plants and All Transportation Events.” The staff has also made two editorial changes to this section: deleting the word “for” from the title and changing the numbering of footnotes resulting from the addition of the footnote.

Criterion I.A

Criterion I.A, entitled “Human Exposure to Radiation from Licensed Material,” is intended to capture significant events associated with human exposure from all NRC- and Agreement State-licensed material. The staff proposes three changes to this criterion.

First, the staff proposes to change the format in I.A.1 criteria for clarity based on a comment from the Agreement States.

Second, the staff proposes changing the language in criterion I.A.3 from “as determined by a physician” to “as determined by an independent physician deemed qualified by the NRC or an Agreement State.” The staff proposes this change to parallel the language that the staff proposes for section III, criterion C. Staff proposes defining “independent physician” in footnote 2 as a physician not on the licensee’s staff and who was not directly involved in the care of the patient. The use of an independent physician for evaluation would avoid bias in situations where a physician was involved in the event.

Third, the staff proposes to add criterion 1.A.4 with the following language: “These criteria do not apply to medical events defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 35.3045 and included in AO criteria III.C.” The staff proposes this change to clearly delineate that events considered under this item do not include medical events defined in 10 CFR 35.3045, “Report and notification of a medical event.” Medical events defined in

10 CFR 35.3045 are addressed in section III, criterion C, “Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects.”

Criterion I.B

Presently, criterion I.B does not have a title. The staff proposes entitling criterion I. B, “Discharge or Dispersal of Radioactive Material from its Intended Place of Confinement,” so that it is consistent with other criterion in this section. In addition, the staff proposes editorial changes, including the inclusion of titles of associated regulations, to this criterion for clarity.

Criterion I.C

Criterion I.C, entitled “Theft, Diversion, or Loss of Licensed Material; Sabotage; or Security Breach,” is intended to capture significant security events. The staff proposes nine changes to this criterion.

The first proposed change is to revise the title to “Theft, Diversion, or Loss of Licensed Material; Sabotage; or Security Breach” for clarity based on an agreement state comment.

Second, the staff proposes to modify the current footnote 2 (proposed footnote 4) to clarify the definition of safeguards information which may be withheld from the report. This change also makes the footnote consistent with the wording used in the previous footnote which defines classified information which might need to be withheld from the report.

Third, the staff also proposes an additional footnote to the title of criterion I.C. Proposed footnote 5 clarifies that the reporting of lost or stolen material is based upon the source activity of the radioactive material at the time the material was lost. It states that the NRC will indicate in the AO report to Congress, if the radioactive material has decayed to below the thresholds listed in Appendix A of 10 CFR Part 37 by the time of the report issuance. The radioactive material and thresholds listed in Appendix A of 10 CFR Part 37 are based on the Category 1 and Category 2 quantities of radioactive material listed in the International Atomic Energy Agency Code of Conduct on the Safety and Security of Radioactive Sources, which could pose a significant risk to individuals, society, and the environment. The staff believes that this added language would better inform Congress about the risk associated with the lost or stolen sources.

Fourth, the staff proposed change is to revise criterion I.C to address the physical protection of byproduct material consistent with regulations codified in 10 CFR Part 37 and to better align with the strategic plan. The staff proposes to remove references to Appendix P to 10 CFR Part 110 and the term “risk-significant radioactive sources” in criterion I.C.1 and replace those with a reference to the radioactive material thresholds listed in Appendix A of 10 CFR Part 37. Additionally, the staff proposes revising the reporting exclusion of criterion I.C.1 to improve clarity and to better align the AO criteria with 10 CFR Part 37.

Fifth, the staff recommends removing diversion from the current criterion I.C.2 and making radiological sabotage stand alone in the proposed criterion 1.C.2. In addition, the staff recommends adding the reference to the definition of radiological sabotage contained in 10 CFR 73.2, “Definitions,” for clarity. In the current criteria, this definition is contained in a footnote.

Sixth, the staff proposes rearranging criterion in I.C.1, I.C.2, and 1.C.3 to avoid repetition and provide clarity. Specifically, the staff recommends (1) moving “diversion” from criterion I.C.2 to

criterion I.C.1, (2) removing “radioactive sources” from I.C.2 because radioactive sources are covered in proposed criterion I.C.1, and (3) moving the “case of actual theft and diversion of formula quantity of special nuclear material” from criterion I.C.2 to criterion I.C.3.

Seventh, the staff recommends removing the term “substantiated” in conjunction with inventory discrepancy in criterion I.C.3 because the inventory difference portion of the criterion is appropriately qualified by the existing terminology stating that the discrepancy is “judged to be caused by theft or diversion.” This modification would result in the definition of substantiated in current footnote 3 (proposed footnote 6) to apply only to loss, theft, and diversion. Therefore, the staff also recommends removing “statistical processing difference” from current footnote 3 (proposed footnote 6), because this term is associated with inventory difference, rather than a loss, theft, or diversion caused by other means.

Eighth, the staff proposes the addition of cyber security to criterion I.C.4 to align the AO criteria with the NRC strategic plan and performance measures. In addition, the staff proposes revising criterion I.C.4 to add protection against loss of licensed material and to revise language that addresses material control and accountability to improve clarity.

Ninth, the staff proposes modifying the definition of substantial breakdown in current footnote 6 (proposed footnote 8) to remove the phrase, “or in a shutdown condition (inimical to the effective functioning of nation’s critical infrastructure) as a result of significant performance problems and/or operational events.” Additional clarification is made to this definition by defining a red finding as under the Reactor Oversight Process (ROP).

SECTION II: “COMMERCIAL NUCLEAR POWER PLANT LICENSEES”

This section, entitled “Commercial Nuclear Power Plant Licensees,” specifies criteria that are intended to capture significant safety events at commercial nuclear power plant facilities. The staff proposes to delete the word “For” in the title of section II, “Commercial Nuclear Power Plant Licensees.” The staff proposes the following changes to this section.

Criterion II.A

The staff proposes editorial changes to criterion II.A.3. Specifically, the staff proposes the inclusion of titles of regulations for clarity.

Criterion II.B

The staff proposes two editorial changes for clarity.

Criterion II.C

This criterion is intended to capture high safety significant events at commercial nuclear power plants. The staff proposes changing criterion II.C to state “Any reactor events or conditions evaluated by the NRC Reactor Oversight Process (ROP) to be of high safety significance of licensee performance.” This language was part of a footnote associated with II.C, and the staff believes that the proposed modification will clarify events that are to be considered under this item.

Criterion II.D

The staff proposes moving the description of Accident Sequence Precursor (ASP) criteria from the current footnote 8 and addressing it in a new criterion II.D to align the AO criteria language with the NRC strategic plan and performance measures. Specifically, the staff proposes the following language for criterion II.D: “Any reactor events or conditions evaluated by the NRC Accident Sequence Precursor (ASP) program that have a conditional core damage probability (CCDP) or a change in core damage probability (Δ CDP) of greater than or equal to 1×10^{-3} .” With the addition of this criterion, the staff recommends adding the following footnote to the proposed criterion II.D to clarify the purpose of the ASP Program results: “Results from the NRC ASP program are used to monitor agency performance against the agency’s strategic safety goal (e.g. ensure the safe use of radioactive materials) and objectives (e.g. prevent and mitigate accidents and ensure radiation safety). A precursor event with a CCDP or Δ CDP of greater than or equal to 1×10^{-3} is used as a performance indicator for the strategic safety goal by determining that there have been no significant precursors of a nuclear reactor accident and that there have been no more than one significant adverse trend in industry safety performance.”

Criterion II.E

If the new criterion for ASP above is approved, the current criterion II.D would be the proposed criterion II.E. The staff proposes editorial changes to this criterion for clarity. Specifically, the staff recommends adding the term “and” as significant performance problems and operational events could both be a factor in a shutdown condition.

In addition, the staff proposes revising language for current footnote 9 (proposed footnote 12) to include Inspection Manual Chapter 0350, “Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns.”

SECTION III: “EVENTS AT FACILITIES OTHER THAN NUCLEAR POWER PLANTS AND ALL TRANSPORTATION EVENTS”

This section is intended to capture significant safety and security events at all facilities other than nuclear power plants (e.g., fuel cycle and medical facilities).

Criterion III.A

The staff proposes two changes in criterion III.A. First, the staff proposes revising the title to “Events involving Design, Analysis, Construction, Testing, or Operation of Licensed Facilities or Transport, Use, or Disposal of Regulated Materials.” Second, the staff proposes removal of “(10 CFR 70.52(a))” at the end of the criterion because it is not relevant.

Criterion III.B

The staff proposes revising criterion III.B.1 to “Absence or failure of all safety controls (engineered and human) such that conditions were present for the occurrence of a high-consequence event involving an NRC-regulated hazard (radiological or chemical hazard).” The revision replaces “lethal” with “high-consequence.” Revision of the AO criterion from a “lethal hazard” to a “high-consequence event” will make the criterion objective and risk-informed, and will align the criterion with the existing regulatory framework for fuel cycle facilities.

The staff also proposes to remove “security-related” from the criterion as security-related events are covered under section I.C of the AO criteria for all licensees, and its inclusion in I.C would be duplicative and unnecessary. Further, staff proposes to replace the language that relates to the presence of lethal hazard with language linked to the potential for the occurrence of a high-consequence event. This provides clarity to ensure that only those conditions in which a potential event was imminent and significant are reported to Congress. Finally, the staff proposes the addition of footnote 14 to explain considerations for the review of fuel cycle events under this revised criterion III.B.1.

Additionally, the staff proposes two editorial changes to criterion III.B. First, the staff proposes changing the title from “For Fuel Cycle Facilities” to “Fuel Cycle Facilities.” The proposed change will keep this title consistent with language used in other titles of the proposed AO criteria. Second, the staff proposes adding footnote 13 with the following language: “Criterion III.A also applies to Fuel Cycle Facilities” to clarify that Fuel Cycle Facilities would also be considered under criterion III.A.

Criterion III.C

The staff proposes six changes to criterion III.C. First, the staff proposes a title revision to change the current title “For Medical Licensees” to “Events Involving the Medical Use of Radioactive Materials in Patients and Human Research Subjects.” The proposed title clarifies that the criteria in this section apply to patients or human research subjects. Second, the staff proposes to include a footnote at the end of the title to clarify that criteria III.A.2, III.A.3, and III.A.4 would also apply to medical licensees. Third, the staff recommends adding a reference to the medical event definition in 10 CFR 35.3045 for clarity. Fourth, the staff proposes editorial changes to criterion III.C.2.

Fifth, the staff proposes change to criterion III.C.1(b). Currently, criterion III.C.1.(b) is a dose of greater than 10 Gy to an organ or tissue other than that described in criterion III.C.1.(a). Many medical procedures have prescribed doses that are greater than 10 Gy to an organ or tissue, and this criterion could be met without the medical event causing any excess dose to the organ or tissue. The staff proposes changing this criterion to include medical events that result in a dose that exceeds, by 10 Gy, the expected dose from the administration defined in the written directive.

Finally, the staff proposes the addition of criterion III.C.3. This proposed criterion would require an AO to be a medical event that results in unintended or unexpected permanent functional damage to an organ or physiological system, a significant unexpected adverse health effect, or death, as determined by an independent physician. Under these new criteria, NRC will identify medical events that are significant from public health and safety perspective and warrant notification to Congress.

Section IV: “OTHER EVENTS OF INTEREST”

The staff proposes moving this section to Appendix B. If approved, the new Appendix B would contain an opening paragraph that would read as follows:

This appendix discusses other events of interest that do not meet the AO criteria in Appendix A. The Commission may determine that events, other than AOs, may be of interest to Congress and the public and should be included in an

appendix to the AO report as “Other Events of Interest.” Such events may include, but are not necessarily limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.