

October 21, 2004

ALL AGREEMENT STATES, MINNESOTA, PENNSYLVANIA

PROPOSED REVISED ABNORMAL OCCURRENCE (AO) CRITERIA (STP-04-078)

This is to inform you that the U.S. Nuclear Regulatory Commission (NRC) is proposing new language amending the criteria used to identify security events, AO Criterion I (C.), and the criteria used to identify medical events, AO criterion IV. The proposed changes are presented in the enclosed document. The specific changes are denoted in bold face and are presented with the current language as published in Appendix A of the AO report, "Abnormal Occurrence Criteria and Guidelines For Other Events of Interest" included in STP Procedure SA-300, and NRC Management Directive 8.1, "Abnormal Occurrence Reporting Procedure." We are requesting that you review and provide comments* by November 19, 2004.

If you have any questions on this correspondence, please contact me or the individual(s) named below.

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Enclosure:
As stated

* This information request has been approved by OMB 3150-0029, expiration 06/30/07. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and FOIA/Privacy Services Branch (T-5F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0029), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

STP-04-078

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REVISED ABNORMAL OCCURRENCE CRITERIA

Proposed Language to Criterion I, "For All Licensees"

The "Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach" element [the security criterion] to AO Criterion I, "For All Licensees" outlines specific thresholds for reporting security* events to Congress. The first proposed change to the security criterion is consistent with Commission direction contained in the staff requirements memorandum (SRM) dated August 21, 2003. The SRM directed the NRC staff to move forward with tracking radioactive sources that if abandoned, unsecured, unrecovered, or stolen could be used for malicious purposes to cause harmful health effects. Under this element, events involving unrecovered losses or thefts of risk-significant sources exceeding threshold quantities specified in the International Atomic Energy Agency's (IAEA) Code of Conduct will be classified as AOs and reported to Congress.

The second proposed change to the security criterion is the addition of a new element. This new element will allow for reporting to Congress of events involving unauthorized disclosures of classified and/or safeguards information. Currently, the AO criteria does not speak to unauthorized disclosures of classified and/or safeguards information that could assist potential terrorists. The proposed wording would apply to any person, whether or not a licensee of the NRC, who discloses classified and/or safeguards information. Both changes to the security criterion are proposed and denoted in **boldface** type below:

Current Wording, AO Criterion I (C.)

- I. For All Licensees
 - C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach
 - 1. Any lost, stolen, or abandoned sources that exceed 0.01 times the A1 values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for special form (sealed/nondispersible) sources, or the smaller of the A2 or 0.01 times the A1 values, as listed in Table A-1, for normal form (unsealed/ dispersible) sources or for sources for which the form is not known. Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur during the time the source was missing; and unrecoverable sources lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 were not known to have occurred.
 - 2. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.

3. Any substantiated loss of special nuclear material or any substantiated inventory discrepancy that is judged to be significant relative to normally expected performance, and that is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.
4. Any substantial breakdown of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.

Proposed Wording, AO Criterion I (C.)

- C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach
1. Any **unrecovered** lost, stolen, or abandoned sources that the **Commission has determined to be risk significant and that exceed the values listed in Table I., Category 2, “Activities Corresponding to Thresholds of Categories,” in the IAEA’s Code of Conduct on the Safety and Security of Radioactive Sources.** Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur during the time the source was missing; and unrecoverable sources lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 were not known to have occurred.
 2. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.
 3. Any substantiated loss of special nuclear material or any substantiated inventory discrepancy that is judged to be significant relative to normally expected performance, and that is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.
 4. Any substantial breakdown of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.
 5. **Any significant unauthorized disclosures (loss or theft) of classified and/or safeguards information.**

Proposed Language to Criterion IV, “For Medical Licensees”

Criterion V, “For Medical Licensee,” outlines specific thresholds for reporting medical events to Congress. The first proposed change to the medical criterion is the addition of a new element. The proposed element adds, “unintended permanent functional damage as determined by a physician” to address the current reporting to Congress of medical events that have not been determined by a physician to cause permanent functional damage to an organ or tissue. The term “tissue” is added, in part, to classify events as AOs where an area received radiation exposure during medical treatment, but the area is not defined as an organ.

The second proposed change to medical criterion increases the dose threshold for the gonads from 1 Gy (100 rads) to 2.5 Gy (250 rads). The proposed change is based on the recommendations of the International Commission on Radiological Protection (ICRP) in Publication 60, “1990 Recommendations of the ICRP”, that a dose range of 2.5 Gy (250 rads) to 600 rads (6.0 Gy) to the ovaries causes permanent sterility. The ICRP dose of 3.5 to 6.0 Gy (350 rads to 600 rads) to the testes, causes permanent sterility. The term “tissue” is also added to this element.

Lastly, language was added to the medical criterion to consider events where the dose or dosage delivered exceeded 50 percent of the intended dose or dosage, but a written directive was not prepared because the intended administration did not require the preparation of a written directive. Additionally, “unsealed byproduct material” was added to reflect the current wording used in 10 CFR Part 35, “Medical Use of Byproduct Material” and to maintain language consistent between 10 CFR Part 35 and the medical criterion. Outlined below in **boldface** type are the proposed changes to Criterion IV, “Medical Licensees.”

Current Wording AO Criterion IV. “Medical Licensees”

IV. For Medical Licensees

A medical event that:

- (a) Results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and
- (b) Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or (2) a prescribed dose or dosage that (i) is the wrong radiopharmaceutical, or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source or sources.

Proposed Wording AO Criterion IV. "Medical Licensees":

IV. For Medical Licensees

A medical event that:

- (a) **Results in unintended permanent functional damage to any organ or tissue as determined by a physician; and**
- (b) Results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow or the lens of the eye, **or (2) equal to or greater than 2.5 Gy (250 rads) to the gonads**, or (3) equal to or greater than 10 Gy (1,000 rads) to any other organ **or tissue**; and
- (c) Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive, **or (2) a dose or dosage administered in the absence of a written directive, for which a written directive was needed, and the dose or dosage is at least 50 percent greater than the intended dose or dosage**; or (3) a prescribed dose or dosage that (i) is the wrong radiopharmaceutical or- **unsealed byproduct material**; or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source or sources.