

to report on ongoing Council initiatives, and to plan for future directions.

Dated: January 4, 1996.

Sandra Perlmutter,

*Executive Director, President's Council on Physical Fitness and Sports.*

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## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[CA-063-1150-00]

#### Cancellation of Public Workshops for the Northern and Eastern Colorado Desert Coordinated Management Plan

The following public meetings announced in the Federal Register will not be held because of the furlough of BLM employees during the partial shutdown of the Federal government:

January 8, Riverside  
 January 9, Long Beach  
 January 10, Twentynine Palms  
 January 11, Palm Springs  
 January 16, Needles  
 January 17, Blythe  
 January 18, El Centro  
 January 22, Rancho Bernardo

For More Information: Contact the Bureau of Land Management, California Desert District, External Affairs Office, 6221 Box Springs Boulevard, Riverside, California 92507, (909) 697-5217.

Dated: January 3, 1996.

Jo Simpson,

*Acting District Manager.*

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## NUCLEAR REGULATORY COMMISSION

#### Abnormal Occurrence Reports: Implementation of Section 208 Energy Reorganization Act of 1974; Proposed Policy Statement

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed policy statement.

**SUMMARY:** This policy statement presents the revised criteria the Commission is considering for use in submitting the quarterly abnormal occurrence (AO) reports to Congress and the public in a timely manner as stated in Section 208 of the Energy Reorganization Act of 1974, as amended. The AO policy statement has been revised to provide more specific criteria for determining those incidents

and events that the Commission considers significant from the standpoint of public health and safety for reporting to Congress, and to make the AO policy consistent with recent changes to NRC regulations. The revised AO criteria contain more discrete reporting thresholds making them easier to use and ensuring more consistent application of the intended AO reporting policy set forth by the Commission.

**DATES:** The public comment period on this proposed policy statement ends April 8, 1996. Comments received after the public comment period will be addressed if it is practicable to do so, but the Commission is able to ensure consideration of only those comments received on or before the last day of the comment period.

**ADDRESSES:** Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington DC 20555, Attn: Docketing and Service Branch. Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. Federal workdays.

Examine comments received at the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Harriet Karagiannis, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 415-6377.

#### SUPPLEMENTARY INFORMATION:

##### Background

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438, 42 U.S.C. 5848), as amended, provides that:

The Commission shall submit to Congress each quarter a report listing for that period any AOs at or associated with any facility which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or pursuant to this Act. For the purposes of this Section, an AO is an unscheduled incident or event which the Commission has determined to be significant from the standpoint of public health and safety. Nothing in the preceding sentence shall limit the authority of a court to review the determination of the Commission. Each such report shall contain:

- (1) The date and place of each occurrence;
- (2) The nature and probable consequence of each occurrence;
- (3) The cause or causes of each; and

(4) Any action taken to prevent recurrence.

The Commission shall also provide as wide dissemination to the public of the information specified in clauses (1) and (2) of this section as reasonably possible within 15 days of its receiving information of each AO and shall provide as wide dissemination to the public as reasonably possible of the information specified in clauses (3) and (4) as soon as such information becomes available to it.

In July 1975, in the exercise of the authority conferred upon the Commission by Congress to determine which unscheduled incidents or events are significant from the standpoint of public health and safety and are reportable to Congress as AOs, the Commission developed interim criteria for evaluating licensee incidents or events. On the basis of these interim criteria and as required by Section 208, the Commission began issuing quarterly reports to Congress on AOs. These reports<sup>1</sup> "Report to Congress on Abnormal Occurrences," have been issued in NUREG 75/090 and NUREG-0090-1 through 5 for the period from January 1975 through September 1976. On the basis of its experience in the preparation and issuance of AO reports, the Commission issued a general statement of policy that described the manner in which it will, as part of the routine conduct of its business, carry out its responsibilities under Section 208 of the Energy Reorganization Act of 1974, as amended, for identifying AOs and making the requisite information concerning each such occurrence available to Congress and the public in a timely manner. This general statement of policy was published in the Federal Register on February 24, 1977 (Vol. 42, No. 37, pages 10950-10952) and provides criteria and examples of types of events that the Commission uses in determining whether a particular event is reportable to Congress as an AO. The Commission has since refined this statement of policy on a number of occasions to reflect changes in regulation and policy. On the basis of these criteria, and as required by Section 208 of the Energy Reorganization Act of 1974, as amended, the Commission has issued quarterly reports to Congress on AOs since March 1977. These reports,

<sup>1</sup> Copies of the NUREG-0090 series may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Mail Stop SSOP, Washington, DC 20402-9328, the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, and the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC. 20037

"Report to Congress on Abnormal Occurrences," have been issued in NUREG-0090-6 through 10 and NUREG-0090, Volumes 1 through 18.

Based on its experience to date in the preparation and issuance of AO reports, the Commission has decided that its responsibilities under Section 208 can be carried out more appropriately if the existing AO criteria are updated to reflect changes in the Commission's policy and changes to the regulations. Accordingly, the Commission is issuing this general statement of policy that describes the manner in which the Commission will, as part of the routine conduct of its business, carry out its responsibilities under Section 208 of the Energy Reorganization Act of 1974, as amended, for identifying AOs and making the requisite information concerning each such occurrence available to Congress and the public in a timely manner. Included in the policy statement are criteria that the Commission will use in determining whether a particular event is a reportable AO within the meaning of Section 208. It is expected that as additional experience is gained, changes in the criteria may be required.

#### Paperwork Reduction Act Statement

This proposed policy statement does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval 3150-0014, 10 CFR Part 20; 3150-0017, 10 CFR Part 30; 3150-0016, 10 CFR Part 31; 3150-0001, 10 CFR Part 32; 3150-0015, 10 CFR Part 33; 3150-0007, 10 CFR Part 34; 3150-0010, 10 CFR Part 35; 3150-0158, 10 CFR Part 36; 3150-0130, 10 CFR Part 39; 3150-0020, 10 CFR Part 40; 3150-0011, 10 CFR Part 50; 3150-0135, 10 CFR Part 61; 3150-0009, 10 CFR Part 70; 3150-0008, 10 CFR Part 71; and 3150-0132, 10 CFR Part 72; 3150-0002, 10 CFR Part 73; and 3150-0093, 10 CFR Part 100.

#### Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number

#### Abnormal Occurrence Reporting

The general statement of policy has been developed to comply with the legislative intent of Section 208 of the Energy Reorganization Act of 1974, as amended, to keep Congress and the public informed of unscheduled incidents or events which the

Commission considers significant from the standpoint of public health and safety. The policy reflects a range of health and safety concerns and is applicable to incidents and events involving a single occupational worker as well as those having an overall impact on the general public.

The policy statement contains criteria that include the reporting thresholds for determining those incidents and events that are reportable by NRC for the purposes of Section 208 of the Energy Reorganization Act of 1974, as amended. The Commission has established the reporting thresholds at a level which will assure that all events that should be considered for reporting to Congress will be identified. At the same time, the thresholds are generally above the normal level of reporting to NRC to exclude those events which involve some variance from regulatory limits, but are not significant from the standpoint of public health and safety.

#### Licensee Reports

This general statement of policy will not change the reporting requirements imposed on NRC licensees by Commission regulations, license conditions, or technical specifications (TS). NRC licensees will continue to submit required reports on a wide spectrum of events, including events such as instrument malfunctions and deviations from normal operating procedures that are not significant from the standpoint of the public health and safety but which provide data useful to the Commission in monitoring operating trends of licensed facilities and in comparing the actual performance of these facilities with the potential performance for which the facilities were designed and/or licensed. Information pertaining to all events reported to NRC will continue to be made available and placed in the public document rooms for public perusal. In addition, NRC publishes annual reports on events (NUREG-1272 series). Information can also be obtained by writing to the U.S. Nuclear Regulatory Commission, Public Document Room, Washington, DC 20555. In addition, the Commission will continue to issue news announcements on events that seem to be newsworthy whether or not they are reported as AOs.

The Commission invites all interested persons who wish to submit written comments or suggestions on the AO criteria in this policy statement. A period of 90 days from the date of publication has been established for receiving comments pertaining to this proposed policy statement. The NRC staff will analyze all comments and

revise the policy statement accordingly and then resubmit it to the Commission for final approval. The policy statement is currently scheduled to be presented to the Commission for final approval during the summer of 1996.

#### General Statement of Policy on Implementation of Section 208 of the Energy Reorganization Act of 1974, as Amended

1. *Applicability*—Implementation of Section 208 of the Energy Reorganization Act of 1974, as amended, Abnormal Occurrence Reports, involves the conduct of Commission business and does not impose requirements on licensees. Reports will cover certain unscheduled incidents or events related to the manufacture, construction, or operation of a facility or conduct of an activity subject to the requirements of Parts 20, 30 through 36, 39, 40, 50, 61, 70, 71, or 72 of Chapter I, Title 10, Code of Federal Regulations (10 CFR).

Under an exchange of information program, Agreement States provide information to NRC on incidents and events involving applicable nuclear materials that have occurred in their States. Those events reported by Agreement States that reach the threshold for reporting as an AO are also published in the quarterly "Report to Congress on Abnormal Occurrences."

2. *Definition of terms*—As used in this policy statement: (a) An *abnormal occurrence* means an unscheduled incident or event at a facility or associated with an activity that is licensed or otherwise regulated, pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended, that the Commission determines to be significant from the standpoint of public health and safety; and (b) an *unintended radiation exposure* includes any occupational exposure, exposure to the general public, or exposure as a result of a medical misadministration (as defined in 10 CFR 35.2) involving the wrong individual that exceeds the reporting values established in the regulations. All other reported medical misadministrations will be considered for reporting as an AO under the criteria for medical licensees. In addition, unintended radiation exposures include any exposure to a nursing infant, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman.

3. *Abnormal occurrence general statement of policy*—The Commission will apply the following policy in

determining whether an incident or event at a facility or involving an activity that is licensed or otherwise regulated by the Commission is an AO within the purview of Section 208 of the Energy Reorganization Act of 1974, as amended.

An incident or event will be considered an AO if it involves a major reduction in the degree of protection of the public health or safety. Such an incident or event would have a moderate or more severe impact on the public health or safety and could include but need not be limited to the following:

- (1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission;
- (2) Major degradation of essential safety-related equipment; or
- (3) Major deficiencies in design, construction, use of, or management controls for licensed facilities or material.

Criteria by type of event used to determine which incidents or events will be considered for reporting as AOs are set out in Appendix A of this policy statement.

#### 4. Commission dissemination of AO information.

(a) The Commission will provide as wide a dissemination of information to the public as reasonably possible. A Federal Register notice will be issued on each AO with copies distributed to the NRC Public Document Room and all local public document rooms. When additional information is anticipated, the notice will state that the information can be obtained at the NRC Public Document Room and in all local public document rooms.

(b) Each quarter, the Commission will submit a report to Congress listing for that period any AOs at or associated with any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended. This report will contain the date, place, nature, and probable consequence of each AO, the cause or causes of each AO, and any action taken to prevent recurrence.

#### Appendix A—Abnormal Occurrence Criteria

Criteria by types of events used to determine which incidents or events will be considered for reporting as AOs are as follows:

##### I. For All Licensees

##### A. Human Exposure to Radiation from Licensed Material:

1. Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more; or the sum of the annual deep dose equivalent and committed dose equivalent to any individual organ or tissue, other than bone marrow, the lens of the eye, or gonads of 2500 mSv (250 rem) or more; or an annual dose equivalent to bone marrow, the lens of the eye, or gonads of 500 mSv (50 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or more.

2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.

3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

##### B. Discharge or Dispersal of Radioactive Material from its Intended Place of Confinement:

1. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee has demonstrated compliance with 10 CFR 20.1301 using 20.1302(b)(1) or 20.1302(b)(2)(ii).

2. Radiation levels in excess of the design values for a package, or the loss of confinement of radioactive material resulting in one or more of the following: (a) A radiation dose rate of 10 mSv (1 rem) per hour or more at 1 meter (3.28 feet) from the accessible external surface of a package containing radioactive material, (b) a radiation dose rate of 50 mSv (5 rem) per hour or more on the accessible external surface of a package containing radioactive material and that meet the requirements for "exclusive use" as defined in 10 CFR 71.47, or (c) release of radioactive material from a package in amounts greater than the regulatory limits in 10 CFR 71.51(a)(2).

##### C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach<sup>2</sup>:

<sup>2</sup>Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Section 208 of the Energy Reorganization Act of 1974, as amended. Any classified details regarding such incidents would be available to the Congress, upon request, under appropriate security arrangements.

1. Any lost, stolen, or abandoned sources that exceed 0.01 times the A<sub>1</sub> values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for special form (sealed/nondispersible) sources, or the smaller of the A<sub>2</sub> or 0.01 times the A<sub>1</sub> 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.

D. Other Events (i.e., those concerning design, analysis, construction, testing, operation, use, or disposal of licensed facilities or regulated materials):

1. An accidental criticality [10 CFR 70.52(a)].

2. A major deficiency in design, construction, control, or operation having significant safety implications requiring immediate remedial action.

3. A serious deficiency in management or procedural controls in major areas.

4. Series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents) that create a major safety concern.

##### II. For Commercial Nuclear Power Plant Licensees

##### A. Malfunction of Facility, Structures, or Equipment:

1. Exceeding a safety limit of license TS [10 CFR 50.36(c)].

2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

3. Loss of plant capability to perform essential safety functions such that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy:

1. Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.

2. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions such that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

### III. For Fuel Cycle Licensees

1. A required plant shutdown as a result of violating a license condition safety limit.

2. A major condition not specifically considered in the SAR or TS that requires immediate remedial action.

3. An event that seriously compromises the ability of a confinement system to perform its designated function.

### IV. For Medical Licensees

A medical misadministration that:

(a) results in a dose that is (1) equal to or greater than 1 gray (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 (1000 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,<sup>3</sup> 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(s).

### V. Guidelines for "Other Events of Interest"

The Commission may determine that events other than AOs may be of interest to Congress and be included in an Appendix to the AO report as "Other Events of Interest". Guidelines for events to be included in the AO report for this purpose are as follows:

Items that may possibly be perceived by the public to be of health or safety significance. Such items do not involve a major reduction in the level of protection provided for public health or safety; therefore, they are not reportable as abnormal occurrences. An example is an event where upon final evaluation by an NRC Incident Investigation Team, or an Agreement State equivalent response, a determination is made that such event does not meet the criteria for an abnormal occurrence.

#### Supplemental Information—Bases for Revised Abnormal Occurrence Reporting Policy Statement

1. *Discussion*—The AO reporting policy has been developed to comply with the legislative intent of Section 208 of the Energy Reorganization Act of 1974, as amended, to keep Congress and the public informed of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety. The policy reflects a range of health and safety concerns related to production and utilization facilities and the possession and use of byproduct, source, and special nuclear materials licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or to the Energy Reorganization Act of 1974, as amended. These safety concerns can include events ranging from an overexposure of a single occupational worker to those having an overall impact on the general public.

The revised policy statement provides a more usable policy for determining which events will be reported to Congress as AOs. The revised AO criteria in Appendix A contain more discrete reporting thresholds than those previously provided in the examples of AOs for easier and consistent application of the provisions established by the policy statement for reporting to Congress.

The consistent application of the AO criteria by the staff, Agreement States, and licensees for proposing events as

potential AOs to the Commission is important and requires established reporting thresholds whenever practicable. These reporting thresholds were selected with the intent of capturing the majority of the significant events and eliminating nonsignificant events from those to be proposed to the Commission.

An additional criterion has been added for those uncommon significant events that could occur without triggering a reporting threshold. This new criterion would require radiation exposures that have resulted in unanticipated permanent functional damage of an organ or physiological system, as determined by a physician, be reported to Congress. See Criterion I.A.3 in Appendix A.

The policy statement has also been revised to include changes that have been made to the regulations.

The revised criteria have been applied to events previously considered as potential AOs to ensure that the new criteria will identify significant events and eliminate nonsignificant events from those to be proposed to the Commission. A similar review of events involving lost, stolen, and abandoned source events has also been performed. The results of these reviews were documented in Attachments 2, and 3 to the Commission paper, SECY-95-083, "Revised Abnormal Occurrence Criteria," dated April 5, 1995.

2. *Definition of terms*—Terms relating to the bases for the AO reporting criteria are defined as follows:

(a) Nonstochastic effects are those health effects, the severity of which varies with the dose, and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called deterministic effect). [10 CFR 20.1003]

(b) Stochastic effects are those health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. [10 CFR 20.1003]

(c) Threshold dose denotes the amount of radiation below which no effect under consideration is likely to occur. Threshold dose is applicable to deterministic effects.

(d) Reporting threshold denotes a discrete value at or above which an occurrence will be considered for reporting as an AO.

3. *Abnormal occurrence criteria*—The AO criteria provide the reporting threshold for determining those events that are reportable for purposes of

<sup>3</sup>The wrong radiopharmaceutical as used in the AO criterion for medical misadministrations refers to any radiopharmaceutical other than the one listed in the written directive or in the diagnostic clinical procedures manual.

Section 208 of the Energy Reorganization Act of 1974, as amended. The Commission has established criteria that contain reporting thresholds intended to identify those events that are likely to be significant from the standpoint of public health and safety. At the same time, the AO reporting thresholds established by the criteria are generally above the normal level of reporting events to NRC to exclude those events which involve some variance from regulatory limits, but are not significant enough from the standpoint of public health and safety to be reported to Congress.

4. *Basis*—The following discussion provides the basis for the changes to the AO reporting criteria as documented in Appendix A of the policy statement.

#### *I. For All Licensees:*

##### A. Human Exposure to Radiation from Licensed Material:

Criterion I.A.1: Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more; or the sum of the annual deep dose equivalent and committed dose equivalent to any individual organ or tissue, other than bone marrow, the lens of the eye, or gonads of 2500 mSv (250 rem) or more; or an annual dose equivalent to bone marrow, the lens of the eye, or gonads of 500 mSv (50 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or more. [10 CFR 20.1201(a)(1), 20.1201(a)(2), and 35.2]

Criterion I.A.2: Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more. [10 CFR 20.1207, and 20.1301]

Criterion I.A.1 and Criterion I.A.2 have been revised to reflect guidance provided by the Commission, and to incorporate the changes to 10 CFR Part 20, that became mandatory on January 1, 1994.

Criterion I.A.1 has been revised to establish reporting thresholds for unintended exposures to adults including TEDEs, and individual doses to organs, lens of the eye, skin, and extremities. The changes to this criterion takes into consideration deterministic and stochastic effects for the purposes of radiation protection. The bases for the reporting thresholds are as follows.

(a) The reporting threshold for an unintended radiation exposure to an

adult (18 years of age and older) resulting in an annual TEDE of 250 mSv (25 rem) or more, is based on the following:

- It is greater than the regulatory allowable TEDE limit (50 mSv [5 rem]) for annual occupational exposure established in 10 CFR 20.1201(a)(1)(i).
- It is equal to the generally accepted level of exposure that is considered by the industry to be a significant unplanned occupational overexposure.
- It is at a level of exposure for which the potential for morbidity is considered for individuals with an increased organ and tissue sensitivity to radiation (e.g., a genetic condition causing an individual to be heterozygous as a result of the ataxia telangiectasia gene<sup>4</sup>).

(b) The reporting threshold for an unintended radiation exposure to an organ of an adult (other than bone marrow, lens of the eye, and gonads) resulting in the sum of the annual deep dose equivalent and committed dose equivalent to any individual organ or tissue of 2500 mSv (250 rem) or more is based on the following:

- It is greater than the allowable regulatory limit for occupational exposure (500 mSv [50 rem]) for the sum of the deep-dose equivalent and the committed dose equivalent to an organ or tissue (other than the lens of the eye) established by 10 CFR 20.1201(a)(1)(ii).
- It is below the different morbidity threshold doses for deterministic effects in radiosensitive organs such as gastrointestinal track mortality, pulmonary lethality, and mental incapacitation. [National Council on Radiation Protection and Measurements (NCRP) Commentary No. 7]

(c) The reporting threshold for an unintended radiation exposure to bone marrow, lens of the eye, or gonads of an adult resulting in 500 mSv (50 rem) or more is based on the following:

- It is equal to the allowable regulatory limit for the sum of the annual deep dose equivalent and committed dose equivalent for occupational exposures (0.5 Sv [50 rem]) to the bone marrow or gonads; and greater than the allowable regulatory limit (150 mSv [15 rem]) for an annual occupational dose equivalent to the lens of the eye as established in 10 CFR 20.1201(a)(2)(i).

• It is at the threshold dose for initial signs of temporary bone marrow depression. [NCRP Commentary No. 7]

• It is at the minimum threshold dose for known deterministic effects in the

lens of the eye. [NCRP Commentary No. 7]

• It is below the threshold dose for permanent sterility from a single dose to the gonads. [NCRP Commentary No. 7]

(d) The reporting threshold for an unintended annual shallow-dose equivalent to the skin or extremities (extremities include the hand, elbow, arm below the elbow, foot, knee, leg below the knee) of an adult, resulting in 2500 mSv (250 rem) or more is based on the following:

- It is greater than the allowable regulatory limit (500 mSv [50 rem]) for annual occupational shallow-dose equivalent to the skin or to any extremity as established in 10 CFR 20.1201(a)(2)(ii).
- It is below the threshold dose for detrimental deterministic effects in the tissue of the skin, and the bone (other than the bone marrow) and muscle of the extremities. [NCRP Commentary No. 7]

Criterion I.A.2 has been added in response to the Commission's request in the SRM of May 19, 1994 on SECY-93-259, to reaffirm that a single reporting threshold for unintended exposure is acceptable. The potential for adverse health effects from radiation is independent of an individual's status as a radiation worker, wrong individual, or member of the general public. Therefore, assigning a single dose value for unintended radiation exposures is consistent with the requirements of Section 208 of the Energy Reorganization Act of 1974, as amended. However, health effects are age dependent because organs and tissues in minors, fetuses, and embryos are more radiosensitive than in a typical adult. Because of increased radiosensitivity, a lower dose threshold for minors (including occupational exposures to minors), fetuses, and embryos has been included for AO reporting.

Criterion I.A.2 contains the reporting thresholds for unintended radiation exposures to any minor. This criterion considers both deterministic and stochastic effects for the purpose of radiation protection.

(a) The reporting thresholds for an unintended radiation exposure resulting in an annual TEDE of 50 mSv (5 rem) or more to a minor or a dose equivalent of 50 mSv (5 rem) or more to an embryo/fetus are based on the potential for permanent adverse health effects during the most radiosensitive period from the point of conception to adulthood and include the following:

- It is greater than the allowable regulatory limit (1 mSv [0.1 rem]) or 10 percent of the limits established in 10

<sup>4</sup> T.J. McMillian; "The Molecular Basis of Radiosensitivity;" In *The Biological Basis of Radiosensitivity*, Second Edition; (EDS: G.G. Steel, G.E. Adams, and A. Horwich); Elsevier Science Publishers B.V.; copyright 1989.

CFR 20.1201) for annual exposures to individuals other than radiation workers and occupational dose limits for minors as established in 10 CFR 20.1301 and 20.1207, respectively.

- It is below the minimum threshold doses for permanent deterministic effects in selective organs of minors because the annual TEDE reporting threshold for minors of 50 mSv (5 rem) equates to individual organ doses less than the known doses that will result in deterministic effects. (Refer to item (b) below.) [NCRP Commentary No. 7]

- It is below the individual threshold dose (100 mSv [10 rem]) for known permanent adverse health effects (mental retardation) during the most radiosensitive period (8 to 15 weeks of

gestation) of embryo or fetus development. The reporting threshold (50 mSv [5 rem]) is at the threshold dose for reduced head size but no adverse health effects are anticipated at this dose. [NCRP Commentary No. 7]

(b) Organ doses limits are not provided in this criterion because the intent of Section 208 is addressed with the single TEDE limit based on the following:

- Individual organ doses for minors as members of the general public would not be consistent with the requirements of 10 CFR 20.1301, "Dose limits for individual members of the general public."

- Individual occupational organ doses for minors are defined in 10 CFR

20.1207. The 50 mSv (5 rem) TEDE reporting threshold for minors is 20 percent of the threshold dose established for adults in Criterion I.A.1. If individual organ reporting thresholds for minor occupational workers were also reduced by 20 percent (Refer to Table 1, "Conversion from TEDE to Organ Dose"), the resulting dose values would be close in magnitude or more conservative than organ doses that would equate to the 50 mSv (5 rem) TEDE reporting threshold. This assessment is based on the "Organ Dose Weighting Factors" as provided in 10 CFR 20.1003 which result in the following data:

TABLE 1.—CONVERSION FROM TEDE TO ORGAN DOSE

Organ	Weighting factor	Organ dose to yield 50 mSv*	Reduced** reporting threshold for minors	Criterion I.A.1 threshold
Whole Body .....	1.0	50 mSv	50 mSv	250 mSv
Gonads .....	0.25	200 mSv	100 mSv	500 mSv
Breast .....	0.15	330 mSv	500 mSv	2500 mSv
Bone marrow .....	0.12	420 mSv	100 mSv	500 mSv
Lungs .....	0.12	420 mSv	500 mSv	2500 mSv
Thyroid .....	0.03	1670 mSv	500 mSv	2500 mSv
Bone surface .....	0.03	1670 mSv	500 mSv	2500 mSv

\* Organ Dose/Weighting Factor.

\*\* 0.2 x Criterion I.A.1 reporting thresholds.

[10 CFR 20.1003, 20.1201, 20.1207, and 20.1301]

- Individual organs that do not have a weighting factor are still considered in the revised criteria by Criterion I.A.3, which requires reporting to Congress any permanent functional damage as a result of an exposure to an individual organ. [10 CFR 20.1003 and 20.1301]

Criterion I.A.3: Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician. [General]

Criterion I.A.3 has been added to identify for reporting those incidents or events that have resulted in an organ or physiological system morbidity or mortality at dose levels below the established AO reporting thresholds.

B. Discharge or Dispersal of Radioactive Material from its Intended Place of Confinement:

Criterion I.B.1: The release of radioactive material to an unrestricted area in concentrations that, if averaged over a period of 24 hours, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless

the licensee has demonstrated compliance with 10 CFR 20.1301 using 20.1302(b)(1) or 20.1302(b)(2)(ii). [10 CFR 20.1301, 20.1302(b)(1), or 20.1302(b)(2)(ii)]

Criterion I.B.1 has been revised to reflect changes to 10 CFR Part 20 that became mandatory on January 1, 1994, and to maintain the same thresholds for reporting as required by the existing AO criterion. The existing reporting threshold of "500 times the regulatory limit of Appendix B, Table II, 10 CFR Part 20" was increased to "5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20" because the implied dose limit of 5 mSv (500 mrem) used to calculate the concentration values in Table 2 of Appendix B was decreased to 0.5 mSv (50 mrem) in the revision to 10 CFR Part 20.

Criterion I.B.2: Radiation levels in excess of the design values for a package, or the loss of confinement of radioactive material resulting in one or more of the following: (a) a radiation dose rate of 10 mSv (1 rem) per hour or more at 1 meter (3.28 feet) from the accessible external surface of a package

containing radioactive material, (b) a radiation dose rate of 50 mSv (5 rem) per hour or more on the accessible external surface of a package containing radioactive material and that meet the requirements for "exclusive use" as defined in 10 CFR 71.47, or (c) release of radioactive material from a package in amounts greater than the regulatory limits in 10 CFR 71.51(a)(2). [10 CFR 71.47(a) and 71.51(i)(1)]

Criterion I.B.2 has been revised to take into consideration additional regulatory requirements in 10 CFR Part 71. This criterion has been changed to include limits for packages that meet the requirements for "exclusive use" as defined in 10 CFR 71.47, a radiation dose rate of 50 mSv (5 rem) per hour or more on the accessible external surface of a package containing radioactive material, or the loss of confinement of radioactive material from a package in amounts greater than the regulatory limits.

The contamination requirement was removed from this criterion because certain shipping casks often experience contamination beyond licensee control after decontamination requirements had

been met as a result of contaminants "leaching" from the pores of the outer surface of the shipping cask. This leaching effect typically occurs as a result of condensation on the exterior of the shipping cask that occurs during shipping. Contamination from this phenomena is not a public health and safety concern and will not be reported to Congress.

**C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach:**

Criterion I.C.1: Any lost, stolen, or abandoned sources that exceed 0.01 times the  $A_1$  values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for special form (sealed/non-dispersible) sources, or the smaller of the  $A_2$  or 0.01 times the  $A_1$  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 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. [10 CFR 20.2201(a)(i), 30.50(a), 40.60(a), and 70.50(a)]

Criterion I.C.1 has been revised to include the reporting of lost or stolen sources that exceed 0.01 times the  $A_1$  values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for "special form" (sealed/nondispersible) sources, or the smaller of the  $A_2$  or 0.01 times the  $A_1$  values, as listed in Table A-1, for "normal form" (unsealed/dispersible) sources. Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned per the requirement 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. These reporting thresholds are based on not exceeding an effective or committed effective dose

equivalent of 50 mSv (5 rem); a committed dose equivalent to any individual organs including the skin of 0.5 Sv (50 rem); or in special cases, a 0.15 Sv (15 rem) dose to the lens of the eye of any member of the general public, assuming that an exposure occurs as a result of a source being stolen or lost.

(a) The  $A_1$  values in 10 CFR Part 71, Appendix A, Table A-1, represent the source strength for sealed (nondispersible) sources that will result in exceeding an effective dose equivalent of 50 mSv (5 rem), from an exterior exposure at 1 meter (3.28 feet [ft]) for 30 minutes. The proximity and duration factors of 1 meter (3.28 ft) for 30 minutes are based on the estimated exposure conditions during a transportation accident involving licensed materials, typically a controlled situation.

For the loss or theft of a sealed source, it has been conservatively calculated in a study<sup>5</sup> performed by Oak Ridge Institute for Science and Education (ORISE) that the accident-weighted average exposure proximity and duration factors are 1 meter for 46 hours for the improper transfer or disposal of licensed material. To account for the longer duration at 1 meter, from 30 minutes to 46 hours (approximately 1:100), conservatively assuming that the entire exposure is received by one individual, the  $A_1$  values in 10 CFR Part 71, Appendix A, Table A-1, will need to be decreased by a factor of 100. The multiples ( $0.01 \times A_1$  values) of the  $A_1$  values in 10 CFR Part 71, Appendix A, Table A-1, will determine the source strength of a source that will result in exceeding an effective dose equivalent of 50 mSv (5 rem) from external exposures.

(b) The  $A_2$  values in 10 CFR Part 71, Appendix A, Table A-1, represent the source strength for an unsealed source (dispersible) that will result in a deep dose equivalent or committed dose equivalent to any individual organs of 0.5 Sv (50 rem), a shallow dose equivalent to the skin of 0.5 Sv (50 rem), or in special cases, a 0.15 Sv (15 rem) dose equivalent to the lens of the eye. These dose values are based on the assumptions that the estimated release fraction ranges from  $10^{-3}$  to  $10^{-2}$  and the uptake fraction ranges from  $10^{-4}$  to  $10^{-3}$  from inhalation and/or ingestion (average fraction-taken-in =  $10^{-6}$ ).

In the ORISE study, the average fraction-taken-in from inhalation and

ingestion of an improper transfer or disposal of an unsealed (dispersible) source was calculated to be  $2 \times 10^{-6}$ . This calculated value was based on the review of an actual accident with extensive uptake information (for 194 cleanup workers and 77 members of the general public). Both average fraction-taken-in values for transportation accidents, and events involving lost or stolen sources are comparable. Therefore, the  $A_2$  values can be used directly to determine the source strengths for lost and stolen unsealed sources that will result in a deep dose equivalent, committed dose equivalent, or shallow dose equivalent of 0.5 Sv (50 rem).

The smaller of the two values, the  $A_2$  or 0.01 times the  $A_1$  values, is used for a dispersible source because the material may not be dispersed and can perform as a sealed source resulting in external exposure. Therefore, if the source strength is greater than the 0.01 times the  $A_1$  value or greater than the  $A_2$  value, the potential exists for exceeding an effective or committed effective dose equivalent of 50 mSv (5 rem); a committed dose equivalent to any individual organs, including the skin, of 0.5 Sv (50 rem); or in special cases, a 0.15 Sv (15 rem) dose equivalent to the lens of the eye. If the form of the source material is unknown, the smaller of the two values is also used to ensure all potentially reportable incidents and events are submitted to the Commission for consideration as an AO.

(c) Sources abandoned in accordance with the requirement of 10 CFR 39.77(c) are excluded from reporting because these sources do not represent an uncontrolled condition or potential effects adverse to public health and safety.

(d) Sealed (nondispersible) sources contained in labeled, rugged source housings are excluded from reporting to Congress because public health and safety have been shown to be reasonably protected during the loss or theft of sources that are contained in source housings. This exclusion is based on the following reasons:

- A sealed source as defined in NRC Regulatory Guide 10.10 is radioactive material contained in a protective envelope (capsule), contained in a foil, or plated on an inactive surface that serves as a dispersion barrier.
- A source housing as defined in American National Standard Institute (ANSI) N538 is an enclosure containing or incorporating the source, source holder, and a means of attenuation (shielding) of the radiation.

A source housing is generally required to be designed and constructed

<sup>5</sup> Daniel J. Strom, Ph.D., C.H.P., Staff Scientist, Operational Health Physics Group, Health Protection Department, Pacific Northwest Laboratory, "Improper Transfer/Disposal Scenarios for Generally Licensed Devices Study," Task 7, June 3, 1994.

with "rugged" characteristics so that its integrity will be maintained under normal conditions of use and under likely accident conditions and with safety mechanisms installed to prevent accidental access to the source. In addition, many general licensed housings are designed to restrict access to the source for other than its specific intended use.

- ANSI N538 3.4.1 recommends sufficient shielding for shielded gauges to limit dose rates to 0.05 mSv (5 mrem) per hour at 30 centimeters (cm) (11.8 inches), and 10 CFR 34.21(a) requires sufficient shielding for radiography sources to limit exposure rates to  $12.9 \times 10^{-5}$  coulombs per kilogram (50 milliroentgen) per hour at 15.2 cm (6 inches). Assuming a conversion factor of 1 roentgen to 1 rem, these shielding recommendations will ensure that an effective dose equivalent of 50 mSv (5 rem) is not exceeded, or in special cases, a 0.15 Sv (15 rem) dose equivalent to the lens of the eye from a 46-hour exposure to these shielded sources at 1 meter.

- The  $A_1$  values in 10 CFR Part 71, Appendix A, Table A-1, assumes that the shielding and containment are completely lost. This loss, however, on the basis of a historical review of 1991-1993 events involving lost and stolen sources that were later found, is unlikely for sources contained in source housings.

- The source housings typically used in these applications make it difficult to access the source.

- Source housings with the proper "radioactive labels" displayed have often been reported by members of the general public to the proper authorities. The radiation symbol is easily identified, relatively well known, and readily recognized as an indicator of a safety hazard.

- A review of the events reported for 1991-1993 that involved the loss or theft of portable gauges and radiography devices contained in rugged source housings verified that no known exposure from the loss of these types of devices had occurred.

(e) Many lost or stolen sources are recovered 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. A recovered source, without any indication of exceeding the dose thresholds specified in AO criteria I.A.1 or I.A.2 is not significant from the standpoint of public health and safety.

(f) Any unrecoverable source lost under such conditions (e.g., plane crash, fire, etc.) 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 is not significant from the standpoint of public health and safety.

Criterion I.C.2: No change to this criterion.

Criterion I.C.3: No change to this criterion.

Criterion I.C.4: No change to this criterion.

D. Other Events (i.e., those concerning design, analysis, construction, testing, operation, use or disposal of licensed facilities or regulated materials):

Criterion I.D.1: No change to this criterion.

Criterion I.D.2: No change to this criterion.

Criterion I.D.3: No change to this criterion.

Criterion I.D.4: No change to this criterion.

## II. For Commercial Nuclear Power Plant Licensees

A. Malfunction of Facilities, Structures, or Equipment:

Criterion II.A.1: No change to this criterion.

Criterion II.A.2: Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

Criterion II.A.2 was edited to better paraphrase the wording in 10 CFR 50.72(b)(B)(ii).

Criterion II.A.3: Loss of plant capability to perform essential safety functions such that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system). [10 CFR Part 50.34(a)(1), 50.72(b)(2)(iii), and 50.73(a)(2)(v)]

Criterion II.A.3 has been revised to include a reference to 5 times the dose limits in 10 CFR Part 50, Appendix A, GDC 19. This reference adds control room habitability reporting requirements consistent with the AO overexposure reporting requirements established in Criterion I.A.1, "For All Licensees."

B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy:

Criterion II.B.1: No change to this criterion.

Criterion II.B.2: Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions such that a release of radioactive materials, which

could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system). [10 CFR 50.34(a)(1) and 50.73(b)(2)(ii)(J)]

Criterion II.B.2 has been revised to include a reference to 5 times the dose limits in 10 CFR Part 50, Appendix A, GDC 19. This reference adds control room habitability reporting requirements consistent with the AO overexposure reporting requirements established in Criterion I.A.1, "For All Licensees."

## III. For Fuel Cycle Licensees

Criterion III.1: A required plant shutdown as a result of violating a license condition safety limit. [10 CFR 50.36(c)]

Criterion III.1 has been revised to more appropriately reference all license conditions rather than just TS.

Criterion III.2: No change to this criterion.

Criterion III.3: No change to this criterion.

## IV. For Medical Licensees

The criterion for AO reporting of medical misadministrations to patients intended to receive a diagnostic or therapeutic exposure has been revised as follows:

A medical misadministration that:

(a) results in a dose that is (1) equal to or greater than 1 gray (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 (1000 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(s). [10 CFR Part 35, International Council on Radiation Protection (ICRP) 41, and NCRP Commentary No. 7]

Medical uses of radiation result in diagnostic or therapeutic exposures for the purpose of diagnosing or treating a disease, alleviating pain, and/or minimizing the spread of disease. With this in mind, the AO reporting criterion has been revised to provide a simpler method for evaluating medical misadministrations, and to assure that only those events determined to be significant from the standpoint of public health and safety are reported. The



threshold doses that were selected are sufficiently below the thresholds for deterministic effects recognizing the normal treatment practice of collimation and fractionation of doses, where one would expect to see permanent organ and tissue damage for most radiosensitive organs in a typical adult, and provide a margin of error to identify the potential for harm.

Doses used for diagnostic purposes are relatively small and result in limited risk of adverse health effects. However, the risk, albeit small, that exists for selected diagnostic procedures has been considered during the selection of the reporting thresholds for the revised criterion.

Doses used for therapeutic purposes in treating cancer customarily approach or exceed the tolerance of normal tissue. Therefore, because therapeutic radiation doses are intended to kill cells, harmful side-effects might be expected from the radiation dose prescribed. The difference between the intended and most misadministered doses has little added effect on long-term risk such as cancer. The demonstrated benefits from the use of byproduct materials in medical applications and the long-term and/or short-term consequences as a result of a medical misadministration, were considered in developing the revised criterion.

The criterion for medical licensees has been revised to consider dose limits that are applicable to teletherapy, brachytherapy, gamma stereotactic radiosurgery, radiopharmaceutical therapy, and sodium iodide and diagnostic misadministrations. A medical misadministration (as defined by 10 CFR 35.2) involving the wrong individual will be considered for reporting as an AO under the revised criteria for unintended exposure (criteria I.A.1 and I.A.2) because it involves an individual who did not give prior consent to being exposed, and who is not expected to receive any benefit from an exposure to radiation. However, an administration to the wrong individual must meet the requirements for a medical misadministration as specified in 10 CFR 35.2 before being considered for reporting as an AO.

(a) The threshold dose of 1 Gy (100 rads) for bone marrow, lens of the eye, or gonads is based on the following:

- It is below the threshold (1.5 Gy [150 rads]) for bone marrow mortality with minimum medical care. [NCRP Commentary No. 7]
- It is equal to the threshold where cataracts begin to form. [NCRP Commentary No. 7]
- It is below the initial threshold (3 Gy [300 rads]) where permanent sterility

may be seen from a single exposure. [NCRP Commentary No. 7]

(b) The reporting threshold of 10 Gy (1000 rads) selected for all organs other than bone marrow, lens of the eye, and gonads, is based on the following:

- It is below the threshold doses at which one would expect to see permanent organ or tissue damage from normal treatment practices for most radiosensitive organs in adults. [NCRP Commentary No. 7]
- It provides a margin of safety for errors in established threshold doses for most radiosensitive organs in adults.
- It is at the estimated threshold dose for some clinically detrimental deterministic effects from conventionally fractionated therapeutic irradiation that can result in permanent adverse health effects in 1 to 5 percent of the patients treated. The permanent effects seen at this threshold dose include the absence of development and arrested growth in the breast and cartilage of children, respectively. [NCRP Commentary No. 7]

These values are based on the minimal normal tissue tolerance dose, which is defined as the dose to which a given population of patients is exposed, under a standard set of treatment conditions, resulting in no more than a 5-percent severe complication rate within 5 years after treatment. These threshold doses apply to conditions of irradiation relevant to radiotherapy, that is, doses of conventionally fractionated "x" or gamma radiation that must be delivered to tissue to cause a serious deterministic effect. In addition, these thresholds allow for a higher dose to be delivered differentially to the tumor. [ICRP 41, and NCRP Commentary No. 7]

#### V. Guidelines for "Other Events of Interest"

The Commission may determine that events other than AOs may be of interest to Congress and the public and therefore should be included in an Appendix to the AO report as "Other Events of Interest". The guidelines for "Other Events of Interest" have been revised to include events that may be perceived by the public to be of health and safety significance and involve substantial regulatory response, but do not otherwise meet the AO criteria. An example is an event where upon final evaluation by an NRC Incident Investigation Team, or an Agreement State equivalent response, a determination is made that such event does not meet the criteria for an abnormal occurrence.

Dated at Rockville, Maryland, this 3rd day of January 1996.

For the Nuclear Regulatory Commission.  
John C. Hoyle,  
*Secretary of the Commission.*  
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BILLING CODE 7590-01-P

[Docket Nos. 50-237 and 50-249]

#### Commonwealth Edison Company; Dresden Nuclear Power Station, Units 2 and 3 Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from certain requirements of its regulations to Facility Operating License Nos. DPR-19 and DPR-25, issued to Commonwealth Edison Company (ComEd, the licensee), for operation of the Dresden Nuclear Power Station, Units 2 and 3, located in Grundy County, Illinois.

Environmental Assessment

#### Identification of the Proposed Action

The proposed action is in accordance with the licensee's application dated November 20, 1995, for an exemption from certain requirements of 10 CFR 73.55, "Requirements for Physical Protection of Licensed Activities in Nuclear Power Reactors Against Radiological Sabotage." The requested exemption would allow the implementation of a hand geometry biometric system of site access control in conjunction with photograph identification badges and would allow the badges to be taken off site.

#### The Need for the Proposed Action

Pursuant to 10 CFR 73.55(a), the licensee is required to establish and maintain an onsite physical protection system and security organization. In 10 CFR 73.55(d), "Access Requirements," it specifies in part that "The licensee shall control all points of personnel and vehicle access into a protected area." In 10 CFR 73.55(d)(5), it specifies in part that "A numbered picture badge identification system shall be used for all individuals who are authorized access to protected areas without escort." It further indicates that an individual not employed by the licensee (e.g., contractors) may be authorized access to protected areas without an escort provided the individual, "receives a picture badge upon entrance into the protected area which must be returned upon exit from the protected area."

Currently, unescorted access for both employee and contractor personnel into the Dresden Station, Units 2 and 3, is