POLICY ISSUE
(Notation Vote)

September 4, 1966 SECY-96-193

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: ABNORMAL OCCURRENCE REPORTS: IMPLEMENTATION OF SECTION 208 ENERGY REORGANIZATION ACT OF 1974; FINAL POLICY STATEMENT

PURPOSE:

To obtain Commission approval to publish the final policy statement that includes revised abnormal occurrence criteria to be used by NRC and Agreement State staff.

BACKGROUND:

In the Staff Requirements Memorandum (SRM) dated November 27, 1995, SECY-95-244, the Commission approved publication in the Federal Register of the proposed revised abnormal occurrence (AO) criteria. The revision includes changes to the misadministration AO criteria and provides consistency with recent changes in NRC regulations. It is consistent with the Commission's initial guidance provided in SRMs dated January 30, 1992; May 19, 1994; February 21, 1995; June 29, 1995; and November 27, 1995. These SRMs included the following Commission guidance:

- The changes made to the NRC's amended 10 CFR Part 20 should be taken into consideration for the revision of the AO criteria (SRM dated May 19, 1994, on SECY-93-259).

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN THE FINAL SRM IS MADE AVAILABLE

Contact:
Harriet Karagiannis, AEOD
415-6377

- A single-dose threshold value should be established to identify doses to an occupational worker, a member of the public, and a wrong individual,[1] that are significant from a health and safety standpoint (SRM dated May 19, 1994, on SECY-93-259).

- Multiple misadministrations should not be considered as AOs unless they result in significant potential for harm to individuals (SRM dated May 19, 1994, on SECY-93-259).

- The AO report to Congress should have a section entitled "Other Events of Interest" to include events of broad public interest that require significant regulatory attention and do not meet the AO criteria (SRM dated June 29, 1995, on SECY-95-083).

- The Commission approved publication of the proposed revision to the AO policy statement for public comment including "Other Events of Interest" (SRM dated November 27, 1995, on SECY-95-244).

The Agreement States and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) were provided an early opportunity to submit comments on the proposed AO criteria and the proposed specific guidelines of the section on "Other Events of Interest." At Agreement State meetings and workshops, the States provided substantial comments on the AO criteria including negative comments on the guidelines for "Other Events of Interest" and recommended elimination of this section on the basis of no legal justification and because it is an unnecessary expenditure of the already strained Agreement State resources. Written comments were submitted by seven Agreement States: Arkansas, Georgia, Kentucky, New York, Texas, Tennessee, and Washington. These comments were evaluated and several were incorporated in SECY-94-275, "Revised Abnormal Occurrence Criteria" that provided the Commission a draft of the revised AO criteria as requested in an SRM dated May 19, 1994.

The staff revised the section on "Other Events of Interest" as directed by the Commission and published the proposed policy statement "Abnormal Occurrence Reports: Implementation of Section 208 Energy Reorganization Act of 1974; Proposed Policy Statement" (Attachment 1) in the Federal Register on January 9, 1996 (61 FR 661). The Federal Register notice (FRN) included the revised "Other Events of Interest" (Attachment 1, page 669) and called for a 90-day public comment period. Because the published FRN did not differ significantly from that discussed with the Agreement States or ACMUI, no additional comments were received from either group.

DISCUSSION:

Five letters of comment were submitted to the NRC on the proposed AO policy statement as published in the Federal Register (January 9, 1996; 61 FR 661). The staff has reviewed the public comments and prepared the attached FRN (Attachment 2) which addresses the public comments and announces the "Abnormal Occurrence Reports: Implementation of Section 208 Energy Reorganization Act of 1974; Final Policy Statement."

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[1] In the Federal Register notice dated September 20, 1995 (60 FR 48623), "10 CFR Parts 20 and 35, Medical Administration of Radiation and Radioactive Material" the term "Wrong patient" was replaced by the term "Wrong individual."

The majority of the comments supported the approach that the staff has taken to revise the criteria and offered specific comments. Each letter listed more than one comment and they are categorized into three groups: 1) modify and/or discontinue the AO reporting process; 2) revise the dose threshold for reporting AO events to Congress on unintended exposures to an adult and a minor or an embryo/fetus; and 3) reevaluate the AO criteria applicable to medical licensees. There was only one public comment on "Other Events of Interest" suggesting its deletion.

The final policy statement also addresses a summary of the written comments provided by the Agreement States on an earlier AO revision before the proposed policy statement was published (January 9, 1996; 61 FR 661). These comments are categorized into two groups: 1) modify, reevaluate, and/or discontinue items of the AO reporting process; and 2) be consistent with the regulations and reconsider the dose threshold for a minor, or an embryo/fetus. Four States provided comments on "Other Events of Interest" suggesting its deletion.

There is no substantive change to the proposed final AO policy statement. One change was made to the general AO criterion I.A.1, "Human Exposure to Radiation from Licensed material" applicable for all licensees, revising the proposed AO dose threshold to the lens of the eye, bone marrow, and gonads, based on a public comment and further staff consideration of the deterministic effects to these organs (Attachment 2, II. Summary of Public Comments and the NRC's Response, section B, first comment).

COORDINATION:

The Office of the General Counsel (OGC) has reviewed the final policy statement and has no legal objection. In addition, OGC has advised the staff that the AO policy statement is not a "rule" under the "Small Business Regulatory Enforcement Fairness Act" because it establishes agency practice and procedure in the area of AO reporting and does not substantially affect the rights and obligations of non-agency parties.

RECOMMENDATION:

The staff recommends that the Commission approve the attached final policy statement on "Abnormal Occurrence Reports: Implementation of Section 208 Energy Reorganization Act of 1974; Final Policy Statement" including the AO policy statement section on "Other Events of Interest" to be published in the Federal Register.

James M. Taylor
Executive Director
for Operations

Attachments:
1. Published AO Policy Statement
   (FRN Vol. 61, No. 6, January 9, 1996)
2. Proposed Federal Register Notice

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Thursday, September 19, 1996.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT September 12, 1996, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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ATTACHMENT 1

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.

[FR Doc. 96–288 Filed 1–8–96; 8:45 am]

BILLING CODE 4160–17–M

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.

[FR Doc. 96–278 Filed 1–8–96; 8:45 am]

BILLING CODE 4310–FP–M

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[1] "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,

[1] 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 [2]:

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/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 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:

[2] 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. 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,[3] 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

[3] 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 CFR20.1207, 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 [4]).

(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

[4] 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[5] 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 2×10^{-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 maintained 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

[5] 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.

[FR Doc. 96–283 Filed 1–8–96; 8:45 am]

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

ATTACHMENT 2

Attachment 2
[7590-01-P]

Nuclear Regulatory Commission

Abnormal Occurrence Reports:

Implementation of Section 208

Energy Reorganization Act of 1974;

Final Policy Statement

Agency: Nuclear Regulatory Commission.

Action: Final policy statement.

Summary: This final policy statement presents the revised criteria the Commission will use in submitting the annual 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.

Effective Date: (Date of publication.)

Addresses: The proposed policy statement published in the Federal Register (January 9, 1996; 61 FR 661), and the comments received may be examined 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, internet: hxk@nrc.gov.

Supplementary Information:

I. Background.

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438, 42 U.S.C. 5848), as amended, required the Commission to 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. In a letter to the Senate Subcommittee on Oversight of Government Management, dated October 1, 1993, the NRC recommended to Congress a change in the AO report publication frequency from quarterly to yearly. As a result, Senate 790, "Reports

Elimination Act," Public Law 104-66, was signed by President Clinton on December 21, 1995, changing the AO report to a yearly publication.

For the purposes of Section 208 of the Energy Reorganization Act of 1974, as amended, an AO is an unscheduled incident or event which the Commission has determined to be significant from the standpoint of public health and safety. 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 also shall 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 the information specified in clauses (3) and (4) as soon as such information becomes available.

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 of the Energy Reorganization Act of 1974, as amended,

the Commission began issuing quarterly reports to Congress on AOs. These reports,[1] "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 would, 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 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 (42 FR 10950) and provided criteria and examples of types of events that the Commission would use 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, "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 in the preparation and issuance of AO reports, the Commission has decided that its responsibilities under Section 208 of the Energy Reorganization Act of 1974, as amended, can be carried out more

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[1] Copies of NUREGS may be purchased from the Superintendent of Documents, U.S. Government Printing Office, (P.O. BOX 37082), Washington, DC 20402-9328. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is available for inspection and/or copying for a fee in the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC. 20037

appropriately if the existing AO criteria are revised to reflect changes in the Commission's policy and changes to the regulations.

The NRC staff proposed to the Commission the final revision of the AO criteria in 1995. The Commission approved publication in the Federal Register of the AO criteria (January 9, 1996, 61 FR 661), for a 90-day public comment period. The NRC staff evaluated public comments and developed the final AO policy statement. The Commission is issuing this final 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 occurrence available to Congress and the public in a timely manner. Included in this 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 of the Energy Reorganization Act of 1974, as amended. It is expected that as additional experience is gained, changes in the criteria may be required.

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 that will ensure 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 that involve some variance from regulatory limits, but are not significant from the standpoint of public health and safety.

Licensee Reports

This final 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 do 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 the NRC will continue to be made available and placed in the public document

rooms for public perusal. In addition, the 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, 2120 L Street, NW. (Lower Level) Washington, DC 20555-0001. 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.

II. Summary of Public Comments and the NRC's Response.

The NRC decided to revise the AO criteria to reflect changes in NRC regulations and policy. Before arriving to the revised AO criteria, the NRC staff evaluated several AO approaches and consulted with experts in the reactor and nuclear material areas, including the Advisory Committee on the Medical Uses of Isotopes (ACMUI), and held workshops with Agreement States to obtain their comments. This effort was to ensure that only events that have the potential for significant health and safety consequences are reported to Congress. After an evaluation several of the early written comments provided by the States were incorporated in SECY-94-275, "Revised Abnormal Occurrence Criteria" that provided the Commission a draft of the revised AO criteria as requested in an SRM of May 19, 1994. An FRN (January 9, 1996; 61 FR 661) on "Abnormal Occurrence Reports: Implementation of Section 208 Energy Reorganization Act of 1974; Proposed Policy Statement" was published for a 90-day public comment period, that included the proposed AO criteria. No additional comments were received from Agreement States or ACMUI on the proposed AO policy statement as published in the FRN.

The NRC received five letters of comment on the revised AO policy statement published in the FRN from the following organizations: Virginia Power; the Clean Water Fund of North Carolina; the American College of Nuclear Physicians, California Chapter; the Government Relations Office of the American College of Nuclear Physicians/Society of Nuclear Medicine; and the Nuclear Energy Institute. These comments may be examined at the U.S. Nuclear Regulatory Commission, Public Document Room, 2120 L Street, NW. (Lower Level) Washington, DC 20555-0001. Each letter contained more than one comment, and these comments are categorized into three groups: 1) modify and/or discontinue the AO reporting process; 2) revise the dose threshold for reporting AO events to Congress on unintended exposures to an adult and a minor or an embryo/fetus; and 3) reevaluate the AO criteria applicable to medical licensees. Public comments on the proposed policy statement and NRC's response are presented below followed by a section on the summary of Agreement State comments and NRC's response.

A. Modify and/or Discontinue the AO Reporting Process.

Comment: Because people who receive the quarterly AO reports do not even read them, and the few that do believe the reports have little true value, the NRC should request legislation to discontinue the AO reporting process.

Response: The value of the AO report to Congress was recently examined in the legislation reducing the publication frequency of the report from quarterly to annually as recommended by the NRC in a letter of October 1, 1993, to the Senate Subcommittee on Oversight of Government Management. As a result,

Senate 790, "Reports Elimination and Sunset Act," Public Law 104-66, was signed by the President on December 21, 1995, changing the AO report to a yearly publication. Because the report was not eliminated in the "Federal Reports Elimination and Sunset Act," the NRC concludes that the AO report remains valuable to Congress.

Comment: Discontinue the appendix of the AO report on "Other Events of Interest" because (a) there is no legal justification for the development of this appendix; (b) the NRC does not have a fair mechanism for ascertaining public perception; and (c) events may be perceived as AOs and give the appearance of safety significance when no such finding was assigned to them.

Response: Based on NRC's experience, some events have attracted wide Congressional and public interest. Examples are events that resulted in petitions to the Commission by public interest groups, events that may have resulted in power reductions or shutdowns for safety-related reasons, and events involving widespread media coverage. Some of these events have also resulted in significant regulatory effort, such as an NRC Incident Investigation Team response. Although these events are not required by law to be listed in AO reports, the Commission, as a matter of discretionary policy, directed the NRC staff to include them to keep Congress and the public fully informed.

The NRC has not developed specific criteria for the appendix of the AO report on "Other Events of Interest." This allows discretion on the part of the NRC in the selection of the events to ensure exclusion of unimportant

events. To avoid confusion, the "Other Events of Interest" listing will have a full description of the basis for inclusion of each event in the report and a clear indication that these events are not AOs.

B. Revise the Dose Threshold for Reporting AO Events to Congress on Unintended Exposures to an Adult and a Minor or an Embryo/Fetus.

Comment: a. Because the revised unintended AO dose threshold values for the whole body and any individual organ or tissue except the lens of the eye are generally consistent with the "Planned special exposures" (PSEs) of 10 CFR Part 20 (five times the annual regulatory limits), for consistency the dose threshold for the lens of the eye should be revised to 750 millisievert (mSv) (75 rem), instead of the proposed AO threshold of 500 mSv (50 rem).

b. 10 CFR 20.1201(a)(1)(ii) specifies the annual occupational limit for the sum of deep-dose equivalent and the committed-dose equivalent to any individual organ or tissue except the lens of the eye. Thus, the bone marrow and the gonads should be in the category of any individual organ or tissue except the lens of the eye, to be consistent with 10 CFR Part 20, using the revised AO dose threshold for other organs of 2500 mSv (250 rem).

Response: The NRC did not intend to be consistent with the dose thresholds as listed in 10 CFR Part 20, "Planned special exposures," which impose doses five times the annual regulatory limits during the individual's lifetime. Based on NRC's experience, unlike a PSE, an AO unintended exposure event is based on radiation consequences from that single event and not the radiation

consequences over the individual's lifetime. The NRC agrees, however, that the AO dose threshold to the lens of the eye, the bone marrow, and the gonads should be increased. To be consistent with the AO threshold used for medical misadministrations, the threshold to the lens of the eye is raised to 1 Sv (100 rem) instead of the proposed 500 mSv (50 r `. The 1 Sv (100 rem) dose threshold is still below the dose for known deterministic effects in the lens of the eye such as cataracts. [NCRP Commentary No.7]

Also, the dose threshold for the bone marrow and gonads will be revised to 1 Sv (100 rem) instead of the 2500 mSv (250 rem) recommended in the comment. The revised dose is still at the threshold for temporary bone marrow depression but below the dose threshold for permanent sterility from a single dose to the gonads or serious consequences due to bone marrow depression. For AO purposes, the bone marrow and the gonads are separated from the rest of the organs (unlike 10 CFR Part 20), due to the deterministic effects to these organs at the revised AO dose thresholds.

Comment: The annual total effective dose equivalent (TEDE) for AO reporting for members of the public should b' educed to less than 4.50 mSv (0.450 rem) instead of the proposed TEDE of 25u mSv (25 rem).

Response: According to the National Council on Radiation Protection and Measurements, the estimated average effective dose equivalent rate to a person in the United States from natural radiation and man-made sources is

approximately 360 mrem per year.[2] This dose value is about the same as the commenter's suggested dose threshold for reporting AOs involving members of the public to Congress. Reporting to Congress each exposure of a member of the public due to NRC-licensed activities at the level of the average dose received annually from natural and man-made sources of radiation in the United States is inappropriate. The NRC selected the revised AO dose on the basis of the potential for radiation adverse health effects to an individual, independent of the individual's status as a radiation worker in an occupational environment or as a member of the public. This threshold is below the level of dose for which the potential for morbidity is considered significant for individuals with an increased organ and tissue sensitivity to radiation.

Comment: The annual TEDE to any minor or embryo/fetus should be reduced to less than 3.50 mSv (0.350 rem) instead of the proposed TEDE of 50 mSv (5 rem).

Response: The NRC understands the sensitivity of an unintended exposure to a minor or an embryo/fetus and recognizes that the radiation health effects are age dependent because organs and tissues in minors, fetuses, and embryos are more radiosensitive than a typical adult. Therefore, a dose threshold of 50 mSv (5 rem) was established for any minor or embryo/fetus, which is lower than the adult AO threshold of 250 mSv (25 rem).

In addition, the commenter's suggested threshold of 3.50 mSv (0.350 rem) is at or below the average dose that a person (including minors) in the United States receives annually from natural radiation and man-made sources as stated in the response to an earlier comment. The threshold established by NRC is

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[2] Ionizing Radiation Exposure of the Population of the United States, NCRP Report No. 93, National Council on Radiation Protection and Measurements, September 1987.

below the minimum threshold doses for permanent deterministic effects in selective organs for a minor or an embryo/fetus.

Comment: The criteria related to a nursing infant, fetus, or embryo as a result of an exposure to a nursing mother or pregnant woman should be deleted from the criteria until the proposed rule addressing these exposures is resolved through the advice of the Advisory Committee on Medical Uses of Isotopes (ACMUI) and a separate public comment period.

Response: The NRC recognizes the lack of a specific regulation to address exposures as a result of an unintended administration of radioactive material to a patient that is pregnant or nursing. Based on NRC's experience, some of these events have the potential for significant health and safety consequences to a minor or an embryo/fetus and should be reported to Congress.

C. Reevaluate the AO Criteria Applicable to Medical Licensees.

Comment: The proposed medical AO criteria are worse than the current criteria because they will continue to inappropriately designate non-significant events as AOs.

Response: The revised medical AO criteria should result in fewer AOs than have been reported previously to Congress. These revisions were made in response to NRC staff recognition of the previous low dose thresholds that resulted in reporting events that did not have significant radiation consequences. In addition, the new criteria also respond to previous public

criticism and to changes in other NRC regulations relating to radiation protection.

Comment: The AO criteria applicable to medical licensees should be excluded from the AO policy statement because the NRC does not have sufficient competence in medicine and pharmacy to determine public safety significance of medical events.

Response: Because the NRC regulates byproduct material including the medical use of this material, criteria for medical events have been developed and must be included in the AO policy statement to comply with Section 208 of the Energy Reorganization Act of 1974, as amended. The revised criteria are based on widely accepted standards for radiation protection and were reviewed by the ACMUI. Therefore, the NRC believes that events exceeding the criteria are sufficiently important to inform Congress and the public.

Comment: Congress may obtain information on significant medical events from the FDA instead of the NRC.

Response: Section 208 of the Energy Reorganization Act of 1974, as amended, requires reporting to Congress licensee events that the NRC determines to be significant from the standpoint of public health and safety. An enactment of law would be necessary to change this requirement and appoint another agency such as the FDA to undertake the AO responsibility.

Comment: ACMUI should review the medical AO criteria.

Response: The revised criteria were presented to ACMUI and comments received were incorporated before publishing them in the Federal Register (January 9, 1996; 61 FR 661). Because only minor changes have been made to the criteria since ACMUI's review, the Commission does not believe that it is necessary for ACMUI to further examine the criteria.

Comment: Add a third condition to the medical AO criteria to read: "and (c) is a radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician" to eliminate reporting events to Congress that do not have any medical significance.

Response: The NRC believes that the dose thresholds of the revised criteria have sufficient margin included to limit the reporting of insignificant events. In addition, the NRC considers it important to report events that have the potential to result in adverse public health and safety. The inclusion of the recommended criterion would preclude reporting of these events. Therefore, the NRC does not intend to include the proposed language.

Comment: Insignificant medical events have been included in the past AO reports to Congress.

Response: The NRC understands the commenters' concerns with the implementation of the medical AO policy before the revision. Because of the low dose thresholds established in the previous criteria, medical events that have not had the potential to result in significant radiation consequences to

patients were determined to be AOs and were reported to Congress. As a result, the Commission is revising the AO criteria dose thresholds for medical events to exclude insignificant events.

III. Summary of Agreement State Comments and NRC's Response.

Seven Agreement States submitted comments to the NRC before development of the Commission paper, SECY-94-275, "Revised Abnormal Occurrence Criteria." These States were Arkansas, Georgia, Kentucky, New York, Texas, Tennessee, and Washington. After evaluating the comments, several were incorporated in the Commission paper. A summary of the Agreement State comments applicable to the AO criteria listed in the proposed policy statement as published in the FRN, and NRC's response are presented below:

A. Modify, Reevaluate and/or Discontinue Items of the AO Reporting Process.

Comment: Four States commented on the specific guidelines of a prior revision of the proposed appendix of the AO report on "Other Events of Interest" or wanted "Other Events of Interest" deleted.

Response: It should be noted that the section on "Other Events of Interest" contained in this final AO policy statement has been revised since the time that Agreement States provided comments, and therefore comments on the specific guidelines of the section do not apply. In reference to the elimination of "Other Events of Interest," see NRC's response to the second public comment under Category A.

Comment: One State suggested that the AO criteria should apply to exposures from non-Atomic Energy Act (AEA) material.

Response: Section 208 of the Energy Reorganization Act of 1974, as amended, provides that the Commission shall submit to Congress each year 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. Therefore, the AO criteria will not apply to events involving the use of non-AEA material since this material is not regulated by the NRC.

Comment: One State commented that the AO policy statement imposes additional requirements on licensees.

Response: The AO policy statement will not change the reporting requirements imposed on NRC licensees by Commission regulations, license conditions, or technical specifications. The NRC licensees will continue to submit required event reports. The AO criteria will only be used by the NRC during internal review and evaluation for reporting significant events to Congress.

Comment: One State commented that criterion I.A.3 is arbitrary.

Response: The NRC disagrees. Because individual sensitivity to radiation varies, the basis of criterion I.A.3 is to capture those events that have resulted in unintended, permanent functional damage to an organ or a physiological system at thresholds below those listed in the AO criteria.

However, the NRC believes that there will be very few of these events. In most cases permanent organ and physiological damage will occur only at doses above the proposed AO thresholds.

Comment: One State commented that criterion I.D.3 is arbitrary.

Response: The NRC disagrees. Based on NRC's experience, certain reported events, although they did not result in significant radiation consequences, had the potential for adverse impacts on public health and safety because of a serious failure of the licensees's radiation protection program and lack of management control and oversight and should be reported to Congress.

Comment: Two States commented that "wrong patient" should be considered in the misadministration AO criteria instead of the general AO criteria applicable to all licensees.

Response: In the SRM of May 19, 1994, on SECY-93-259, the NRC staff was directed by the Commission to establish a single-dose threshold value to identify doses to an occupational worker, a member of the public, and a wrong individual (wrong patient),[3] which are significant from a health and safety standpoint. The basis was that, for the purpose of reporting to Congress, the potential for physical harm to an individual resulting from the unintended exposure is the same whether the exposure was received in an occupational

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[3] In the Federal Register notice dated September 20, 1995 (60 FR 48623), "10 CFR Parts 20 and 35, Medical Administration of Radiation and Radioactive Material," the term "Wrong patient" was replaced by the term "Wrong individual."

setting, as a patient who was not intended to receive a prescribed dose, or as a member of the public.

Comment: Three States suggested providing credentials for a "physician" as listed in criterion I.A.3.

Response: For general purposes the term "physician" is defined in 10 CFR Part 35.2, where "Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine."

Although the NRC regulations do not specify the detailed credentials of a "physician" for incident evaluation purposes, the NRC staff has developed an NRC Inspection Manual Chapter (IMC 1360) "Use of Physicians and Scientific Consultants in the Medical Consultant Program" that lists a group of physicians that the NRC staff may obtain as consultants in case of an incident. The NRC staff has reviewed the credentials of these physicians and has determined that they have the expertise in specialized areas using byproduct material for the evaluation of radiation consequences. The Inspection Manual is available in the NRC public document room, 2120 L Street, NW. (Lower Level), Washington, DC 20555-0001.

B. Be Consistent with the Regulations and Reconsider the Criterion for a Minor, or an Embryo/Fetus.

Comment: One State commented that the AO criteria should be consistent with 10 CFR Part 20.

Response: To the extent practical, the NRC has been consistent with 10 CFR Part 20, and at the same time has established thresholds to include only events that have the potential to result in deterministic effects due to unintended exposures.

Comment: Two States expressed concern about developing an AO dose threshold for events regarding a minor, or an embryo/fetus since the NRC has not yet developed a regulation establishing a dose threshold for reporting these events to the NRC.

Response: See response to fourth public comment under Category B.

IV. The Commission Policy - 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).

Through an exchange of information, Agreement States provide information to the 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 "Report to Congress on Abnormal Occurrences."

2. Definition of terms. As used in this policy statement:

(a) An "abnormal occ rence" means an unscheduled incident or event at a facility or associated w' . an activity that is licensed or otherwise regulated, pursuant to t.e 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 § 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. This type of 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 year, 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 an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ or tissue other than the lens of the eye, bone marrow and the gonads, of 2500 mSv (250 rem) or more; or an annual dose equivalent to the lens of the eye, of 1 Sv (100 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow, and the gonads, of 1 Sv (100 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 § 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.[4]

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/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 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.

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[4] 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 these incidents would be available to the Congress, upon request, under appropriate security arrangements.

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 technical specification (TS) [§ 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 so 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 so 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 license 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,[5] 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 the public 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 items that may possibly be perceived by the public to be of health or safety significance. Such items would not involve a major reduction in the level of protection provided for public health or safety; therefore, they would not be reported 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 the event does not meet the criteria for an abnormal occurrence.

Dated at Rockville, Maryland, this _____ day of _____ 1996.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.

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[5] 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 clinical procedures manual.