62 FR 18820 **Published 4/17/97** Effective 4/17/97

Abnormal Occurrence Reports: Implementation of Section 208 Energy Reorganization Act of 1974; Revision to Policy Statement

AGENCY: Nuclear Regulatory

Commission.

ACTION: Revise policy statement.

SUMMARY: This 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 incorporates minor changes to implement the Commission's direction to develop conforming changes as necessary and revise criteria III., "For Fuel Cycle Licensees," to include facilities that are not licensed but are

otherwise regulated and will receive NRC certification such as gaseous diffusion plants. The revision clarifies the AO criteria for all fuel facilities including gaseous diffusion plants. Such revision provides criteria which are more specific for fuel facilities in determining those incidents and events that the Commission considers significant from the standpoint of public health and safety for reporting to Congress.

EFFECTIVE DATE: April 17, 1997. ADDRESSES: The final policy statement published in the Federal Register (December 19, 1996; 61 FR 67072) 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:

 Background II. The Commission Policy

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 occurrence; 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 of 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.

The Commission published a further revision to the AO policy statement and criteria in the Federal Register on December 19, 1996 (61 FR 67072) to reflect changes in the Commission's policy and changes to the regulations. In the Staff Requirements Memorandum dated November 7, 1996, SECY-96-193, approving this most recent revision to the AO criteria the Commission directed the NRC staff to determine whether modifications to criteria III., "For Fuel Cycle Licensees," were necessary to explicitly include fuel cycle facilities that are not licensed but are otherwise regulated by NRC such as the gaseous diffusion plants. The NRC staff evaluated the criteria applicable to fuel cycle facilities and has revised the criteria as follows:

A. AO criteria published December 19, 1996:

III. For Fuel Cycle Licensees.

 A required plant shutdown as a result of violating a license condition or other 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.

B. Revised AO criteria to include gaseous diffusion plants:

IV. For Fuel Cycle Facilities.

- 1. A shutdown of the plant or portion of the plant resulting from a significant event and/or violation of a law, regulation, or a license/certificate condition.
- 2. A major condition or significant event not considered in the license/ certificate that requires immediate remedial action.
- 3. A major condition or significant event that seriously compromises the ability of a safety system to perform its designated function that requires immediate remedial action to prevent a criticality, radiological or chemical process hazard.

It is expected that as additional experience is gained, further changes in the criteria may be required.

Abnormal Occurrence Reporting

The AO 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 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. 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

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.

Commission business and does not impose requirements on licensees ² or certified facilities. 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 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 § 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 child, 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 above specified values.

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:

- 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 facilities or radioactive material licensed by or otherwise regulated by the Commission.

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. Information on potential AOs (events that may meet the AO criteria) will be sent to the NRC Public Document Room and all local public document rooms as soon as possible after the staff determines that the incident is a potential AO. A Federal Register notice will be issued on each AO report 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

- 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.
- 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 Breach³
- 1. Any lost, stolen, or abandoned sources that exceed 0.01 times the A₁ values, as listed in 10 CFR Part 71, Appendix A, Table A-1,

³In addition to the criteria listed in Appendix A, section III. "For Fuel Cycle Facilities," which are applicable to licensees and certificate holders, such as the gaseous diffusion plants (GDPs), other criteria of the policy statement which reference "licensees" or "licensed facility" or "licensed material" may also be applied to events at certified facilities such as the GDPs.

³ 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.

for special form (sealed/nondispersible) sources, or the smaller of the A_2 or 0.01 times the A₁ values, as listed in Table A-1, for normal form (unsealed/dispersible) sources or for sources for which the form is not known. Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur during the time the source was missing; and unrecoverable sources lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 were not known to have occurred.

- 2. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.
- 3. Any substantiated loss of special nuclear material or any substantiated inventory discrepancy that is judged to be significant relative to normally expected performance, and that is judged to be caused by theftor 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.
- 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)].
- 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 Facilities

- 1. A shutdown of the plant or portion of the plant resulting from a significant event and/or violation of a law, regulation, or a license/certificate condition.
- 2. A major condition or significant event not considered in the license/certificate that requires immediate remedial action.
- 3. A major condition or significant event that seriously compromises the ability of a safety system to perform its designated function that requires immediate remedial action to prevent a criticality, radiological or chemical process hazard.

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;
- (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.⁴ 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 11th day of April, 1997.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Acting Secretary of the Commission.

⁴The 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.