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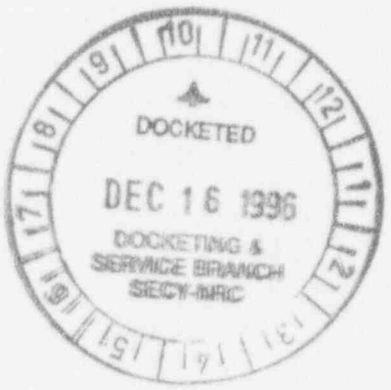

Nuclear Regulatory Commission

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: December 19, 1996 (Date of publication.)

L-4-1 Proposed Rulemaking

X-O+M-8 Rpts to Congress

DS11

Pub. on 12/19/96 at 61FR67072

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. A Federal Register Notice (FRN) (January 9, 1995; 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 revising 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 rem). 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 be reduced to less than 4.50 mSv (0.450 rem) instead of the proposed TEDE of 250 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 child, 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). Only minor changes have been made to the criteria since ACMUI's review.

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 provides guidance on the use of NRC consultants in case of an incident. In addition, the NRC staff has developed NRC Management Directive 8.10, "NRC Medical Event Assessment Program" to ensure timely and comprehensive review of medical events. IMC 1360 and Management Directive 8.10 are 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 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:

(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 potential AO and 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.

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 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.

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 13th day of December, 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.