STATE AGREEMENTS PROGRAM

DIVISION I

INTERNAL PROCEDURES

Post-Agreement Activities

D.18 - Procedure for Review and Distribution of Agreement State Abnormal Occurrence Reports

I. Introduction

A. This section describes the general objective and procedures for receipt, review and distribution of abnormal occurrence reports submitted by Agreement States.

B. Section 208 of the Energy Reorganization Act of 1974 requires that the NRC submit to Congress a quarterly report listing any abnormal occurrences at or associated with licensed facilities. Although Section 208 does not address abnormal occurrences involving Agreement State licensees, NRC requested Agreement State cooperation in providing such information to Congress. The NRC implemented an Agreement State abnormal occurrence reporting system on July 1, 1977.

C. The responsibility for the technical review of Agreement State abnormal occurrence reports is assigned to a professional staff member by the Assistant Director.

II. Abnormal Occurrence Criteria

An event will be considered an abnormal occurrence if it involves a major reduction in the degree of protection of the public health and safety. Such an event would involve a moderate or more severe impact on the public health or safety and could include but need not be limited to: (1) Moderate exposure to; or release of, radioactive material licensed by or otherwise regulated by the NRC or an Agreement State; (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.

III. Examples of Abnormal Occurrences

A. Human Exposure to Radiation from Licensed Material

1. Exposure of the whole body of any individual to 25 rem or more of radiation; exposure of the skin of the whole body of any individual to 150 rem or more or radiation; exposure of the feet, ankles, hands or forearms of any individual to 375 rem or more of radiation; or equivalent exposure from internal sources.

2. An exposure to an individual in an unrestricted area such that the whole body dose received exceeds 0.5 rem in one calendar year.

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, exceeds 500 times the regulatory limit of Appendix B, Table II, 10 CFR Part 20.

2. Radiation or contamination levels in excess of design values on packages or loss of confinement of radioactive material such as: (1) a radiation dose rate of 1,000 mrem per hour three feet from the surface of a package containing the radioactive material, or (b) release of radioactive material from a package in amounts greater than the regulatory limit.

C. Theft, Diversion, or Loss of Licensed Material

1. Any loss of licensed material in such quantities and under such circumstances that substantial hazard may result to persons in unrestricted areas.

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 which is judged to be significant relative to normally expected performance and which is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.

D. Other Events

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

2. Serious deficiency in management or procedural controls in major areas.

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

IV. Contents of Abnormal Occurrence Reports

Each abnormal occurrence report should include the following:

A. The date and place of the occurrence. If a particular licensee is involved, the licensee should be identified. Individuals are normally not identified.

B. The nature and probable consequences of the occurrence.

C. The cause or causes of the occurrence.

D. Any action taken to prevent reoccurrence. The State should describe action taken by the licensee and by the State, including enforcement action if applicable.

V. Review and Distribution of Abnormal Occurrence Reports

A. Agreement States participate in the abnormal occurrence reporting program on a voluntary basis and in most cases submit reports to OSP on a timely basis. Occasionally, it may be necessary to call the States to remind them of the reporting procedure. The State, however, should not be pressured to take staff time to prepare a report at a time when important enforcement action or other necessary tasks with respect to the occurrence need to be addressed.

B. When reports are submitted, they are reviewed by OSP to assure that the event meets the AOR criteria and that they contain the items listed in Section IV of this procedure. Any questions regarding the information in the report should be directed to the State immediately by phone. If minor corrections are required, handwritten corrections to the report are adequate. If a more extensive rewrite is required, the report should be returned to the State (Neither RSAR's nor OSP personnel should prepare abnormal occurrence reports. Only the regulatory agency having jurisdiction over the event has the necessary information to prepare a report.)

C. When a report has been reviewed and there are no outstanding questions, a copy is forwarded to the Office for Analysis and Evaluation of Operational Data (AEOD). A copy is also sent to the appropriate RSAR. Questions raised by AEOD with regard to the report should be handled by OSP.

D. Agreement State incidents that may have significant generic implications related to a class or classes of licensees may be appropriate for inclusion in the IE Information Notice system. If such is the case, a copy of the report and any follow-up information should be provided to the Office of Inspection and Enforcement.

Question 3b
Enclosure 1

State Agreements Program Standard Approval

The attached D.18, "Procedure for Review and Distribution of Agreement State Abnormal Occurrence Reports" is submitted for final approval.

John R. McGrath
John R. McGrath

1/31/85

Donald A. Nussbaumer
Donald A. Nussbaumer, Assistant Director
for State Agreements Program

1/31/85

Form NRC-489
(1-76)

U. S. NUCLEAR REGULATORY COMMISSION
NRC MANUAL
TRANSMITTAL NOTICE

CHAPTER NRC-0212 ABNORMAL OCCURRENCE REPORTING PROCEDURE

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Appendix	NRC-0212	7/18/84

REMARKS:

This issuance is revised to:

1. reflect changes in organization and responsibilities within the NRC since the chapter was first published.

2. add an appendix, which provides guidance for the selection of events and the processing procedures for abnormal occurrence reports and other related items.

c. assures that Commission comments on staff recommendations are resolved.

033 The Director, Office for Analysis and Evaluation of Operational Data (AEOD):

a. implements provisions of this chapter. Establishes internal procedures to assure expeditious processing of reportable items.

b. assigns a coordinator and an alternate to represent AEOD on matters pertaining to AO and Other Related Items reporting.

c. proposes and coordinates changes with the staff and Commission, as necessary, to the reporting procedures, criteria, and guidelines for selection of events for reporting to the Commission and Congress.

d. coordinates with the staff and Commission events proposed by AEOD and other Offices for reporting as AOs and Other Related Items. Assures that all reportable items receive a security review.

(1) prepares and coordinates a Commission paper and a Federal Register notice (FRN) for individual reports of potential AOs and the quarterly report to Congress.

(2) resolves staff comments and disagreements. If an impasse is encountered, submits supporting documentation and an AEOD recommendation to the EDO for resolution.

(3) coordinates with SECY, EDO, and the appropriate Offices for any briefings of the Commissioners.

(4) resolves Commission comments and revises reports as necessary. Transmits final FRNs to SECY, via EDO, for signature and publication. Arranges for the publication and distribution of the quarterly reports in conjunction with the Offices of Administration and Congressional Affairs.

(5) maintains a file of supporting documentation for each event and quarterly report submitted to the Commission.

034 Directors of the Offices of Inspection and Enforcement (IE), Nuclear Reactor Regulation (NRR), Nuclear Material Safety and Safeguards (NMSS), and Nuclear Regulatory Research (RES); and Regional Administrators:

a. implement provisions of this chapter. Establish internal procedures for expeditious identification, review, and processing of potential AOs and Other Related Items.

b. assign a coordinator and an alternate to represent the Office for matters pertaining to AOs and Other Related Items. Identify these individuals to AEOD.

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REMARKS:

This issuance is revised to:

1. reflect changes in organization and responsibilities within the NRC since the chapter was first published.

2. add an appendix, which provides guidance for the selection of events and the processing procedures for abnormal occurrence reports and other related items.

c. provide information regarding potential AOs and Other Related Items to AEOD within five and 15 working days, respectively, after sufficient information has been obtained. (See a recent copy of NUREG-0090 and its associated Commission paper for format and examples.) For each such event:

(1) prepare a writeup and forward it to AEOD for processing. The forwarding letter should state the specific criteria, example, and/or guideline used to select the event for reporting. The text of the writeup should describe the circumstances leading up to the event, the event itself (including, if applicable, a description of the components and systems involved, and their functions), actual or probable consequences (safety issue), the immediate actions taken to mitigate the event, and the actions (immediate and long term) taken to prevent recurrence. NRC response should be described, e.g., activation of Operations Center, inspections, independent studies made, meetings, orders or license modifications, enforcement actions, etc.

The cognizant office may request AEOD guidance or assistance, as resources permit, in preparing draft writeups of reportable items. However, in order for AEOD to assist, the cognizant office must provide all pertinent documents (i.e., copies of orders, letters to and from the NRC, inspection and enforcement reports, minutes of meetings, safety evaluation reports, enforcement letters, etc.) pertaining to the event.

(2) provide information and assistance to AEOD during evaluation (including any Commission briefings) of the subject events.

(3) provide updating material as the information becomes known.

d. respond to AEOD's requests for review of proposed reportable items.

For concurrences and editorial comments, telephonic or facsimile responses from the Office or Regional coordinator to the AEOD coordinator are acceptable. For nonconcurrence of a possible AO, the response must be by formal reply, signed by the Office Director or Regional Administrator. Detailed reasons for the nonconcurrence must be provided.

e. respond to AEOD's quarterly requests for a listing and assessment of any significant items which appear reportable as potential AOs or Other Related Items. The assessment (in summary form) should include the significance of each item and reasons why it appears reportable. Typical significant items are:

(1) the identification of a generic safety concern.

(2) activation of Operations Center due to significant events reported by licensees in accordance with the Immediate Notification requirements.

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(3) significant enforcement actions, i.e., Severity I and II items; civil penalties; orders to cease and desist; license suspension, modification, or revocation for safety reasons; show cause orders.

(4) orders or license modifications in response to significant security or safeguards incidents.

f. assure that the cognizant Offices are informed of items which may be potential AOs. For example:

(1) each Headquarters Office should inform the cognizant Regional Offices of any event, which may be a potential AO, first reported by a licensee to the Headquarters Office, or of any generic issue identified by the Headquarters Office staff. The cognizant Regional Offices can then, if necessary, investigate, gather information, and evaluate the event or issue.

(2) each Regional Office should keep the cognizant Headquarters Office informed of any event or issue which may be a potential AO.

035 The Executive Legal Director:

a. assigns a coordinator and an alternate to represent the Office for matters pertaining to the reporting process. Identifies these individuals to AEOD.

b. provides comments and concurrence to AEOD on incidents proposed for AO reporting and on the quarterly reports to Congress.

036 The Director, Office of State Programs:

a. assigns a coordinator and an alternate to represent the Office for matters pertaining to the reporting process. Identifies these individuals to AEOD.

b. assures that cognizant Regional personnel are informed of events reported by Agreement State licensees directly to the Headquarters Office or of any generic issues identified by the Headquarters Office staff. Similarly, cognizant Regional personnel should assure that Headquarters Office personnel are kept informed of events reported by Agreement State licensees directly to the Regional Offices, or any generic issues identified.

c. notifies AEOD within five working days of notification by an Agreement State of a proposed AO

d. establishes internal procedures to assure expeditious processing of potential AO writeups submitted by the Agreement States. Reviews Agreement State writeups of AOs to assure they are in proper format, complete, up to date, understandable, and that the specific AO criterion or example used is clearly stated.

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e. provides to AEOD any updating and/or closeout information on previously reported AOs in Agreement States as it becomes available.

037 The Director, Office of Public Affairs:

a. assigns a coordinator and an alternate to represent the Office for matters pertaining to the reporting process. Identifies these individuals to AEOD.

b. notifies AEOD of events which are receiving widespread public (more than local) interest for possible consideration as Other Events of Interest.

038 The Director, Office of Congressional Affairs:

a. assigns a coordinator and an alternate to represent the Office for matters pertaining to the reporting process. Identifies these individuals to AEOD.

b. notifies AEOD of events which are receiving widespread Congressional interest for possible consideration as Other Events of Interest.

c. notifies AEOD when the quarterly reports have been delivered to Congress. AEOD will then release the report for general distribution.

0212-04 DEFINITIONS

041 Abnormal Occurrence. An AO, as defined in Section 208 of the Energy Reorganization Act of 1974, as amended, is an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety. The criteria for such determinations are given in Part I of Appendix 0212 to this Chapter. For medical misadministrations, the AO criteria and their examples are supplemented by the specific guidelines given in Part II of Appendix 0212 to this chapter.

042 Potential Abnormal Occurrence. Any event which appears to meet the criteria or guidelines for AO reporting.

043 Other Related Items. Other Related Items are those things that are not AOs but are discussed in the AO quarterly report or in the Commission Paper that forwards the AO quarterly report to the Commission for review and approval. Other Related Items include Other Events of Interest, Other Events Considered for Abnormal Occurrence Reporting, and Updating Material. Other Related Items also include any changes proposed to this chapter or its appendix.

044 Other Events of Interest. Any event which, though determined by the NRC not to be of public health significance, may be perceived as such by the public. Guidelines for selection and processing procedures for these events are given in Part III of Appendix 0212 to this chapter.

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045 Other Events Considered for Abnormal Occurrence Reporting. Any event which is considered as a potential AO, but which was subsequently judged not to meet the criteria for abnormal occurrence reporting. Guidelines for selection and processing procedures for these events are given in Part IV of Appendix 0212 to this chapter.

046 Updating Material. Any new, significant information which becomes known in regard to previously reported AOs. Guidelines for processing updating material are given in Part V of Appendix 0212 to this chapter.

0212-05 BASIC REQUIREMENTS

051 Applicability. This chapter applies to and shall be followed by NRC Headquarters Offices and Regional Offices.

052 Appendix. The criteria and guidelines for selection of events for possible AO reporting, and the selection and processing of Other Related Items, are contained in Appendix 0212 to this chapter.

053 Federal Register Notices.

a. Information concerning AOs at NRC licensees is publicly disseminated through the Federal Register, with copies sent to the NRC Public Document Room and to the local public document rooms. Generally there is a Federal Register notice issued which contains the details of each AO and, where additional information is anticipated, the notice indicates that this information can be obtained at the Public Document Room.

b. Required minimum information for the Federal Register notice is date, place, nature and probable consequences of the event. Subsequent information (e.g., cause and actions taken to prevent recurrence, any significant updating information) will be promulgated either by updating summaries deposited in the public document rooms or through the quarterly reports to Congress, or both.

c. AOs at NRC licensees are to be reported to the public by issuing the Federal Register notice generally within 15 days after Commission approval of the AOs.

d. A Federal Register notice is also issued upon publication and delivery to Congress of each quarterly AO report. The notice lists the AOs included in the report and describes the availability of the report.

054 Reporting Requirements.

a. Any individual, NRC Office, other government agency, licensee, or member of the public may propose an event to any NRC organizational unit for evaluation as a potential AO. Any such event, together with the reasons why it does or does not appear to meet the AO criteria, should then be submitted to AEOD for evaluation and processing.

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b. Any individual, NRC Office, other government agency, licensee, or member of the public may recommend (to AEOD) changes in the AO reporting program, evaluation and determination procedures, or method of dissemination to the public or Congress.

c. In order to report AOs to the public in a timely manner, Office responses to AEOD's requests for review and comment of AOs should be submitted within five and 10 working days from the date of the AEOD requests, for individual AOs and for the quarterly AO reports, respectively.

d. A goal for the issuance of the quarterly AO report to Congress is 120 days after the end of each calendar quarter. The quarterly reports are issued in the NUREG-0090 series.

e. After delivery of the quarterly reports to Congress, copies are sent to the NRC Public Document Room and to the appropriate local public document rooms. Copies are also released for regular distribution and for purchase from the NRC/GPO Sales Program.

055 References.

a. Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438, 42 U.S.C. 5848) states that the Commission shall submit to the Congress each quarter a report listing for that period any abnormal occurrences at or associated with any facility which is licensed or otherwise regulated by the NRC. For the purposes of Section 208, an abnormal occurrence is an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or 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 reoccurrence;

the Commission shall also provide as wide dissemination to the public of the information specified in items (1) and (2) above as reasonably possible within fifteen days of its receiving information of each abnormal occurrence and shall provide as wide dissemination to the public as reasonably possible of the information specified in items (3) and (4) above as soon as such information becomes available to it.

b. The present AO criteria were submitted to the Commission on September 10, 1976, by SECY-76-471 and approved by a memorandum from S.J. Chilk to L.V. Gossick dated December 2, 1976. Subsequently, these criteria were included in an NRC Policy Statement, implementing Section 208, which was published in the Federal Register (42 FR 10950) on February 24, 1977.

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c. Staff guidelines for selection of medical misadministrations as potential AOs were submitted to the Commission for approval by SECY-84-60 on February 3, 1984 and approved by a memorandum from J.C. Hoyle to W.J. Dircks dated June 4, 1984.

d. The Commission requirement that the memorandum submitting the draft quarterly AO reports to the Commission document a representative sample of Other Events Considered for Abnormal Occurrence Reporting is contained in the previously referenced memorandum from S.J. Chilk to L.V. Gossick dated December 2, 1976.

e. The Commission requirement that consideration be given to the inclusion in the quarterly AO reports of Other Events of Interest is contained in the previously referenced memorandum from S.J. Chilk to L.V. Gossick dated December 2, 1976. Guidelines for the selection of such events were submitted to the Commission for information by SECY 78-460A on December 1, 1978.

f. The Commission requirement that Agreement States screen events and voluntarily report to NRC those occurrences that meet the criteria established as a threshold for reporting under Section 208 is contained in a memorandum from S.J. Chilk to L.V. Gossick dated February 22, 1977. If the NRC agrees that the Agreement State events meet the AO criteria, they are to be included in the quarterly AO reports to Congress.

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CONTENTS

PART I

ABNORMAL OCCURRENCE CRITERIA

A. GENERAL CRITERIA

An Abnormal Occurrence (AO) is an event involving a major reduction in the degree of protection of the public health or safety. Such an event would involve a moderate or more severe impact on the public health or safety and could include but need not be limited to:

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.

B. EXAMPLES OF EVENT TYPES

Examples of the types of events that are evaluated in detail using these criteria are:

1. For All Licensees

   a. Exposure of the whole body of any individual to 25 rems or more of radiation; exposure of the skin of the whole body of any individual to 150 rems or more of radiation; or exposure of the feet, ankles, hands or forearms of any individual to 375 rems or more of radiation (10 CFR § 20.403(a)(1)), or equivalent exposures from internal sources.

   b. An exposure to an individual in an unrestricted area such that the whole body dose received exceeds 0.5 rem in one calendar year (10 CFR § 20.105(a)).

   c. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 500 times the regulatory limit of Appendix B, Table II, 10 CFR Part 20 (10 CFR § 20.403(b)).

   d. Radiation or contamination levels in excess of design values on packages, or loss of confinement of radioactive material such as (1) a radiation dose rate of 1,000 mrem per hour three feet from the surface of a package containing the radioactive material, or (2) release of radioactive materal from a package in amounts greater than the regulatory limit (10 CFR § 71.36(a)).

e. Any loss of licensed material in such quantities and under such circumstances that substantial hazard may result to persons in unrestricted areas.

f. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.

g. Any substantiated loss of special nuclear material or any substantiated inventory discrepancy which is judged to be significant relative to normally expected performance and which is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.

h. 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.

i. An accidental criticality (10 CFR § 70.52(a)).

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

k. Serious deficiency in management or procedural controls in major areas.

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

2. For Commercial Nuclear Power Plants

a. Exceeding a safety limit of license Technical Specifications (10 CFR § 50.36(c)).

b. Major degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

c. Loss of plant capability to perform essential safety functions such that a potential release of radioactivity in excess of 10 CFR Part 100 guidelines could result from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

d. Discovery of a major condition not specifically considered in the Safety Analysis Report (SAR) or Technical Specifications that requires immediate remedial action.

e. Personnel error or procedural deficiencies which result in loss of plant capability to perform essential safety functions such that a potential release of radioactivity in excess of 10 CFR

Part 100 guidelines could result from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

3. For Fuel Cycle Licensees

a. For Reprocessing Facilities

(1) A safety limit of license Technical Specifications is exceeded and a plant shutdown is required (10 CFR § 50.36(c)).

(2) A major condition not specifically considered in the Safety Analysis Report or Technical Specifications that requires immediate remedial action.

b. For All Fuel Licensees

An event which seriously compromised the ability of a confinement system to perform its designated function.

PART II

STAFF GUIDANCE FOR SELECTION OF MEDICAL MISADMINISTRATION EVENTS FOR ABNORMAL OCCURRENCE REPORTING

A. INTRODUCTION

The existing NRC policy statement for determination of abnormal occurrences (AOs), as published in the Federal Register on February 24 1977 (43 FR 10950), was developed before the requirements (10 CFR § 35.41-35.45) for licensees to report medical misadministrations to the NRC became effective. Few of the examples in the policy statement for AO reporting are applicable to medical misadministration events. Therefore, for the latter events, a set of Guidelines has been developed which augment the policy statement examples. These Guidelines are delineated below.

B. PROCEDURES

The staff should select medical misadministration events as potential AOs using both the NRC policy statement for AOs, and the Guidelines below. The cognizant Regional or Headquarters office should prepare an AO writeup and forward it (together with the specific policy statement and/or Guideline example which is applicable) to AEOD for review and staff coordination. Subsequently, AEOD will forward those events that appear to meet the AO reporting threshold to the Commission for approval as AOs. The Commission paper will inform the Commission which specific policy statement and/or Guideline example is applicable. If a report is based only on a Guideline example, the writeup will state that the event is being reported under the general criterion for AO determinations (i.e., an event involving a major reduction in the degree of protection of public health or safety).

C. SPECIFIC GUIDELINES

Table 1 shows types of events which typically qualify for possible reporting as AOs; these supplement the examples (e.g., serious deficiency in management or procedural controls in major areas) described in the NRC policy statement for AOs. The first column describes various types of medical misadministrations. Items 1 through 5 are based on misadministrations reportable per 10 CFR § 35.41, while items 6 and 7 refer to recurring and generic medical misadministrations, respectively. The second and third columns of Table 1 show the AO reporting threshold for each type of event described, for diagnostic and therapeutic exposures, respectively. A conservative approach should be used (i.e., even events considered to be marginal should be proposed to AEOD for reporting). "Adverse health effects" is defined in Paragraph E below.

In Table 1, "adverse health effects" has a special meaning consistent with "adverse health effects worse than expected." The former refers to events in which a person, or a specific part of the body, receives radiation when no radiation was supposed to have been given to that person or that specific part of the body. The latter refers to events in which a person, or a specific part of the body, is scheduled to receive radiation, but the actual radiation received is greater than scheduled and causes observable health effects worse than would have been expected for the ranges of radiation normally associated with the particular diagnostic or therapeutic procedure. Therefore, the former is a special case of the latter, in which the "expected" health effect is zero. Of course, the actual doses received would also have to exceed the limits described in 10 CFR § 35.41, since otherwise the events need not be reported by the licensee to the NRC.

The health effects on a patient may be described in the licensee's report, which would facilitate use of these Guidelines. Occasionally, additonal information may need to be requested from the licensee. At times, a recommendation for reporting an AO may involve reviewing the NRC's medical consultant report, if the NRC has requested a medical consultant to review the event. Established medical literature can also be used in determining an adequate basis for reporting.

D. GENERAL GUIDANCE

1. Reports are to be consistent with the provisions of the Privacy Act and the Freedom of Information Act.

2. Drug defects, adverse drug reactions, or other problems outside the purview of the NRC will not generally be included.

3. In some cases, a collection of events may be presented in a report as a summary of specific data. For example, for similar events (such as recurring events or a series of events), the date and place, nature and probable consequences, cause or causes, may be presented in a table of data; the corrective actions to prevent recurrence could then be presented collectively in more detail.

E. ADVERSE HEALTH EFFECTS

Adverse health effects are acute symptoms directly related to various levels of radiation such as death; vomiting; erythema; diarrhea; fatigue; epilation; reduction in lymphocytes, platelets, and/or total white blood count; lesions and/or other tissue breakdown or damage. Whether or not the problems can be controlled, alleviated, or halted by further medical treatment is not germane for the purposes of defining an AO.

Even for prescribed amounts of radiation, some adverse health effects may occur or may be expected to occur. When a person or a part of the body receives radiation exceeding the limits normally prescribed for that diagnostic or therapeutic procedure, and the event is reportable by the licensee under 10 CFR § 35.41, only the adverse health effects which

exceed those expected by the limits of the diagnostic or therapeutic procedure are considered for AO reporting. However, as described previously, when a person or a part of a body receives radiation (but none was prescribed for that person or part of body), any observable adverse health effects form a basis for AO reporting. The licensee's followup and/or NRC's medical consultant's report, and established medical literature, will generally provide the basis for necessary judgments.

Many prescribed procedures involving radiopharmaceuticals or sealed sources, even though targeted primarily for a particular part of the body, will also subject other parts of the body to radiation exposure. The latter parts of the body must also be considered when applying the Specific Guidelines.

Table 1
AO Reporting Thresholds for
Medical Misadministration Events

Event Type	AO Reporting Threshold: Diagnostic Exposure	AO Reporting Threshold: Therapeutic Exposure
(1) Administering a radiopharmaceutical or radiation from a sealed source other than the one intended. See 10 CFR § 35.41.(a).	If the improper administration results in any part of the body receiving unscheduled radiation, an AO report should be proposed if: (a) the actual dose to the wrong body part is greater than five times the upper limit of the normal range of exposures prescribed for diagnostic procedures involving that body part, or (b) there are clinical indications of any adverse health effects to the wrong body part. If the parts of the body receiving radiation improperly would have received radiation anyway, had the proper administration been used, an AO report should be proposed if: (a) the actual dose is greater than five times that intended to the above described body parts, or,	If the improper administration results in any part of the body receiving unscheduled radiation, an AO report should be proposed for any such event. If the parts of the body receiving radiation improperly would have received radiation anyway, had the proper administration been used, an AO report should be proposed if: (a) the actual dose is greater than 1.5 times that intended to the above described body parts, or, (b) the actual dose is less than 0.5 times that intended to the above described body parts, or, (c) the above described body parts show signs of adverse health effects greater than expected had the proper administration been used, or (d) the event (regardless of any health effects) affects two or more patients at the same facility.

Table 1 (Continued)

Event Type	AO Reporting Threshold: Diagnostic Exposure	AO Reporting Threshold: Therapeutic Exposure
	(b) the above described body parts show signs of adverse health effects greater than expected had the proper administration been used.	
(2) Administering a radiopharmaceutical or radiation to the wrong patient. See 10 CFR § 35.41(b).	An AO report should be proposed if: (a) the actual dose to the wrong patient exceeds five times the prescribed dose for the intended patient, or (b) the event results in any adverse health effects.	An AO report should be proposed for any such event.
(3) Administering a radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician. See 10 CFR § 35.41(c)	Same guidelines as for Event Type 1.	Same guidelines as for Event Type 1.
(4) Administering a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent. See 10 CFR § 35.41(d).	An AO report should be proposed if: (a) the actual dose is greater than five times the prescribed dose, or, (b) the event results in adverse health effects worse than expected for	Not applicable.

Table 1 (Continued)

Event Type	AO Reporting Threshold: Diagnostic Exposure	AO Reporting Threshold: Therapeutic Exposure
	the normal range of exposures prescribed for the diagnostic procedure.	
(5) Administering a therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent; or administering a therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent. See 10 CFR § 35.41(e) and (f).	Not applicable.	An AO report should be proposed if: (a) the actual dose is greater than 1.5 times the prescribed dose, or, (b) the actual dose is less than 0.5 times the prescribed dose, or (c) the event results in adverse health effects worse than would be expected for the norm range of exposures prescribed for the therapeutic procedure, or, (d) the event (regardless of any health effects) affects two or more patients at the same facility.
(6) Recurring or series of events (regardless of the number of patients or facilities involved).	For either diagnostic or therapeutic exposures, an AO report should be proposed for recurring events or a series of events (where each individual misadministration is not of major importance) which create a significant public health or safety concern.	
(7) Generic events.	For either diagnostic or therapeutic exposures, an AO report should be proposed for misadministrations with generic implications which create a significant public health or safety concern.	

PART III

GUIDELINES FOR SELECTION AND PROCESSING PROCEDURES FOR OTHER EVENTS OF INTEREST

A. GUIDELINES FOR SELECTION

These events will be chosen for recommendation to the Commission based upon one or more of the following guidelines.

1. Non-routine events which have attracted wide (more than local) public interest (e.g., events resulting in petitions to the Commission by public interest groups, generic events which have resulted in power reductions or shutdowns for safety-related reasons, or widespread media coverage). Widespread media coverage generally means that the event has been disseminated by a national news service.

2. Non-routine events which have attracted considerable Congressional interest.

3. Inventory differences which exceed the AO reporting threshold when first reported by the licensee, but which are reduced to an acceptable level by a subsequent inventory. (If they cannot be so reduced, they are candidates for AO reporting.)

4. Events at nuclear power plants under construction and with no fuel on site, which would have qualified as an AO if the facility had an operating license.

5. Non-routine events of the following types, or events of equivalent importance, which are either considerably more extensive than expected or the result of an unexpected cause, but which are below the AO reporting threshold:

   a. Exposures (either plant personnel or public),

   b. Radioactive releases (e.g., contamination of individuals, widespread contamination within the site boundaries, releases to unrestricted areas),

   c. Failures of systems designed to contain radioactive material (e.g., fuel cladding, primary coolant boundary, containment boundary, glove boxes, dams),

   d. Failures of systems designed to control the radioactive process and/or to mitigate accident consequences,

   e. Design or operational problems requiring considerable corrective actions and/or shutdown time,

f. Shipping problems, or

g. Safeguards problems.

B. PROCESSING PROCEDURES

1. Those events which appear to meet the guidelines for reporting should be written up by the cognizant office in a narrative format. The information should include pertinent details of the event, including the date and place, nature and probable consequences, causes, licensee and NRC actions. Also, the reasons why it is not an AO should be clearly stated. See a recent copy of NUREG-0090 for format. This writeup should be forwarded to AEOD, as soon as it is completed, rather than waiting until the end of the quarter. This should help to decrease the time required to prepare, process and submit the quarterly reports to the Commission for approval.

   As discussed in Paragraph 034 of Chapter 0212, the cognizant office may request AEOD guidance or assistance, as resources permit, in preparing event writeups provided all related documentation regarding the event is supplied to AEOD.

2. AEOD will review and edit the writeup and request assistance as necessary from other offices to assure accuracy and timeliness of the writeup. The event will be proposed to the Commission for inclusion in the next quarterly AO report to Congress.

PART IV

GUIDELINES FOR SELECTION AND PROCESSING PROCEDURES FOR OTHER EVENTS CONSIDERED FOR ABNORMAL OCCURRENCE REPORTING

A. GUIDELINES FOR SELECTION

By definition, these are events which were considered as AOs but rejected after further reviews. (If rejected as AOs, they should then be evaluated for possible reporting as Other Events of Interest). Such events would include:

1. Any event reviewed in detail and seriously considered by one or more of the staff offices for AO applicability, but eventually rejected by that office or offices.

2. Any event determined by one or more staff offices to meet the AO criteria and forwarded to AEOD for processing, but eventually rejected after staff considerations.

These items are included as an enclosure to the Commission papers forwarding the draft quarterly AO reports to the Commission for approval; the items are not included in the AO reports, unless stipulated otherwise by the Commission.

B. PROCESSING PROCEDURES

1. Those events or items which appear to meet these guidelines for reporting should be written up by the cognizant office in a format similar to that for Other Events of Interest items. The information should include pertinent details of the event, including the date and place, nature and probable consequences, causes, licensee and NRC actions.

   Also, the reasons why it is not considered an AO or Other Events of Interest item should be clearly stated either at the end of the text or in a transmittal memo. This writeup should be forwarded to AEOD as early as possible during the calendar quarter and no later than 15 days after the end of the calendar quarter in which the event occurred, provided sufficient information is available.

   As discussed in Paragraph 034 of Chapter 0212, the cognizant office may request AEOD guidance or assistance, as resources permit, in preparing event writeups provided all related documentation regarding the event is supplied to AEOD.

2. AEOD will review and edit the writeup and request assistance as necessary from other offices to assure accuracy and timeliness of the writeup. The event will be considered for inclusion in the

Commission paper forwarding the next quarterly AO report for approval.

PART V

GUIDELINES FOR PROCESSING OF UPDATING MATERIAL

A. DISCUSSION

Updating material to previously reported AOs is required for the following.

1. Federal Register Notices. As described in Paragraph 053 of Chapter 0212, the minimum information to be reported in the Federal Register notice is the date, place, nature and probable consequences of the event. Subsequent information (cause and actions taken to prevent recurrence, and any significant updating information) will be promulgated either by updating summaries deposited in the public document rooms or through the quarterly reports to Congress, or both.

2. Quarterly Reports to Congress. In addition to the updating information described above, the quarterly reports should include any significant updating material for previously reported AOs. In the quarterly reports, the text for each new and updated AO should state whether or not the incident is considered closed for purposes of the report. In succeeding quarterly reports, efforts should be made to keep each open item current.

B. CLOSE OUT OF ABNORMAL OCCURRENCES

Close out of AOs is generally appropriate under one or more of the following conditions.

1. The affected licensees have taken satisfactory corrective actions.

2. A civil penalty has been paid, or otherwise resolved.

3. A revoked or suspended license has either been reinstated or the licensee decides not to contest the action.

4. An item, such as a generic item, becomes an unresolved safety issue and will be reported upon periodically to Congress accordingly.

5. A safety analysis report or other long-term evaluation is complete and appropriate implementing actions have been made.

6. No new significant information can reasonably be expected.

C. REOPENING OF CLOSED ITEMS

AOs that have been previously reported closed in the quarterly reports should be reopened if significant new information becomes available. Similarly, previously reported Other Events of Interest items can be updated if significant new information becomes available.

D. PROCESSING PROCEDURES

Each cognizant office should provide AEOD with any known significant updating material, (1) as soon as the information is available for AOs reported by Federal Register notice as described in Paragraph A.1 above and, (2) in the cognizant office's response to AEOD's memorandum issued near the end of each calendar quarter requesting staff assistance for the preparation of that quarterly report to Congress.

Form NRC-489
(1-76)

U. S. NUCLEAR REGULATORY COMMISSION
NRC MANUAL
TRANSMITTAL NOTICE

CHAPTER NRC-0212 ABNORMAL OCCURRENCE REPORTING PROCEDURE

SUPERSEDED:			TRANSMITTED:		
	Number	Date		Number	Date
			TN	0200-39	9/9/87
Chapter			Chapter		
Page			Page		
Appendix			Appendix		

REMARKS:

Please make the following pen-and-ink changes to this chapter:

1. Paragraph -033.d (4) - substitute "Office of Administration and Resources Management" for "Offices of Administration".

2. Paragraph -034 - substitute "Directors of the Offices of Nuclear Reactor Regulation (NRR), Nuclear Material Safety and Safeguards (NMSS), Nuclear Regulatory Research (RES), and Special Projects (SP), and Regional Administrators:" for present title line.

3. Paragraph -035 - substitute "Office of General Counsel" for "Executive Legal Director".

4. Paragraph -036 - substitute "The Director, State, Local, and Indian Tribe Programs" for "The Director, Office of State Programs".

5. Paragraphs -037 and -038 - delete "Office of" in both title lines.

6. Paragraph -054.e - substitute "U. S. Government Printing Office and the National Technical Information Service" for "NRC/GPO Sales Program".