UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUN 0 1 1983

MEMORANDUM FOR: Harold R. Denton, Director, NRR
Richard C. DeYoung, Director, IE
John G. Davis, Director, NMSS
G. Wayne Kerr, Director, SP
Joseph J. Fouchard, Director, PA
Guy H. Cunningham, Executive Legal Director
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FROM: C. J. Heltemes, Jr., Director
Office for Analysis and Evaluation
of Operational Data

SUBJECT: REVISION TO STAFF GUIDANCE FOR SELECTION OF MEDICAL MISADMINISTRATION EVENTS FOR ABNORMAL OCCURRENCE REPORTING

SECY-82-92, dated March 7, 1983, submitted the draft Fourth Quarter CY 1982 Abnormal Occurrence (AO) Report to the Commission for approval. One of the Enclosure 3 items (i.e., items considered for classification as AOs, but rejected after further study) concerned a medical misadministration in which a patient received a dose to a localized area of 12,000 rads, rather than the prescribed 4,000 rads. The item was not proposed as an AO since it did not meet the existing guidelines which require severe damage to "vital organs," acute radiation syndrome, or death.

On May 12, 1983, the Commission replied that the event should be upgraded to an Appendix C item (i.e., other events of interest) in the quarterly report. In addition, the Commission stated that the present guidelines set unduly high thresholds for reporting medical misadministrations as AOs and that the definition of "vital organs" is too narrowly defined. The Commission requested the staff to reexamine the present guidelines and submit the reexamined guidelines for Commission approval.

Based on our review, we propose that future AO determinations be based primarily on severe adverse health effects, regardless of the part of the body involved. Generally, this would involve therapeutic rather than diagnostic exposures (diagnostic exposures are generally many orders of magnitude lower than therapeutic exposures) since the potential for severe adverse health effects

due to errors is much greater. This greater potential is also reflected in the medical misadministration reporting requirements, i.e., only errors greater than 50% must be reported for diagnostic exposures while errors greater than 10% must be reported for therapeutic exposures. At the same time, we recognize that even properly administered therapeutic treatment frequently results in adverse health side effects. Therefore, only adverse health effects associated with the unprescribed exposures which are worse than what would have been associated with prescribed exposures are germane for AO reporting purposes. At times, such distinction will require judgment. However, if the licensee's reports are adequately written, such information should be contained in the report. In addition, the NRC medical consultants could be requested to provide their judgment, if needed.

In regard to the quality of licensee reports, AEOD has previously expressed concern about the lack of report detail, particularly diagnostic misadministration reports. This was most recently stated in the AEOD report of medical misadministrations for the 18-month period of January 1981 through June 1982 (reference: AEOD/N204B, dated November 1982). In a memorandum dated December 29, 1982 from R. E. Cunningham to C. Michelson, NMSS believed that medical misadministration reporting requirements should not be increased since some medical groups were considering filing petitions for repeal of the reporting rule; therefore, NMSS believed it best to first see such petitions and the resulting public comments before taking any further action regarding the rule.

It is our understanding that such petitions have not yet been filed. Even if they are, it is uncertain when, or if, the rule will be rescinded. Meanwhile, the inadequacy of many reports remains a problem. Therefore, AEOD plans to draft an Information Notice and forward it to IE with a recommendation that it be sent to the appropriate licensees. The Information Notice will contain suggestions for making the reports more meaningful, particularly in regard to the effect on the patient and actions to prevent recurrence and the brief description of the event as presently required by 10 CFR Parts 35.42 and 35.43.

Based on the discussions above, we have prepared the enclosed draft Commission Paper and proposed revised staff guidelines for selecting medical misadministrations for reporting as AOs. Due to the tight timetable (a staff recommendation is due at EDO on June 24, 1983), we request your review and comments by June 13, 1983.

The AEOD contact is Paul Bobe on x24426.

C. J. Heltemes, Jr., Director
Office for Analysis and Evaluation
of Operational Data

Enclosure:
Draft Commission Paper with
Proposed Revised Staff Guidance

cc w/enclosures:
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DRAFT

For: The Commissioners

From: William J. Dircks
Executive Director for Operations

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

Purpose: Approval of the subject staff procedures.

Discussion: As described in the background information (Enclosure 1), the staff has reviewed the present staff guidance for selection of medical misadministration events for abnormal occurrence (AO) reporting in accordance with the Commission's request stated in the May 12, 1983 memorandum from S. J. Chilk to W. J. Dircks.

The medical misadministration events reported from January 1, 1981 through June 30, 1982 (as described in the report AEOD/N204B for the same time period, dated November 1982) clearly show that the most serious events are those associated with therapeutic

treatment. However, none were judged to meet the present staff guidelines for AO reporting primarily due to the restrictive definition of the term "vital organs." The staff now considers that the emphasis should be on adverse health effects regardless of the part of the body involved. This is particularly true for therapeutic exposures since prescribed exposure levels are quite high. The exposure levels prescribed for diagnostic tests are generally quite low and very significant errors (generally many orders of magnitude) would be needed to result in observable adverse health effects.

It should also be noted that for the prescribed levels of exposures required for therapy, it is not uncommon for a patient to experience adverse health reactions (i.e., reactions frequently are expected). Therefore, with few exceptions, only adverse health effects which are greater than those expected for an exposure at the limit for licensee reporting as medical misadministrations will be considered for AO reporting. For some events, this will require judgment. It may be necessary to request an opinion from licensees submitting medical misadministration reports and/or from the NRC medical consultants.

Based on the above discussion, the proposed revised staff guidelines for selection of medical misadministrations as AOs are shown in Enclosure 2.

Recommendations: That the Commission:

1. Approve the staff guidelines presented in Enclosure 2, and

2. Note that upon approval, AEOD will inform all cognizant NRC offices of the revised staff guidance, and

3. Note that the revised guidances will be incorporated in the next formal revision of NRC Manual Chapter 0212 ("Abnormal Occurrence Reporting Procedure").

Scheduling: There are no specific circumstances requiring Commission action by a particular date.

William J. Dircks
Executive Director for Operations

Enclosures:
1. Background Information
2. Proposed Staff Guidance for Selection of Medical Misadministration Events for AO Reporting

Enclosure 1

BACKGROUND INFORMATION

The policy statement on Abnormal Occurrence (AO) reporting was published in the Federal Register (42 FR 10950) on February 24, 1977. At that time, licensees were not required to report medical misadministrations to the NRC; therefore, specific guidance was not developed to include such events in the AO reporting process. Nevertheless, the NRC did report some cases of severe patient overexposures under the general AO criterion (i.e., events involving a major reduction in the degree of protection of the public health or safety).

On May 4, 1980, the NRC published "Misadministration Reporting Requirements," in the Federal Register (45 FR 31701), which became effective on November 10, 1980. After some experience with the rule had been obtained, AEOD developed (with staff concurrence) specific staff guidance for selecting medical misadministration events to be considered for AO reporting. These guidelines were submitted to the Commission for information by SECY-81-523 on September 1, 1981.

The Fourth Quarter CY 1982 AO Report to Congress was forwarded to the Commission for approval by SECY-83-92 dated March 7, 1983. Enclosure 3 to the Commission Paper (i.e., events seriously considered for AO reporting, but rejected after further study) contained a medical misadministration event involving a patient receiving a localized dose of 12,000 rad rather than the prescribed 4,000 rad.

The event was considered for AO reporting; however, it did not appear to meet the staff's present guidelines as an AO. The Commission reply (reference: S. J. Chilk memorandum to W. J. Dircks, dated May 12, 1983) stated that the current guidelines set unduly high thresholds and provide too narrow a definition of "vital organs." The Commission requested the staff to reexamine the staff's internal guidelines and submit the guidelines to the Commission for final approval.

Enclosure 2

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 (Vol. 43, No. 37, pages 10950-10952), does not contain any specific examples pertaining to medical misadministrations. Therefore, the staff should select such events as potential AOs by the Guidelines below. The potential AOs will then be recommended to the Commission for approval using the general criterion for AO determinations (i.e., an event will be considered an AO if it involves a major reduction in the degree of protection for public health or safety).

B. Specific Guidelines

The specific guidelines in Table 1 outline the types of events which typically qualify for reporting as AOs. A conservative approach should be used (i.e., even events which are considered to be marginal should be proposed to AEOD for reporting).

Table 1 - Specific Guidelines

Event	Diagnostic Exposure	Therapeutic Exposure
(1) Administering a radiopharmaceutical or radiation from a sealed source other than the one intended; or administering a radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician.	The event results in acute or likely long-term health effects which are, or are likely to be, worse than would be expected from the prescribed radiopharmaceutical, source, and/or route of administration.	

Table 1 - Specific Guidelines

	Event	Diagnostic Exposure	Therapeutic Exposure
(2)	Administering a radiopharmaceutical or radiation to the wrong patient.	Not generally reportable as an AO, unless the event results in adverse health effects.	Any such event should be proposed as an AO.
(3)	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.	Not applicable.	The event results in acute or likely long term health effects worse than would be expected had the dose not been more than 10% greater than the prescribed dose; or, Any event that affects more than two people.
(4)	Administering a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent.	The event results in a dose greater than five times the prescribed dose; or, The event results in acute or likely long-term health effects worse than would be expected had the dose not been more than 50% greater than the prescribed dose.	Not applicable.

Table 1 - Specific Guidelines

Event	Diagnostic Exposure	Therapeutic Exposure
(5) Recurring or series of events.		Recurring events or a series of events (where each individual misadministration is not of major importance) which create a major public health or safety concern.
(6) Generic events.		Misadministrations with generic implications which create a major public health or safety concern.

Both acute and long-term effects on the patient may be included in the licensee's report, which should facilitate use of these Guidelines. Occasionally, however, a basis for reporting may have to wait for the medical consultants reports, if a medical consultant has been requested to review the event. Occasionally, additional information may need to be requested from the licensee.

C. General Guidance

(1) Events determined to be at or above the threshold established by the Guidelines will be subject to reporting per Section 208 of the Energy Reorganization Act of 1974.

(2) Reports are to be made consistent with the provisions of the Privacy Act and the Freedom of Information Act.

(3) Drug defects, adverse drug reactions, or other problems that are outside the purview of the NRC will not generally be included.

(4) In some cases, events may be presented quarterly in the reports to Congress as summaries of specific data. For example, for similar events (such as recurring or 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.

D. Key Definitions

Even for prescribed amounts of radiation, some adverse health effects may occur or may be expected to occur. For purposes of Abnormal Occurrence reporting, only those adverse health effects which exceed those associated with the limits of the misadministration reporting rule require reporting. The licensee's followup report and/or medical consultants report will generally provide the basis for any necessary judgments. With this proviso, the following key definitions are made:

(1) Acute health effects - Symptoms which may be associated with various levels of radiation such as vomiting; erythema; diarrhea; fatigue; epilation; reduction in lymphocytes, platelets, and/or total white blood count; lesions and/or other tissue breakdown or damage; death; etc.

(2) Long-term health effects - Effects associated with radiation which either have resulted in, or are likely to result in long-term health problems. Whether or not the problems can be controlled, alleviated, or halted by further medical treatment is not germane for the purposes of defining an Abnormal Occurrence. Some examples include fibrosis, tissue breakdown, anemia, leukemia, cancer of any part of the body, etc.