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

OFFICE OF THE
SECRETARY

May 19, 1994

MEMORANDUM TO: James M. Taylor
Executive Director for Operations

FROM: John G. Hoyle, Acting Secretary

SUBJECT: SECY-93-259 - FEDERAL REGISTER NOTICE - ABNORMAL OCCURRENCE REPORTS: REVISION TO APPENDIX A TO POLICY STATEMENT TO INCLUDE EXAMPLES FOR REPORTING MEDICAL MISADMINISTRATIONS AS ABNORMAL OCCURRENCES AND MINOR CONFORMING CHANGES TO EXISTING ABNORMAL OCCURRENCE EXAMPLES

The Commission (with all Commissioners agreeing) has approved a modification of Option 2, as presented by the staff, for reporting to Congress as abnormal occurrences (AOs), situations in which a patient was exposed due to a medical misadministration where the patient was originally intended to receive an exposure.

Specifically, for such misadministrations to be considered AOs, the proposed approach would be:

(1) a dose threshold of:

(a) 1 Gy (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or

(b) 10 Gy (1000 rad) to all other organs; and

(2) it represents either:

(a) a dose or dosage 50 percent greater than prescribed in the written directive, or

(b)(i) a prescribed dose or dosage that is the wrong radiopharmaceutical, or

(b)(ii) is delivered by the wrong route of administration, or

SECY NOTE: THIS SRM, SECY-93-259, AND THE VOTE SHEETS OF ALL COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 10 WORKING DAYS FROM THE DATE OF THIS SRM.

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(b)(iii) is delivered to the wrong treatment site, or

(b)(iv) is delivered by the wrong treatment mode, or

(b)(v) is from leaking sources.

Additionally, for unintended exposures, the Commission has concluded that a single threshold dose should be established for exposure to humans (not intended to receive an exposure under medically prescribed conditions). The potential for physical harm to an individual resulting from an unintended exposure is the same whether the exposure was received in an occupational setting, as a patient, or as a member of the public; thus, for reporting AOs to Congress, a single value is appropriate. The staff should reaffirm that the 25 rem value remains an acceptable criterion for this single threshold value to identify doses which are significant from a health and safety standpoint. AO reporting of a wrong patient misadministration (i.e. a patient who receives an exposure, but was not intended to) would be covered by this single threshold criteria.

The Commission disapproved the staff proposal to designate multiple misadministrations attributable to a single cause as AOs unless they result in significant potential for harm to individuals as determined above or involve a serious deficiency in management or procedural controls in major area.

Further, the Commission concludes that all of the revisions to conform the AO examples to NRC's amended Part 20 should be made concurrent with the above changes.

Therefore, the staff should develop a single revision to the policy statement in accordance with the guidance above. The revised policy statement should be submitted for Commission review and approval. The revision should be published for public comment and provided to Congress after Commission approval.
(EDO) (SECY Suspense: 9/26/94)

The staff should develop guidance for reporting, in Appendix C of the Abnormal Occurrence Reports to Congress, events involving human exposures in unrestricted areas that exceed regulatory limits but which would no longer be categorized as AOs per the above revisions, and multiple misadministrations attributable to a single cause which do not exceed the criterion for AO reporting.
(EDO) (SECY Suspense: 9/26/94)

The Abnormal Occurrence Reports should continue to be developed based on the existing policy statement until public comments have been received and resolved on any proposed revision.

cc: The Chairman
Commissioner Rogers
Commissioner Remick
Commissioner de Planque
OGC
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)