

NOTATION VOTE

RELEASED TO THE PDR

RESPONSE SHEET

6-9-94 [signature]
date initials

TO: SAMUEL J. CHILK, SECRETARY OF THE COMMISSION

FROM: COMMISSIONER REMICK

SUBJECT: SECY-93-259 - FEDERAL REGISTER NOTICE - ABNORMAL OCCURRENCE REPORTS: PROPOSED 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

APPROVED [X] In part/consent DISAPPROVED [X] In part ABSTAIN

NOT PARTICIPATING REQUEST DISCUSSION

COMMENTS:

Please see attached

9406150275 940503
PDR COMMS NRCC
CORRESPONDENCE PDR

[Signature]
SIGNATURE

RELEASE VOTE [X]

100153

3 May 94
DATE

WITHHOLD VOTE

ENTERED ON "AS" YES [check] No

[Handwritten initials]

Commissioner Remick's comments on SECY-93-259:

The oversight placed on the regulated community by Congress is clouded by differing thresholds for identifying occurrences with potential public health impacts. As a result, I concur with Commissioner de Planque in disapproving the revision to the policy statement on reporting Abnormal Occurrences (AOs) until such a revision is made which identifies a single threshold for exposures to humans (not intended to receive an exposure under medically prescribed conditions).

I agree that the policy statement should be revised to conform to the new 10 CFR Part 20 concurrently.

I believe that the revised policy statement should be published for comment and Congress informed of the policy shift, and that until a final policy statement is published the current policy statement should be used to identify AOs unless the regulated community is willing to report AOs in accord with the proposed revised policy statement.

I agree with the staff in its selection of option 2 of SECY-93-259 to identify AOs in situations in which a patient was exposed due to a medical misadministration, where the patient was originally intended to receive an exposure.

I also agree that Appendix C to the Report to Congress on Abnormal Occurrences, "other occurrences of interest," could be used as a vehicle to provide information to Congress on situations which may be of interest to the public. Specifically, Appendix C should contain reports of public exposures in excess of regulatory limits, 1 mSv, (100 mrem); this includes exposures to patients not intended to receive an exposure. However, I caution that any occurrence reported in the report to Congress may be perceived as "abnormal."