NOTATION VOTE

RESPONSE SHEET

TO: SAMUEL J. CHILK, SECRETARY OF THE COMMISSION

FROM: COMMISSIONER DE PLANQUE

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 OCCURRENCES

APPROVED _____ DISAPPROVED X(w/comment) ABSTAIN _____

NOT PARTICIPATING _____ REQUEST DISCUSSION _____

COMMENTS:

See attached comments.

E. Gail de Planque
SIGNATURE

RELEASE VOTE /XX/

March 3, 1994
DATE

WITHHOLD VOTE /___/

ENTERED ON "AS" YES XX NO ___

Commissioner de Planque's comments on SECY-93-259

Staff proposes to publish for comment a revised Policy Statement on Abnormal Occurrences (AOs) so as to include examples, in Appendix A of the Policy Statement, for reporting medical misadministrations as Aos. Staff also notes its plans to make further revisions at a later date to conform other AO examples with NRC's amended Part 20 regulations which became mandatory on January 1, 1994. I do not approve revising the Policy Statement in two stages. Rather, staff should prepare a single revision of the Policy Statement incorporating the revision to Part 20 and the principles explained below. Interim criteria given below should be used for reporting abnormal occurrences to Congress until a final revised Policy Statement becomes effective.

Revision of the Policy Statement

Section 208 of the Energy Reorganization Act of 1974 requires the Commission to submit to Congress a quarterly Abnormal Occurrence Report (AOR). The statute defines an abnormal occurrence as "...an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety" (emphasis added). The present Policy Statement contains two different sets of criteria for determining the significance of human exposure to radiation from licensed material: one for occupational exposures and one for members of the public. See Policy Statement, Appendix A, I.A.1. and 2. The present SECY would add a third set of criteria for patients. However, 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. Therefore, in my view, a single set of criteria (dose thresholds) should be used to identify an unintended dose received by an individual which is of the significance requiring reporting to Congress as an AO.

In formulating criteria, staff should consider the following. Historically, 25 rem has been used for the purpose of identifying occupational exposures which should be considered abnormal occurrences for the purpose of reporting to Congress[1]. It appears that this value remains an acceptable criterion with respect to stochastic effects (e.g.the risk of latent cancers). The staff should, however, reaffirm that this continues to be the best value as a criterion to identify doses which are significant from the standpoint of health and safety[2]. For non-stochastic effects (e.g.thyroid ablatement) the staff should develop an approach which would identify the potential for harm in an equivalent manner. The policy statement should address the rationale for the selection of these values and solicit specific comment on their appropriateness for determining if an event is significant from the standpoint of health and safety.

In the case of a misadministration where a dose to a patient was intended, an alternative approach is needed. In this case, the 25 rem criteria would be inappropriate since the potential for harm is by definition balanced against

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[1]See SECY-76-471

[2]I note that a dose less than the annual occupational limit of 10 rem (5 rem routine plus 5 rem PSE) is not appropriate as an indicator of significant harm. Likewise, it would seem that the 50 rem value recommended in NCRP 116 for emergency exposures is a reasonable upper bound for this purpose.

expected medical benefits. In this respect, the difference between the intended dose and the delivered dose can often be much greater than 25 rem without being significant from a health and safety perspective. In addition, dose to an intended patient, unintentionally applied to the wrong location may or may not be significant from a health and safety perspective. Therefore, in these cases, the staff's recommended option 2 in SECY-93-259 is an acceptable method to determine if the event should be reported to Congress as an abnormal occurrence.

I disagree with the premise that multiple misadministrations per se should be considered abnormal occurrences, unless they result in significant potential for harm to individuals as determined above. The number of persons involved in an misadministration does not alter the potential health or safety significance for those individuals. However, it may be an indicator of a programmatic problem and should be addressed through appropriate enforcement. I also disagree that a misadministration to the wrong patient should be considered an abnormal occurrence per se, since the potential for harm is again dependant on dose. Only the potential for harm should be considered in determining whether or not either of these types of incidents should be reported to Congress as an abnormal occurrence. This is not to say that rigorous investigation, follow up and enforcement should not occur for misadministrations which are not abnormal occurrences. Multiple occurrences, misadministrations to the wrong patient and overexposures to members of the public and workers are serious concerns and should continue to be afforded the full attention of the staff. Enforcement actions should continue to consider the potential significance of such occurrences as possible indicators of the effectiveness of the licensee's program to properly protect the health and safety of the public in the future.

Interim Criteria

While the staff is revising the policy statement, during the public comment period and as the policy statement is finalized in response to comments, an interim policy is appropriate. Therefore, any abnormal occurrence reports to Congress which must be made during this period should be made using the following criteria.

1. Any exposure to a member of the public, an occupationally exposed worker, or a patient not intended to receive a dose shall be considered an abnormal occurrence when doses potentially resulting in stochastic risks exceed 25 rem TEDE.

2. Any organ dose to a member of the public, an occupationally exposed worker or a patient not intended to receive a dose shall be evaluated on a case by case basis. Any exposure which results in a potential for harm analogous to that described in criterion 1 above shall be considered an abnormal occurrence.

3. Misadministrations to patients intended to receive a dose shall be evaluated and reported as proposed in staff option 2 of SECY-93-259.

4. Dose to wrong patients shall not be considered abnormal occurrences unless they meet the criteria in 1 or 2 expressed above.

5. Multiple misadministrations, to patients intended to receive a dose, shall not be considered abnormal occurrences unless they meet the criteria in 3 expressed above.

The staff should move forward with this revision expeditiously and resubmit it to the Commission for approval. Should the criteria in the final Policy Statement be substantially different from that which is presented in this interim guidance, a supplemental report shall be submitted to Congress as appropriate.