



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 27, 1998

MEMORANDUM TO: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

FROM: *for* Thomas T. Martin, Director
Office for Analysis and Evaluation
of Operational Data

A handwritten signature in cursive, appearing to read "J. Conzel".

SUBJECT: PROPOSED RULE: MAJOR REVISION OF 10 CFR PART 35

This is in response to your memorandum dated April 10, 1998, requesting concurrence on the subject proposed rule. In order to meet your schedule, we have only reviewed the section of "Subpart M - Reports" that pertains directly to the AEOD's functions. As we have discussed with your staff, our concurrence is provided with the understanding that the following comments on the proposed Federal Register notice (Attachment 3 to the proposed rule package) will be addressed:

1. Page 304, §35.3045(a)(1) — Include, in addition to an "organ or tissue," medical events involving skin.
2. Page 304, §35.3045(2) — Use a lower case Roman numeral in parentheses at the beginning of the line.
3. Page 304 §35.3045(a) — Revise to ensure that medical events resulting in under-doses are also reported.
4. Page 306, §35.3045(2)(iii), first line — Change "wrong patient" to "wrong individual" to be consistent with the recent change to 10 CFR Part 35.
5. Page 307, §35.3047 (a), 3rd line — Change the "effective dose equivalent" to "absorbed dose" since there are no weighting factors applicable for the organs or tissues of an embryo/fetus.
6. Page 306, § 35.5046, "Reports of precursor events" — In addition to hardware/software, specify other precursors that are major contributors to risk. The selection of additional precursors for inclusion should be based on an examination of events reported to NRC since 1981.
7. Clarify Subpart M to ensure that a dose to the wrong treatment site is calculated as the absolute dose, regardless of the dose the site would have received if the treatment was completed as prescribed. This is to address Commission concerns discussed in SECY-98-042, "Amendment to SECY-97-288, 'Report to Congress on Abnormal Occurrences for Fiscal Year 1997.'"

D. A. Cool

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We will be glad to work with your staff to resolve our comments. The AEOD contact, Harriet Karagiannis, can be reached at (301)415-6377 or e-mail HXK.