

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook
Secretary of the Commission

FROM: CHAIRMAN MESERVE

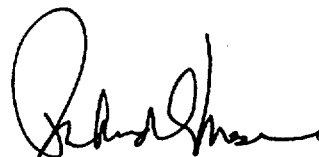
SUBJECT: SECY-99-201 - DRAFT FINAL RULE - 10 CFR PART 35,
"MEDICAL USE OF BYPRODUCT MATERIAL"

Approved XX Disapproved Abstain

Not Participating Request Discussion

COMMENTS:

See attached comments.



SIGNATURE

January 3, 2000

DATE

Entered on "AS" Yes No

COMMENTS OF CHAIRMAN MESERVE ON SECY-99-201

I approve the staff's draft final rule language and draft responses to comments, subject to the observations below. The staff should strive to submit the revised final Part 35 rulemaking package and the Medical Policy Statement to the Commission within 3 months from the date of the SRM.

The following are my specific comments:

Risk Assessment: I agree with the staff recommendation that no additional risk assessment is necessary to support this rulemaking. The development of the draft final rule used a risk-informed approach and incorporates risk insights to focus licensee and regulatory attention on operational issues commensurate with their importance to health and safety. Also, the draft final rule represents a significant reduction in regulatory burden. Our action on this rule does not prohibit the medical community or other stakeholders from preparing a risk assessment relating to the medical uses of nuclear materials that could be considered by the Commission in connection with a petition for rulemaking.

Training and Experience: I approve the proposed training and experience requirements for authorized user physicians, RSOs, physicists, and nuclear pharmacists as proposed by the staff. I also agree with the concerns raised by the ACMUI regarding the need for a uniform national standard for training and experience. Therefore, I agree with Commissioners McGaffigan and Dicus that the compatibility level assigned to the T&E requirements be changed from "C" to "B" to ensure that the provision of medical services nationwide is not disrupted by some Agreement States imposing more restrictive training requirements.

Event Notification: I approve the alternative notification requirement proposed by the staff that would require verbal notification of the patient and a certification of that notification to NRC. However, I agree with Commissioners Merrifield and Diaz that there should be a copy of the notification placed in the patient's medical record. If the licensee is the patient's physician, the licensee should place a copy of the records required under 35.2045 in the patient's medical record. If the licensee is not the patient's physician, the licensee should, in addition to retaining a copy for 3 years, provide a copy of the records required under 35.2045 to the patient's physician with a request that the copy be included in the patient's medical record.

Reporting Threshold for Unintended Exposure to an Embryo, Fetus, and Nursing Child: I approve the establishment of a reporting threshold (not a dose limit) for unintended exposure to the embryo, fetus, or nursing child at 5 rem. I believe that the medical community has made a valid argument that a lower reporting threshold could significantly impact the practice of medicine because it might cause pregnancy testing in connection with many diagnostic procedures. This could result in desirable nuclear medicine procedures not being performed in some instances. In addition, I approve the staff's proposal to evaluate whether a rulemaking is needed to add a similar requirement in 10 CFR Part 20 or Parts 30, 40, and 70 for reporting an unintended exposure to an embryo, fetus, or nursing child that is not covered under 10 CFR Part 35. The staff should provide the Commission with either a rulemaking plan or a paper explaining why a rulemaking is unnecessary.

Public Briefing: I do not believe a public briefing on the draft final rule is necessary. However, if the staff perceives a significant demand for a briefing, I do not oppose such a briefing.

Specialty Boards: I approve the staff proposal to begin the process of recognition of the medical specialty boards before publication of the final rule.