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

April 18, 2000

MEMORANDUM TO: Catherine Haney
Rulemaking and Guidance Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

FROM: Brenda Jo. Shelton, Chief
Records Management Branch
Office of the Chief Information Officer

SUBJECT: CONCURRENCE IN THE REVISION OF 10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL, FINAL RULE

The Office of the Chief Information Officer has reviewed the subject rule and has the following major concern that must be resolved before the rule can be published or the clearance package forwarded to OMB. Because we deferred our review of the draft final rule, we did not review this change earlier. Although the concern also affects another section that was present in the proposed rule, unfortunately, we did not catch it until the language was strengthened in the final rule.

OMB as a general rule does not approve information collections that require both the submittal and the retention of the same information by a respondent. OMB's position is that if the information is reported, the agency has the information that it needs for its purposes, and therefore, there is no reason for the agency to require that respondents also maintain the records. Conversely, in the case of NRC licensees, if the licensee is required to maintain a record, the agency may examine the record during inspections and, therefore, should have no reason to require the licensee to submit the information. Two recordkeeping sections, 35.2045 and 35.2047, require information to be maintained that is virtually identical to the information to be reported in sections 35.3045 and 35.3047. Licensees commented that neither section 35.3045 nor section 35.3047 were needed. Because it appears that these sections cannot be deleted and still meet Congressional requirements, we suggest you delete the related recordkeeping sections. Section 35.3045 also contains a requirement to provide a copy of the section 35.2045 record to the referring physician. Because the only difference in the information required by sections 35.2045 and 35.3045 is that the record identifies the individual while the report does not, we suggest that section 35.3045 be amended to require that the NRC report be annotated with the individual's name and forwarded to the referring physician. This would obviate the need for NRC to require the record because all information required by the record would be provided to the physician. One would expect the licensees to maintain the records required by the proposed sections 35.2045 and 35.2047 as a part of good business practices. Should you decide to keep the two subject recordkeeping sections in the final rule, you must strongly defend your position in the preamble to the rule and in the OMB clearance package, but understand that OMB may reject these provisions.

We recognize that, overall, the changes made in the final rule have produced a vastly improved rule. However, attached for your consideration is a list of suggested rule changes, areas where the preamble should be strengthened, and some editorial comments for clarifying the rule language or correcting minor errors. We are submitting our comments on the final rule clearance package directly to Sam Jones of your staff. However, we have not addressed sections 35.2045 and 35.2047 of the clearance package pending resolution of the rulemaking issue.

We have placed the rule on hold with the Office of Administration pending OCIO approval of the OMB clearance package. We will continue to work with you and cognizant staff to finalize the submittal. Should you have any questions on our concerns and comments, please contact Beth St. Mary at 415-5878 or e-mail bcs.

Attachment:
As stated

cc: D. Meyer, ADM
D. Flack, NMSS
D. Cool, NMSS
F. Cardile, NMSS
J. McCausland, NMSS