(9)

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

April 29, 1998

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

FROM: Edward L. Halman, Director
Office of Administration

SUBJECT: OFFICE CONCURRENCE ON A PROPOSED RULE ENTITLED "MEDICAL USE OF BYPRODUCT MATERIAL; PROPOSED REVISION"

The Office of Administration (ADM) concurs, subject to the comments provided, on the package that presents a proposed rule that would amend the Commission's regulations governing the medical use of byproduct material in 10 CFR Part 35. We commend the Part 35 Task Force for producing a high-quality proposed rule package in view of the scope of this effort and the time allocated for its development. We have attached a marked copy of the package that presents our comments.

The Regulatory Flexibility Analysis must provide sufficient information to support the contention that the proposed alternative is the least costly alternative that adequately protects workers and patients from radiation exposure. The Regulatory Flexibility Analysis should be expanded to --

- Emphasize the findings of the preliminary regulatory analysis indicating that the total cost of the proposed requirements to licensees would be a considerable reduction when compared to the costs imposed under the current regulations;
- Emphasize that the proposed rule would permit licensees much greater flexibility in complying with the proposed requirements;
- Note that actual costs to a specific licensee will depend on the modalities that the licensee intends to use; and
- Indicate that there is a relationship, if not a definite correlation, between the size of a licensee and the modalities the licensee uses and that, as a result, smaller licensees would generally incur smaller compliance costs.

We have revised the Summary statement and the headings of the document to comply with the publication requirements of the Office of the Federal Register (OFR). We have also adjusted the presentation of regulatory text, the codification pattern within the regulatory text, and the cross-references used within regulatory text as necessary to conform to the OFR's publication requirements and accepted style.

The discussion of proposed amendments in the Supplementary Information section should reflect this stage of the rulemaking proceeding by indicating that the amendments being

discussed are contemplated and may be subject to further change. We have edited this section so that the language is more appropriate to this stage of the rulemaking proceeding.

When your staff prepares the list of documents centrally relevant to this proposed rule that is required by NRC's regulatory history procedures, please instruct them to place the designator "AF97-1" in the upper right-hand corner of each document concerning the proposed rule that is forwarded to the Nuclear Documents System.

If you have any questions concerning this matter, please have a member of your staff contact David L. Meyer, Chief, Rules and Directives Branch, at 415-7162 (DLM1) or Michael T. Lesar, ADM, at 415-7163 (MTL).

Attachment: As stated