Ref: SA/LAB

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

August 31, 1982

MEMORANDUM FOR: Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety, NMSS

FROM: G. Wayne Kerr, Director
Office of State Programs

SUBJECT: PROPOSED REVISION OF 10 CFR PART 35

We have reviewed the proposed revision of 10 CFR Part 35, Human Use of Byproduct Material and have enclosed some comments.

The Agreement States appointed two representatives, Mr. Whatley and Mrs. Blazek, who met with your staff and OSP staff on January 27, 1982. They expressed some concerns over the proposed modification of the rule as did a number of Agreement States in commenting on an early draft. Although some brief statements are made regarding these concerns on page 13 of Enclosure 3 to the staff paper, it is not obvious that the concerns of the States have been fully considered and they have not been addressed in the body of the staff paper.

The Executive Board of the Conference of Radiation Control Program Directors (CRCPD) met recently and expressed their concern over the proposed revision. They have appointed an ad hoc committee to review the draft of the proposed rule. The States' concerns generally relate to the concept of self-regulation as opposed to a more detailed pre-licensing evaluation of applicant qualifications, procedures and equipment by a regulatory agency. This is reflected in the draft proposed rule by major emphasis on a post-licensing inspection program as opposed to a prelicensing evaluation. The bottom line, as I see it, is whether the effort should be applied at the pre-licensing stage vs. the post-licensing stage and which method is more efficient and cost effective.

In our memorandum of June 14, 1982, copy attached, we commented that the staff paper should include a cost analysis on the effect of this revision on the material inspection program. We do not see that this has been addressed in the current paper. States are concerned that NRC inspection

efforts under the new rule will be minimal based on the historically low priority for inspection of medical licensees by the NRC. We believe a revised inspection priority system reflecting the need for increased inspection effort should be submitted in conjunction with this paper.

Although Enclosure 3 states that this rule will not be a matter of compabilitity, there is no question it sets precedents that may ultimately impact on the Agreement State programs.

We are not opposed to publication of the proposed rule for comment at this time but believe the paper should more fully address the comments made by the Agreement States. In addition, it would be useful for your staff to prepare a summary of Agreement State's positions accepted or rejected and the related rationale that we could send to the Agreement States at the time of publication.

G. Wayne Kerr

G. Wayne Kerr, Director
Office of State Programs

Enclosure:
As stated

cc: L. Cobb, IE, w/encl.

ENCLOSURE

Comments on Part 35 Revision - August 31, 1982

1. Page 8 of the Commission paper.

   We do not agree with the language at the top of page 8 and in lieu of that we would like the following:

   Since this rulemaking represents a change in licensing procedure related to medical operations conducted at fixed locations, the NRC does not plan to make it a matter of compatibility with respect to the Agreement States.

2. Page 10, enclosure 1. Definitions.

   The reason for including a definition of Agreement State should be changed to read:

   The term "Agreement State" was included to identify those States to which the Commission has relinquished the authority and the States have assumed the authority to regulate the safe use of byproduct, source and formula quantities of special nuclear material.

3. Page 10, enclosure 1. Definitions.

   The definition of "Management" should include safety audits as a management responsibility.