JUN 14 1982

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

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

SUBJECT: PROPOSED REVISION OF 10 CFR PART 35

The effort to revise Part 35 so as to provide for a clear and consolidated set of requirments for human use of byproduct material is commendable. Also, we agree with the approach of moving away from the "customized" review toward a more standardized method for medical licensing. We see no decrease in health and safety provided the entire system as described in the paper is implemented. We feel that since the preevaluation of applicant's equipment and procedures will be eliminated, it is essential that there be an early inspection of such licensees to identify any significant safety problems. The paper should stress that this is a key safety feature of the regulatory program and should layout the resources needed and the importance of having them available. In keeping with what we understand the NRC philosphy for regulations to be, we suggest that the regulations state performance objectives to be met. Detailed procedures or specifications for meeting the objectives, such as how survey instruments are to be calibrated, should be addressed in regulatory guides. We have several comments regarding the proposal which are provided in the enclosure to this memorandum. Provided our comments are satisfactorily addressed in the paper, we are prepared to concur. Since the Part 35 revision relates to a change in licensing practice, we do not plan to make it a matter of compatibility with the Agreement States.

The proposed revision has been sent to the Agreement States for comment. We expect that the consensus opinion of the Agreement States will be negative because of the shift, from a custom review of each application prior to the issuance of a license, to an increased empahsis on review of base program data during on-site inspections. We will continue to provide you with additional Agreement State comments as they are received.

Original signed by
G. Wayne Kerr

G. Wayne Kerr, Director
Office of State Programs

Enclosure:
As stated

Comments/Questions on the Proposed Revision of 10 CFR Part 35

1. Page 12 of Enclosure 1

It is anticipated that the revision of Regulatory Guide 10.8 for medical programs will contain at least one procedure acceptable to the Commission for meeting each of the requirements in the proposed regulations for human use. It is proposed that licensees who wish to use alternative, but equivalent, procedures may do so at their own discretion.

Comment

We believe that alternative procedures should be submitted for review and incorporated into the licensee file. This would insure that serious consideration was given to such procedures, whether by the licensee or by a consultant. We feel that too much confidence is being placed on the licensee's discretion.

2. Page 12 of Enclosure 1

Since procedures would no longer be submitted to NRC for review .... this simplification will permit licensees to modify procedures used by their professional staff to meet NRC requirements without obtaining a licensee amendment.

Comment

As noted above, too much is being left to the licensee's discretion. The submittal of data will, in our opinion, insure that proper attention is paid to the modification of procedures.

3. Page 7 of Enclosure 3, (1) (f)

An early on-site inspection of the facility and program for new licensees would be performed by licensing personnel.

Questions

The above statement needs amplification for the reader to understand how the new system will work. For example, will early on-site inspections be performed for all new applications and amendments involving major program changes? What is the timing for these inspections? How early are we inspecting? Will the financial and personnel resources of the Commission and the regions be able to support these extra inspections? We also feel that the staff paper should include a cost analysis on the effect of this revision on the materials inspection program

Enclosure

4. Page 41 of Enclosure 1, (a)(1)

Comment

Membership of the radiation safety committee lacks a representative of the nursing staff. This point was covered in the Notice of Final Rulemaking to amend 10 CFR Part 35.11(b), which we concurred in on May 26, 1982.