UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TEXAS 76011

JUN 07 1982

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

THRU: John T. Collins, Regional Administrator, Region IV

FROM: Glen D. Brown, Chief, Technical Program Branch, Region IV

SUBJECT: PROPOSED REVISION OF 10 CFR PART 35

As previously stated, we support the proposed revision of 10 CFR Part 35, however, we are of the opinion that the arguments set forth in the enclosures on the savings of NRC resources are overstated. By conducting post licensing inspections and the increased effort required for routine inspections we have only delayed the licensing review. In addition, since the enclosures emphasize that one of the reasons supporting the proposed rule is the high degree of understanding of technology and safety associated with medical uses of isotopes, the statement that the savings in licensing resources can be devoted to new safety issues does not make much sense. The savings in licensing resources in our estimation will have to be devoted primarily to the inspection process. Our evaluation of the weakness in justification of the benefits to the NRC are detailed in attachment B to this letter.

The benefits to the license applicant as stated appear to be valid and should be the impelling reason for the rule.

Our comments on suggested changes in the proposed rule are detailed in attachment A.

Glen D. Brown, Chief
Technical Program Branch

Attachments: As stated

ATTACHMENT B

Comments on Enclosures and the draft Commission Letter.

Commission Letter

Page 4

By definition, general licensees are low risk and have a low priority for inspection as individual licenses. Special inspection studies may be conducted to verify this assumption. Therefore, the statement concerning difficulty of being able to inspect is misleading.

Enclosure 1

Page 9

We assume since the licensee will still have to have procedures that consultants will still play a role.

Page 13

Are post licensing visits part of the inspection process or the licensing function. With regionalization this is probably academic.

Page 14

After attending a briefing by Sandia Corporation on MIS held June 2, 1982, we are of the opinion that the logic presented for adaptation to MIS is exaggerated. MIS could be of benefit to the present licensing process.

Page 17

A nursing service representative is not included in the proposed rule of the composition of the Radiation Safety Committee.

Enclosure 3

Page 9

These are not standards but regulatory requirements.

35.70(a)

What is a low range meter? It would be better to specify capability of detecting 500 dpm/100 $cm^2$, etc. Term also used in paragraph 35.80(e) and 35.92(a)(2).

35.70(c)

Why keep records at all? Our inspection interval exceeds one year.

35.606(e)

Is an amendment really necessary for removal?

35.621(f)

What is promptly? Five minutes, one day, one week?

35.641(a)(1)

An acceptable method for determining the average is not specified.

35.900

This whole section as to what constitutes criteria for the RSO is confusing. Section 6 for example appears to satisfy qualification is one area, however, the duties of the RSO are much broader since an institutional licensee usuallly has only one RSO. Also, section (d) implies that the RSO must have the specified training, yet section (a) states that the listed certification(s) fill the bill. At worst, this section should state "either-or" criteria.

35.961(b)

The American Board of Health Physics is not mentioned here but appears on the application form.

Errors

Page 37 item (6) take out one and in sentence on "mobile service"

Page 40 35.30(b) change on to in.

ATTACHMENT A

PROPOSED REVISION OF 10 CFR PART 35

35.15 Definitions

RHM is used in paragraph 35.644, however, this acronym is not defined in the proposed rule.

35.31(a)(2) Radiation Safety Committee

Quarterly may be too frequent for a small diagnostic program.

35.32(e)

What happens when RSO is absent? Can he preauthorize?

35.32(h)

How about procedures for receipt and opening of packages; dose calibration tests, and quality control to prevent misadministration?

35.51(a)(1)

Does this mean that each licensee must have an ionization chamber instrument?

35.51(a)(2)

What types of sources and activity levels are required?

35.51(d)

Most survey instruments are used intermittently during the work shift. What constitutes a use? Perhaps a work shift check is sufficient.

35.52-57

Are these paragraphs reserved or missing?