STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

[redacted]

Pls forward cy to NMSS

DW

Department of Health
CANNON BUILDING
Davis Street
Providence, R.I. 02908

10 November 1982

Mr. Donald A. Nussbaumer
Assistant Director for State Agreements Program
Office of State Programs
United States Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Nussbaumer:

This is in response to your memorandum of 8 September 1982 which requested comments on the second draft of the proposed revision of Part 35. We have reviewed it, along with the comments prepared by the CRCPD ad hoc committee dated 27 September 1982.

We find ourselves in agreement with the concerns of the ad hoc committee. While it is true that much improved equipment and procedures have become available to the nuclear medicine field, our experience indicates that license applications nevertheless contain procedures and equipment which are inadequate or inappropriate. These faults seem to occur even when consultants are involved in preparing applications.

Our objection to making license review an inspection task is also based upon our experience with X-ray facilities. These facilities are presently regulated under a system similar to that proposed for Part 35. That is, they may operate after filing a simple application and agreeing to comply with the X-ray regulations. There is no detailed review of their operating procedures at registration. This regulatory system results in periods of operation during which health and safety are not adequately protected. Much noncompliance could be eliminated by a pre-registration review similar to the materials licensing process. In the state radiation control program we are trying to elevate X-ray safety to the level experienced by radioactive material licensees. From our perspective, the method proposed for implementing Part 35 will serve to compromise that standard of compliance, causing nuclear medicine safety to deteriorate to the level of the X-ray situation.

In summary, we support the idea of codifying universally accepted standards for safe use of radioactive materials. We cannot spport the cessation of pre-licensing review on the basis of our experience with medical licensees and X-ray facilities.

We agree with the majority of the technical comments made by the ad hoc committee and wish to make a few additional comments, which are attached to this letter.

Sincerely,

COMMUNITY HEALTH SERVICES

James E. Hickey

James E. Hickey, Chief
Division of Occupational Health
and Radiation Control

dls

attachment

35.15 "Institution" was not previously defined in the regulations and institution licenses were granted only to hospitals. The new definition of institution would appear to include entities other than hospitals, such as clinics, group practices, etc. Does NRC not intend to license such entities as institutions, thus requiring a radiation safety committee and a management structure?

35.30 (b) Involvement of the Radiation Safety Committee per se with the ALARA program is not specified. The required involvement of "all authorized users" in the ALARA program should be organized by that Committee.

35.31 The management representative should be ex officio chairman of the radiation safety committee and should also have line authority over all authorized users. The committee should be required to have written operating procedures (by-laws) specifying how it will fulfill its responsibilities.

35.51 Survey instrument calibration requirements should include all instruments that will be used for the surveys required by 20.201. Examples are laboratory instruments used for leak tests, smears and bioassays, air sample analysis (including calibration of the air samplers), and ventilation measurement instruments. Our experience has been that licensees tend to overlook these calibrations or cannot document their existence.

General: Subparts F and G should contain requirements for the licensee to have written operating procedures for using groups V and VI. For some reason, only nursing procedures have been included in Regulatory Guide 10.8. However, revision 1 of NUREG-0267 outlines appropriate procedures.