PROPOSED RULE PR-30,31,32 etal. (50 FR 30616) (98)

STATE OF NEW YORK
DEPARTMENT OF HEALTH
ALBANY

DAVID AXELROD, M.D.
COMMISSIONER

'85 DEC -9 P1:15

December 4, 1985

Gentlemen:

Re: 10 CFR Parts 30, 31, 32, 35 and 40

The Department of Health staff have reviewed the proposed changes to 10 CFR Part 35, "Medical Use of Byproduct Material."

While we find the proposed changes to improve the licensing process on the whole, some of the provisions do not appear desirable and others should be modified. Specific comments on these changes are attached.

We appreciate the opportunity to comment on these proposed regulations.

Sincerely,

David Axelrod, M.D.
Commissioner of Health

Secretary of the Commission
US Nuclear Regulatory Commission
ATTENTION: Docketing and Service Branch
Washington, D.C. 20555

Att.

DS10
add: Kerman & McElroy, 39655
Wm. Olmstead, 9609MNBB

DEC 23 1985

Acknowledged by card.....

COMMENTS ON THE PROPOSED REVISION OF 10CFR PART 35
"MEDICAL USE OF BYPRODUCT MATERIAL"

The proposed revision makes major changes in the Nuclear Regulatory Commission's process for licensing and regulating the medical use of radioactive material. Essentially it consolidates the radiation safety requirements presently contained in regulations, common license conditions, regulatory guides and staff positions. It will allow licensees more flexibility in updating their radiation safety procedures and reduce the time that must be spent reviewing applications.

On the whole, it appears that this will significantly improve the licensing process; however, some of the provisions do not appear desirable and others should be modified in our opinion. It should be noted that at the present time, the contents of Part 35 are not a matter of compatibility between NRC's and New York State's regulations.

Comments on Specific Code Sections

35.30 - An ALARA (as low as reasonably achievable) program should be required of all licensees, not just institutions. The required yearly review could be performed by the individual Physician-Licensees. Almost all of these have technologists and/or consultant Physicists to whom they delegate some of the duties of Radiation Safety Officer. A formal review requirement would at least require Physician-Licensees to check all aspects of the safety program on an annual basis. A written report should be generated and maintained for inspection.

35.36(a) - Changes in areas of use of radioactive materials within a building should require an amendment to a license. A licensee could initiate and cease use in an area between inspections and if records were not kept, we would never be aware of it or inspect it for residual contamination. This is not a change that many of our licensees make often so it should not inconvenience their programs to have to apply for an amendment first and it would not have a sigrificant impact on the licensing workload.

35.2(b) and 35.38 - If any physician could perform Nuclear Medicine diagnostic procedures and radiation therapy procedures under the "supervision" of an authorized user, it would invalidate the training requirements of Subpart J unless it were specified that this had to be in the course of training or tutelage. It would be a disincentive to physicians to acquire the training necessary to qualify as authorized users and may make it difficult for physicians who have such training to obtain positions if it is more economical for hospitals to staff with less highly trained individuals under the supervision of a single authorized user. This would appear to be a disservice to patients.

35.200 - Many problems related to ventilation requirements have been encountered during the licensing process for the use of radioactive xenon gas. It does not appear prudent to have its use approved without specific evaluation of the licensee's procedures and physical plant.

35.310 and 35.410 - There should be a specification for when safety instructions shall be given. A phrase such as "immediately prior to the treatment" should be inserted after the word "therapy" at the end of the first sentence.

35.406(c) - A requirement should be added for comparing the survey meter reading to the value calculated from the specific gamma-ray constant as recommended on page 18 of NCRP Report No. 40.

35.620 - A portable ion chamber survey instrument should be required. If a low level GM meter were carried into a room where the teletherapy source was exposed, the meter could saturate and erroneously indicate that no radiation hazard was present.

35.633(e) - To make the intent clear, it would be more accurate to say "the qualified therapy calibration expert shall promptly notify the licensee in writing of the results of each spot-check, or the results of the expert's review of each spot check made by the licensee".