Colorado

COLORADO DEPARTMENT OF HEALTH

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Governor

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Executive Director

October 18, 1982

Mr. Donald A. Nussbaumer
Assistant Director for State Agreements Program
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Nussbaumer:

This letter is in response to the proposed revision of 10 CFR Part 35 "Human Uses of Byproduct Material" and its subsequent amendment.

The consolidation of Part 35 and Regulatory Guide 10.8. is welcome and necessary. Our concern is not with the content, but with the changes in licensing procedure that goes with it. These proposed revisions, taken as a whole, are inappropriate; they will not eliminate the problematic licensing burden, but will simply transfer the burden onto compliance inspectors.

Licensees will not be inspected as soon as its license is issued. Under these revisions, the licensee may use radioactive material for months, if not a year or more, before the licensee's radiation safety program can be evaluated by inspectors. This situation could seriously compromise the welfare of staff and the patients in the hospital.

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In addition to be above comments, I would like to comment on the following portions of 10 CFR Part 35 Revision 2:

35.2 Inclusion of General Licensees is a good move. They will be easier to inspect and control.

35.51 It has been the policy of this Division to require yearly calibration checks for G-M meters. We cannot condone this provision.

35.58 In-House calibrations seem to be automatically ok'd here without regard for professional competency or calibration procedures.

35.70 There is no mention here of wipe tests for contamination.

35.80 The regulations should require the delivery of an accurate quantity of radiopharmaceuticals but not preclude methods of accomplishing this.

35.100.8 Does an IND constitute authorization by the FDA? Is the FDA prepared to take up the slack in the Agreements States Program?

35.630 This should be rewritten to clairfy that calibration is to take place every 4 years with an interm calibration or intercomparison to take place at the two year midpoint.

With the proper modifications, the proposed revision to Part 35 will be a valuable licensing tool for the U.S.N.R.C. and Agreement States alike.

Sincerely,

Albert J. Hazle, Director
Radiation Control Division

AJH/LAD/kp