ARIZONA
RADIATION REGULATORY AGENCY

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June 10, 1982

Mr. Lloyd A. Bolling
Office of State Programs
U.S. Nuclear Regulatory
Commission
Washington, D.C. 20555

Dear Mr. Bolling:

The Agency staff and I have studied the proposed revision to 10 CFR 35 on Human Use of Byproduct Material (transmitted on May 13, 1982, by D. A. Nussbaumer). The following comments are considered germane:

1. Specific Section Comments

   a. 35.51(b)(1) - "all" should be defined.

   b. 35.70(b) - survey must be required before removal.

   c. 35.900(a) - Groups identified in (2), (3), (4) and (6) may not have either the education, training or experience to qualify per se.

      35.900(b) appears to be a circular definition and, as such, is unacceptable.

      35.900(c) and (d) appear to be incompatible unless both apply.

2. Since radiological health is a matter of education, training, experience and attitude, it is recommended that 35.900(a) and (b) be deleted and 35.900 shall specify only requirements given in (c) and (d). We also urge that, with the exception of small quantity users (lowest risk group), the definition of RSO, given as the proposed 35.15, be reworded to include words to the effect "the individual is a full-time professional staff member".

3. The definition of "Mobile Service" is felt to be weak. The following is offered in substitution:

   "Mobile Service" or "Mobile Nuclear Medicine Service" means the transportation of radiopharmaceuticals and associated medical instrumentation to, and usage at, two or more separate locations.

4. It is also suggested that the recordkeeping requirements be reviewed for required retention times. Appropriate records should be retained permanently; all others should be required to be retained a uniform five (5) years. This will simplify recordkeeping and disposal.

5. Even though the document states that the proposed revision of Part 35 will not be made a matter of compatability, the following thoughts should be considered:

   (a) The placement of Human Use licensing requirements in a single document does not insure an effective licensing program. In fact, it may bury the significant items that the licensee should address which are now addressed in individually prepared actions.

   (b) Accordingly, due to less inspections and less attention to individual licensee needs, the future noncompliance items will probably rise.

   (c) Cost effectiveness can be achieved by withdrawal from any program.

   (d) Apparently, the inspection process will be directed to a single initial inspection, with the Management Information System used to determine future problems.

To summarize, the Agreement State programs devoted to individual licensing action and timely on-site inspection, are considered to be far superior in achieving a legitimate health and safety program for the concerned citizenry.

Sincerely,

Charles F. Tedford

Charles F. Tedford
Director

CFT:jr