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ARIZONA
RADIATION REGULATORY AGENCY

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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~~ Don:

The review has been completed on the revised proposed revisions to 10 CFR Part 35. The following comments are offered in regard to adoption.

1. In Enclosure No. 1, the Draft Federal Register Statement on Page 11 in the paragraph entitled "Enforcement" - in the next to the last line the following phrase is noted: "... would subject the individual to an enforcement action." (underline added) The current NRC practice is to direct enforcement actions against the licensee as a person and not against individual users or employees of the licensee. The statement above, however, suggests that the NRC is contemplating enforcement action directly against individuals who use radioactive material rather against the license holder.

2. In Enclosure No. 1, on Page 19, in the section entitled "Records Retention", the second paragraph - it is noted that radiopharmaceutical dosage records relate directly to the care of individual patients. Accordingly, the disposal of these records at an early date may not be consistent with the requirements of a State Medical Practice Act. The records retention provisions should be changed to require patient dosage records be retained indefinitely, or at least as long as required by other applicable law.

3. In 35.17(d) - current license practice allows group licencees in groups 1 and 2 to possess materials in amounts "as needed". The wording here suggests that NRC will change its licensing practice to specific numerical limits for these materials. If this is the intent, the economic impact of this change should also be considered.

4. In 35.30, concerning the ALARA program - the provision here exempts private practioners from the requirement to have a formal ALARA program. The proposed revision to 10 CFR Part 20, however, will require that every licensee have a formal ALARA program. How will the conflict between these two provisions be resolved?

5. In 35.32, concerning the Radiation Safety Committee - NRC should justify the requirement that numerical results of all ballots be recorded in the committee minutes. The staff is unable to ascertain how the fact that a procedure was approved on a vote of 4 to 3 will contribute any more or less to radiation safety than the fact that the same procedure may have been approved by a vote of 5 to 2.

6. In 35.38, on Supervision - the provision should be re-worded to require that the Radiation Safety Officer and the Radiation Safety Committee, if appropriate, evaluate and approve any procedures for supervision of individuals, as well as the qualifications of individuals supervised, prior to allowing them to commence their duties. In particular, the RSO should review the instructions given to these workers to insure their adequacy and completeness.

7. In 35.50(b)(3), Dose Calibrator Linearity Testing - the tests should be conducted between 10 microcuries and the highest dosage that will be ordinarily administered, rather than the highest dosage that would ever be administered. Also, in 35.50(c)(4) - if results of a geometric dependency test are supplied by the manufacturer, these should be retained by the licensee and no further geometry dependency test required.

8. In 35.50, Dose Calibrators - the NRC should adopt a position statement on the temporary use of radiopharmaceuticals without checking calibration as a "continuation of service" when the licensee's dose calibrator fails unexpectedly and can not be used or immediately replaced.

9. Can 35.50 and 35.53 be combined, or renumbered to form adjoining rules?

10. In 35.51(b)(2), Requirements for Survey Instrumentation Calibration - it is recommended that this be changed to read "Calibrate two readings seperated by 50% of full-scale reading on each scale that must be calibrated; and ...".

11. It may be in order to define "low-range survey meter" as one which has a most sensitive calibrated scale having full-scale reading not greater than 1 mR/hr. This could effectively be done in 35.120 by changing the word 'level' in line 3 to the word "range".

12. In 35.92, Decay-in-Storage - it is recommended that the provisions of sub-paragraph (a)(1) and (a)(2) both be required, and that a provision be added to read "or; (a)(2)(i) May dispose of material held less than 10 half-lives if survey with a very low-range survey meter of material held in small unshielded containers finds no radiation level that exceeds twice the measured background level. For the purposes of this rule a "very low-range survey meter" would be defined as one with a calibrated range with full-scale reading not greater than 0.1 mR/hr and small containers would be defined as 3 cubic feet or less."

13. In 35.200, Subpart E, Imaging and localization (Group II/III) - the list of authorized materials contains a number of materials which are no longer in routine use having been superceded by materials which are more suitable under most circumstances. Some of these materials may be best suited for use with equipment which is no longer part of an ordinary practice, i.e., scanning devices with thick scintillation crystals. The staff believes that these materials should be removed from the group authorization. It is presumed that the materials can be added as specific license items in cases where a particular need is expressed and suitable equipment is available.

14. In 35.200, Subpart E, Imaging and localization - the staff most emphatically does not concur with the use of Xenon-133 as a group material. No other material in the group requires evaluation of a licensee's ventilation system. As a minimum, evidence of compliance with 35.205 should be demonstrated before authorizing the use of Xenon gas.

15. In 35.220, Survey instruments - recommend changing the word 'level' in the second line to the word "range". Why is it specified that the survey instrument with a full-scale deflection 1 R/hr be an ionization type? Does this suggest that only ion-chamber type instruments are not suitable for the lower ranges?

16. In 35.420, Survey instruments (for implant therapy) - suggest that a low-range survey meter should be available for use with Iodine-125 seed implants. It is also suggested that the licensee should

be required to assure that the energy response of the survey meter is adequate for use with Iodine-125.

17. In Enclosure No. 4, Part 4, the following paragraph describes the anticipated consequences of the proposed actions in Arizona.

> "Arizona would have to partially re-train the staff to orient inspectors to seek compliance with general rules rather than specific license conditions. The Agency would also increase pre-licensing inspections of medical licensees to approximately 100% since additional judgment of licensee actions in compliance is required to evaluate the adequacy under a more flexible rule. It is anticipated that additional time and effort during inspections would be required. Considering the economic impact of the presence of an inspector in the licensee facility, the total regulatory impact of this action on Arizona licensees may actually increase rather than decrease."

18. Why does the draft regulatory guide refer to Section 35.11 (table 1 on Page 9)? This section does not exist in the draft regulations.

19. As a general comment to the concept of group licensing - could the regulations be simplified by listing only the isotope to be possessed and a general type of use (i.e., imaging) permitted? In Part 35.49, Suppliers - the licensee is limited to acquisition of radiopharmaceuticals containing radioactive material distributed under a specific distribution license. Since the distribution license would specify the chemical and physical form of the pharmaceutical, its intended use could also be specified at this point. The group licensees could then be restricted to using only those radiopharmaceutical forms and using material only for those purposes authorized in the distributor's specific license. Addition of radiopharmaceuticals or new uses would require only amendment to the distributor licenses, rather than amendment to the regulatory framework.

In summary, considerable progress has been made in the effort to revise and update the Part 35 regulations. Considerable additional effort is required before the regulations are published in final form.

Sincerely,

Charles F. Tedford

Charles F. Tedford
Director

CFT/gej