UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

pt 1 = 2182
mem

September 16, 1982

NOTE FOR: Jim Lieberman, ELD

FROM: John Klucsik, ELD JK

SUBJECT: REGULATION AND LICENSING OF TECHNOLOGISTS IN NUCLEAR MEDICINE

In our recent phone conversation we discussed portions of the proposed Part 35 which deal with the activities of unlicensed medical technologists and the supervising physicians who would be identified on a hospital license. I understand your concern to be over the proposed rule's recognition of the technologist's activities and the imposition of regulatory requirements upon the technologist and the authorized (physician) user of byproduct material, rather than upon the (hospital) licensee.

Proposed section 35.2(a) includes the standard prohibition against handling material except in accordance with a license. If nothing further were said, several choices would be available:

1. The unlicensed technologist could be precluded from handling material;

2. Each license could expressly authorize material-handling by identified technologists;

3. Each license could be interpreted to authorize or could expressly authorize material-handling by any agent of the licensee;

4. The regulations could expressly authorize material-handling by any agent of the licensee; or

5. The regulations could expressly authorize material-handling by any agent of the authorized (physician) user under his supervision.

Option 5 is the approach embodied in the proposed revision of Part 35. I understand option 3 to be the one you favor.

CONTACT: 43295

Option 1 would disrupt the delivery of nuclear medicine services. Option 2 would be administratively cumbersome and as a practical matter would not work (although this is the system which is and would continue to be used for physicians).

Options 3 and 4 would follow the model used in reactor licensing. The licensee would be responsible for the acts of his agents. This approach will work in the medical setting if the agency relationships there are the same as those in the utility setting. Often they are not. Frequently, the hospital is the licensee. Physicians who are not on the hospital staff (are not agents of the licensee) may have practice privileges at the hospital and may be identified on the hospital's license as persons authorized to perform nuclear medicine procedures there. The technologist may be on the hospital staff but will take direction from the independent physician. (The technologist may be a borrowed servant when carrying out the independent physician's orders).

Options 3 and 4 would place civil liability upon the licensee hospital for actions of its borrowed servant, taken under the direction of a physician who was performing no service for the hospital and whom the hospital could control only by denial of his practice privileges. The principal drafters of the proposed revision of Part 35 believe that fixing liability upon a licensee who may have little practical control over how byproduct material is administered to patients will not result in the desired patient and worker safety regardless of the level of enforcement activity or the magnitude of the penalty imposed.

I believe that relying on an agency relationship between the violator and the licensee may present substantial evidentiary problems. One would have to establish the agency relationship between the licensee hospital and the authorized user physician (which may not exist); and between the licensee hospital and the technologist (which may not exist if the technologist is a borrowed servant or if the technologist is supplied by an independent nuclear medicine service). These problems are compounded if the licensee is such an independent service. Such a service would have absolutely no control over the authorized user (physician) regardless of whether he was on hospital staff or was an independent practitioner.

Option 5 avoids at least some of these problems by placing liability at the point of control. The authorized user

directs the technologist when the technologist is administering material. (See § 35.38). Where the licensee is more likely to have direct control, the duty of compliance is upon the licensee (see §§ 35.53, 35.70).

I understand you to have some reluctance to impose civil penalties upon impecunious technologists. You have noted that radiographers are in a similar position and that we there impose the penalty upon the licensee employer or principal. There are two differences. One is in the agency relationship discussed above. The other is in the effect of noncompliance. A radiographer's noncompliance may result in overexposure of himself and a piece of pipe. A medical technologist's or authorized user's noncompliance may result in overexposure of himself and the patient. The principal drafters believe it appropriate to place liability squarely upon those who have direct control over administration of material to patients. You should note that the duties placed directly upon authorized user physicians and supervised technologists relate only to the actual administration of material to patients. See §§ 35.200, 35.300, 35.400, 35.500. Other duties relating to surveys, calibrations, etc., are generally imposed upon the licensee.

After you have had a chance to review the attached portions of the propose Part 35, please give Bill Walker, FCML, a call to schedule a conference among the three of us, Leo Higgenbotham, IE, and members of Bill's task force as appropriate. Bill can be reached at X-74232.

Attachment:
Portions of Proposed
Part 35

cc: W. Walker, FCML
N. McElroy, ORPBR ✓
L. Higgenbotham, IE
T. Dorian, ELD