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

September 1, 1982

MEMORANDUM FOR: R. E. Cunningham, Director
Division of Fuel Cycle and Material Safety, NMSS

FROM: Richard C. DeYoung, Director
Office of Inspection and Enforcement

SUBJECT: PROPOSED REVISION OF 10 CFR PART 35 (YOUR MEMO DTD 8/17/82)

We support the principal objectives of the proposed revision of Part 35. These are to consolidate in one place the scattered requirements pertaining to medical licenses, give licensees more flexibility in the operation of their regulated activities while protecting public health and safety, and to reduce the regulatory cost to the NRC and the licensees. Obviously much thought and effort have gone into this project. However, at this time we are unable to concur with the proposed rule as drafted for the following reasons:

1. We believe that generally NRC requirements should be placed on the institution that holds the license, not on named individuals or positions in the licensee organization. The licensee should have the flexibility to decide how best to meet the NRC requirements. Although it may be necessary to specify requirements that individuals in the organization must carry out, these should be few in number and imposed only when there is no reasonable alternative. The goal should be to require the licensee itself to meet the performance standard, not to prescribe the duties of individuals in the licensee organization. In our opinion, the proposed rule departs significantly from the basic concept. Examples of this problem are found in §35.2(b); §35.31(a)(5); §35.32(c), (e), (g) and (i); and §35.38(a) and (b).

2. We disagree with the calibration requirements as stated in §35.51. There is no basis for the distinction made between ion chamber and other instruments regarding calibration frequency. The last statement in §35.51 of the rule summary is misleading. The basis in §35.51 of the rule summary for the 500 mr/hr calibration threshold is weak; there are several situations in nuclear medicine programs where higher exposure rates are encountered. We do not agree with the concept of including all details of calibration in the rule; there should be a general requirement in the regulation with details or acceptance standards spelled out in a regulatory guide.

Enclosure 1 contains a detailed explanation of our nonconcurrence. Enclosure 2 contains other items with which we do not agree but not to the point of nonconcurrence. Enclosure 3 contains other comments on the rules and supporting documents.

We would be happy to meet with you or your staff if this would be useful in resolving our major concerns.

James H. Smith/for

Richard C. DeYoung, Director
Office of Inspection and Enforcement

Enclosures: As stated

cc: P. G. Norry, ADM
G. H. Cunningham, ELD
G. W. Kerr, SP
Regional Administrators

ED Flack

Enclosure 1

Disagreement; do not concur.

1. §35.2 License required.

Subsection (b) states, "An individual (emphasis added) may receive, possess, use, or transfer byproduct material under the supervision of an authorized user as provided in §35.38."

This is an unusual and unique statement to appear in a licensing regulation, particularly when considered along with the supporting statement in the summary section (§35.2) of the rule and companion requirements included in §§35.38, "Supervision," of the rule itself.

> The supporting statement in the rule summary reads, "Individuals who are employees of a licensee and who are working under the supervision of an authorized user do not need a license. This does not relieve them of the requirement to conduct their work in accordance with the license and the regulations of the chapter."
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> One of the companion requirements in §35.38 states, "The authorized user supervising the unlicensed (emphasis added) receipt, possession, use, or transfer of byproduct material authorized by §35.2(b) shall: ..."
>
> The other companion requirement in §35.38 states in part, "The supervised individual receiving, possessing, using or transferring byproduct material under §35.2(b) shall: (1) follow instructions ..., (2) follow the procedures ..., and (3) comply with the regulations ..."

Summary

The statement in §35.2(b) of the rule is not necessary and should be deleted. One reason is the very statement (quoted above) used in the rule summary to justify and support the particular statement. Issuance of the license bestows on the licensee the responsibility to ensure that its employees conduct their work safely and in accordance with the license and regulation.

Another reason is a statement in the companion requirements of §35.38(a), which is indeed an odd one. It implies that the (§35.2(b)) individual employee of the licensee is performing an unlawful (unlicensed) act because the employee (personally) does not have a license or is not specifically named on a license. There is also the implication that we believe individual employees should be licensed but are exempting them under §35.2(b). While yet another implication is that the "authorized user" is specifically licensed by the fact of being "named" in the license.

The requirements in §35.38(b) are unnecessary details for a regulation, and an intrusion into the responsbility bestowed on the licensee by issuance of the license.

If the objective of the statements and requirements in §35.2(b) and §35.38 is to clarify the condition of use of material "by and under the supervision" of the authorized user, then we haven't been entirely successful -- the minor exceptions being the last three statements in §35.38(a). If this is the objective, we suggest another review of problems experienced with that license condition in the past, along with careful consideration of the exact conditions of supervision we want to impose on the licensee. We believe this can be done in the rule without a statement such as that appearing in §35.2(b) and with requirements other than that appearing in the prepared §35.38.

2. §35.31 Radiation Safety Committee and §35.32 Responsibilities of the Radiation Safety Officer.

Subsection (a)(5) of §35.31 requires the Radiation Safety Officer specifically to maintain copies of the minutes of meetings of the Radiation Safety Committee. Subsections (e), (f), (g), (h), and (i) of §35.32 collectively require the Radiation Safety Officer specifically to: authorize the purchase, receipt and distribution of byproduct material; establish and maintain a recordkeeping system for all records required by the rule; to maintain certain specified records; and to establish and implement written policy and procedures for specified operations.

While we agree these requirements should be included in the rule, we disagree with the approach of imposing those requirements on a specific individual in the licensee's organization. This is, in our view, an unnecessary intrusion into the responsibilities and prerogatives of the licensee.

3. §35.51 Calibration and check of survey instruments.

Subsection (a) requires ionization chamber survey instruments be calibrated annually and following repair and other survey instruments be calibrated on receipt and following repair. Subsection (b) contains conditions under which the requirements in (a) are satisfied, among which is the requirement to calibrate all scale readings below 500 milliroentgens per hour.

The supporting statement in the rule summary reads in part, "The 500 mr/hr limit was chosen because that is the highest radiation exposure rate which is likely to be encountered in the medical environment." ... "The more frequent calibration frequency for ionization chambers is consistent with ANSI N323-1978 Section 4.7.1."

There are three issues: (1) the distinction between ion chamber and other instruments regarding calibration requirements, (2) the 500 mr/hr threshold for calibration, and (3) the inclusion in the rule of details of "calibration requirements."

There is no good technical reason for the difference in calibration requirements and the agency, in its rules and guides heretofore, has never made such a distinction. Also, ANSI N323-1978 makes no distinction in types of survey instruments in specifying calibrations standards. Section 4.7.1 of ANSI N323-1978 reads, in entirety:

"4.7.1 Primary Calibration Frequency. All instruments shall receive the precalibration inspection described in 4.1 and the primary calibration described in 4.2 prior to first use. Primary calibration will be required at least annually even where the performance test requirements outlined in 4.6 are met. Where instruments are subjected to extreme operational conditions, hard usage, or corrosive environments, more frequent primary calibration should be rescheduled. Recalibration shall be scheduled after any maintenance or adjustment of any kind has been performed on the instrument. For this requirement, battery change is not normally considered maintenance."

The supporting statement for the 500 mr/hr "calibration threshold" is weak. There are several situations in nuclear medicine applications where higher exposure rates may be encountered. The application of certain brachytherapy sources is one, therapeutic doses of certain radiopharmaceuticals is another, and emergency situations in teletherapy facilities could present higher rates for extremity and whole body exposures. We realize certain difficulties in calibrating at higher exposure rates, but believe the specified threshold is not supported.

We do not support the inclusion in the rule of detailed calibration "standards." As with the position IE expressed in a similar requirement proposed for Part 20, we support a general requirement in the rules and the details expressed in a regulatory guide.

Enclosure 2

Disagreement; reluctant concurrence

There are two parts of the rule which should be broadened; broadened in the sense of removing certain detailed requirements and thereby placing the responsibility on the licensee. One of the areas involves the requirements specified for amendments in §§35.17(b) and (c), and the other involves the specific details included in §§35.60, 35.61, 35.62, 35.63.

§35.17 Amendments

This section requires the licensee to apply for and receive an amendment (as specified in (b) before the licensee permits a physician, other than a visiting authorized user described in §35.34, to work as an authorized user under the license, and (as specified in (c)) before the licensee permits an individual not listed on the license to perform the duties of the Radiation Safety Officer.

The supporting statement in §35.17(3) of the rule summary states these changes are potentially significant and require a license amendment so the Commission may determine that the training and experience of the new individual is sufficient to assure safe use of material.

We believe the licensee should be charged with the responsibility for assuring the qualifications of the authorized users and Radiation Safety Officer and made responsible for designating those persons without a license amendment. The following summarizes our agreement:

a. All the necessary qualifications and training standards are specified in the rule.

b. The licensee (actually the licensee's radiation safety committee) is already required to review and approve or disapprove any of these individuals prior to a license or amendment application.

c. The argument that the Commission must assure proper training and qualifications is weak, considering the degree of detail required to be submitted in the application. The application contains no more than a signed statement of the individual indicating, by checking off of a statement, how the individual meets the requirements. (See the proposed application form in the package.) Moreover, as explained in the Commission paper, the "review" by the Commission involves the use of a computer program scanning data entered from the application.

d. The requirement is inconsistent with that in §35.34, visiting authorized user, which allows licensees to permit visiting authorized users to use material under the terms of the license. Our agreement on this point (not given in detail here) involves the above points, and is essentially that the licensee is in a better position to determine and assure qualification of these individuals. Including them by name in the license seems an unnecessary requirement. There is a compromise which could be used and which we would be glad to advance.

§§35.60, 35.61, 35.62, 35.63

These sections are specific requirements for labeling and shielding of vials and syringes containing radiopharmaceuticals. The issue here is the "singling" out of these specific items for labeling and shielding. There are other things (besides labeling and shielding, and syringes and vials) equally important from the standpoint of safety, yet these are the only ones included in the rule.

We cannot and should not include all specific requirements in a rule, so why single out only these. Are they the most important?

Enclosure 3

Other Comments on the Revision

Page 2 of Commission paper. The word "national" in the 7th line should be changed to "agency".

Page 6 of Commission paper. The statement in the 18th line should read "... copy to the NRC Regional Office," not regional office of Inspection and Enforcement.

Page 7 of Enclosure 1. We agree with the statement in the 13th - 15th lines that, "In its inspection and enforcement role, the NRC would be concerned with whether the requirements in the regulations are being met, not with the details of the procedures used to meet them." We would add the words, "... be concerned with whether material is being used safely and the requirements in ..." We agree the inspection will not include a detailed examination of all procedures.

Page 7 of Enclosure 1. The statement in line 26 is overdrawn and should be qualified. We do not believe that all human use requirements have been included in the rule, nor should they be.

Page 9 of Enclosure 1. In the 6th line, we do not understand the term, "...Inspection and Enforcement orders, ..." in the context of the statement.

Page 12 of Enclosure 1. We have the same problem with statements in §35.18 as we have with the requirements in §35.17. This is explained in our Enclosure 2 in the comments for §35.17.

Page 13 of Enclosure 1. The supporting statement in the last sentence under §35.28 is weak. Our reason is the same as that given in our Enclosure 2 in paragraph c. under the comments for §35.17

Pages 19 and 22 of Enclosure 1. The statements regarding exempt concentrations and referencing §§30.18 and 30.71 are misleading and should be deleted.

Pages 44 and 45 of Enclosure 1. The definitions for "authorized user", "qualified teletherapy calibration expert," and "radiation safety officer" are incomplete. They should state, in appropriate words, that these individuals, by virtue of meeting the necessary training and experience requirements in the rule, are professionally qualified to carry out their specific duties.

Page 47 of Enclosure 1. The last sentence under §35.30(c) should be reworded. It states that, "the review and education must assure that individuals make every reasonable effort to maintain individual and collective occupational dose equivalent as low as reasonably achievable." For example, what reasonable efforts will be required of an individual to maintain the collective dose ALARA?

Page 49 of Enclosure 1. In the 4th line, subsection (6) should read, "(6) Review at least annually, with the ..."

Page 2 of Enclosure 2. The statement in line 14-16 is somewhat overdrawn by including the words "comprehensive safety requirements." Our reason is the same as given above for the word all on page 7 of enclosure 1.

Page 3 of Enclosure 3. We do not fully understand the statement in lines 2-4. For one point, we believe the relief from certain of the requirements for license amendments could be rectified by changing the licensing process or procedures without a change to the rule.