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September 11, 1985

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attention: Docketing and Service Branch

Re: Proposed Rule 10 CFR Part 35 -- Medical Use of Byproduct Material

Dear Sir:

I am writing to comment on the proposed re-write of 10 CFR 35 published in the Federal Register July 26, 1985.

Overall, I support the revision. I think that your stated objectives have been achieved. However, I have five specific comments.

1) 35.32 (a) (1) Membership of radiation safety committee

Masse and Miller ("Exposure to Radiation and Informed Consent," IRB 7(4):1-4, July/August 1985) suggest that membership on the committee that reviews applications that involve the administration of radionuclides to human subjects ". . . must include (1) a physician specialist in nuclear medicine; (2) a trained radiopharmacist; and (3) a radiation safety/dosimetry specialist (health physicist)."

Since these applications frequently involve non-routine situations, such as the use of an investigational new drug (IND), use in diseased patients who may have markedly different biodistribution patterns, use in patients concurrently receiving some type of drug therapy, etc., a trained radiopharmacist (nuclear pharmacist) would be the appropriate professional to provide valuable information and to assist in deliberations regarding patient and personnel safety in these cases.

Therefore, I suggest that trained radiopharmacist be added to the list of individuals included in this paragraph.

DS10
add: Norman L. McElroy, 3965 S
William Olmstead, 9604 MNBB

Acknowledged by card SEP 18 1985

2) 35.37 (d) Records of misadministrations

Many institutions assign a unique hospital identification number to each patient instead of using the patient's social security number. I suggest that this paragraph be reworded to include hospital identification number as an acceptable alternative to social security number.

3) 35.63 Vial shield labels

I strongly believe that the radiopharmaceutical name only on a vial shield label is inadequate for appropriate identification. For example, labels with the radiopharmaceutical name only would not discriminate between two vials each containing the same radiopharmaceutical. In this particular example, it would therefore be difficult, if not impossible, to meet the record-keeping requirements of 35.53 (c). Furthermore, the use of vial shield labels with only the radiopharmaceutical name may increase the likelihood of misadministrations. In fact, Samuel Pettijohn, in his "Report on Medical Misadministrations for 1981," concluded that "The primary contributing factors [to diagnostic misadministrations] appear to be simple errors associated with (1) labeling and identifying radiopharmaceuticals in lead shields . . . ."

Therefore, I suggest that vial shield labels include not only the radiopharmaceutical name but also the lot number (or other positive identifying information: activity, date, time, volume, expiration).

4) 35.92 (b) Records for decay-in-storage

Since 35.92 (a) (1) states storage time in terms of half-lives, I feel that storage time in terms of half-lives is an appropriate item of information for inclusion in the disposal record.

Therefore, I suggest that storage time in terms of half-lives be included in this paragraph as an acceptable alternative to "the date on which the byproduct material was placed in storage."

Since 35.92 (a) (2) states that the monitoring procedure be performed with a "low range survey meter set on its most sensitive scale," and since 35.120, 35.220, 35.320, 35.520, and 35.620 state that the licensee "shall have in its possession a portable low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour," I conclude that monitoring of decayed waste, by

4) 35.92 (b) Records for decay-in-storage (cont'd)

necessity, must be performed in an area having a background exposure rate of less than 1 milliroentgen per hour. At such low background exposure rates, I fail to see the importance of recording both the background exposure rate and the exposure rate at the surface of the waste container.

Therefore, I suggest that this paragraph be reworded to include, as an acceptable alternative to recording both the background exposure rate and the exposure rate at the surface of the waste container, the recording of the fact that the exposure rate at the surface of the waste container is equal to background.

5) 35.900 Training requirements for radiation safety officer

Nuclear pharmacists working in commercial nuclear pharmacies generally function as the on-site, day-to-day radiation safety officer. In fact, Joseph DelMedico ("NRC's Approach to Nuclear Pharmacy Education," American Pharmacy NS21:600-601, October 1981) has stated that "any individual who is named as an authorized user on a commercial nuclear pharmacy license is considered qualified to serve as radiation safety officer on that license or similar licenses." Further, DelMedico states that "At the present time, NRC's training and experience requirements for authorized users on nuclear pharmacy licenses are based on the criteria that we use for the physician or radiation safety officer of a hospital nuclear medicine department." Since radiation safety officers and physicians may qualify by being certified by various health physics and/or medical boards (35.900(a), 35.910(a), 35.920(a), 35.940(a), 35.950(a), 35.960(a)), I think that nuclear pharmacists who are appropriately board certified should also be qualified. Therefore I suggest that this section be expanded to include Board of Pharmaceutical Specialties in Nuclear Pharmacy.

Thank you for this opportunity to offer my comments.

Sincerely,

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and Clinical Associate Professor,
College of Pharmacy
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JAP/pd