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December 3, 1985

Secretary of The Commission
US Nuclear Regulatory Commission
Washington, DC 20555

ATTENTION: Docketing and Service Branch

Gentlemen:

On behalf of the 17,000 physician and physicist members of the American College of Radiology, I take this opportunity to comment on the proposed revision of the NRC rules on the medical use of byproduct material (Federal Register, July 26, 1985, page 30616).

We commend the commission for advancing the concept of bringing all the requirements for medical users of byproducts into one part. In previous testimony and submitted comments, the College has encouraged this revision so that applicants for licensure for the medical use of byproduct material could find their task substantially simpler. We believe the commission shares with the College the goal of making this licensure process as clear, concise and efficient as possible.

The following comments represent substantial review of the proposed rule by the ACR Commission on Nuclear Medicine and the Commission on Physics. As a result of those discussions, the ACR submits the following specific comments on the propcsed rule.

SUB-PART J - TRAINING AND EXPERIENCE REQUIREMENTS

Section 35.971 contains the requirement that a six month training program is necessary for sufficent training and experience to use byproduct materials safely. The Council of the American College of Radiology adopted a resolution in September 1984 which stated that a four month training period as a part of an approved residency program in radiology, nuclear medicine or cardiology which includes a minimum of 200 hours of basic science training and 650 hours of clinical training in radionuclide handling should be sufficient to meet Nuclear Regulatory Commission requirements to assure public health and safety for licensure to use all approved Groups I, II and III radionuclides in all approved forms.

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The ACR also believes that certification by the American Board of Radiology should be sufficient evidence of competency for licensure. Certification by the American Osteopathic Board of Radiology should also be accepted as sufficient, as should competence in nuclear medicine recognized by the American Board of Radiology.

Similarly, under 35.900, the ACR suggests that certification by the American Board of Radiology is adequate evidence of training for fulfilling the responsibilities as radiation safety officer.

TRAINING FOR THERAPEUTIC USE OF RADIOPHARMACEUTICALS

Section 35.930 stipulates training for therapeutic use of radiopharmaceuticals. This section provides that certification in nuclear medicine by the American Board of Nuclear Medicine is sufficient for licensure as an authorized user. We feel that this section should also include physicians certified in therapeutic radiology by the American Board of Radiology.

Under the requirements for supervised clinical experience, it states that training must include:

(ii) Use of soluble phosphorous-32 for the treatment of polycythemia vera, leukemia or bone metastases, 3 cases.

(iii) Use of colloidal phosphorous-32 for intracavitary treatment of malignant effusions in 3 individuals.

(v) Use of colloidal gold-198 for intracavitary treatment of malignant effusions in 3 individuals.

These uses (ii, iii, v.) were common ten to twenty years ago. At present there is very little use of these agents, even in teaching institutions. It may be difficult or impossible for a trainee to find the opportunity to comply with these now largely discontinued uses of radiopharmacueticals. We suggest that a license for these uses should be available if requested, but experience with these little used agents should not be a requirement for general authorization for use of radiopharmaceuticals.

RECORDS AND REPORTS OF MISADMINISTRATION

The ACR Commission on Nuclear Medicine believes that the misadministration rule, as applicable to diagnostic procedures, should be deleted or substantially modified. Our

commission believes that the frequency of misadministration of radioactive drugs is much less than the estimated frequency of misadminstration for all other types of drugs.

The hazards to the patients associated with misadministration of diagnostic radiopharmaceuticals are also much less than those associated with misadministration of other drugs. In most instances of diagnostic radiopharmaceutical misadminstration, the patient sustains neither actual nor theoretically significant potential injury.

Our commission believes that the data collected by the NRC since promulgation of the misadministration rule shows that the misadministrations have been related to human errors rather than programatic deficiencies. The fact that misadministrations resulting from naturally occuring or accelerated produced radioactive materials or from radiations resulting from these sources need not be reported in NRC regulated states, highlights the need for substantial modification of the misadministration rule.

The ACR Commission on Nuclear Medicine believes that periodic review by the institution radiation safety committee would be sufficient. Records of the radiation safety committee would then be available for review by NRC inspectors and for periodic analysis of trends by NRC staff.

RADIATION SAFETY COMMITTEE

Section 35.32 (B)3 requires that an institution's radiation safety committee review the basis of safety and approve or disapprove each proposed method of use of the byproduct material. The ACR believes that once the radiation advisory committee has approved use of a particular radiopharmaceutical in a particular dosage range by a particular route of administration, further requirements that variations be separately approved is unnecessary.

Application of this requirement significantly limits the flexibility of nuclear radiology practitioners in meeting clinical requests for new methods of use. This is particularly true in many smaller institutions, where radiation safety committees meet only quarterly, which is the mimimum requirement. Consequently, it may not be possible for a practitioner to obtain committee approval to undertake a new method of use in a timely manner. The ACR suggests that an annual audit of methods of use is sufficent to allay radiation safety concerns.

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The American College of Radiology appreciates this opportunity to submit comments on the proposed rule, Part 35 - Medical Use of Byproduct Material. We urge your favorable consideration of the suggested changes made above. If you have questions about any of these comments please feel free to call on us.

Sincerely,

Otha W. Linton
Associate Executive Director

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