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AMERICAN SOCIETY OF HOSPITAL PHARMACISTS

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June 8, 1979

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Docketing and Service Branch

Re: Human Uses of Byproduct Material; Change in License Conditions
for Certain Medical Licenses, 44 F.R. 21203 (April 9, 1979).

To Whom It May Concern:

The American Society of Hospital Pharmacists, the national professional organization representing pharmacists practicing in hospitals and other settings of organized health care is pleased to comment on the above referenced proposal; membership in the Society exceeds 17,000. Many of our members specialize in radiopharmacy practice and hence are very interested in this proposal.

Comment One: General. The Society supports amendment to 10 C.F.R. Part 35 proposing establishment of a new "radiation safety" committee, with authority limited to issues of radiation safety, and elimination of the existing medical isotope committee, which has authority over both medical research and therapeutic uses of radioisotopes and radiation safety. The Society has previously advised both the Food and Drug Administration and the Nuclear Regulatory Commission that the Food and Drug Administration should assume responsibility for regulation of all drugs, including the "pharmaceutical" aspect of radiopharmaceuticals, and that the Nuclear Regulatory Commission should retain responsibility only for "environmental aspects" of radioisotopes (i.e., untoward public and individual exposure to radiation). We are pleased that this proposal generally reflects the Society's views.



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Acknowledged by card 6/11/79. *Wish*

Comment Two: Committee Responsibility. We are concerned that the broad mandate to "coordinate use of byproduct material" provides inadequate guidance to the proposed "radiation safety" committee and might cause conflict between it and other committees with involvement in the control and use of drugs in medical research and for therapeutic purposes. We believe this new committee's purposes should be clarified and limited in accord with 42 U.S.C. 2134 and the division of regulatory responsibility between the Nuclear Regulatory Commission and the Food and Drug Administration. Specifically, the radiation safety committee's responsibilities should be limited to assuring compliance with appropriate environmental, occupational and safety requirements designed to avoid accidental exposure or release of radiation. We are not recommending specific language changes to the proposal because we think the problem can be adequately resolved by detailing committee responsibilities with more clarity in the preamble to the final rule.

Comment Three: Committee Membership. We recommend Section 35.11 be amended as follows:

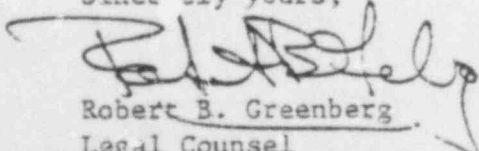
. . . Membership of the committee shall include a specialist (where applicable a physician) from each department or area where radioactive material is used or stored, compounded or formulated . . .

[New language underlined.]

This change would clarify that when radiopharmaceuticals are kept or handled by the department of pharmacy, a representative of that department must be a member of the radiation safety committee. The Accreditation Manual of the Joint Commission on Accreditation of Hospitals requires a hospital's pharmacy service to assume responsibility for all drugs used within an institution; in the case of radiopharmaceuticals, this includes any unique controls necessitated by the radioactive nature of the drug. As we have previously documented, (see, Statement of the American Society of Hospital Pharmacists Before the Advisory Committee on Medical Uses of Isotopes of the Nuclear Regulatory Commission, May 6, 1977) radiopharmacists play significant clinical roles in therapeutic and research use of radiopharmaceuticals, assure the safety of the product and are key elements in environmental and occupational controls on accidental release of radiation. We believe it essential that where pharmacies are responsible for safe storage, formulation and control of radiopharmaceuticals, as they are for all drugs, an appropriately qualified radiopharmacist be a member of the proposed radiation safety committee.

The American Society of Hospital Pharmacists appreciates the opportunity afforded it to comment on this proposal. Please feel free to contact us if we can be of any additional assistance to you.

Sincerely yours,


Robert B. Greenberg
Legal Counsel

RBG:dz