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

ATTENTION: Docketing and Service Branch

REFERENCE: Federal Register Vol. 44, Number 69  
Page 21023, Monday April 9, 1979

Dear Sir:

The proposed change to 10 CRF 35.11 (b) has one good feature and several bad features.

The good feature is that a nurse is, in effect, included as a member of the committee. Nurses deal with radiation sources which are both within NRC jurisdiction and outside of NRC jurisdiction. Having nurses have a hand in radiation planning is a good idea from both the technical competence viewpoint and the psycholological well being of nurses.

Bad features of the proposed change in 10 CFR 35.11 include the following:

1. Technical competence of the committee is downgraded.
2. Jurisdictional disputes within the hospital will be initiated with consequent detriment to the radiation safety program.
3. The summer meeting of the Society of Nuclear Medicine will occur after expiration of the comment period.
4. Does the change in name of the committee indicate a change in emphasis?

More extensive discussion of each bad feature follows:

1. Technical competence of the committee is downgraded.

A person trained in radiation safety is a required member in the proposed revised committee. But no person competent

Indexed by card... 6/7/79

364 338

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in internal radioisotope dosimetry and no person competent in clinical effects of radiation is required as a committee member, and the present committee structure requires such persons to be members of the committee.

"Training" in radiation safety may be limited to dealing with x-ray machines, lasers, microwave ovens, in burying radioactive waste, or in handling film badges. This limited knowledge would be enough to qualify the only radiation expert required by the proposed revision.

A major task of the committee, of regulating exposure of patients, will be diluted by reducing the required talent in medical effects of radiation and knowledge of radiation physics. The 10 CFR 35.11 (b) committee has traditionally regulated the exposure of patients to radiation from byproduct material as well as protection of radiation workers.

The proposed revision should be rejected because no person with adequate training or knowledge of radioisotopes and their effects on humans is required by the proposal.

## 2. Jurisdictional Disputes.

The Nuclear Medicine Department and the Radiation Oncology Department both make the greatest use of byproduct materials on humans in a hospital and have employees knowledgeable in radiation. Various other departments, such as Cardiology, will make use of byproduct materials in the near future. Various laboratory services make use of  $^{125}\text{I}$  and  $^{131}\text{I}$  for *in vitro* studies, for example Pathology and Endocrinology.

The present structure of 10 CFR 35.1 (b) places control of byproduct material in the hands of individuals most knowledgeable about radioactive materials.

The revised structure of 10 CFR 35.11 (b) may allow control to slip into the Cardiology or Pathology Department. Usually no one in those departments knows anything about radioactive materials.

Cardiology and Pathology Departments have great power in many hospitals. The revisions to 10 CFR 35.11 (b) set up a fight between these two departments and Radiology or Nuclear Medicine Departments, in which radiation expertise resides.

The proposed revision should be rejected because of the political fights within the hospital which the proposal will cause.

3. The professional organizations whose members have the greatest stake in the proposed change is the Society of Nuclear Medicine. This Society has a major meeting approximately two weeks after expiration of the comment period.

The comment period should be extended until after the meeting because of the great importance of a major change in medical use of radioisotopes to members of the Society of Nuclear Medicine. Members should be given an opportunity to discuss the proposed change and to comment on it through the Society.

4. Does the change in composition of the 10 CFR 35.11 (b) committee indicate a change in purpose of the committee?

The proposed new composition of the committee indicates that the NRC concern has shifted from protection of the patient. The new focus of the committee appears to be entirely directed at radiation safety to workers within the hospital.

If the NRC has shifted emphasis and dropped concern for radiation exposure to patients, this point should be made clear by the NRC.

Very truly yours,

*A. Sidney Johnston*  
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364 338

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