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April 29, 1998

Dr. Shirley Ann Jackson, Chairman
U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, Maryland 20852-2738

Dear Dr. Jackson,

I understand that the Nuclear Regulatory Commission (NRC) is undergoing a process of revising its regulations to be more risk-based and performance oriented. The part of this process that is of concern to me involves revision of 10 CFR Part 35, which applies to the medical use of radioisotopes. While I support the direction in which the commission is moving, some of my constituents in the radiology community are concerned about the trend that is reflected in early drafts of the revisions of Part 35 relating to the training and experience necessary to become licensed to use radioisotopes diagnostically.

The record of safe usage of radioisotopes compiled over many years under NRC Licensure is a very good one. I and my constituents are concerned that, with the severe reductions in required training and experience under 10 CFR Part 35.100, 200 and 300 that are being considered, this record of safe usage will end and more incidents that jeopardize patient care will occur. I urge you, as leader of the Commission, to consider carefully the implications of the proposal that the NRC staff is preparing for your approval. We believe that patient care would best be served if the training and experience requirements were revised as recommended in comments submitted to the NRC staff by the American College of Radiology. It would be unfortunate to move too far in a direction that jeopardizes patients in the name of a more forward looking regulatory process.

I would appreciate a letter in response from you indicating the position that you intend to take on this issue.

Sincerely,

David McIntosh
Member of Congress
Second District, Indiana

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NRC Revision of 10 CFR Part 35

ISSUE

The NRC is in the process of revising Part 35 of the Code of Federal Regulations relating to the medical use of radioisotopes. The ACR is concerned about some of the changes being proposed for this revision. The ACR believes that some changes can be made to adjust the regulatory burden, but, as the representative of the largest component of the regulated community, we are concerned about the extent of the draft proposal.

ACTION REQUESTED

Please ask your Representative and Senators to:

- Send a letter to the Chair of the NRC (draft to be provided at the State Chapter Meeting) concerning the prospect that proposed changes in the NRC Medical Use Program proposal may jeopardize patient care and create a situation where incidents that are deleterious to patient care will begin to occur with greater frequency than occur today. The ACR comments on the draft supported the concept that some relaxation of the training and experience requirements might be appropriate. However, the comments expressed the view that shortening the Training and Experience requirements for the diagnostic use of radioisotopes beyond those recommended by the ACR may result in compromises in patient care (copy of ACR comments enclosed).

Background

The Nuclear Regulatory Commission (NRC) has been undertaking for the last four years a review of its Part 35 regulations covering the medical use of byproduct materials. This has included an internal NRC management review, an independent external review by the National Academy of Sciences' Institute of Medicine (IOM), and is part of the NRC's current "Strategic Assessment and Rebaselining Initiative." As a result of these studies, the NRC has concluded that it should restructure its Part 35 regulations to be "risk-informed and more performance-based."

More recently, the NRC released at the end of January a "strawman draft" to revise the Part 35 regulations. Although there are many changes in the draft from what currently exists in regulation, the College's comments primarily focused on proposed changes to the training and

experience requirements for non-American Board of Radiology (ABR) physicians who wish to become NRC authorized users of isotopes for medical purposes.

In brief, the NRC draft proffers substantial reductions in the training and experience requirements from the current regulations. It appears that the general intent of the NRC 'strawman' proposal is to separate the training and experience requirements necessary for radiation safety protection from those necessary for proper clinical performance.

The 'strawman' draft was reviewed at the March meeting of the NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI). The ACR submitted written comments arguing against the major reductions proposed in the NRC draft. The College comments recommended retention of the status quo in the areas of most risk, i.e. sources used in oncology, and advocated a middle ground between the current requirement and the NRC draft in the 'lower risk' area. In addition, Dr. Frank Wilson, a radiation oncologist from the Medical College of Wisconsin, represented ACR at the ACMUI meeting and addressed issues related to radiation oncology. Dr. Larry Holder from Johns Hopkins University addressed the diagnostic nuclear medicine related issues.

The Committee accepted the status quo position in the areas of sources used in radiation oncology, and recommended to the NRC that they essentially retain the current requirements for use of those types of sources. The key argument seemed to be that, in the area of oncology, the hazards are so great from the sources used that it is impossible to separate radiation protection training from clinical training. However, the Committee did not make this same distinction in the diagnostic area. They accepted the NRC draft position for sources used in diagnostic nuclear medicine, and recommended that the NRC draft requirements of 40 hours of classroom training and 80 hours of experience be adopted as the NRC proposal.

The NRC staff is currently considering the advice of the ACMUI and will make recommendations to the NRC Commissioners at their scheduled May meeting. It is anticipated that a proposed rule to revise Part 35 will be published some time this summer. ACR will be actively monitoring the NRC's activities and will keep the radiology community apprised of the developments in any proposed revisions to the Part 35 regulations. Your help at this meeting, by contacting your elected representatives, will enhance the ACR's efforts to assure that this process does not compromise patient care.