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INDIANA RADIOLOGICAL SOCIETY INC.*Chapter of The American College of Radiology*

322 Canal Walk • Indianapolis, IN 46202-3268

April 23, 1998

The Honorable Richard G. Lugar
United States Senate
Washington, D.C. 20510

Dear Senator Lugar:

On March 31, Lynn Broderick, M.D., and I had the pleasure to meet with Troy Bryan of your office to discuss issues of importance to the Indiana Radiology Society (IRS) and its patients. We appreciate the time that Mr. Bryan spent with us to discuss these issues.

I am enclosing for you a proposed letter to Dr. Shirley Ann Jackson, Chairman of the Nuclear Regulatory Commission, concerning the proposed revision of 10 CFR Part 35. I hope that you find the contents of the proposed letter agreeable and will send a similar letter to Dr. Jackson prior to the commission's May meeting.

Although the IRS supports the direction in which the Commission is moving, we remain concerned about the NCR's draft proposal which would significantly reduce the amount of training on the use of sources in diagnostic nuclear medicine to 80 hours of classroom training and 40 hours of experience. We believe that this drastic reduction in training would significantly increase the risk of harm to both patients and medical support staff.

I am also enclosing a summary of the American College of Radiology's (ACR) position on the reauthorization of the Mammography Quality Standards Act (MQSA) of 1992. This legislation is currently pending before the House Commerce Committee. The IRS supports reauthorization of the Act with the changes recommended by the ACR. Any assistance that you could provide on this issue would be greatly appreciated.

Again, it was a pleasure to meet with Mr. Bryan on your behalf. If you have any questions, please free to call me at (317) 261-2060.

Sincerely,

James M. Zieba
Legislative Counsel

Enclosures

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

Dear Chairman 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,

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Outline of NRC Discussion

1. The field of diagnostic nuclear medicine has compiled an enviable safety record and made remarkable medical progress over the past years. This record is at risk because of the changes being considered by the NRC, part 35 for diagnostic nuclear medicine.
2. The ACR suggests that the comprehensive training and experience requirements of the NRC and the careful oversight of the NERC be retained, or at most only minimally revised.
3. Understanding radiation safety issues and experiencing practice and patient problems related to safety first hand requires a minimum of 200 classroom hours, or a minimum of 3 to 6 months of practice experience.
 - a. An example: conduct of a heart study involving IV injections during a treadmill exercise test. Periodically the IV will block during injection and radioactive material will spray, contaminating the patient, the staff, and the environment. This is only a single example of problems that a trainee needs to experience directly in order to practice independently. The training period of 1 week being considered by the NRC is inadequate to assure appropriate and necessary experience to deal with this type of incident.

This raises the underlying premise that the NRC is following, which is that the radiation safety training can be separated from clinical experience. We do not believe this to be true in either the oncology area or in
— diagnostic nuclear medicine. Many related problems will not be experienced or understood with the restricted training being considered.

- b. The delivery of relatively low, 'safe' radiation doses does not mean that the preparation of these doses is a low dose situation. There are larger amounts of radiation and possible exposure to patients and employees, especially if not used correctly.



4. There have been few problems because of the current comprehensive education, training and oversight requirements of the NRC. If there is any merit in the arguments to reduce paperwork, it should not be confused with reducing training and experience. If there is merit in the attempt to separate radiation protection from clinical training, the reduction should be much smaller than that being considered, to see if the reduction can be accomplished safely. The harm to the public, to workers, and to patients from a public perception of radiation danger will do irreparable harm to a valuable area of medical practice.

5. In summary, the elimination or vast reduction of the NRC training and experience requirements will lead to proliferation of untrained, inexperienced users of radioactive materials. This will impact on patient safety, and the safety of employees and the public. It will also lead to misadministrations, problems with waste disposal, and create such bad publicity that the whole profession and nuclear industry will be harmed.

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MQSA Reauthorization

ISSUE

The Mammography Quality Standards Act (MQSA) of 1992 will need to be reauthorized this year. The ACR supports reauthorization of this important law, with amendments to enhance the quality for the early detection of breast cancer nationwide.

ACTION REQUESTED

- Support MQSA reauthorization legislation that will enhance the quality and cost-effectiveness of this national standard for mammography facilities. The ACR believes that amendments to MQSA should include:
 - + Demonstration projects to improve the quality, reduce duplication of effort, and advance the cost-effectiveness of mammography facility inspections.
 - + Technical changes to preserve the integrity and quality of the clinical image review process.
 - + Providing directly to every patient a summary of the radiologist's findings from the mammogram in terms easily understood by a lay person.

BACKGROUND

Since enactment of the Mammography Quality Assurance Standards Act (MQSA) in 1992, women in the U.S. have gained confidence in the providers of their mammograms, through the knowledge that mammography facilities were being certified in accordance with federal standards. The successful collaboration of radiologists, mammography facility operators, and federal and state regulators, which was carefully designed into the law, has produced significant improvements in the quality of mammograms nationwide. The federal standards are built on the ACR Mammography Accreditation Program that was established in 1987.

Reauthorization of MQSA provides an opportunity to review the Act's progress to date, as well as the implications of the overall program. Issues raised during the initial implementation process, during the public comment period, and at public meetings of the National Mammography Quality Assurance Advisory Committee (NMQACC) reflect concerns that the inspection program has not been implemented in the most cost-effective way, taking into account past performance of facilities.

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To that end, it is recommended that FDA conduct demonstration projects that carefully examine the relationship between the duration and/or frequency of on-site inspections and the quality standards established in MQSA so that facilities are not subject to inefficient, duplicative or excessive oversight. The projects should examine the practices of facilities that demonstrate consistently high levels of performance on annual on-site inspections. In addition, two technical changes are recommended to strengthen the statute to assure the objectivity and quality of the review of clinical images. We believe that these modifications will help to preserve the integrity of the clinical image review process.

With regard to notification of mammography results, the Agency for Health Care Policy Research (AHCPR) strongly recommended that both women and their referring physicians be directly notified of the results of mammograms. Currently, under MQSA, results are sent directly to women who are not referred by a primary care physician (self-referral). However, an increasing number of mammography facilities have begun to report both normal and abnormal findings directly to the woman, as well as her referring physician. We recommend that all facilities be required to provide results in lay language directly to all women after mammography so long as relationships with referring physician are not disrupted.