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August 17, 1998

Karen L. Thurman  
U.S. House of Representatives  
440 Cannon House Office Building  
Washington, DC 20515-0905

Interest  
Assigned To

NAME

DATE

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Reviewed By  
Submitting F.

RE: Nuclear Regulatory Commission Revisions to Training and Experience Requirements for the Medical Use of Radioisotopes

Dear Congresswoman Thurman,

The Nuclear Regulatory Commission (NRC) is currently in the process of revising its regulations concerning the medical use of radioisotopes in an effort to make the training and experience requirements more reflective of the level of radiation risks they present. Two areas of concern are diagnostic nuclear cardiology and experimental intravascular brachytherapy. The NRC's advisory council for the medical use of isotopes has endorsed streamlining the radiation safety training and experience requirements for diagnostic nuclear cardiology because of its minimal risk to patients and public safety. I strongly advocate the more reasonable level of regulation of the training needed for these diagnostic tests and strongly support the NRC staff's proposed reduction in required training. Radioisotope have been used for several decades to create images of the heart with minimal risk to patients and public safety. The cardiology community has developed effective training programs for cardiovascular specialists who perform nuclear cardiology procedures. These physicians are also trained in the use of medical isotopes.

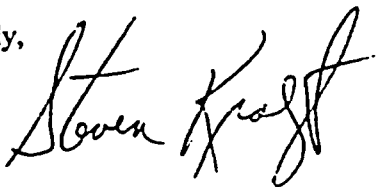
Intravascular brachy therapy is an experimental procedure which hopefully prevents arteries from reclosing after being opened by "balloon angioplasty" or other such procedures. In this procedure, a cardiovascular specialist exposes the coronary artery walls to a low level radioactive source while clearing the arterial blockage. Because it is so experimental, this procedure is only being performed in large academic medical centers under the approval of institutional review boards using strict protocols. These cardiologists are teaming with medical physicists and radiation oncologists to determine the best method for using this form of therapy. The radiology community, however, is telling members of Congress that the changes being proposed by the NRC will "jeopardize patient care" and cause incidents "deleterious to patient care" to occur with greater frequency. I am unaware of any evidence that supports these claims.

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Please be advised that there are two sides to the issue. I wish to request you to contact the NRC and voice your support of its risk based approach to revising its training and experience requirements for the medical use of radioisotopes. It is too early for the NRC to set any definite training and expertise requirements for physicians using intravascular brachytherapy. Myself and the American College of Cardiology suggests that the NRC reserve judgement in this area until the technology has developed to the point where regulatory standards can be developed with confidence based on the risks of the radioisotopes selected.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Steven Kraft".

Steven M. Kraft, M.D., F.A.C.C., F.A.C.P

SMK/bds