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DOCKETING & SERVICE
BRANCH

Secretary of the Commission
Office of Nuclear Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Sir:

As evidenced by the ongoing proposed revisions in procuring nuclear licensing and regulatory guides recommended by the U.S. Nuclear Regulatory Commission, the field of nuclear medicine is rapidly expanding. Nuclear medicine, in specific nuclear diagnostic studies, are no longer indigenous to radiologists. Diseases of the heart and blood vessels remain the Number 1 cause of death even when compared to all other causes combined. Cardiac and peripheral angiograms remain the gold standards for confirming surgically correctable heart and cerebrovascular disease respectively. These studies are not without their inherent risk and expense.

Nuclear cardiac imaging has proven itself invaluable in early diagnosis and treatment of ischemic heart disease and other heart problems. I am a practicing cardiologist in private medicine who performs nuclear stress testing in an office setting. With the use of this procedure I am able to detect early coronary artery disease, avoid sending patients with mild disease to the catheterization lab and detect those patients with serious coronary artery disease with mild symptoms. The latter group obviously undergoing cardiac catheterization to determine the need for surgical intervention. First pass radionuclide angiography requires the use of technetium 99 DTPA with no tagging substances. Our technetium is delivered in unit doses which obviates the need for a generator.

It is with the above in mind that I write this letter in response to the proposed changes in licensing and training requirements in nuclear medicine. I feel strongly that the field of nuclear cardiology should be given separate consideration for the licensing and training requirements in this subspeciality of nuclear medicine. With response to the Federal Register issued July of 1985, Title 10, CFR, part 35.100 and 35.200 no special consideration was given to nuclear cardiologists who just want to do nuclear cardiology and not all nuclear medicine procedures. Not only has nuclear cardiology become a subpart of nuclear medicine, but has its own

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subspecialty areas. There are those cardiologists who perform and interpret only thallium perfusion studies, whereas, others have limited their practice to either First Pass or MUGA angiograms. Perhaps the NRC should also recognize this distinction and provide for a specific license category in revision of Title 10, CFR, as well as in the Regulatory Guide.

I have noted the proposed Title 10, CFR, 35.920 requirements for the licensee for imaging and localization studies. I firmly believe in the 200 hours of basic radioisotope handling, including the 100 hours of radiation physics and instrumentation, the 30 hours of radiation protection, 20 hours of mathematics, 30 hours of radiopharmaceutical chemistry and 20 hours of radiation biology. However, the amount of hours one needs to spend under supervision and in a clinical preceptorship would depend on the type of nuclear cardiology one intends to perform. Perhaps the NRC should make special training requirements for those individuals. Obviously, these individuals would be limited from performing all other nuclear imaging procedures. I am sure that the NRC Advisory Committee on the medical uses of isotopes and the ACNC Legislative and Regulatory Committee could develop special training requirements and considerations where appropriate. In the interim, I would recommend that the existing training requirements remain unchanged until such a task has been completed.

As you are aware, there are many changes taking place in medicine today. With third-party reimbursement physicians are being influenced on how they practice medicine. It has become obvious that the NRC is attempting to do the same. In a recent article in the Journal of Nuclear Medicine the NRC states that "some licensees have been sited for noncompliance with requirements by allowing physicians who are not authorized users to interpret diagnostic studies". The purpose of a nuclear license is to insure that that individual has the proper knowledge to safely use radionuclear material and adequately provide for the safety of the individuals using it. One does not need a nuclear license to be able to interpret and thereby act upon the results of a nuclear study. In other words, one does not need to be an electrical engineer to be able to interpret and act upon electrocardiograms. In addition, the NRC in its new licensing guide has requested voluntary economic data from all applicants. This information would include the annual receipts and number of employees. I am unclear as to how this information would assure that the licensee is performing to the guidelines established in his license according to the NRC.

The American College of Nuclear Cardiology is a group of dedicated individuals who are willing to work with the NRC in establishing new rules and regulations specific to the field of nuclear cardiology. It is important that we work closely together so that nuclear cardiology will continue to grow and provide for the highest quality of care possible to our patients.

Thank you for your time in reading this letter.

Sincerely,

R. Philip Canosa, D.O.

RPC/sgc

CC: Charles H. Rose
Administrator
American College of Nuclear Cardiology