

July 13, 1990

John Telford  
Section Leader, Rulemaking Section  
Office of Nuclear Regulatory Research  
Regulatory Applications Division  
U.S. Nuclear Regulatory Commission  
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Dear John,

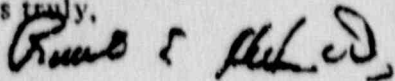
Thank you for taking the time to discuss the issue of the proposed rule on Quality Assurance with me after the recent ACMUI meeting. To reiterate my feelings on the matter:

1. Nuclear Medicine has yet to accept that any Quality Assurance rule is necessary to account for the 3 patients per year who received misadministration of I-131. The amount of effort required to deal with these three patients would result in a potential decrease of the quality of care for the remaining 10,000,000 nuclear medicine patients. We have a finite pool of resources; which we must allocate for the greatest good in the community. If we had unlimited resources we might find it easier to accept and implement your approach.
2. If NRC determines that some version of a Quality Assurance Rule will exist we must point out that nuclear medicine cannot serve two masters, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the NRC. We must make an effort to see how the currently mandated JCAHO requirements could be made to fit NRC's objectives. If NRC were to accept JCAHO accreditation as evidence of a QA program (we are speaking here only of QA functions) that would help immeasurably.
3. For those hospitals who cannot show evidence of JCAHO inspection, then a free standing program might be required.

While not yet accepting the premise that any QA rule is required to fix a problem that is not broken, I will agree to add to the agenda of our July 23 meeting the topics of the necessity for a QA Rule and JCAHO compliance as an option in an NRC QA rule.

Again, thank you for your time and understanding.

Yours truly,



Robert E. Henkin, M.D.

REH:sd

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