Nuclear Medicine Associates, Inc.

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(12)

Robert S. Minogue
Director, Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

DOCKET NUMBER
PROPOSED RULE PR-35
(46 FR 43846)

Dear Mr. Minogue:

Please consider this a response to Proposed Regulation 35.15 and 35.16 of Title 10 of the Code of Federal Regulations.

Several questions have arisen in our organization which is a consulting group servicing approximately 250 hospitals throughout the central United States. The intent of Regulations 35.15 and 35.16 is well understood and in most cases concurred with. However, we do feel that these regulations will impose certain problems for small institutions, pathology laboratories, and private practice clinics.

The requirement that all doses be assayed is not clear as to whether or not this includes brachytherapy sources such as I-125 seeds, Iridium ribbons, etc. The current state of the art dose calibrators do not carry with them sufficient correction factor data to make assay of these sealed sources accurate. For this reason, we must pose the question, is the intent of 35.15 to include the assay of brachytherapy sources prior to their implantation into patients?

Another point which requires clarification is the statements included in proposed 35.15 which require the assay of in vivo radiopharmaceutical doses of less than 10uCi. In most cases, this will be a simple task. However, in small institutions doing only pathology work or in institutions where the laboratory is separated both administratively and geographically from the nuclear medicine department, a dose calibrator may not be available for the assay of such things as Co-57 Schilling test capsules, I-125 isojex syringes, and low dose I-131 capsules for thyroid uptake studies. The question therefore is two-fold: 1. Will the NRC accept manufacturer's statement of dose activity as sufficient means of documenting the dose activity amount? and 2. Will licensing entertain a method of assay other than dose calibrators for the assaying of such low activity level radiopharmaceuticals? We find that some small institutions doing only occasional thyroid uptake studies are checking dose activity by counting uptake capsules versus a

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known standard count rate.

If these specific problems can be addressed prior to the formal introduction of these two proposed regulations into Title 10 in such a manner as to provide us clarity when dealing with clients in advising hospitals and clinics on dose assay, we would be most appreciative.

Please feel free to contact me on the above matters.

Best regards,

David T. Williams
Consultant

DTW/amc