Laboratory of Clinical Medicine
Clinical Pathology
Anatomic Pathology
Nuclear Medicine
Diagnostic Ultrasonography

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PROPOSED RULE
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Secretary of the Commission
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Docketing and Service Branch

Dear Sir:

Enclosed please find comments on proposed rules for medical use of byproduct materials.

Section 35.80 Mobile Nuclear Medicine service technical requirements. Item A: Transport to each location of use only syringes or vials containing prepared pharmaceuticals. Comment: I have no problem with intent of this proposal but feel some considerations must be addressed.

Sparsely populated areas of rural America have an inherent problem with availability of nuclear medicine. Because of the size of these facilities and the tremendous distances between facilities, the most practical approach is for them to use mobile services.

Since the implementation of diagnostic related groups, DRGS, within our client hospitals, the objective is to provide the patient with adequate care while not allowing a hospital stay longer than authorized for payment.

Since patients are now admitted and dismissed on a more frequent basis, mobile services cannot always anticipate the actual number of patient examinations on the scheduled day of the visit to the clients hospital. If there is a request for an additional examination, unless there is a cancellation of the same test, this patient cannot be accommodated. This causes great inconvenience as well as compromised patient care. Due to the majority of mobile services clients being small medical facilities and the great distances traveled to provide service, many institutions are visited on a weekly basis. Additional visits to facilities that maybe required simply due to an additional patient examination request, provides not only an economic hardship to the mobile service for duplication of visits, but to the hospital as well.

DS10
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Acknowledged by card SEP 18 1985

Additionally, most manufacturers produce inserts recommend that reagent kit doses not be used after six hours following preparation. Typically, reagent kits are prepared in hot lab facilities between 3:30am and 4:30am. By early or midafternoon the recommended time limit for use of the dose has been exceeded. This fact has been documented on patient examination films that suggest a tag breakdown. At times, higher than normal target to nontarget ratios can be visualized, as well as thyroid, stomach and bladder.

I am confident that kits may be prepared in hospitals serviced by mobile services without submitting the general public or occupational and nonoccupational employees to an additional risk. Appropriate spill measures, shielding, and survey techniques can be implemented to assure this safety. I would emphasize that reagent kit preparation should be performed only for additional unscheduled or emergency patients or when product life exceeds manufacturers recommended time span.

Taking into consideration the limited use of this authorization, the vast territory versus the sparseness of the population, patient care and economics, it is appreciated that an objective view of the unique circumstances be taken by your office. If you should have any questions regarding this matter, please do not hesitate to contact me.

Sincerely,

Roger M. Rae, C.N.M.T
Chief of Diagnostic Imaging

RMR:js