PROPOSED RULE PR-30 31,32 etal. (50FR 30616) (51)

PROPOSED RULE PR-Misc Notice (Reg Guide)

James G. Ledbetter, Ph.D./Commissioner

GEORGIA DEPARTMENT OF HUMAN RESOURCES

Radiological Health Section, Suite 600

878 PEACHTREE STREET, N.E. / ATLANTA, GEORGIA 30309

November 12, 1985

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

ATTENTION: Docketing and Service Branch

Gentlemen:

The following comments are offered in response to the Commission's Revision of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," and Federal Register Notice 10CFR Part 35; Proposed rule.

We agree with the overall concept proposed in these two documents pertaining to the utilization of radioactive materials in Medical Programs; however, we disagree or have concerns with the following proposals as outlined below:

RE: Revision to Regulatory Guide 10.8

In regard to the proposed revision of Regulatory Guide 10.8 we are concerned about the implementation of item 1.a. in Appendix N regarding diagnostic administrations in patients rooms, not requiring surveys as long as care is taken to remove all paraphernalia. We feel that this area is vague in view of the fact that spills occur or other problems may arise that would not be corrected by simple removal of all paraphernalia; thus we feel that stricter requirements or clarification of "all paraphernalia" is needed before we can agree to accept the suggested proposal.

RE: Part 35 Federal Register Notice

As a licensing Agency we disagree with the proposal in part 35.200 to add Xenon 133 to radiopharmaceutical groups for Imaging and localization. It is our view that the licensees desiring to utilize Xenon 133 should submit a separate request for utilization of this radiopharmaceutical, to ensure that the licensee's proposed procedures meet the radiation safety requirements regarding the utilization of Xenon 133.

DS10 add:

Norman L. McElroy, 396-SS
Wm. Olmstead, 9604 MNBB
Ed Hill, 11305S

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We also disagree with your proposal in part 35.36 regarding the licensee being granted authority to make changes in radiation safety practices and procedures, without submitting an amendment request to the pertinent licensing agency. Due to the lack of input to the administration in many smaller programs and programs in rural areas, we feel that the effects of such changes on the overall radiation safety of the facility could not or would not be adequately reviewed to ensure that all conditions of the license and regulations will be met.

We thank you for this opportunity to comment on the Revisions in Regulatory Guide 10.8, and the proposed rule changes in Part 35 of 10 cfr.

Sincerely,

Bobby G. Rutledge, Director
Radiological Health Section

BGR/SMM:dg