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PROPOSED RULE PR - Misc Notice
Reg. Guide

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

Sir:

I wish to submit the following comments on the proposed Regulatory Guide 10.8, "Guide for the preparation of applications for medical programs."

Appendix A: Acceptable training and experience for medical uses of Byproduct Material.

Under Alternatives: I suggest that certification by the American Board of Radiology in General Radiology or Diagnostic Radiology should also serve as evidence of the training required in this appendix for the use of Groups I, II, and III. This training is a requirement of approved residency programs. See additional comments, on the second page of this communication.

Appendix D, Section 2.E: Test of instrument linearity:

The requirement to use the maximum anticipated activity or a first elution of a new generator is inappropriate for the following reasons:

1. This activity far exceeds the activity range of doses given patients.

2. The use a first elution wastes the usable activity which could be used for patient care. It is usual to receive a new generator on Mondays, the clinically busiest day. This requirement is not in line with the President's request to hold medical care costs down.

I suggest, as an alternative, using the elution of the last previous generator. This will supply activity of up to 100 millicuries, depending on the size of the generator normally ordered, and the date of the generator's calibration. The activity so used to test linearity will test the performance of the dose calibrator in the range of doses given the patient.

Appendix D, Section 2.F: Test for geometrical variation:

The use of Technetium-99m should be suggested, rather than Cobalt-57. This will reduce the problem of waste disposal.

Appendix D, Section H.6: To avoid the implication that the activity need be calculated on a daily basis, I suggest the portion of this sentence beginning with the words, "based on decay....." be deleted.

Acknowledged by card 6/13

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Appendix I, Area survey procedures, paragraphs 4.b and 6.:

The restrictions on removeable activity are unreasonable:

1. This requirement is two orders of magnitude more restrictive than that for commercial transportation of radioactive material in non-controlled areas.

2. No consideration is given to the radionuclide involved. In the case of Technetium-99m, a count of 100 dpm would be 95 dpm in 5 minutes, while that for tritium, or Iodine-125, would remain constant for that time period.

3. No differentiation is made for the quanitity of activity used, nor of its use. For instance, in vivo use of Technetium-99m, with the involvement of needle, syringe, and patient injection, is, of its nature, more apt to cause contamination than the use of microcurie quantities of Iodine-125 tagged radioimmunoassay agents.

I suggest the restriction of 10CFR20, Section 20.205, (a) (2) be used as a guildeline.

Statement on use of Regulatory Guides:

In reviewing applications for licenses, reviewers of the Commission have taken the position that the guides, even those proposed, have the force of regulations, and make decisions from this viewpoint. Some method should be devised to arbitrate differences between applicants and reviewers, which will protect the applicant from the threat, real, implied, or inferred, that such action will bring reprisals from the Commission's reviewers. Too often, I have heard this fear expressed from applicants.

Further, I believe the qualifications of the reviewers should be spelled out, by some means available to the public, so that we may know whether these individuals are qualified, other than by employment by the Commission, to judge the merits of an application.

One final comment: An outstanding ommission from this guide is any mention of the technologists who actually perform the work with the radionuclides. The user, in almost all cases a radiologists or pathologist, will review the results of the tests or scans, to arrive at a clinical judgement. However, he doesnot elute the generator, calibate the doses, calibrate the equipment, prepare the radiopharmaceuticals, dose the patient, nor perform the test or scan. In my experience, and this is shared among my physicists colleagues, the user doesn't, in most cases, even give close supervision to these procedures.

Thank you for the opportunity to submit these comments.

Sincerely,

James A. Hancock, Jr.