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July 14, 1997

Cheryl Trottier, Chief
Radiation Protection and
Health Effects Branch
Division of Regulatory Applications
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: Draft Regulatory Guides for the Preparation of Applications for Commercial Nuclear Pharmacy Licenses (DG-0006), Distribution to Commercial Nuclear Pharmacies and Medical Use Licensees (DG-0007) and the Supplement for Medical Use Programs (DG-0009)

Dear Ms. Trottier:

Staff of the Department has reviewed your Draft Regulatory Guides DG-0006, DG-0007 and DG-0009 issued for public comment on March 21, 1997. These guides represent vital information for the manufacturing, distribution and use of radiopharmaceuticals within the medical community. A revision to the guidance in these areas has been anticipated for some time particularly in regard to nuclear pharmacies.

Regarding Draft Guide DG-0006, the Department finds this to be a much improved document over the previous version. Of notable improvement were the sections on pharmacist/RSO training, radioiodine handling and return of wastes. We have the following specific comments on this document:

1. In Section 3, Items 5 and 6, the Department generally makes reference to 10 CFR 35 authorizations for radiopharmaceuticals which may be prepared at pharmacies as opposed to listing specific nuclides for every item. If in fact a pharmacy wishes to compound a large variety of radiopharmaceuticals not authorized under 10 CFR 35, a broad authorization of some kind may be approved for the raw materials.

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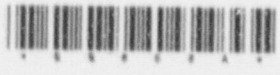
ITP-11
Guides + manuals



(Item 1. cont'd)

We are aware that there is some concern from pharmacists/physicians who may wish to prepare radiopharmaceuticals not approved by FDA. It is our belief that this can be accomplished under the "Pharmacy Practice Act" and the "Practice of Medicine" through state professional licensing boards. This has been ongoing for some time with positron emission tomography radiopharmaceuticals.

2. Figures A-1 and A-2 appear to be missing from the draft for pharmacist training in Appendix A. Generally, we liked the forms used in the original FC-410-4 Draft Guide.

3. In Appendix C, it would be very beneficial if the NRC could list as guidance a minimal number of hours acceptable for training of supervised users.

4. In Item 9, the NRC indicates that verification should be obtained for local ordinances and zoning laws regarding the location of pharmacies. Please indicate how NRC handles these verifications. We are in the process of implementing a rule where we must notify local government agencies of the presence of these facilities and are attempting to establish a mechanism for this practice without impeding the licensing process.

5. In Item 10, it appears that NRC may no longer accept electronic calibrations followed by a source check for survey instruments. Please explain.

6. In Appendix E, the Department is glad to see that the "sleeve method" of performing linearity is included. Has NRC reviewed and approved some of the current sleeve methods currently on the market against this appendix?

7. Item 10.10.2 should also reference Regulatory Guide 8.9 for additional bioassay methodologies and calculations.

8. In Item 10.10.3, instruction to convert bioassay results from microcuries to a committed dose should also be provided.

9. In Item 10.11, it may be very useful to include surveys for stress tests areas that are sometimes used for thallium studies as well as non-radiological studies. Protocol for unrestricted use is important in these areas.

10. In Exhibit B, there is a specific condition for return of waste to the pharmacy. Can this be tied down through condition 19, in this case, as opposed to having a separate condition?

11. In Section 4, Item 1, the Department is under the impression that FDA frowns on the redistribution of "opened" generators in that the radiopharmaceutical quality (sterility, nonpyrogenicity) of the product can no longer be guaranteed. Please explain.

12. In Appendix D, we note that you have dropped the requirement for documented quarterly source checks of instruments. We have this requirement in our medical regulations and several guides. We would like to remove it as well. Please provide us a history of the decision to delete this item.

Draft Guide DG-0007 seems to be void of any real technical content not explicitly detailed in the other guidance. It may be feasible to include this category of license with one of the other guides or simply let the rule take care of the licensing requirements.

There was one noteworthy item in Section 1.1 of DG-0007. It is not clear why licensees authorized for distribution of medical products must also have a license for the possession of the products as well. In Illinois, these activities are generally authorized under one license. Please explain why two licenses are required by NRC.

DG-0009 is a very useful supplement to the current Regulatory Guide 10.8, Revision 2 (August 1987) particularly in regard to human research. Because there have been many regulatory changes to 10 CFR 35 and 10 CFR 20 since this guide was published, it may be worthwhile to issue a revision 3 to this guide and include DG-0009 in the text of this document. We have the following comments on this draft guide:

1. The Department is glad to see that NRC has addressed the subject of human research in Appendix Y. This has long been a gray area in our regulations. We have not adopted this definition as part of our medical regulations. We prefer to require the approval of the Institutional Review Board (or other FDA approval) and informed consent to allow human research as outlined in Item 2. We will review this definition at the next revision to our medical rules.

2. In Items 9 and 10 of this guide, the Department does not allow the licensee to determine whether or not changes to their facilities, equipment and radiation safety procedures are adequate. We do not agree with your use of "ministerial changes" except at broad scope facilities with adequate peer review. Amendment requests must be submitted to our office for these items.

The Department is an advocate of maintaining updated guidance for key licensing issues. With the advent of new technologies on a daily basis in the medical community, it is especially critical that we accommodate these advances in our guidance while preserving public health and safety. If you have any questions regarding these comments, please contact Gibb Vinson of the Division of Radioactive Materials Licensing Section at (217) 785-9947.

Sincerely,

Steven C. Collins

Steven C. Collins, Chief
Division of Radioactive Materials

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