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FCML:CFM
(17414)
030-02735

Veterans Administration Medical Center
ATTN: Khairoon M. Ally
Chief, Nuclear Medicine Service
4100 West Third Street
Dayton, OH 45428

Gentlemen:

This is in reference to the application dated March 8, 1984, signed by Khairoon M. Ally, Chief, Nuclear Medicine Service, requesting an amendment to renew your Byproduct Material License No. 34-05015-01. In order to continue our review, we need the following additional information:

1. In reference to Item 14 of your procedures for safely opening packages, you stated that these procedures shall not be applicable to prepackaged in vitro kits. Note that all packages containing radioactive material must be included in your procedures for safely opening packages.

   Please confirm that the procedures for safely opening packages will also be followed for prepackaged in vitro kits containing radioactive material.

2. In Item 19 of your radiation safety procedures for therapeutic use of radiopharmaceuticals (Appendix K), it was stated that the nursing instructions in Appendix K shall not apply to phosphorus-32 except in the colloidal form. Note that currently you are authorized for phosphorus-32 in the soluble form and not the colloidal form as mentioned above.

   Because the Nuclear Regulatory Commission's (NRC) policy regarding nursing instructions pertain to the safe use of therapeutic drugs in patients, nurses and visitors, we feel that it is important for your institution to have procedures for soluble phosphorus-32 that will insure its safe use. Therefore, you must either follow the safety procedures in Appendix K or submit alternative procedures to insure that soluble phosphorus-32 is being handled safely.

3. In regard to your request to name Richard M. Steidl, M.D. and Nosrat M. Hillman, M.D. as authorized users of byproduct material listed in Section 31.11(a) of 10 CFR 31, note that before these physicians can be

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added to your license, you will need to give evidence that they have had experience with the types and quantities of byproduct material for which they wish to use, and that they have been adequately trained and experienced in the basic techniques of radioisotope handling.

Supplement A of Regulatory Guide 10.8 should be submitted to document their training and experience as described in Appendix A. Until such time as Drs. Steidl and Hillman are approved as authorized users on your license, they may use radioactive materials under the direct supervision of Dr. Ally or Dr. Gilbert.

We will continue the review of your application upon receipt of the requested information. Please reply in duplicate and reference Control No. 17414.

Sincerely,

Cassandra F. McDonald
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosure: Regulatory Guide 10.8

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