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JUN 17 1985

Iso-Diagnostic Services
of Michigan
ATTN: Mr. Steven Sands
President
575 Robbins Drive
Troy, MI 48083

Control No. 78733

Gentlemen:

We have reviewed your application dated April 12, 1985 requesting a nuclear pharmacy license and find that we will need additional information as follows:

1. Please supplement your facility description to include the type, thickness and arrangement of shielding available in the compounding and dose preparation area(s) (i.e., L-blocks, etc.) as well as the type, thickness and arrangement of shielding in the "drop-off" area.

2. Please outline your access arrangements with facilities adjoining your hot lab for the purpose of performing surveys to maintain compliance with 20.201(b). Such techniques as routine area surveys or placement of personnel monitoring devices on the occupant side of adjoining walls would be acceptable methods of meeting this requirement.

3. With regard to your radiation safety program, please:

   a. Confirm that all records of survey instrument calibrations will be maintained for a period of two years from the date of calibration.

   b. Confirm that your package opening procedures will include the assaying of final source container wipes for removable contamination.

   c. Confirm that your emergency procedures shall be posted in each area of use or storage.

4. Please supplement your waste collection procedures to include an estimate of the volume of dry waste you anticipate receiving and a description of the volume available for storage of this waste.

5. Please provide evidence of licensure by your State Pharmacy Board. We will be unable to issue a license for your activities until we have received evidence of such licensure.

6. With regard to labeling, packaging and transportation of radioactive material, please:

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REG3 LIC30
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a. Modify your existing labels to include the amount of molybdenum-99 present in all technetium-99m doses or indicate where this information will be printed on the labels you have already submitted.

b. Clarify what exposure rates you expect at the surface of the shielded containers. Does "mR/" indicate mR/hr?

c. Submit step-by-step procedures that will assure that material is packaged in accordance with DOT regulations. From these instructions, it should be apparent that the package design criteria of 49 CFR 173.412 are met, as well as the contamination control criteria of 49 CFR 173.443. You should also supply evidence that the containers you will be using for transportation and delivery of unit doses, etc. have met DOT type 7A standards.

d. Provide a copy of your radiation safety and delivery procedures to be provided to delivery personnel. As a minimum, these should:

(1) Be conspicuously available within the vehicle,

(2) Direct drivers to lock the vehicle when it is left unattended and

(3) Direct drivers to leave deliveries only in the secure area previously designated by the users.

7. If you wish to "distribute" items that you have received from a supplier who has manufactured, packaged and labeled these items in accordance with 10 CFR 32.71 through 10 CFR 3274 you are, in effect, "redistributing" this material. Such redistribution requires additional information. With regard to:

a. In-vitro Kits.

If you want to redistribute in vitro kits to GENERAL licensees, provide the following information:

(1) Specify that the prepackage in vitro kits to be redistributed will have been obtained from a manufacturer authorized to distribute the in vitro kits in accordance with a specific license issued pursuant to 10 CFR §32.71 or under equivalent licenses of an Agreement State;

(2) Specify that the manufacturer's packaging and labeling of the in vitro kits will not be altered in any way;

(3) Specify that each redistributed in vitro kit will be accompanied by the manufacturer-supplied package insert, leaflet or brochure that provides radiation safety instructions for general licensees.

If you want to redistribute in vitro to SPECIFIC licensees, provide the following information:

(1) Specify that you will obtain prepackaged in vitro kits (as described in 10 CFR §31.11(a)) for redistribution to specific licensees;

(2) Specify that you will ensure that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed in vitro kits do NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., 10 CFR §31.11);

(3) Specify that you will ensure that labeling on redistributed in vitro kits conforms to the requirements of 10 CFR §20.203.

b. Sealed Calibration or Reference Sources

If you want to redistribute sealed calibration or reference sources to group medical licensees, provide the following information:

(1) Specify to what categories of (e.g., group medical licensees; other licensees specifically authorized to receive the sources) you wish to redistribute the sources. (Note: Although a nuclear pharmacy's customers for the sources are primarily group medical licensees, many nuclear pharmacies also request authorization to redistribute the calibration and reference sources to other specific licensees.);

(2) Specify that the calibration or reference sources to be redistributed will have been obtained from a manufacturer authorized to distribute the sources in accordance with a specific license issued pursuant to 10 CFR §32.74 or under equivalent regulations of an Agreement State;

(3) Specify that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure or other document that provides radiation safety instructions for handling and storing the sources.

c. Reagent Kits

If you want to redistribute reagent kits to group medical licensees, provide the following information:

(1) Specify that reagent kits to be redistributed will have been obtained from a manufacturer authorized to distribute reagent kits in accordance with a specific approval issued pursuant to

10 CFR §32.73 or under equivalent regulations of an Agreement State;

(2) Specify that reagent kits will be redistributed as received from the manufacturer in the "kit sleeve" (i.e., cardboard enclosure holding a styrofoam container with multiple reaction units) and accompanied by the manufacturer-supplied package insert, leaflet, brochure or other document that describes the procedures to be followed and the equipment and shielding to be used in processing radioactive material with the reagent kit.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 78733.

Sincerely,

Original Signed By
William J. Adam, Ph.D.
Materials Licensing Section

RIII
wjg
Adam/jl
6/14/85