

SEP 5 1985

Veterans Administration Hospital
ATTN: Donald L. Ziegenhorn
Medical Center Director
3200 Vine Street
Cincinnati, OH 45220

Gentlemen:

Enclosed is Amendment No. 25 to your NRC License No. 34-00799-03.

We have amended your license to authorize the possession of xenon-133 in your new Nuclear Medicine facility. We have also authorized the use of the Atomic Products Lineator. In reference to the other items in your request, please make special note to the following:

1. We have not given authorization for the use of other equivalent linearity check devices. In order to obtain authorization to use other linearity devices that have not been reviewed and approved by the Nuclear Regulatory Commission or an Agreement State, you must provide a description of the device for our evaluation and approval.
2. This is in regard to your request to obtain FDA approved NDA's and IND's from the University of Cincinnati Medical Center. Please note that before we can review and approve a request of this nature, in which radiopharmaceuticals are received from someone other than a supplier as required by 10 CFR 35.14(b)(1) the following information must be submitted:
 - a. Justification for this request, i.e., the reason that the facilities involved cannot receive materials solely in accordance with 10 CFR 35.14.
 - b. It is unclear from your request as to whether you wish to use FDA approved NDA's as authorized in the groups (e.g., Groups I, II, III, etc.) or other specific NDA's not yet added to the groups. Please state the specific groups or list the individual NDA's you wish to be authorized to obtain from the University of Cincinnati.
 - c. A general, but complete description of how a typical transfer will work (i.e., which institution will transfer material, how a typical transfer will be initiated, the title of the person responsible for initiating and implementing the transfer, a general description of the events that will follow once the materials are on the site of the receiving institution, etc.)
 - d. Identification of the individuals who will transport the material, and the training they will receive. This training should, as a minimum, include all the items outlined in 10 CFR 19.12 and decontamination procedures in case of spills.

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- e. Safety measures to be used in transporting the radioactive materials in the applicants' vehicles (e.g., security against unauthorized removal, away from passenger compartment, absorbent paper, lead shields, etc.).
- f. Emergency procedures to be followed in case of accidents involving spills or loss of radioactive materials.
- g. Confirmation that vehicles used for transporting materials will be surveyed for contamination after each transfer.
- h. Confirmation that receipt and package opening procedures will be at least equivalent to those outlined in Appendix F of Regulatory Guide 10.8, October 1980.
- i. Submit a letter of concurrence from the University of Cincinnati stating that they agree to participate in such transfers.

We appreciate your cooperation in providing this information to complete our review, and we apologize for any inconvenience that our partial authorization may cause.

Information submitted in response to this letter should state that it is additional information and not a new amendment request.

Please review the enclosed document carefully and be sure that you understand all conditions. You must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Possess radioactive material only in the quantity and form indicated in your license.
3. Use radioactive material only for the purpose(s) indicated in your license.
4. Notify NRC in writing of any change in mailing address.
5. Request and obtain appropriate amendment if you plan to change ownership of your organization, change locations of radioactive material, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. Any amendment request should be accompanied by the appropriate fee specified in 10 CFR Part 170.

6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.
7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material prior to your expiration date.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions and representations in your license application will result in enforcement action against you in accordance with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

If you have any questions or require clarification of any of the above stated information, contact us at (312) 790-5625.

Sincerely,

Original Signed By
Cassandra McDonald
Materials Licensing Section

Enclosure(s): Amendment No. 25

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McDonald/cm
08/29/85