

November 5, 1984

LICENSE NO. 37-21345-01MD
DOCKET NO. 030-20537
CONTROL NO. 02802

Mallinckrodt, Inc.
Diagnostic Imaging Services
ATTN: Clyde N. Cole
Manager, Nuclear Pharmacy Operations
Independence Court Bay #20
Folcroft, PA 19032

Gentlemen:

This is in reference to your letter, dated October 15, 1984, in response to questions raised in our letter dated September 12, 1984. In order to continue our review of your xenon protocol, we need the following additional information:

1. Because the volume of effluent from your facility is so small (92 cubic feet/min), it is important that you provide justification for your assumption that no more than 20 millicuries of xenon-133 can be released in any one week. Therefore, please provide:
 - a) A detailed description (including sketches) of the form in which xenon doses are received.
 - b) The storage or packaging materials and handling procedures which will assure that multiple vials cannot be broken at the same time. In other words if 10 doses are ordered, why can't 10 doses be handled, dropped, and broken at the same time?
2. The concentration of xenon-133 in effluent will exceed 0.0000003 microcuries per milliliter if you release more than 8 millicuries of xenon-133 per week for 52 weeks. Since this represents only 0.4% of the possession limit you are requesting, and is beyond the capability of your assay methods to detect, it appears that you may need to increase the exhaust rate in your facility or provide stack monitoring capable of

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detecting 0.0000003 microcuries per milliliter. Please describe the method you will use to evaluate releases of xenon-133 effluent as required by Section 20.106 of 10 CFR 20 (enclosed).

We will continue our review of your application upon receipt of this information. Please reply in duplicate and refer to Control No. 02802.

Sincerely,

Original Signed By:
John E. Glenn

John E. Glenn, Ph.D., Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

Enclosure: 10 CFR 20

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