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14519 DETROIT AVENUE LAKEWOOD, OHIO 44107 PHONE (216) 521-4209

August 18, 1982

Mr. J. R. Miller, Chief U. S. Nuclear Regulatory Commission, Region III Technical Inspection Branch 799 Roosevelt Road Glen Ellyn, Illinois 60137

Re: License #34-01197-01

Dear Sir:

With reference to your letter of July 21, 1982, regarding the inspection of our facility on June 30, and July 1, 1982 by Mr. W. P. Reichhold, during which certain apparent items of non-compliance were noted, request is made to void the enclosed Notice of Violation based on the following:

1. In our amendment application dated September 6, 1979, requesting the use of Xe-133 gas, it was stated that a Ventil-Con II gas delivery system marketed by RadX Corporation would be used in our cerebral blood flow evaluation program. This Ventil-Con system has a Xenon storage compartment monitored by an in-line G-M tube. Once charged, the system displays compartment Xenon concentration in millicuries/liter on a control panel meter. The concentration can be adjusted downward by the addition of oxygen.

The Ventil-Con is affixed by tubing to the patient and following adjustment of valving, the patient is allowed to breath Xenon at the concentration displayed on the meter. The patient does not inhale all of the activity in the unit nor is the activity used up during the procedure. The only Xenon lost is that which goes to the trap via the overflow bag during washout.

We have relied on the Ventil-Con reservoir concentration multiplied by the spirometer volume reduction at the conclusion of the study to estimate Xenon utilization. The dose to the patient in our records is entered as the product of the reservoir concentration times the reduction in spirometer volume as noted during maximum inhalation and exhalation during the rebreathing phase. There is no way the dose could be measured in the dose calibrator. For this reason, we feel the citation of noncompliance is unwarranted.

2. In our application dated September 28, 1979, there was a commitment made to monitor at three feet incoming packages to determine if damage in shipment has left a source unshielded or leaking. The damage could be identified prior to opening the package by comparing the transport index

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entered on the D. O. T. label to the mR/hr reading found at three feet. 'f higher levels are found on measurement, package opening could be accelerated and greater care taken to avoid unnecessary exposure from a dislodged or leaking source.

D. O. T. labels affixed to all of the Xe-133 shipments we have received to date have been Radioactive White I labels. These labels do not carry a transport index entry as do the Yellow II and III labels. For this reason, we feel the citation of noncompliance is unwarranted.

In retrospect, we find that Mr. Reichhold's observation regarding the package surveys may be beneficial in reducing unnecessary exposure simply by knowing that a surface measurement should not exceed 0.5mR/hr. We have therefore implemented a surface measurement procedure on all incoming packages containing Xe-133 gas.

Sincerely.

Harry J. VandeVelde Assistant Administrator

HJV/cm