E.I. DU PONT DE NEMOURS & CO. (INC.)
BIOMEDICAL PRODUCTS DEPARTMENT

March 21, 1985

Mr. Thomas E. Murley
Regional Administrator
U.S.N.R.C., Region I
631 Park Avenue
King of Prussia, PA 19406

RE: License No. 20-00320-13
Docket No. 030-04581
Response to inspection No. 84-02

Dear Mr. Murley:

On December 11, 1984, a package offered for transportation, containing 450 mCi of Cobalt-58, had undergone a significant reduction in integrity during transport. This resulted in the surface radiation levels on the package exceeding the regulatory limit upon receipt by a customer in Murray Hill, New Jersey.

Although this DOT 7A package was designated for "any fitting generator assembly unit or any fitting containment vessel," the Type M lead safe used, had not been included in the certification testing prior to this incident. Because the Type M lead safe did not fit the styrofoam insert properly, the weight of the shield crushed and compacted the styrofoam enough to effectively change the geometric configuration of the source and shield and produce a higher surface radiation reading.

Immediately upon notification of the damaged package incident, NEN Products reviewed testing results and initiated packaging design modifications. A packaging modification was subsequently tested and incorporated into packages containing Type M lead safes. The modifications eliminated possible shifting of the safe within the package during transportation, preventing loss of package integrity even subsequent to a 30 foot drop test. All shipments of Type M lead safes were held up until testing of the packaging modifications were completed and approved.

NEN Products has tested and will incorporate a new polyethylene copolymer that is very resistent and will resist deformation under conditions of high impact. This material will replace the present styrofoam packaging and will be in routine use in 3-6 months.

All new packaging will now be required to be approved by a central, packaging engineering staff.

In February, May, September and October of 1984, NEN Products shipped 1 to 5 mCi of Sulfur-35 tagged methionine to an NRC licensed hospital. On December 14, 1984, the hospital called to verify their authorization to receive this material. At this time, it was realized that they lacked the necessary authorization for this radionuclide.

Based on an investigation, it was determined that the errors were made by the Customer Service Department at the time that the orders were placed. The errors were the result of incorrect readings or interpretation of the customer verification information displayed on their computer's CRT screen. To have accepted the order, the customer verification display should have indicated authorization under 33.100 (referring to authorization for non-human use materials under 10CFR 33.100). Instead, the display showed 35.100 (referring to authorization for human use materials under 10CFR 35.100). The representative reviewing the computer CRT, mistakenly read it as authorization for 33.100 materials and not the actually authorized approval for materials under 35.100.

Immediate corrective action was taken by retraining personnel and providing each with a memorandum requiring them to verify all NRC licenses that display licensure under 33.100 (10CFR 33). In addition, random internal audits of the license verification system will be performed to identify areas needing improvement. A long range corrective action will be to redesign the license verification computer programming, which will contain a number of edits designed to distinguish between such items as requests for materials under 10CFR 33.100 and 10CFR 35.100, and thus preclude processing of an incorrect order by "flagging"or blocking unauthorized requests. This program is planned to be incorporated over the next two years and should decrease the potential error rate dramatically.

Sincerely,

Dennis Dumas

Dennis Dumas
Area Supervisor
Safety and Environmental
Affairs

DD/jb

cc: Dean Findley