NOV 8 1982

Grape Community Hospital
ATTN: Mr. William May
Administrator
Highway 275 North
Hamburg, Iowa 51640

License No. 14-20246-01
30-18142

Gentlemen:

This is to acknowledge receipt of your October 11, 1982 letter in response to our September 21, 1982 letter.

Paragraph two of your letter states that precalibrated unit doses of radiopharmaceuticals should not be considered packages. For your information, please consider the following:

> 10 CFR 71.4(k) defines "package" as the packaging and its radioactive contents.
>
> 10 CFR 71.4(i) defines "packaging" as one or more receptacles and wrappers and their contents excluding fissile material and other radioactive material, but including absorbent material, spacing structures, thermal insulation, radiation shielding, devices for cooling and for absorbing mechanical shock..... and other supplementary equipment.
>
> 49 CFR 171.8 defines "package" or "outside package" as the packaging plus its contents.
>
> 49 CFR 171.8 defines "packaging" as the assembly of one or more containers and any other components necessary to assure compliance with the minimum packaging requirements of subchapter C.

Using any of the above definitions, the attache case and the lead shielding referred to in your October 11, 1982 letter are considered "packaging". The attache case, lead shielding, and the radioactive contents are the "package".

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DATE ▶							DMB:IE07

License Condition 16 referencing your application received on November 27, 1981, states that the procedures described in Appendix F of the NRC medical licensing guide 10.8, Revision 1, dated October 1980, shall be followed for safely opening packages containing radioactive materials. Appendix F requires that all shipments of liquids greater than exempt quantities will be tested for leakage. If you receive greater than 1 millicurie of liquid technetium-99, that shipment must be tested for leakage. There are additional survey procedures for opening packages. The additional survey procedures include:

1. Measuring the exposure rate at the surface of the package.

2. Measuring the exposure rate at 3 feet from the package surface.

3. Wipe test of the external surface of the final source container.

4. Monitoring the package material prior to discarding.

These additional survey procedures for opening packages apply to all packages containing greater than exempt quantities of licensed by-product material.

Paragraph two of your letter dated October 11, 1982, states that a directive outlining the procedures for opening packages containing radioactive materials as described in Appendix F, NUREG-0338, Revision 1, was sent to all technologists. Be advised, your license references the procedures described in Appendix F of the NRC medical licensing guide 10.8, Revision 1, dated October 1980, which are different from the procedures described in Appendix F, NUREG-0338, Revision 1. Enclosed is a copy of the NRC medical licensing guide 10.8, Revision 1, dated October 1980.

Regarding Item No. 2 in the Notice of Violation dated September 21, 1982, we will review this matter during the next inspection; however, Item No. 1 states that no records of package surveys were maintained. In your letter dated October 11, 1982, you failed to address this problem. In your response to this letter, please describe:

1. Your corrective actions to ensure that package survey results are recorded.

2. Your actions to ensure that package survey records are maintained.

3. The date when you will implement your corrective actions.

Submit your response within thirty days of the date of this letter.

Original Signed by J. R. Miller

J. R. Miller, Chief
Technical Inspection Branch

Enclosure: Reg. Guide 10.8

cc w/ltr dtd 10/11/82 b/w
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DMB/Document Control Desk (RIDS)

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