

NEOMEDICA
450 East Ohio Street
Chicago, Illinois 60611

July 11, 1985

B.J. Holt
Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Ref: Control #78836

Dear Ms. Holt:

This is to provide supplemental information to our undated letter (copy enclosed) delivered to NRC Region III around July 10, 1985 in reply to your letter of June 20, 1985. This is in reference to our pending license amendment application letter dated April 22, 1985. This information is being supplied in reply to your verbal inquiry to Ms. Lee Maglio of our office on or around July 10, 1985.

1. In item 2b of our undated July 1985 letter, where we say "licensed transporter", we mean "NRC licensed physician user".

As we stated in the last paragraph of item 2, page 2 of that letter "We understand we are exempt from the transportation requirements of 10 CFR 71.5 only if the licensed material is transported by one of our authorized (licensed) physician users and not by any other staff members". This specific exemption for physicians licensed under 10 CFR Part 35 is stated in 10 CFR 71.9.

2. We confirm the NRC licensed physician user - driver, doing the transporting of the bone densitometer, would notify Neomedica in the event of an accident. In the event of such an incident in which there could be any question of damage to the I-125 sealed source (special form) contained in the bone densitometer source holder head on the instrument, Neomedica would be responsible for evacuating the accident area and keeping it roped off or secure, until the extent of any radiological health hazard, if any, could be determined. This determination would be made by the NRC, who is immediately notified by the driver as stated in our earlier letter, or by a similar qualified emergency response team with specific license or authority to perform such determinations. Examples of other such response persons could include State Police with radiological health training, Argonne National Lab specialists, or consultants such as S. A. Huber Consultants, Inc., of New Lenox, Illinois, who are specifically licensed for sample analyses, decontamination tasks, leak tests, etc.

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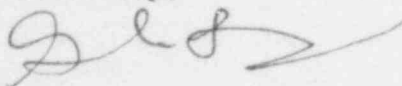
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3. The primary quality assurance check, performed on a "day-of-use" basis, involves checking the readout display of millicuries of I-125 remaining in the sealed source. This is compared to the known original calibrated activity, as corrected for decay. If the known calculated activity would not agree with the displayed activity within +5%, this would signal the need to call the manufacturer (Nuclear Data, Inc.) for a service call. If there are any problems with the computer software control system, this becomes immediately obvious by "error" display on the system or the system does not proceed with processing.

We hope this additional information will permit our pending license amendment to be issued and will appreciate anything you can do to expedite this request.

Thank you.

Sincerely,



Gordon R. Lang, M.D.
Chairman of the Board

:vmf