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Docket No. 030-22158 Control No. 104875

Osteoporosis Diagnostic Center of Washington, Inc. ATTN: Stanford A. Lavine, M.D. 1145 19th Street, N.W. Suite 300 Washington, D.C. 20036

Gentlemen:

This is in reference to your application dated January 7, 1986 for a byproduct material license. In order to continue our review, we need the following additional information:

- In item 1C of your application, you have requested a maximum activity of 250 millicuries for each sealed source. Information currently available to the NRC on the Registry of Radioactive Sealed Sources for the Nuclear Data, Inc. Bone Density Scanner Model ND 1100 has a maximum activity of 200 millicuries for each sealed source. Please specify the maximum activity for each sealed source.
- 2. In item 7 of your application, you request that Mr. James Speros be listed as an authorized user. Section 35.13 of 10 CFR Part 35 requires a physician to use licensed material on the human body. Please provide the State or Territory that Mr. Speros is licensed to practice medicine. If Mr. Speros is not a physician, he may use the Bone Density Scanner only under the supervision and in the physical presence of an authorized physician and will not be listed on the license.
- 3. In the Certificate of Training that Alara Management Co. has provided for Dr. Stanford Lavine it states "... trainee has the necessary training and experience to make a specific application for a Byproduct (Radioactive) Material License to possess and use a LIXI (+m) Scope. Since Or. Lavine has not requested a Lixiscope, please clarify which device Dr. Lavine was trained to use.
- 4. In item 10.4 of your application, you state that source exchange will only be performed by manufacturer or personnel of Elma Nuclear Corporation. Information currently available to the NRC specifies that Nuclear Data, Inc., the manufacturer, does not install the source into the holder or into the bone scanner and that Elma Nuclear Corporation is not specifically authorized by their New York license to do source exchange replacements or servicing of bone density scanners. Please provide your procedures for installing the source(s) and source exchange-replacements.

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We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 1048/5.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely.

Original Signed By:
Jack Davis
Jack Davis
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

Enclosure: 10 CFR Part 35

RI:DRSS Davis/ki 1/24/36 January 4, 1986

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Dear Mrs. Foster:

Thank you for being so much help in the processing of our NRC Lisence Application for the Osteoporosis Diagnostic Center of Washington, Inc.

Enclosed you should find the material that we need processed for the lisence, as soon as possible.

At this time, we have had the single and dual photon bone densitometors for two months, and we have been guaranteed that the isotopes will be sent immediately to us once our lisence to operate has arrived.

At this point, I'm not sure who's fault it was for not filing for the NRC lisence earlier, but the main thing is that we have over 60 patients scheduled for bone scans in the month of January alone, and we have yet to receive our lisence.

As you can see, time is of the essence, and I would greatly appreciate anything that you can do to speed up the process. Of course I will do anything on my end to help expedite this process as well. If you should need to reach me for anything, my number is (202) 223-5753.

I will contact you next week to make sure you have received the necessary information.

I appreciate your assistance in this matter very much, as does our medical director, Stanford Lavine, M.D.

Sincerely,

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Jim Speros

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Director, Osteoporosis Diagnostic Center of Washington, Inc.

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STANFORD A. LAVINE, M.D.

1146 - 19th St., N.W., Suite 360 Washington, D.C. 20036 Phone: 223-8612

Your Appointment is On:

With the second second

D.C. Office

r

Med: (202) 223-5753 Bus: (301) 424-5753

STEOPOROSIS IAGNOSTIC ENTER OF TASHINGTON INC.

1145 19th Street NW Suite 300 Washington DC 20036

JAMES L. SPEROS Director

104875

Elma Nuclear

RADIATION SAFETY CONSULTANTS

3320 Bailey Avenue • Buffalo, New York 14215

Suite 300 Washington, D.C. 20038

Osteoporosis Center of Washington, D.C. NRC Application

Dear Dr. Lavine.

Enclosed please find the NRC application for bone scanning. To complete the application, please do the following:

- Bign the application as listed in Item #13 on the application.
- Commission for the amount of \$580.
- Enclose a resume from Jim Speros.
- Forward the application and all information to Region #1 of the U.S. Nuclear Regulatory Commission as listed on the application.

It you have any questions, I will be talking with Jim Speros next week.

Sincerely,

Micheal J. Komorek, Jr. President/Health Physicist

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