



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

WASHINGTON, D.C. 20555-0001

APR 12 2000

Dr. R. J. Flanagan
DRAXIMAGE, Inc.
16751 Trans Canada Highway
Kirkland, Quebec
Canada H9H 4J4

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON MODEL LS-1

Dear Dr. Flanagan:

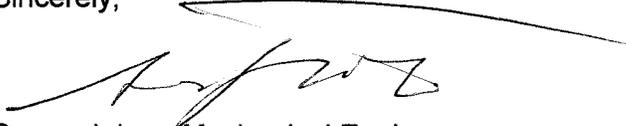
This letter is in response to your application dated February 21, 2000, requesting sealed source evaluation and registration of your iodine-125 brachytherapy source. We are in the process of evaluating your request. In order to continue our evaluation, we need additional information attached in the Enclosure.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

Please also note that NRC cannot issue a registration of your source until FDA has approved it for medical use in this country. Therefore, please send us a copy of Form 510(k) when you receive it.

If you have any questions, please contact me at (301) 415-5787 or Dr. John Jankovich at (301) 415-7904.

Sincerely,



Seung J. Lee, Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

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IRAI

Seung J. Lee, Mechanical Engineer
 Materials Safety and Inspection Branch
 Division of Industrial and
 Medical Nuclear Safety
 Office of Nuclear Material Safety
 and Safeguards

Enclosure: As stated

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