DRAXIMAGE, Inc.

ENCLOSURE

We are in the process of reviewing your application for brachytherapy source Model LS-1 using iodine-125. However, in order to continue our review, we need the following information:

1. Because the NRC has no jurisdiction over the foreign entity, the NRC has followed the regulation of 10 CFR Part 110.53 requiring for a foreign vendor to establish an address in the United States to which the NRC can correspond and serve papers as necessary to accomplish its mission. Please provide an US office address.

2. The NRC does not review the draft documents in the application. Please provide the complete and final documents for those which are marked as draft in the application (e.g., indications for use on Page 3 of Section 2, shipping pot label, primary container label, warning insert in Section 4, promotional material in Appendix 2).

3. In Section 2, please provide the estimated or surveyed annual radiation exposures for hospital personnel preparing for and performing the implant procedure and people near the patient after the implant with the sources having maximum activity of 75 mCi.

4. In Section 3.3, there is a discrepancy regarding the tolerances between the end cap and the annulus. You indicated that these components will be “pressure fitted.” However, when the values of the tolerances are considered, a 0.0002" clearance could exist between the inner and the outer diameters. Please clarify the issue of pressure fit. Please also consider if the X-ray marker can slide against the annulus, how can you prevent that the X-ray marker will not damage the isotope carrier bead?

5. In Section 3.5.1, the molecular sieve zeolite beads are screened to have diameters between 0.710 and 0.600 mm. However, the maximum space would permit insertion of an object with a diameter of 0.59 mm into the end tube. Please clarify the beads can be dispensed into each end tube.

6. In Section 4, please revise the trefoil symbol in accordance with 10 CFR 20.1901 on the shipping pot label, primary container label, and warning insert.

7. In Section 4, please add the following statement to the label in accordance with 10 CFR 32.74(a)(3): “The U.S. Nuclear Regulatory Commission has approved distribution of the LS-1 to the persons licensed to use byproduct material identified in 35.57, 35.400, or 35.500 of 10 CFR, as appropriate, and to persons who hold an equivalent license issued by an Agreement State.”

8. In Section 4, per 10 CFR 32.74(a)(2)(viii), please provide the radiation safety instructions for handling and storing the source. These instructions are to be included on a durable label attached to a permanent storage container for the source. If these instructions are lengthy for such label, they may be summarized on the label and printed in detail on a brochure which is referenced on the label.

9. In Section 5, please provide the information on the well-type sodium iodide detector.

DRAXIMAGE, Inc.

10. In Section 5, please provide integrity test results for the transportation/storage package. Your application has addressed the prototype testing of the individual beads. However, the integrity of the package, containing the beads, must also be addressed. Please provide information on package integrity. When addressing likely accident conditions for the package, please address such scenarios as dropping the package from the table top height to a concrete floor, or somebody placing a heavy object on the package.

11. In Section 6, the radiation dose measurements were shown using the 2.88 mCi. However, the maximum activity you request is up to 75 mCi, please provide the radiation field using the maximum activity of 75 mCi.

12. In Section 6.3, please clarify the values for the radiation dose constant for iodine-125: 0.7 rem-cm^2/mCi/hr is specified in "Engineering Compendium on Radiation Shielding," Vol. 1, pp. 21-30, while a value of 1.45 is shown in your application.

13. In Section 7, please provide the quality assurance manual. Please clarify the statement "leak testing by a method approved by NRC" (p. 18); if the method is in accordance with NRC requirements, please state it in such terms.

14. Please describe how the test results provided in Appendix 3, in accordance with ISO and ANSI integrity tests, apply to the Model LS-1 with the maximum activity of 75 mCi.

15. Table 2.4 in Appendix 3, the detection limit was determined to be 0.05 nCi and was calculated as 4 times the square root of the background. Whereas, in Table 3.1, the detection limit was determined to be 0.01 nCi and was calculated as 4 times the square root of the background. Please clarify this discrepancy (0.05 nCi vs 0.01 nCi).

16. In Appendix 3, the Table 3.2 shows that the activity after the test is higher than before the test. Please explain why it happens.

17. Please confirm that in Figure 1, page 5, the "well region" displays the tapering correctly. If incorrect, please provide a revised drawing.

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,

/RA/

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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Seung J. Lee, Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
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Enclosure: As stated