



by Courier,

Mr Seung J. Lee,
Materials Safety and Inspection Branch,
Division of Industrial and Medical Nuclear Safety,
Office of Nuclear Material Safety and Safeguards,
United States Nuclear Regulatory Commission,
Washington,
DC 20555-0001

29 May 2000

Dear Mr. Seung,

In response to your letter of May 16th, 2000 concerning the DRAXIMAGE LS-1 Brachytherapy implant we are pleased to provide the attached responses.

If you need additional information we would be pleased to answer any questions that you might have.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Flanagan". The signature is fluid and cursive.

Richard J. Flanagan Ph.D.
Executive Vice President.

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Question 1

Please provide FDA 510(k) certification.

Answer

We are still waiting for the FDA official certification. We received two questions from the FDA on May 16th and have replied. As soon as the certification is received we will forward a copy to the Nuclear Regulatory Commission.

Question 2

In your Application and Review Checklist, both specific and general licensees is checked. Do you want the Model LS-1 to be generally licensed source? If so, there are so many information missing in your application, we have to reject your application. Please confirm your intention for Model LS-1 use.

Answer

We wish our Model LS-1 to be specifically licensed.

Question 3

ISO 9978-1992 requires the brachytherapy sources be leak tested by the immersion test. Please provide the comparison between your proposed method and ISO 9978 method.

Answer

Please find below a report describing the differences between the ISO 9978 immersion leak test and the one proposed by DRAXIMAGE.

Comparison of leakage test proposed in the LS-1 licence application with the test put forward by the ISO 9978-1992 standard.

The ISO 9978 Standard puts forward 4 varieties of immersion test, any of which may be chosen to demonstrate compliance. However, none of these tests is designed for high throughput seed production. Our license application proposes an alternative immersion test which is more severe, particularly with respect to surface leaching and liquid penetration, than any of the immersion tests in the Standard and which allows for high throughput rates.

The leak test liquid is not exactly defined in the ISO 9978 Standard. The solution must be suitable for the purpose, considering the radioisotope in question and its chemical form.

A tabular comparison of the conditions of the proposed test with one of the tests put forward in the Standard is given below.

<u>Condition</u>	<u>Proposed test for LS-1 seed</u>	<u>Immersion test (hot liquid) from ISO-9978</u>	<u>Remarks</u>
Liquid composition.	Water containing 1 g/L each of NaOH, Na ₂ S ₂ O ₃ and KI, and 1mL/L of liquid detergent.	Not defined.	Solution to be used in proposed test has good properties with respect to surface action and hole penetration and will retain I-125 in solution.
Temperature	> 130°C.	50°C.	Proposed test is much more severe in its leaching and dissolving actions.

<u>Condition</u>	<u>Proposed test for LS-1 seed</u>	<u>Immersion test (hot liquid) from ISO-9978</u>	<u>Remarks</u>
Pressure applied above atmospheric.	2 atmospheres.	0 atmospheres.	Excess pressure of proposed test will force liquid into crevices and any paths to interior of seed. When pressure is removed, this liquid will flow out bringing removed radioactivity with it. The Standard test relies upon convection only.
Time.	> 10 minutes above 130°C. > 30 minutes above 50°C	4 hours at 50°C.	Exposure time of proposed test is shorter but this is offset by the temperature and pressure conditions.