DRAX IMAGE

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

12 June 2000

Dear Mr. Seung,

In response to your letter of June 1st, 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,

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

NRC-03.doc

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Question 1

Please provide quantitative, experimental data, or other physical evidence that (1) 10 min. at 130 C and 3 atm is sufficient for the solution to penetrate the containment in those cases where the containment is permeable and likely to leak and (2) the cooling period from 130 C to room temperature is sufficient to reveal any leaks in the containment and indicate how long this period is.

Answer

We have carried out a series of experiments to specifically answer these questions

Experiments

All of the comparative experimental work and measurements were carried out on June 6 and June 7, 2000.

A set of 16 sources of similar activities was assembled. Of these sources, 12 were left unwelded and therefore unsealed, and 4 were welded and thereby sealed. The identities and activities of the sources are given in Table 1 attached.

Half of the sources, 6 unwelded and 2 welded, were simultaneously subjected to the Immersion Test (Hot Liquid) as given in Section 5.1.1 of ISO 9978:1992. The other half were simultaneously subjected to a leak test consisting of a 1 hour cycle such as that proposed by DRAXIMAGE for routine source production. The heat cycle for the DRAXIMAGE test is given in Table 2 attached. Two blanks (i.e. leak test solution but no seeds) were carried with each test.

The liquid used in the tests was high purity water containing 1g/L each of potassium iodide, sodium hydroxide and sodium thiosulfate, and 1 mL/L of liquid detergent. The test portions were assayed for activity post-test by counting them in a test tube using the calibrated DRAXIMAGE QA well-type NaI detector as previously described. In the case of the ISO 9978 test, the full leak test solution volumes of 0.5 mL were taken for assay. In the case of the DRAXIMAGE production leak test, 0.05 mL aliquots were taken from the full leak test solution volumes of 0.5 mL. The results of the post test solution assays are given in Table 3 attached.

Results

It is apparent from the data in Table 3 that the proposed DRAXIMAGE test is more effective than the ISO 9978 test in removing activity from the LS-1 sources in situations where the containment is permeable and likely to leak The cooling period from 130 °C to 50 °C in the DRAXIMAGE test is 30-45 minutes.

TABLE 1: Results of ionization chamber measurements of leak tested seeds

ID number of LS-1 source	Activity (U, June 6)	Activity (approx. mCi, June 6)
1	0.277	0.218
2	0.264	0.207
3	0.264	0.207
4	0.259	0.204
5	0.259	0.204
6	0.263	0.207
7	0.264	0.207
8	0.274	0.216
9	0.264	0.207
10	0.262	0.206
11	0.269	0.212
12	0.260	0.205
13	0.260	0.205
14	0.263	0.207
15	0.262	0.206
16	0.264	0.207

TABLE 2: Heat cycle for DRAXIMAGE leak test

Time on June 7, 2000	Leak Test Fixture Temperature, °C	Remarks
18:30	19	Hotplate setting 150 □ 200
18:35	50	
18:40	86	
18:42	96	Hotplate setting 200 □ 300
18:46	116	
18:48	130	Hotplate setting 300 □ off
18:49	135	
18:50	141	Fixture removed from hotplate onto insulator pad
18:55	131	
19:00	122	Fixture removed from hotplate onto steel table top
19:05	92	
19:10	78	
19:15	67	
19:20	61	
19:30	51	Fixture opened

TABLE 3: Post-test assay of leak test solutions

ID number of leak test solution (corresponds with ID of LS-1 source in Table 1)	Condition of seed	Leak test applied	Activity found in full volume of leak test solution used in test (nanocuries, June 7)
1	Unwelded	ISO 9978	223
2	Unwelded	ISO 9978	385
3	Unwelded	ISO 9978	155
4	Unwelded	ISO 9978	80
5	Unwelded	ISO 9978	171
6	Unwelded	ISO 9978	236
7	Welded	ISO 9978	0.3
8	Welded	ISO 9978	1.1
Blank 1	No seed	ISO 9978	< 0.03
Blank 2	No seed	ISO 9978	< 0.03
9	Unwelded	DRAXIMAGE	1220
10	Unwelded	DRAXIMAGE	2390
11	Unwelded	DRAXIMAGE	1440
12	Unwelded	DRAXIMAGE	2020
13	Unwelded	DRAXIMAGE	1370
14	Unwelded	DRAXIMAGE	1180
15	Welded	DRAXIMAGE	1.3
16	Welded	DRAXIMAGE	1.0
Blank 3	No seed	DRAXIMAGE	< 0.3
Blank 4	No seed	DRAXIMAGE	< 0.3

Conclusion:

It can be seen from Table 3 that the DRAXIMAGE variation on the ISO 9978:1992 leak test assay is in fact more sensitive.

Question 2

The function of a US distributor is, in addition to licensing issues, to assure the quality of the products prior to distribution in the US. Therefore, please delineate how this function for a US distributor will be accomplished.

Answer

DRAXIMAGE would be responsible for all shipments into the United States. As part of that responsibility we would maintain a US customer license database and would ship directly to approved US customers.

DRAXIMAGE has a FDA compliant Quality Assurance and Control Department and Manufacturing Department. We currently have five approved NDA's, an SNDA submission in progress and two IND's in progress. We have been audited by the FDA for Sterile Pharmaceutical production and are routinely inspected by the Canadian Therapeutic Products Program and the Canadian Atomic Energy Control Board.

DRAXIMAGE currently ships radioactive materials directly to customers in the United States and our Type A packages are fully compliant with the International Air Transport Association (IATA) requirements.

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