



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

May 14, 1997

Richard Brown
Elscint, Inc.
505 Main Street
Hackensack, NJ 07601

Dear Mr. Brown:

This letter is in response to the facsimile dated March 12, 1997, from Michael Seveg, Elscint Ltd. in Israel, to R. Brown, Elscint, Inc. in New Jersey USA, regarding registration of Model TransACT Gadolinium-153 line source housing. In order to continue our safety evaluation, the following information is necessary:

1. Please verify that the information contained in the facsimile is being submitted by Elscint Inc., in support of the safety evaluation request. Please be aware that all statements and commitments made in support of the safety evaluation are the responsibility of Elscint Inc.
2. It is our understanding that Elscint Inc. is no longer seeking to withhold any information submitted from public disclosure pursuant to 10 CFR 2.790. All information submitted will be placed in the NRC's Public Document Room.
3. Please be aware that all required labeling must remain attached at all times to the portion of the device that contains the radioactive material. Since the arm of the TransACT is designed to be routinely removed from the motion mechanism cover for storage, the arm must contain the required labeling. It is not acceptable to label the motion mechanism cover in lieu of the arm, but the cover may contain additional labeling. Please note in addition, that the device as registered will consist only of the arm, and its attachment method to the motion mechanism. The motion mechanism is not considered a part of the device for registration purposes.

Please submit details regarding the labeling and position of the labeling on the registered device (source housing) itself. This labeling should contain the information currently contained on the label shown in Dwg# 705-3671-1305. Please indicate the materials of construction and method of attachment for this label.

4. Please provide additional details regarding the LED on/off indicator, specifically: how the mechanism of the LED indicator functions to ensure that the LED indicator is on when the source is NOT FULLY shielded, and that is off when the source is in the FULLY shielded position; and how the tests verify that the LED indicator is working properly.



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5. Since the arm is designed to be routinely removed from the device for storage, it should be easily identifiable to the user, when the arm is detached from the motion mechanism, whether the shutter is in the fully shielded position. It is suggested that the lever be labeled or marked in such a way to provide easy identification of the on and off shutter positions. This could include labeling the device near the lever with an on/off notation, or labeling or painting the lever itself.
6. The drop and puncture testing as described is not sufficient to demonstrate that, during normal use conditions, over the expected lifetime of the housing, the byproduct material will not be released to the environment, and the source will not be inadvertently unshielded. Specifically, the information submitted appears to address only penetration of an object through a 4mm thick aluminum plate. Additional information is needed to determine whether the device will provide adequate containment for the radioactive material, and to ensure that the external radiation levels around the device will not significantly increase.

Please also be aware that Elscint Inc. may perform these tests on a device containing a dummy (non-radioactive) source. Testing with a dummy source must still verify that there has been no breach to the source capsule (ex. bubble test).

7. Please provide details that illustrate how it is ensured that the source is properly seated at both ends during installation of the source into the device? Also, it is not apparent from the drawings how the source is attached to the solenoid by pressure. Please provide additional details.

Please provide the requested information within thirty (30) days of the date of this letter. If you have any questions, please contact me at (301) 415-5868 or John Lubinski at (301) 415-7868.

Sincerely,

LSI

Michele L. Burgess, Mechanical Engineer
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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