August 15, 1995

Charles L. Skutches, Ph.D.
The Lankenau Medical Research Center
100 Lancaster Avenue
West of City Linc
Wynnewood, PA 19096

Dear Dr. Skutches:

Based on the information submitted in your letters dated June 2, 1995, and June 22, 1995, with enclosures thereto, we have transferred registration certificate NR-598-D-126-S to inactive status. The registration number of the certificate has been changed to NR-598-D-801-S.

Please review the registration certificate (copy enclosed) in its entirety and notify us immediately if there are any errors or omissions.

If you have any questions, please contact me at (301) 415-7868 or Mr. Steven Baggett at (301) 415-7273.

Sincerely,

/S/

John W. Lubinski, Mechanical Engineer
Sealed Source Safety Section
Source Containment and
Devices Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc w/encl: SKimberley, LFDCB

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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-598-D-801-S DATE: August 15, 1995 PAGE 1 OF 7

DEVICE TYPE: Gamma Irradiator

MODEL: Mark-1 Series, Sub Model 68-A-1, Serial #1070

MANUFACTURER/DISTRIBUTOR: J.L. Shepherd & Associates
1010 Arroyo Avenue
San Fernando, CA 91340-1822

SEALED SOURCE MODEL DESIGNATION: J.L. Shepherd & Associates
Model 6810

ISOTOPE:

Cesium-137

MAXIMUM ACTIVITY:

5000 Ci (185 TBq)
(Up to two sources)

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (J) Gamma Irradiator, Category I

CUSTOM DEVICE: ___X___ YES _____ NO

CUSTOM USER: The Lankenau Medical Research Center
100 Lancaster Avenue
West of City Line
Wynnewood, PA 19096

9509280304

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-598-D-801-S DATE: August 15, 1995 PAGE 2 OF 7

DEVICE TYPE: Gamma Irradiator

DESCRIPTION:

The device is a Mark-1 Series, Sub Model 68-A-1 irradiator manufactured by J.L. Shepherd. The device was originally registered by the California Department of Health Services. However, Lankenau's device, serial number 1070, was modified to include a recycle timer and an incubator attached to the inside of the device. The modifications of the device were performed by J.L. Shepherd. At the time the modifications were made, documentation submitted to NRC for approval of the corresponding amendment to Lankenau's license, and information obtained from the State of California, led the staff to believe a custom registration was required. A custom review was performed and a registration certificate issued. About 30 months later, Lankenau submitted additional information they had received from the State of California. This additional information indicated that the modified device can be licensed for use based on the registration certificate issued by the State of California. Therefore, the custom registration is being transferred to inactive status.

The basic Mark-1 irradiator consist of (1) an irradiation chamber with a door on the front side; (2) one cylindrical sealed source attached to the end of a source rod which can be moved vertically (in the highest position it is located at the back of the irradiation chamber); and (3) shielding around the source and irradiation chamber, including the walls and door of the chamber.

Dimensions of the device and radiation levels are listed in Attachment 1.

The door to the irradiation chamber is opened and closed manually. The source is raised from the "Off" to "Irradiate" position by either a manual, preset, or recycle operation. In all cases, the source falls from the "Irradiate" to the "Off" position by gravity.

Manual operation of the irradiator requires setting the control to Manual Mode and setting the device to Single Cycle. The source is returned to the "Off" position by activating the "Source Return" button. Preset operation of the irradiator requires setting the control to Preset Mode, setting the device to Single Cycle, and entering a desired "Preset Time" for exposure.

DEVICE TYPE: Gamma Irradiator

DESCRIPTION (cont'd):

The source will return to the "Off" position after the present time has elapsed. Recycle operation of the irradiator requires setting the control to Cycle Mode and setting the device to Recycle Mode. The operator must enter the desired "Irradiate" time and "Off" time. The source(s) will cycle between the "Irradiate" and "Off" positions for the times entered. Pressing the "Reset" button will clear all times and return the source(s) to the "Off" position.

The source is locked in the "Off" position by means of a spring loaded solenoid latch to the source rod which can be released only by passing electric current through the solenoid. Four safety switches are wired in a series circuit with the solenoid. Three of these safety switches are closed by moving the door to its closed position and the other one is closed by a spring loaded latch to the door only when the latch holds the door locked in its closed position. One of the three safety switches which closes when the door is closed is built into a completely independent mechanical interlock safety system which requires greater than 200 pounds (890 N) pressure to operate. When the door is locked in its closed position by the latch, the latch can be released only by passing electrical current through a solenoid. This can occur only when the source is latched in the "Off" position. Additional safety features include 0.5" (1.27 cm) diameter stainless steel studs welded to the base plates of both the standard interlock and the mechanical pressure interlock which penetrate through the box covers for these systems so that a padlock can secure these boxes to prevent tampering.

The device is wired so that the source returns to the "Off" position in case of any of the following:

(1) Power failure.
(2) Pushing source return button - overrides preset timer.
(3) The bolt which locks the door in the closed position is not fully engaged.
(4) The door is not fully closed.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Gamma Irradiator

DESCRIPTION (cont'd):

The irradiator is equipped with a turntable which is rotated by an electric motor outside the chamber. The turntable is connected to the electric motor by a drive chain which passes through the tubes in the chamber wall. In line with each tube is a scatter shield outside the wall to attenuate scattered radiation emerging from the tube.

The wires for the incubator pass through one of four tubes in the wall of the irradiator. Three of the holes are filled with plugs. The fourth, the one the incubator wires pass through, has its plug modified with a 1/4" groove running down its length for the wires. A scatter shield is mounted in line with the tubes on the outside of the irradiator.

LABELING:

The device bears a 3" x 4" (7.62 cm x 10.16 cm) yellow and magenta label which contains the radiation symbol, isotope, activity, date of assay, manufacturer's logo, and the words "CAUTION-RADIOACTIVE MATERIAL". A second label provides the manufacturer's logo, model number, and serial number of the device.

DIAGRAM:

See Attachments 1-3.

CONDITIONS OF NORMAL USE:

The device is intended for use in a laboratory environment for irradiation of biological, horticultural, and chemical samples. The device is for the exclusive use of The Lankenau Medical Research Center.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Gamma Irradiator

PROTOTYPE TESTING:

J.L. Shepherd has manufactured Mark-1 Series irradiators with single sources since 1968. The addition of the incubator and recycle timer does not require any additional prototype testing.

EXTERNAL RADIATION LEVELS:

Each Mark-1 irradiator is designed for radiation levels at one meter from the surface not to exceed 0.2 mR/hr (2 μSv/hr) per 1000 curies (37 TBq) of cesium-137. Attachment 1 shows the maximum radiation levels for this Sub Model 68-A-1 irradiator. The Lankenau Medical Research Center has submitted information to assure that the modifications to the device do not cause the radiation levels to exceed those listed in Attachment 1.

QUALITY ASSURANCE AND CONTROL:

Quality assurance and control programs are not required for custom devices. However, the manufacturer has a quality assurance and control program for the manufacture of the Mark-1 Series irradiator.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The device was only used by The Lankenau Medical Research Center.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- Before initial use of the device, The Lankenau Medical Research Center verified that the radiation levels around the device did not exceed those listed in this certificate. The Lankenau Medical Research Center has not notified NRC of any discrepancies.
- Maintenance and repair of the device shall be performed by the manufacturer or persons licensed by NRC or an Agreement State to provide such services.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Gamma Irradiator

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (cont'd):

- Interlocks shall be tested at intervals not to exceed 6 months.
- The manufacturer recommends that a warning system with an audible alarm actuated by a preset radiation level be installed near the door of the irradiator.
- The device shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 μCi (185 Bq) of removable contamination.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

As of the date of this document, pursuant to the additional information submitted by Lankenau Medical Research Center in their referenced letters of June 2, 1995 and June 22,1995, the Mark-1, Sub Model 68-A-1 irradiator, serial number 1070, does not require a custom registration. This device may continue to be used pursuant to the State of California's registration certificate for J.L. Shepherd and Associates' Mark-1 Series Irradiators.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Gamma Irradiator

REFERENCES:

The following supporting documents for the Model Mark-1 Series, Sub Model 68-A-1, Serial #1070 irradiator are hereby incorporated by reference and are made a part of this registry document.

- U.S. NRC internal memorandum from Robert L. Baer, Chief, SCDB, to Diane Dandois, Chief, LFDCB, dated July 28, 1995.
- The Lankenau Medical Research Center's letters dated June 22, 1995, June 2, 1995, October 6, 1994, April 22, 1992, March 20, 1992, February 11, 1992, and July 10, 1991, with enclosures thereto.
- J.L. Shepherd & Associates' registration certificate CA-598-D-104-S.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: _____ Reviewer: _____
John W. Lubinski

Date: _____ Concurrence: _____
Steven L. Baggett

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

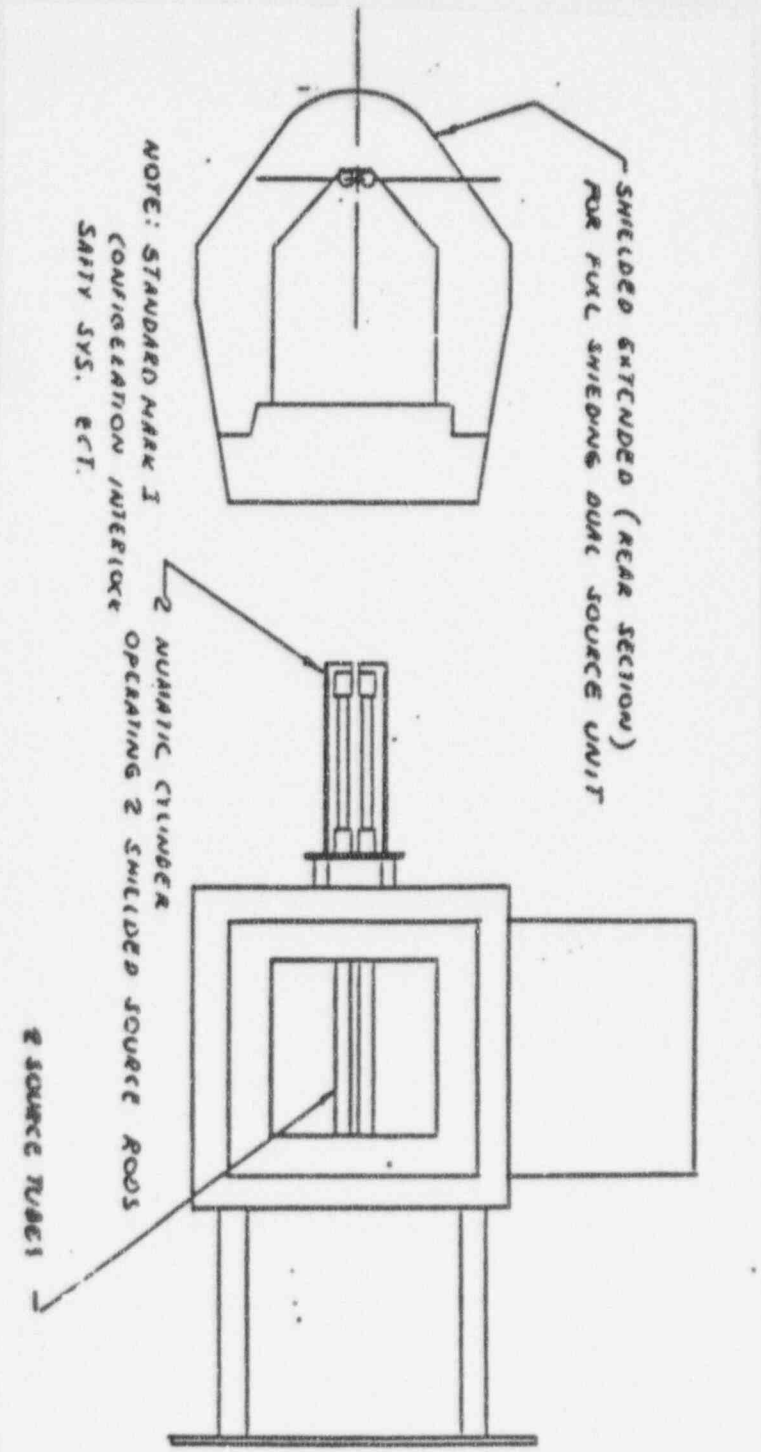
NO.: NR-598-D-801-S DATE: August 15, 1995 ATTACHMENT 1

Mark-1 Series, Sub Model 68-A-1
Serial #1070

Cavity:	12" x 14"
Lead Thickness:	5-3/8"
Shield Diameter:	12"
Overall Diameter:	32"
Overall Height:	72"
Maximum Radiation in the working area:	5.0 mR/hr at 2.5 cm
Maximum Radiation behind the device:	10.0 mR/hr at 2.5 cm
Maximum Radiation at 1 meter:	0.50 mR/hr

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

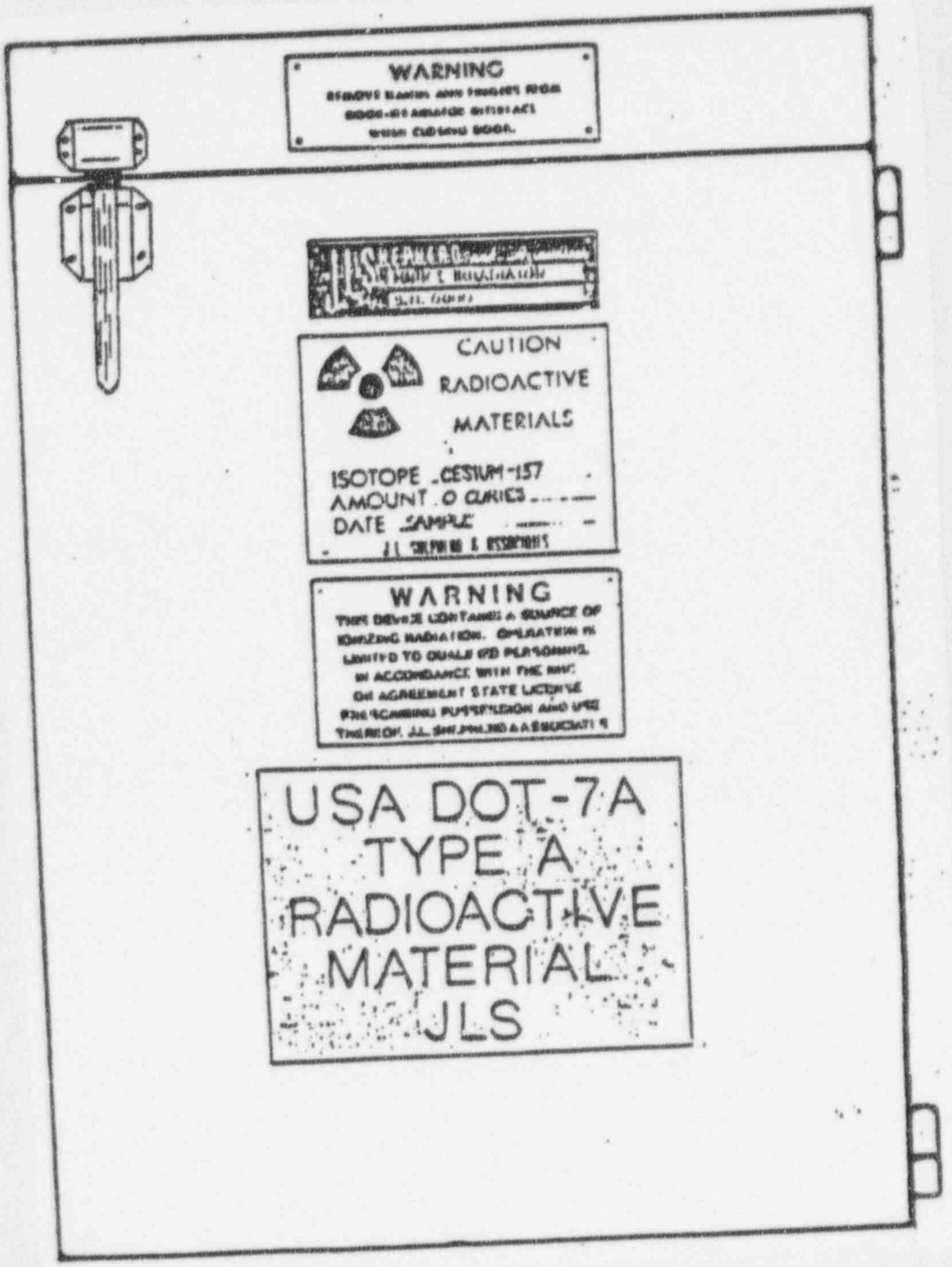
NO.: NR-598-D-801-S DATE: August 15, 1995 ATTACHMENT 2



LAY OUT FOR DUAL SOURCE MARK I

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-598-D-801-S DATE: August 15, 1995 ATTACHMENT 3



JUL 2 8 1995

MEMORANDUM TO: Diane Dandois, Chief
License Fee and Debt Collection Branch
Division of Accounting and Finance
Office of the Controller

FROM: Robert L. Baer, Chief /s/
Source Containment and
Devices Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

SUBJECT: LANKENAU MEDICAL RESEARCH CENTER - NR-598-D-126-S

As requested in your June 29, 1995, memorandum, we have reviewed the new information provided by Lankenau Medical Research Center in their June 22, 1995 letter. This new information was not previously available to us during the decision making process. Had the State and the vendor come forward with this information in 1992, we would not have done a custom device evaluation at that time. However, the information provided in 1992, indicated that the change was not submitted to the state and, therefore, these types of design modifications were not approved. We continue to believe that the actions taken to originally custom license the device was appropriate and with the full knowledge of its ramifications by the Vice President, of Administration at Lankenau.

Given this new information, we are in the process of making the certificate inactive.

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