REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(Amended in its entirety)

NO: NR-558-S-101-S DATE: JAN 2 0 1983 PAGE 1 OF 6

DEVICE TYPE: Intersitital Implant Source and Storage Container

MODEL: R/1 (seeds) and P-1, P-2, P-3, P-4 Storage Containers

MANUFACTURER/DISTRIBUTOR: RAD/IRID, Inc.
600 "U" Street, N.W.
Washington, D.C. 20001

MANUFACTURER/DISTRIBUTOR:

ISOTOPE: Iridium-192 MAXIMUM ACTIVITY: 15 millicuries

LEAK TEST FREQUENCY: Six months

PRINCIPAL USE: (V) General Medical Use

CUSTOM DEVICE: _____ YES __X__ NO

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DEVICE TYPE: Intersitital Implant Source and Storage Container

DESCRIPTION:

The RAD/IRID, Inc. Model 1 sources are designed for interstital treatment of cancer. The source is constructed of 30% Iridium, 70% Plutonium alloy wire and have dimension of 0.020 inches in diameter and up to 0.01 inches in length. Thus, giving a minimum activity of 1 millicurie per wire. This wire is encapsulated in 2 type 304 stainless steel capsules. The inner capsule has an inside diameter of 0.095 mm. The outer capsule has an outside diameter of 0.50 mm. Capsules are cold welded by shearing forces. These capsules are then forced into nylon tubing (ribbons) which have an inner diameter slightly smaller than the outside diameter of the capsule (0.45 mm). The elasticity of the nylon holds each capsule in place. Each ribbon contains a maximum of 12 seeds usually spaced 1 cm from center-to-center for a total length of 11 cm. The leading end of the ribbon is about 1 meter long to facilitate handling.

RAD/IRID, Inc. (R/I) Models R/1 P-1, R/1, P-2, R/1 P-3 storage containers consist of channels to receive ribbons of Iridium-192 bearing "seeds" and lead shielding measuring 7 inches long by 3 incnes diameter. Model R/1 P-1 container has 30 small, stainless steel channels located around a 5/8-inch diameter circle in the center of shield body. A 3/8-inch diameter hole extends from end to end and is plugged with a stainless steel friction stopper at one end and a friction fitted lead stopper at the other. The lead plug prevents the nylon ribbon bearing seeds from being inadvertently removed from the device. The device has a stainless steel jacket.

Model R/1 P-2 device has a solid lead shield that has a stainless steel outer housing and small handle on top. Sixteen stainless steel channels open on both ends around a 2-1/4-inch circle but slant toward a 1/2-inch diameter circle located around the longitudinal axis so as to outline a shallow "U" shaped path. Tension and friction between the channel wall and nylon ribbon hold the ribbons in place.

Model R/1 P-3 devices are not jacketed. A tight bundle of 14 channels enters one end of bare lead shielding near the corner and exists on a diagonal from the other while taking a lazy "S" configuration through the shield. Again, the nylon ribbons are held in place by means of friction and tension.

Model R/1 P-4 device is a solid lead shield that has a stainless steel outer housing. A cylindrical plug has been removed from the outside of the device to allow ribbons to be coiled for storage. The lead plug is then replaced to limit radiation exposure to users.

Below is a summary list of the storage containers and maximum capacity of ribbons with 12 seeds per ribbon:

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DEVICE TYPE: Intersitital Implant Source and Storage Container

DESCRIPTION (Cont'd):

Model No.	Maximum Capacity	Maximum Activity
R/I P-1	30 ribbons	450 millicuries
R/I P-2	16 ribbons	240 millicuries
R/I P-3	14 ribbons	210 millicuries
R/I P-4	18 ribbons	270 millicuries

Prior to shipping each of the above storage containers, they are properly packaged into a 12" x 12" x 12" container.

LABELING:

Seeds and ribbons are not labeled. However, each container bears a label stating the following markings:

"CAUTION-RADIOACTIVE MATERIAL"
Trefoil symbol
RAD/IRID, Inc.
2212 Georgia Avenue, N.W.
Washington, D.C. 20001

"RAD/IRID, Model 1 IR-192 sources are licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 10 CFR, Sections 34.14 and 35.100 Group VI or under equivalent licenses of Agreement States. For handling and storage instructions, see package insert." Additionally, a data sheet decay chart and bill of lading are sent with each shipment. The data sheet and bill of lading include the caution "Repeated autoclaving is not recommended. This set should not be used after two (2) months."

DIAGRAM:

See attachments.

CONDITIONS OF NORMAL USE:

These sources and containers are designed for use in hospital or clinical environments for the treatment of cancer under the normal conditions encountered in clinical practice.

PROTOTYPE TESTING:

These sources have been previously approved for use by the NRC on December 24, 1975. Prior to that time, they had been approved for use by the AEC in 1953.

DEVICE TYPE: Intersitital Implant Source and Storage Container

PROTOTYPE TESTING (Cont'd):

RAD/IRID further states that the sources have been in use for 30 years and no problems have been encountered in clincal practice.

Tests to which the sources have been subjected are:

- Sources have been exposed to water and to cold and warm isotonic saline solution (0.025% sodium Chloride by weight) for periods up to six months without any signs of corrosion or deterioration.
- Prolonged exposure to concentrated "zepherin" (antiseptic solution) up to six months shows no signs of corrosion or deterioration.
- Sources are autoclaved at pressure up to 350 psi and temperatures up to 250°F for 30 minute periods without any adverse affects notices.

EXTERNAL RADIATION LEVELS:

Source radiation dose rates for the most commonly used activity of 1 millicure per seed are:

@ 5 cm ≈ 184 millirem/hour
@ 30 cm ≈ 5.1 millirem/hour

Source containers and radiation profile are:

(Maximum reading in millirem per hour with maximum activity)

	Model No.			
	R/1 P-1	R/1 P-2	R/1 P-3	R/1 P-4
Top	90	30	50	40
Bottom	40	60	35	50
Side	96	50	45	40

Shipping containers radiation profile maximum reading in millirem per hour with maximum activity:

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DEVICE TYPE: Intersitital Implant Source and Storage Container

EXTERNAL RADIATION LEVELS:

	Model No.			
	R/I P-1	R/I P-2	R/I P-3	R/I P-4
Top	20	8	20	20
Botton	15	25	15	25
Side	20	10	10	15

QUALITY ASSURANCE AND CONTROL:

RAD/IRID states that quality assurance and control are provided routinely throughout the manufacture and use of the sources. The stainless steel tubing from which the capsules are made is certified by the manufacturer (Superior Tube Company) to be type 304 stainless steel hyperdermic needle tubing with chemical composition and mechanical properties tested and notorized. The manufacturer (Engelhard Industries) of the wire used certify it to be an alloy of 30% Iridium and 70 Platinum. During seed fabrication representative numbers are individually inspected with a microscope to ensure the cold weld when fabrication is complete, all seeds are individually inspected for unformity, bent, or damaged seeds are discarded. After seeds are irradiated they are comparatively measured with a standard of known activity. Representative are then smear tested for possible contamination.

Model 1 ribbon sources are assayed by RAD/IRID for content of radioactive material using an ionization chamber and a calibrated Cesium-137 source. Conversion units are:

1 mg radium equivalent = 0.85 mRh-cm = 1.5 mCi Ir-192

Each batch of seeds are given a code number for traceability. Each ribbon is smear tested for contamination to an acceptance limit of 10^{-6} microcuries.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- Sources and containers may be distributed to persons specifically licensed pursuant to Sections 35.13, 35.14, and 35.100 Group VI, 10 CFR 35, or under equivalent regulations of Agreement States.
- Sources should not be subjected to autoclave pressures in excess of 350 psi and temperatures in excess of 250°F, nor to these temperatures and pressures for periods in excess of 30 minutes.
- These sources shall be leak tested at intervals not to exceed six months using techniques approved by the licensing authority and capable of detecting 0.005 microcurie of removable contamination.

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DEVICE TYPE: Intersitital Implant Source and Storage Container

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

- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- Instructions and guidance for the safe handling of the Iridium-192 are given by an instruction sheet but are not adequate in themselves to satisfy requirements of 10 CFR 20.
- This registration sheet and the information contained within the reference shall not be changed or transferred without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

The Model sources consist of Iridium-192 metal wire doubly encapsulated in stainless steel and each source is contained in a nylon ribbon. Although the seed/ribbons have high surface dose rates, they will be used and handled by a trained radiotherapist for the interstital treatment of cancer. Source identical in design, construction, and in manufacturing have been in use in this country and around the world for more than 30 years and no problems have been encountered in clinical procedures. This does not include problems associated with improper handling and use techniques.

From the information and test data in the references cited below, we conclude that these sources in nylon ribbon will be manufactured pursuant to the requirements specified in Section 32.74 of 10 CFR 32, and that the sources and device will maintain integrity under stresses likely to be encountered in normal use and accidents and, therefore, are acceptable for licensing purposes.

REFERENCES:

The following supporting documents are hereby incorporated by reference and are made a part of this registry document:

- RAD/IRID, Inc. application dated December 24, 1980 and letter dated October 22, 1981
- RAD/IRID, Inc. license number 08-14043-01 and 08-14043-02MD
- Supersedes registration sheet No. NR-558-D-101-U dated December 24, 1975.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: JAN 2 (1983 Reviewer: _____

Date: _____ Concurrence: _____

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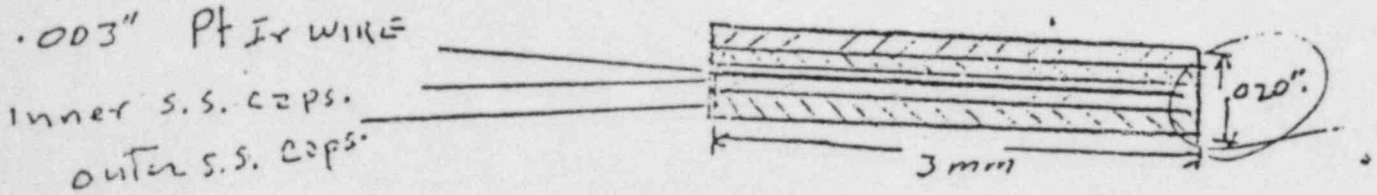
JAN 2 6 1983



model 1 seed

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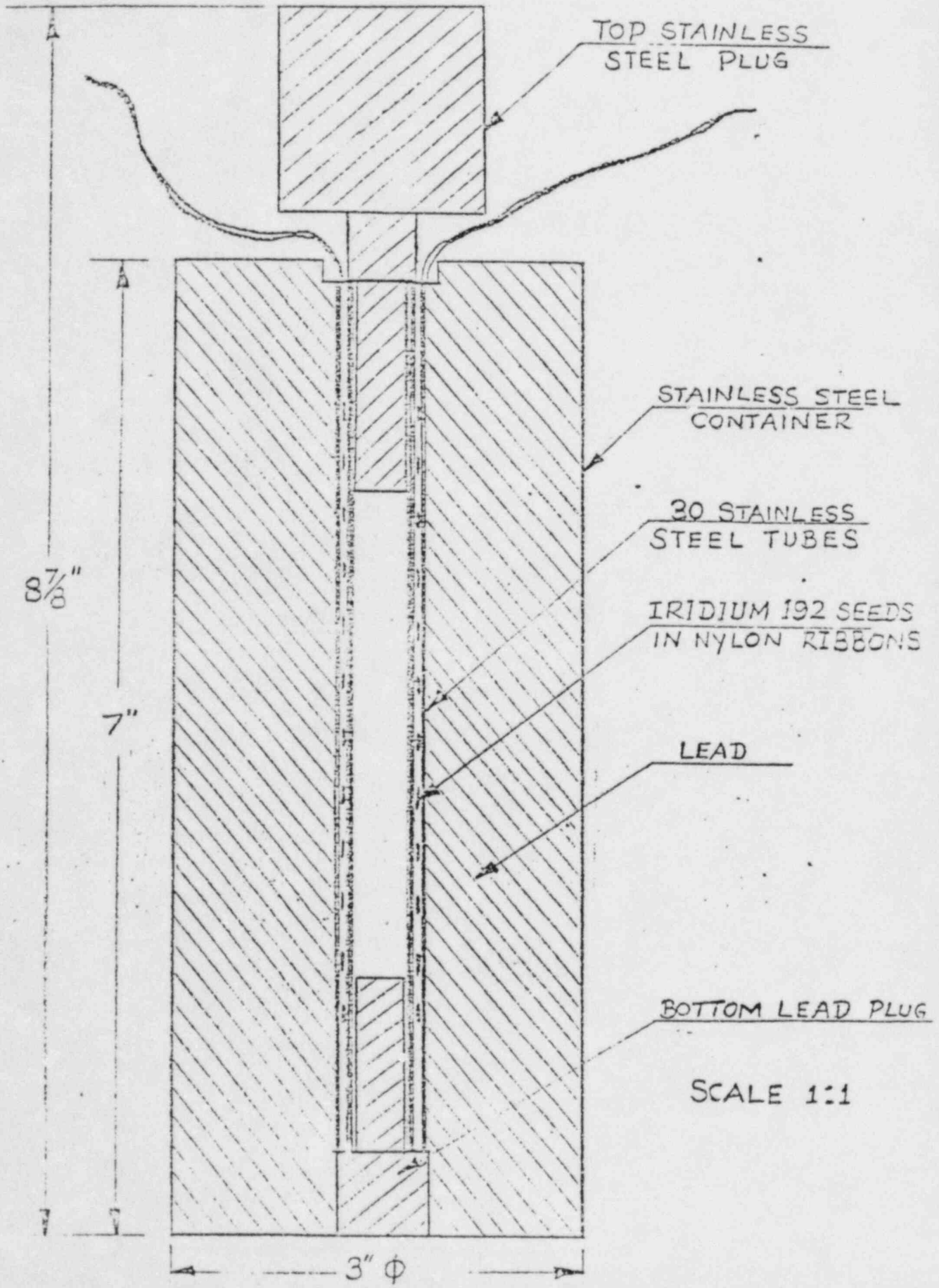

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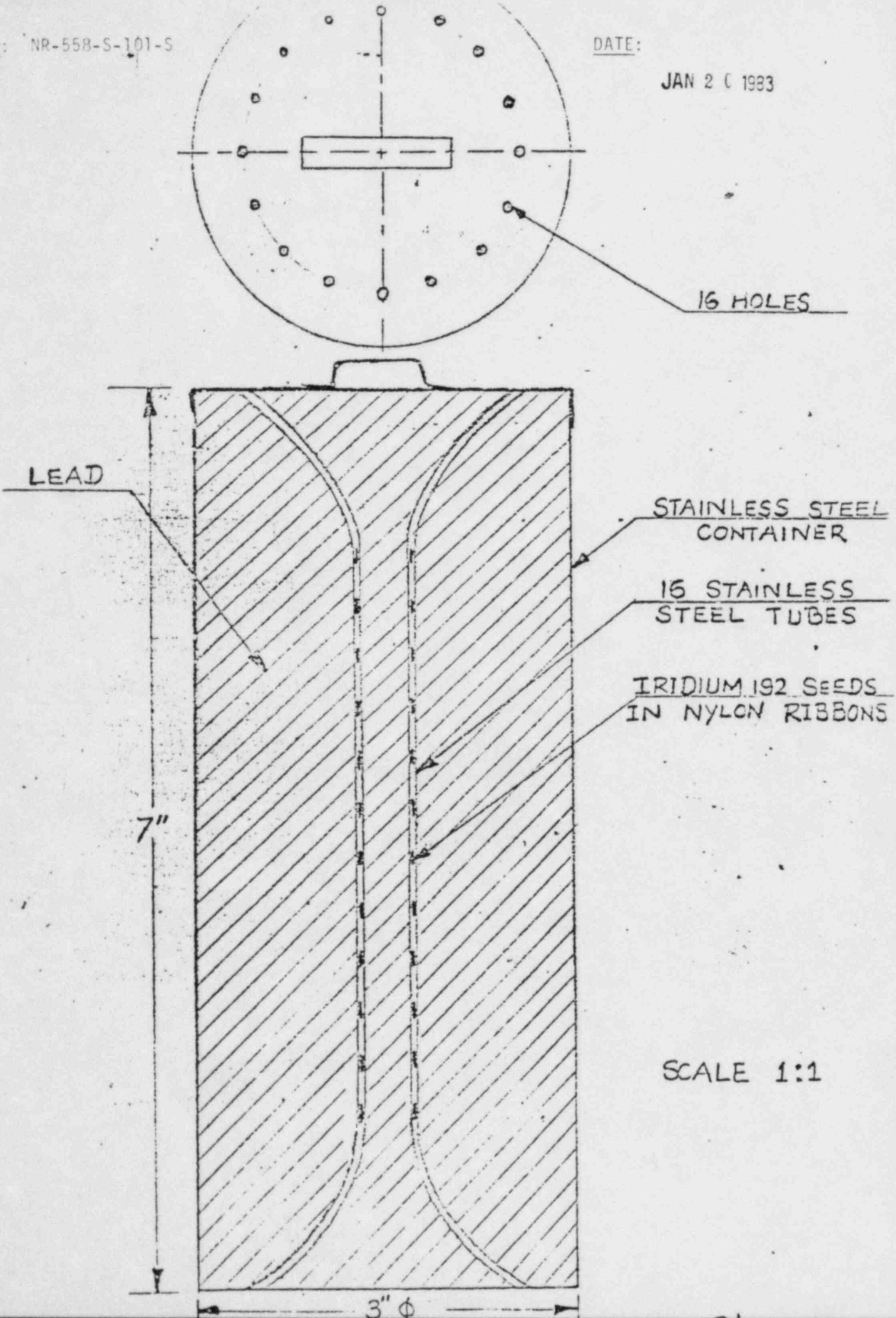
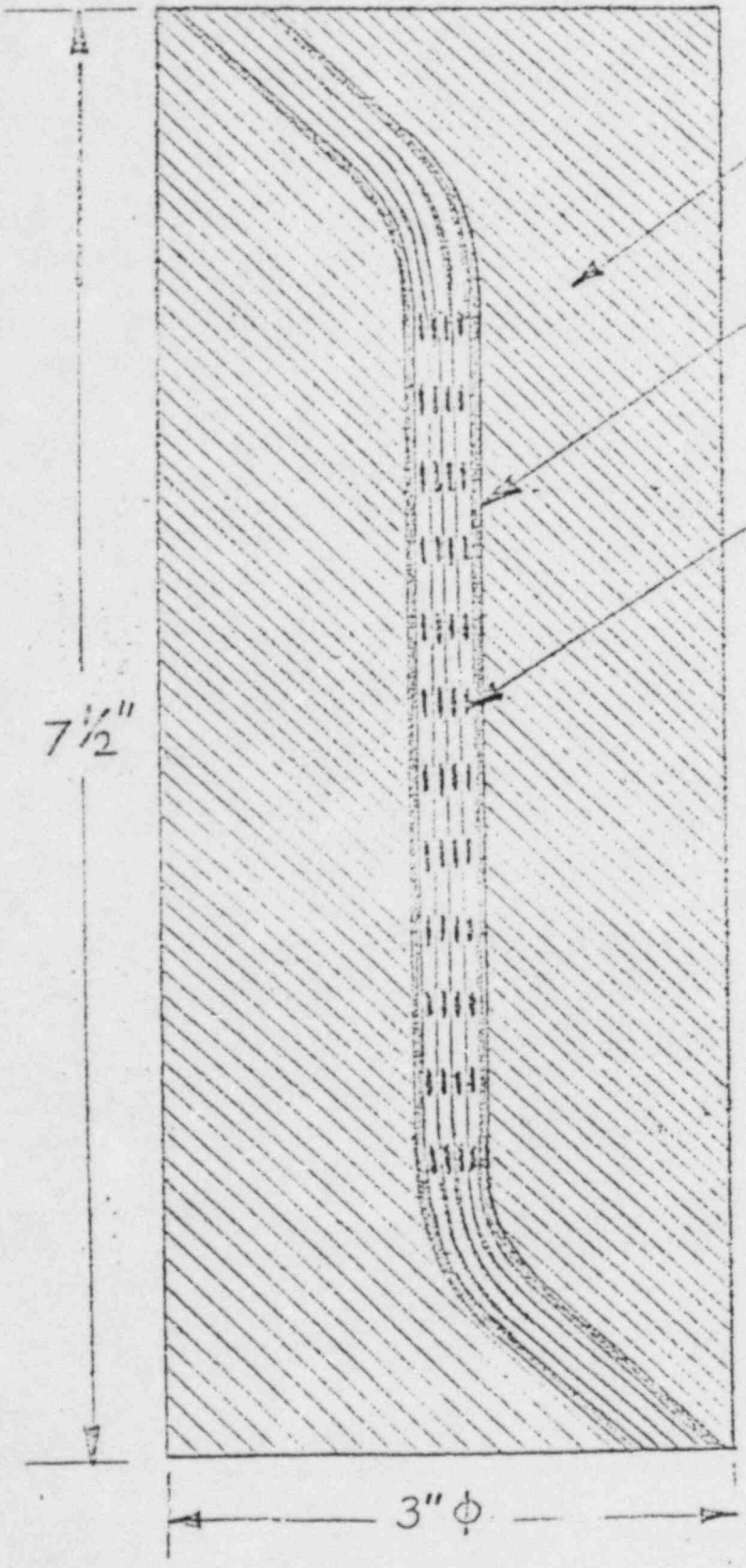


SCALE 1:1

NO. MD-553-5-101-5 DATE: JAN 2 6 1983



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RI p-3

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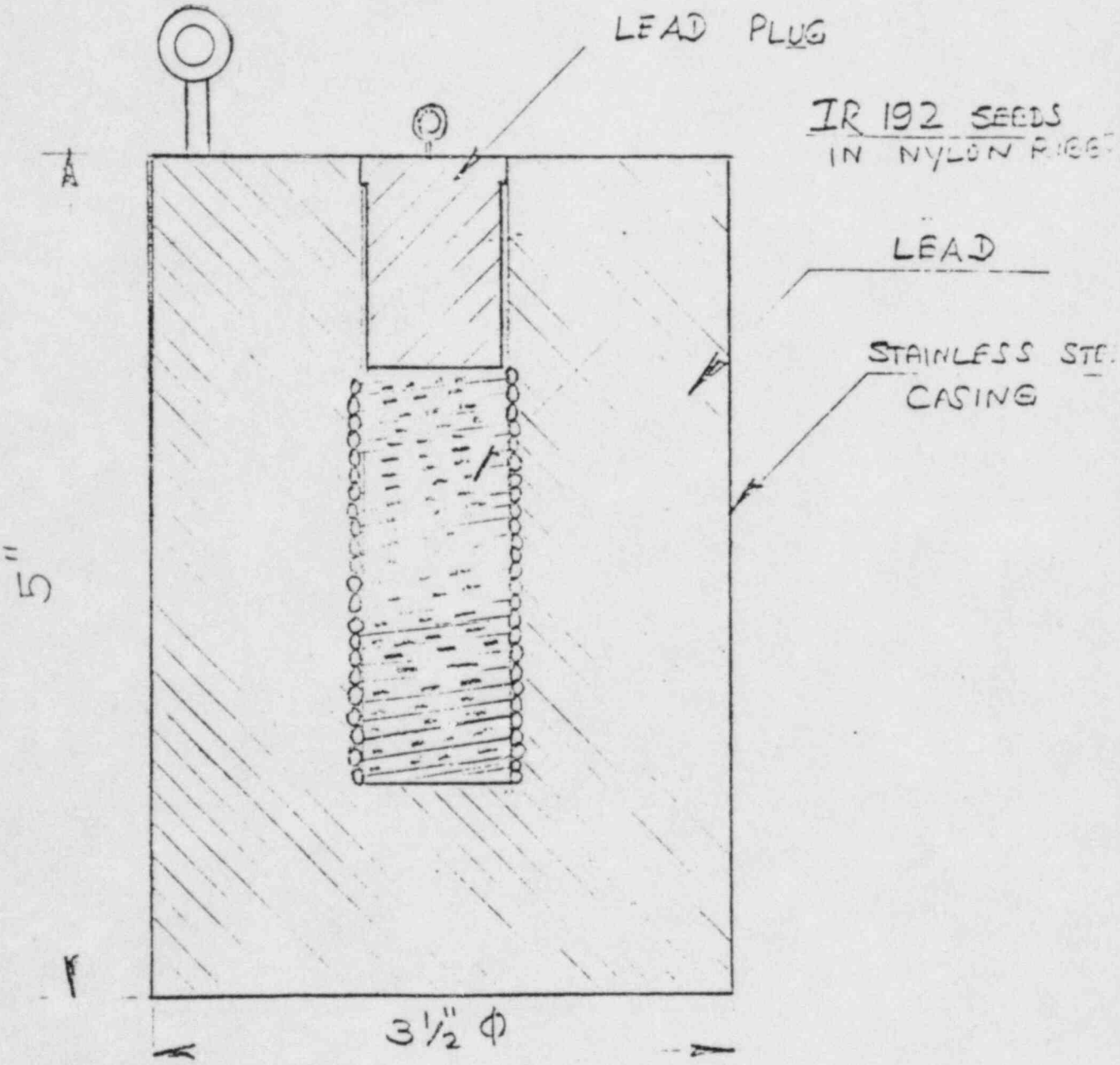

Model R/1, P-4