



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF SEALED SOURCE

No.: NR-8147-S-801-S                      DATE: April 30, 2004    PAGE 2 OF 11  
(Previously NR-569-S-801-S)

SOURCE TYPE:    Interstitial Implant Source and Storage Container

DESCRIPTION:

Seeds were basically right-circular cylinders (with ends slightly tapered and rounded from manufacture). Each seed contained approximately 0.14 milligrams (0.3E-6 lb) of Iridium, in the form of Platinum 70/Iridium 30 alloy wire. These seeds (RSNP-Ir) were identical to seeds manufactured by Best Industries (Model 81-01) and RAD/IRID, Inc. (Model 1).

As indicated in the sketch in Attachment 1, RSNP-Au seeds were doubly encapsulated in Type 304 stainless steel. The "core" of the seed was 2.8 mm (0.11") length of 0.1 mm (0.004") O.D. wire, which had a composition of 70% Platinum and 30% Iridium. The "Outer" and "Inner" capsules were 0.020" (0.51 mm) O.D. x 0.011" (0.28 mm) I.D. and 0.010" (0.25 mm) O.D. x 0.006" (0.15 mm) I.D., respectively. The stainless steel used in the encapsulation was medical hypodermic needle-grade Type 304 stainless steel. The ends of the seeds were "cold welded" by crimping/shearing, and then slightly rounded to ensure closure.

The seeds were irradiated in a reactor to activate the Ir-191 to Ir-192. Upon receipt of seeds from the reactor, the seeds were assayed and separated according to activity.

Prior to shipment to customer(s) and subsequent usage, the seeds were loaded into nylon ribbons with a typical spacing of one (1) centimeter (0.37") from center to center. Each ribbon might contain up to a maximum 12 seeds for a maximum total active length of 11.3 cm or approximately 4.5 inches. Standard ribbons would have three (3) cm (1.18") of inactive leader and 50-100 cm (19.69 - 39.37") of inactive tail to facilitate after loading.

DIAGRAM:

See Attachments 1 through 7.

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SOURCE TYPE:    Interstitial Implant Source and Storage Container

LABELING:

Due to the small size of the Iridium seeds, labeling of individual seeds was impossible and impractical.

The storage/shipping container used in the DOT Type A-7A package would be labeled with the following information:

"Caution-Radioactive Material," Radiation Symbol, Isotope, Number of Seeds, mCi of Ir-192, and the Date of Assay.

A computer sheet detailing the above information would accompany each shipment. (See Attachment 2)

Attachment 3 includes a decay chart to aid the user in calculating the activity of the seeds for a 60 day period.

CONDITIONS OF NORMAL USE:

These seeds were to be used for interstitial implantation in cancerous tumors by persons authorized to possess and use therapeutic radiation sources pursuant to 10 CFR Part 35 or similar Agreement State licenses.

They would be used in a hospital/clinic/medical environment, by persons trained and licensed to use therapeutic radiation sources.

PROTOTYPE TESTING:

Iridium-192 seeds from RSNP were identical to sources that had been in use in the medical community since the early 1950's, with no significant health and safety problems.

They would be used in a hospital/clinic/medical environment, by persons trained and licensed to use therapeutic radiation sources. As such, no extreme physical factors, i.e., high temperature, pressure, abusive use, etc., were expected which would compromise the integrity of the seeds.

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PROTOTYPE TESTING (Cont'd):

Iridium-192 seeds of this composition and design had been subjected to the following tests:

- a. Autoclaving at temperature of 250°F (121.1°C) and pressures of 350 psi (2.41 MPa) for thirty minute period with no deterioration of integrity;
- b. Exposure to concentrated antiseptic solutions "zephherin" for 6 months with no corrosion or deterioration;
- c. Six month exposure to water and 25% isotonic saline solutions without deterioration or corrosion.

EXTERNAL RADIATION LEVELS:

Sealed sources at 5 cm (1.97") and 30 cm (11.81") for typical seed:

0.8 mg Ra equivalent (1.2 mCi Ir-192) = 221 mR/hr @ 5 cm and  
= 6.1 mR/hr @ 30 cm

QUALITY ASSURANCE AND CONTROL:

RSNP had an established quality assurance program for its laboratory analytical assay instrumentation, i.e., constancy checks, geometrical variation checks, NIST approved laboratory cross checks, etc.

This QA program was submitted in support of our application to manufacture and distribute Gold-198 seeds, and would be adhered to in the assay of our Iridium-192 seeds.

Below find an item-by-item breakdown of the quality assurance that went into the manufacturing of the inactive seeds:

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QUALITY ASSURANCE AND CONTROL (Cont'd) :

- (1) During seed fabrication, representative samples (at least one in 100) will be individually inspected under a microscope or magnifying glass to assure the closure(s) at the ends of the seeds are complete.

- (2) The supplier of the stainless steel tubing will supply certification that the encapsulation is of Type 304 stainless steel (hypodermic needle-grade).

- (3) Damaged or bent seeds will be discarded.

- (4) Irradiated seeds are analyzed in a sealed ion chamber, with cross checks performed in a Nuclear Chicago Dose Calibration which has a well chamber. The conversion units used are:

1 milligram Radium equivalent = 0.85 mRh-cm  
= 1.5 mCi Ir-192

- (5) Assayed seeds will then be batched into "lots" such that the activity spread in any lot will not exceed 0.05 mg Ra equivalent. A unique number is assigned to each lot for accountability.

- (6) Prior to irradiation, all seeds are ultrasonically cleaned to remove any cutting or shavings and other possible contaminants which may lead to radioactive contamination after irradiation.

- (7) Upon receipt of the irradiated seeds from the reactor, they will be leak tested by:

- (a) Soaking in liquid scintillation medium, with swirling and/or stirring for at least 12 hours.

- (b) The LSC medium will be analyzed for activity, with a maximum removable limit of 0.005 mCi (185 Bq).

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QUALITY ASSURANCE AND CONTROL (Cont'd):

- (c)    A leak test certificate will accompany each shipment (See Attachment 2).
- (d)    As an alternate method of leak testing, the ribbons will be smeared prior to shipment and analyzed to verify the removable contamination is less than 0.005 mCi (185 Bq).

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

RSNP would only distribute to persons and/or facilitates that were specifically licensed by the US NRC or an Agreement State to possess and use these sources. In accordance with regulations, we would require that each customer send us a copy of his/her current license to verify his/her authorization. A separate file was established for each customer which contained that specific license.

(1)    Leak Testing

Individual users were not required to perform leak tests on the Iridium seeds, unless they kept the seeds for periods of six months or longer.

As indicated in Section (7) of QA above, RSNP would leak test the seeds prior to shipment and would supply the user with a certificate.

(2)    Unpacking

Attachment 4 details "OPENING INSTRUCTIONS FOR "TYPE A" PACKAGE CONTAINING RADIOACTIVE MATERIALS," which would be included with the packing slip for each shipment of Iridium seeds. User(s) would be instructed to sterilize the Iridium seeds and/or ribbons prior to use.

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

(3)    Handling

The customer/user was instructed to "follow all local procedures. State and federal Regulations for the safe handling of radioactive material to reduce personnel exposure and minimize the spread of contamination will be followed."

(4)    Disposal

The customer/user would be instructed that the disposal of these Iridium seeds must be in compliance with State and/or federal regulations. RSNP would include in each shipment a set of shipping papers and correct labels if the customer prefers to return the seeds for disposal (See Attachment 5).

SAFETY ANALYSIS SUMMARY:

Iridium-192 seeds in nylon ribbons had been in use in the medical community for approximately 40 years, with no significant health and safety problems.

Seeds would be used in hospital/clinical/medical environment, by persons trained and licensed to use therapeutic radiation sources. No extreme physical factors, i.e., high temperatures, pressure, abusive use, etc. were expected which would compromise the integrity of the seeds.

These seeds had been subjected to tests described in PROTOTYPE TESTING Section, which tests exceeded any set of conditions to which they would reasonably be subjected during normal usage.

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SOURCE TYPE:    Interstitial Implant Source and Storage Container

STORAGE CONTAINERS:

DESCRIPTION:

RSNP, Inc. Storage Devices Model Number RSNP-2 were constructed from lead filled Schedule 40 steel pipe with an outside diameter of 3.5" (8.89 cm) (nominal), and a wall thickness of 0.226" (5.74 mm). They were approximately ten (10) inches (25.4 cm) long and have threaded caps on each end. Handles were bolted onto them to facilitate carrying (See Attachment 6).

These containers had 24 stainless steel or copper tubes located around a two (2) inch (5.08 cm) diameter circle welded into a plate, which was welded in place at ½ inch (1.27 cm) from the top of the shield such that they were surrounded by a minimum of one (1) inch (2.54 cm) of lead for a length of at least four (4) inches (10.16 cm). The bottom of the tubes would be left open for orders which required extra leader on the Iridium seed-bearing ribbons.

The nylon ribbons were held in place by means of friction and tension within the storage tubes. The 50-100 cm (10.69 - 39.37") long "tails" would pass through a slot in the top of pipe, and be taped to the body of the container. With the threaded cap installed, the ribbons were held securely in place for transport to the customer.

A number of wire security seal would be connected between the two (2) caps to provide evidence that the package had not been illicitly opened.

LABELING:

RSNP-Ir (Seeds), RSNP-2 (Storage Device). Each container bears a label containing the following information:



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SOURCE TYPE:    Interstitial Implant Source and Storage Container

LABELING (Cont'd):

"CAUTION-RADIOACTIVE MATERIAL"  
RSNP, Inc.  
3589 West 500 South  
Salt Lake City, UT 84104

Radiation Symbol  
Isotope and Amount  
Date

SHIPPING:

For shipment, this container (RSNP-2) was center in a DOT Type A-7A fiberboard container described below:

a.    Outer Container

- (1)    Spec 12B fiberboard box, with Styrofoam inserts to maintain shield (RSNP-2) in center of box.
- (2)    Fiberboard box to be 12" x 12" x 12" (30.48 cm x 30.48 cm x 30.48 cm), double-sided (2-ply) and waterproofed (See Attachment 7).
- (3)    Outer container is a DOT A-7A container, and has met in the test conditions specified in 49 CFR 173.398(b)(3).
- (4)    The majority of packages will require a "DOT-RADIOACTIVE II" label, as the Transport Index will be less than 1.0, however, those shipments whose TI > 1.0 will require a "RADIOACTIVE III."

IMPORTANT NOTE:

EVERY INDIVIDUAL PACKAGE WILL BE MONITORED TO DETERMINE TRANSPORT INDEX AND APPROPRIATE LABEL.

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SOURCE TYPE:    Interstitial Implant Source and Storage Container

SHIPPING (Cont'd):

b.    Specifications and Restrictions

- (1)    Authorized gross weight - 50 lb (22.68 kg).
- (2)    Marking of package must be in compliance with 49 CFR 173.24(c) (1).
- (3)    Security seals must be provided as required in 49 CFR 173.393(b).
- (4)    Contamination levels, external radiation levels, and labeling must be in compliance with 49 CFR 173.393.
- (5)    Maximum activity for shipping in RSNP-2 container: 250 mCi (9.25 GBq) of Iridium-192.

DIAGRAMS:

See Attachments 6 and 7 for diagrams of the Storage Container (RSNP-2) and the DOT Type A-7A Package for shipping.

EXTERNAL RADIATION LEVELS:

- (a)    Source container loaded to maximum (250 mCi [9.25 GBq] Ir-192):
  - Top - - - 100 mrem/hr (1.0 mSv/hr)
  - Side - - 100 mrem/hr (1.0 mSv/hr)
  - Bottom - 90 mrem/hr (0.9 mSv/hr)
- (b)    Shipping container loaded to maximum (250 mCi [9.25 GBq] Ir-192):
  - Top - - - 30 mrem/hr (0.30 mSv/hr)
  - Side - - 30 mrem/hr (0.30 mSv/hr)
  - Bottom - 28 mrem/hr (0.28 mSv/hr)
  - Transport Index (mrem/hr @ 1m [39.37"]) - - 4.0

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EXTERNAL RADIATION LEVELS (Cont'd):

Each RSNP-2 container would be stamped with a unique serial number, and a radiation profile would be performed on each container to verify the integrity of the lead shielding prior to its use. Records of these tests would be maintained for inspection by regulatory personnel.

SAFETY ANALYSIS SUMMARY:

The manufacturer stated that Models RSNP-Ir (Seeds) and RSNP-2 (Storage Device) are no longer manufactured and distributed and does not have any intention to produce them in the future. Therefore, the registration certificate is being converted to an inactive registration.

REFERENCES :

- Radiation, Safety and Nuclear Products letter dated January 17, 1985, and April 23, 1985, with enclosures thereto.
- Radiation, Safety and Nuclear Products, Inc. letter dated February 22, 1999, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: April 30, 2004      Reviewer: /RA/  
John P. Jankovich

Date: April 30, 2004      Concurrence: /RA/  
Ujagar S. Bhachu

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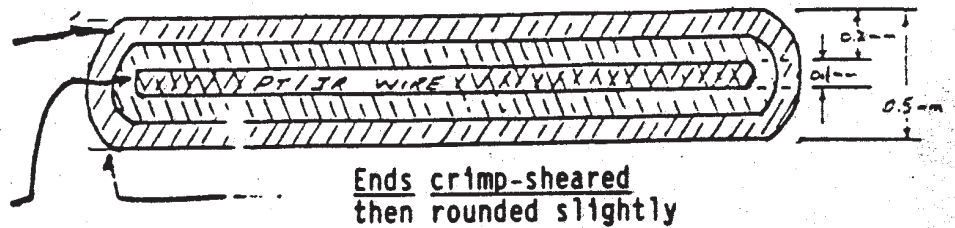
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ATTACHMENT 1

(Previously NR-569-S-801-S)

Outer Capsule  
0.020" O.D.  
x 0.011" I.D.

Inner Capsule  
0.010" O.D.  
x 0.006" I.D.



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ATTACHMENT 2

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IRIDIUM-192 SEED ASSAY CERTIFICATION

CUSTOMER:

LICENSE #:

ASSAY DATES:

SHIP DATE:

CARRIER:

AIRBILL #:

Storage Position	# of seeds	Type of Loading	Soaking (cm.)	mCi Ir-192 per Seed	mg. Ra Equiv.	TOTAL ACTIVITY mCi Ir-192	mg. Ra Equiv.
1	10	UNIFORM	1	1.00	0.67	10.00	6.67
2	10	UNIFORM	1	1.00	0.67	10.00	6.67
3	10	UNIFORM	1	1.00	0.67	10.00	6.67
4	10	UNIFORM	1	1.00	0.67	10.00	6.67
5	10	UNIFORM	1	1.00	0.67	10.00	6.67
6	10	UNIFORM	1	1.00	0.67	10.00	6.67
7	10	UNIFORM	1	1.00	0.67	10.00	6.67
8	10	UNIFORM	1	1.00	0.67	10.00	6.67
9	10	SINGLE	1	1.00	0.67	10.00	6.67
10	10	SINGLE	1	1.00	0.67	10.00	6.67
11	10	SINGLE	1	1.00	0.67	10.00	6.67
12	10	SINGLE	1	1.00	0.67	10.00	6.67
13	10	SINGLE	1	1.00	0.67	10.00	6.67
14	10	UNIFORM	1	1.00	0.67	10.00	6.67
15	10	SINGLE	1	1.00	0.67	10.00	6.67
16	10	UNIFORM	1	1.00	0.67	10.00	6.67
17	10	UNIFORM	1	1.00	0.67	10.00	6.67
18	10	UNIFORM	1	1.00	0.67	10.00	6.67
19	10	UNIFORM	1	1.00	0.67	10.00	6.67
20	10	UNIFORM	1	1.00	0.67	10.00	6.67
21	10	UNIFORM	1	1.00	0.67	10.00	6.67
22	10	UNIFORM	1	1.00	0.67	10.00	6.67
23	10	SINGLE	1	1.00	0.67	10.00	6.67
24	10	UNIFORM	1	1.00	0.67	10.00	6.67
TOTALS--	240					240.00	160.00

LEAK TEST RESULTS: <0.005 MICROCURIES

DATE: \_\_\_\_\_

SIGNATURE: \_\_\_\_\_

Radiation, Safety & Nuclear Products, Inc.  
3641 West 1987 South  
Salt Lake City, UT 84104

\* IMPORTANT! \*

THESE IRIDIUM-192 SEEDS AND RIBBONS  
ARE NOT STERILE AND MUST BE STERILIZED  
PRIOR TO USAGE. RSNP ASSUMES  
NO RESPONSIBILITY FOR COMPLICATIONS  
WHICH MAY ARISE FROM USER NOT  
HEEDING THIS WARNING.

Iridium-192 seeds (Model RSNP-Ir) are  
licensed by the Utah Bureau of Radiation  
Control for distribution to persons  
licensed pursuant to URC-22-070(J)  
and Group VI of URC-22-200 Schedule A,  
or under equivalent regulations of the  
U.S. Nuclear Regulatory Commission, an  
Agreement State or a Licensing State.

\* FOR THERAPY USE ONLY! \*

IRIDIUM-192 SEEDS ARE FOR THERAPY USE  
ONLY, AND MAY BE ONLY ADMINISTERED TO  
HUMANS BY PHYSICIANS LICENSED TO DISPENSE  
DRUGS IN THE PRACTICE OF MEDICINE

CAUTION: RADIOACTIVE MATERIAL!

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**IRIDIUM-192 DECAY FACTORS**

HALFLIFE = 72.4 DAYS

DAY NUMBER	DECAY FACTOR	DAY NUMBER	DECAY FACTOR
0	1.000	30	0.756
1	0.991	31	0.749
2	0.981	32	0.742
3	0.972	33	0.735
4	0.963	34	0.728
5	0.954	35	0.721
6	0.945	36	0.714
7	0.937	37	0.708
8	0.928	38	0.701
9	0.919	39	0.695
10	0.911	40	0.688
11	0.902	41	0.682
12	0.894	42	0.675
13	0.885	43	0.669
14	0.877	44	0.663
15	0.869	45	0.657
16	0.861	46	0.651
17	0.853	47	0.645
18	0.845	48	0.639
19	0.837	49	0.633
20	0.830	50	0.627
21	0.822	51	0.621
22	0.814	52	0.615
23	0.807	53	0.610
24	0.799	54	0.604
25	0.792	55	0.598
26	0.784	56	0.593
27	0.777	57	0.587
28	0.770	58	0.582
29	0.763	59	0.576

**NOTE:**

To calculate the activity of an Iridium-192 Seed or source on any day up to 50 days after calibration, multiply the original activity by the decay factor for that day--

**EXAMPLE--**

You want to calculate the activity of an Iridium-192 Seed on the 20th day after calibration. Original activity = 1.2 mCi Ir-192

$$\text{ACTIVITY} = 1.2 \text{ mCi} \times 0.830 = 0.996 \text{ mCi Ir-192}$$

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DATE: April 30, 2004 ATTACHMENT 4

OPENING INSTRUCTIONS FOR TYPE "A" PACKAGE  
CONTAINING RADIOACTIVE MATERIALS

This package contains radioactive material and it is made up as follows:

- a. The radioactive material is contained in seeds, which are sealed into nylon ribbons and placed inside a lead storage container.
- b. The storage container is centered in the package, and has a numbered security seal to assure it has not been illicitly opened.
- c. The nylon ribbons have been inserted into numbered tubes, and can be removed only by removing the cap at the top of the container.
- d. The metal container with its associated packaging is a Specification 7A shipping container.

TO OPEN:

Protective clothing such as gloves, lab coat, etc. should be worn. The package should be placed in a properly controlled radiation area where the following steps should be taken:

- a. Measure the radiation dose rate (TI) from the package and compare it with the dose rate (TI) written on the label. Any appreciable difference should be reported to the resident radiation safety personnel and also the snipper.
- b. Open the outer container (fiberboard box) and remove the lead storage container.
- c. Remove the tape from the storage container to free the "tails" of the nylon ribbons. The cap should be removed in a proper manner to prevent direct radiation exposure to any parts of the body.
- d. The ribbons can be removed from the storage container for use in some other shielding arrangement, however, remote handling tools should be used to minimize exposure to the hands.
- e. Follow all local procedures, State and Federal regulations for the safe handling of radioactive material to reduce personnel exposure and minimize the spread of contamination.

SEE REVERSE SIDE FOR HANDLING AND STORAGE INSTRUCTIONS!!

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HANDLING AND STORAGE INSTRUCTIONS

1. CAUTION - These Iridium-192 Seeds are THERAPY radiation sources, with a high specific activity. They should be handled with extreme care.
2. The specific gamma emission from an Iridium-192 Seed is 4.6 R/hr/mCi at 1 cm. Thus, for a 1.2 mCi seed, the radiation level would be 5.5 R/hr, 92 mR/minute, or 2 mR/second at 1 cm.
3. Do NOT touch or otherwise handle these sources with bare hands. Always use tongs or forceps to increase the distance and minimize exposure to your hands, eyes and whole body.
4. Sources should not be removed from shipping shield until sterilization prior to use. Additional lead shielding may be required to reduce exposure levels in occupied areas to the regulatory limits.
5. Remember to follow all local procedures and the applicable State and Federal regulations for the safe handling of radioactive materials to reduce personnel exposure and minimize the spread of contamination.

NOTE: RSNP, INC. MAKES NO CLAIM THAT THE Iridium-192 SEEDS, RIBBONS, AND AFTERLOADING TUBES, AS SHIPPED, ARE STERILE AND PYROGEN-FREE. WE WILL ASSUME NO RESPONSIBILITY OR LIABILITY SHOULD RELATED PROBLEMS OR COMPLICATIONS ARISE FROM THEIR USE.

DISPOSAL INSTRUCTIONS

IMPORTANT: These Iridium-192 Seeds contain a licensable quantity of Radioactive material, and must be disposed of in a proper manner.

1. They may be held for decay, or
2. They may be transferred to persons (companies) specifically licensed to receive and possess Iridium-192 in the form of seeds for disposal.

TO RETURN Iridium-192 SEEDS TO RSNP, INC. YOU MUST COMPLY WITH THE FOLLOWING:

1. Package the storage container, ribbons, and seeds in the same manner you received them:

a. Insert the ribbons into the tubes from the top of the storage container.

b. Tape the "tails" to the side of the storage container.

c. Screw the cap onto the top of the storage container.

d. Place the storage container in the box with the appropriate styrofoam spacers to maintain the position of the container.

e. Seal the box with strong (nylon reinforced) tape.

f. Place the security seals (included in packet) on closures.

g. Measure the radiation levels at the surface of the box, and at 1 meter with a calibrated survey meter.

h. Record the "1 meter reading" in mR/hr (rounded up to the nearest tenth) on the Shipper's Certification Form in the "Transport Index" column, and also on the DOT "RADIOACTIVE II (111)" labels.

i. Fill in the remaining blanks on the Shipper's Certification Form with the ACTIVITY.

j. The name, title, telephone number, and signature of the shipper must be completed.

k. MAXIMUM READINGS FOR "RADIOACTIVE II" - 50 mR/hr (surface) AND 1.0 (T.I.), MAXIMUM READINGS FOR "RADIOACTIVE III" - 200 mR/hr (surface) AND 10.0 (T.I.)

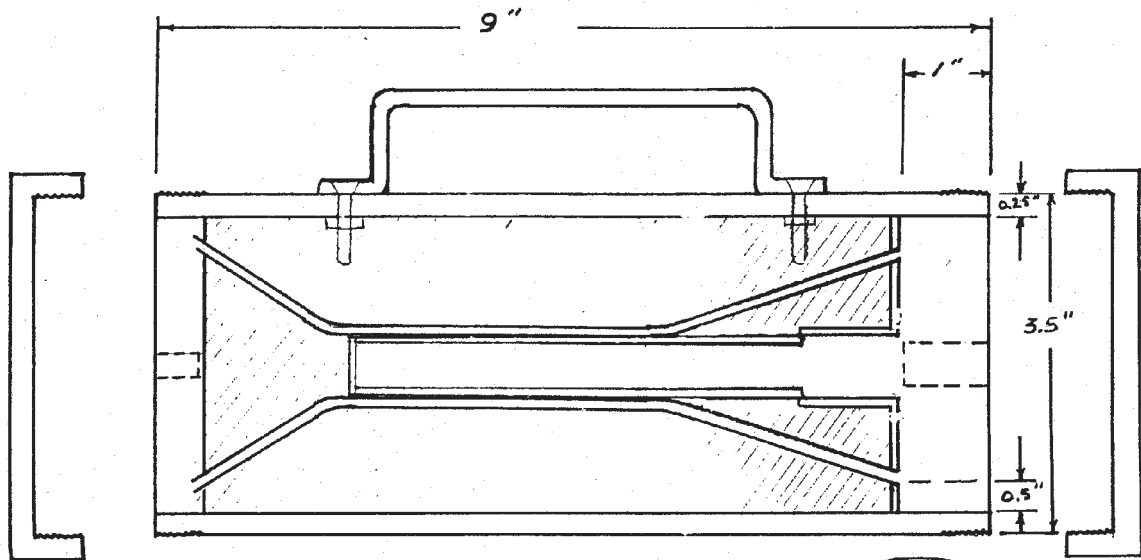
NOTE: THE DOT REGULATIONS ARE CONFUSING!! IF YOU HAVE ANY QUESTIONS ABOUT YOUR SHIPMENT, CALL US BEFORE YOU SHIP. WE WILL NOT ASSUME ANY RESPONSIBILITY FOR OUR SHIPMENTS THAT ARE NOT PROPERLY PACKAGED.



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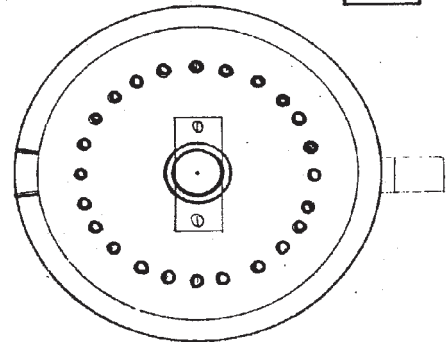
Scale:  $\frac{3}{4}" = 1.0"$

STORAGE/SHIPPING CONTAINER  
FOR IRIIDIUM-192 SEEDS IN RIBBONS

MODEL NO: RSNP-2

RADIATION, SAFETY & NUCLEAR PRODUCTS, INC.  
3641 W. 1987 S., SALT LAKE CITY, UT

JANUARY 17, 1985



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF SEALED SOURCE

NO: NR-8147-S-801-S  
(Previously NR-569-S-801-S)

DATE: April 30, 2004 ATTACHMENT 7

