Form AEC-313 (2-73) 10 CFR 30	UNITED STATES ATOMIC ENERGY COMMISSION APPLICATION FOR BYPRODUCT MATERIAL LICENSE	Form approved Budget Bureau No. 38-R0027

INSTRUCTIONS.—Complete Items 1 through 16 if this is an initial application or an application for renewal of a license. Information contained in previous applications filed with the Commission with respect to Items 8 through 15 may be incorporated by reference provided *references are clear and specific.* Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail two copies to: U.S. Atomic Energy Commission, Washington, D.C., 20545, Attention: Materials Branch, Directorate of Licensing. Upon approval of this application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Part 20, and the license fee provisions of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 16 and the appropriate fee enclosed. (See Note in Instruction Sheet).

1. (a) NAME AND STREET ADDRESS OF APPLICANT. *(Institution, firm, hospital person, etc. Include ZIP Code and telephone number.)*

Rad/Irid Incorporated
2212 Georgia Avenue, N.W.
Washington, D.C. 20001

(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. *(If different from 1(a). Include ZIP Code.)*

Same as in 1 (a)

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

Same as in 1 (a)

3. PREVIOUS LICENSE NUMBER(S). *(If this is an application for renewal of a license, please indicate and give number.)*

08-14043-01
Exp. Date = May 31, 1976

4. INDIVIDUAL USER(S). *(Name and title of individual(s) who will use or directly supervise use of byproduct material. Give training and experience in Items 8 and 9.)*

David G. Mahan, BS., Ph. D.

5. RADIATION PROTECTION OFFICER. *(Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Items 8 and 9.)*

Jagannadha R. Nibhanupudy
M.SC., M.S.E.

6. (a) BYPRODUCT MATERIAL. *(Elements and mass number of each.)*

Iridium 192

(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR PHYSICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME. *(If sealed source(s), also state name of manufacturer, model number, number of sources and maximum activity per source.)*

30% Iridium-70% Platinum
alloy enclosed in Stainless Steel.
Possession limit = 15 curies.

7. DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. *(If byproduct material is for "human use," supplement A (Form AEC-313a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source will be stored and/or used.)*

For preparation of sources to be used in interstitial, intracavitary and surface radiation therapy.

(Continued on reverse side)

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 *(Use supplemental sheets if necessary)*

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection			Yes No	Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments	See attached sheet.		Yes No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity			Yes No	Yes No
d. Biological effects of radiation			Yes No	Yes No

9. EXPERIENCE WITH RADIATION. *(Actual use of radioisotopes or equivalent experience.)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		See attached sheet.		

10. RADIATION DETECTION INSTRUMENTS. *(Use supplemental sheets if necessary.)*

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm²)	USE (Monitoring, surveying, measuring)
Capintech, Calibr, CRC					
CRC-2	1	Beta gamma			measuring
Victreen Mod. 440	1	Beta gamma	0.1-300		survey
Eberline RM-14	1	Beta gamma			monitoring
Eberline E-120	2	Beta gamma	0.1-50		survey
GM counter					

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE.

Calibration with cesium-137 standard sources every three months.

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED. *(For film badges, specify method of calibrating and processing, or name of supplier.)*

Eberline TLD-badge Service, Sante Fe, New Mexico.
Both whole body badges and Finger badges' changed monthly.
Direct-reading dosimeters assigned all persons in laboratory.

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS IN DUPLICATE

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached. *(Circle answer)* (Yes) No See additional sheet.

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable. Name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.

See additional sheet.

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved. Union Carbide Reactor, Tuxedo, N.

CERTIFICATE (This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

License Fee Category $ 3B

Fee Enclosed $ 1000.00

Rad/Trid, Incorporated.
Applicant named in item 1

By: David G. Mahan
David G. Mahan, President.
Title of certifying official

Date April 27, 1976

WARNING.—18 U. S. C., Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

ITEM #8

Dr Mahan, with Dr. Ulrich Henschke has pioneered the development and use of artificial redioisotopes interstitial, intracavitary and surface radiation therapy and has co-authored six papers in radiological and scientific journals and monographs on the development of reactor produced radioisotopes for interstitial and intracavitary application. He has also co-authored chapters in standard text books by Watson and by Ariel.

He has worked with Iridium-192 continuously since 1954. Formal training at Bluefield State College, Tuskegee Institute, Ohio State University, City College of New York, Sloan - Kettering Memorial Center for Cancer, New York, and Howard University Hospital.

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ITEM #9

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE
^{226}Ra.	5 grams	Ohio State University	18 Months.
^{60}Co.	5 curies	Memorial Center for Cancer.	15 Years
^{192}Ir.	5 curies	Memorial Center for Cancer	15 Years.
^{192}Ir.	15 curies	Howard University, Howard Supply Corp. - Rad/Irid, Inc.	6 Years

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ITEM NO. 13

(A) ORGANIZATION AND RESPONSIBILITIES:

The Rad/Irid, Inc., manufactures and distributes Iridium-192 seeds for medical use in the Radiotherapeutic treatments by interstitial, intracavitary and surface implants.

Presently, the personnel associated with Rad/Irid, Inc. consists of Dr. Mahan, President, Mr. Krishnan Suthanthiran, Vice President, Mr. J. Rao Nibhanupudy as Radiation Safety Officer, Ms. Alice Buffong as Treasurer, Ms. Ruth Parham as Secretary, Mr. A. Krishna and Mr. Byron Teele as Radiation Technicians.

Isotope receipt and disposal, active seed loading into nylon ribbons and shipment of active seeds for medical use, are performed under the supervision of Dr. Mahan or J. Rao Nibhanupudy. The information on experience and training of Dr. Mahan is listed under items no. 8 & 9. A resume of Mr. J. Rao Nibhanupudy is attached under item no. 14.

Rad/Irid, Inc. is located at 2212 Georgia Avenue, N.W., Washington, D.C. zip code no. 20001. All Iridium 192 sources are received in the Isotope section which is located on the first floor in the rear of the building. The entire building is rented and controlled by Rad/Irid, Incorporated. The other rooms on the first floor are used for laboratory showroom and workshop and offices.
The second floor is used for office space. There is no second floor over the isotope section. The back of the isotope section is surrounded by a fenced in yard. All windows and doors are secured with iron bars.

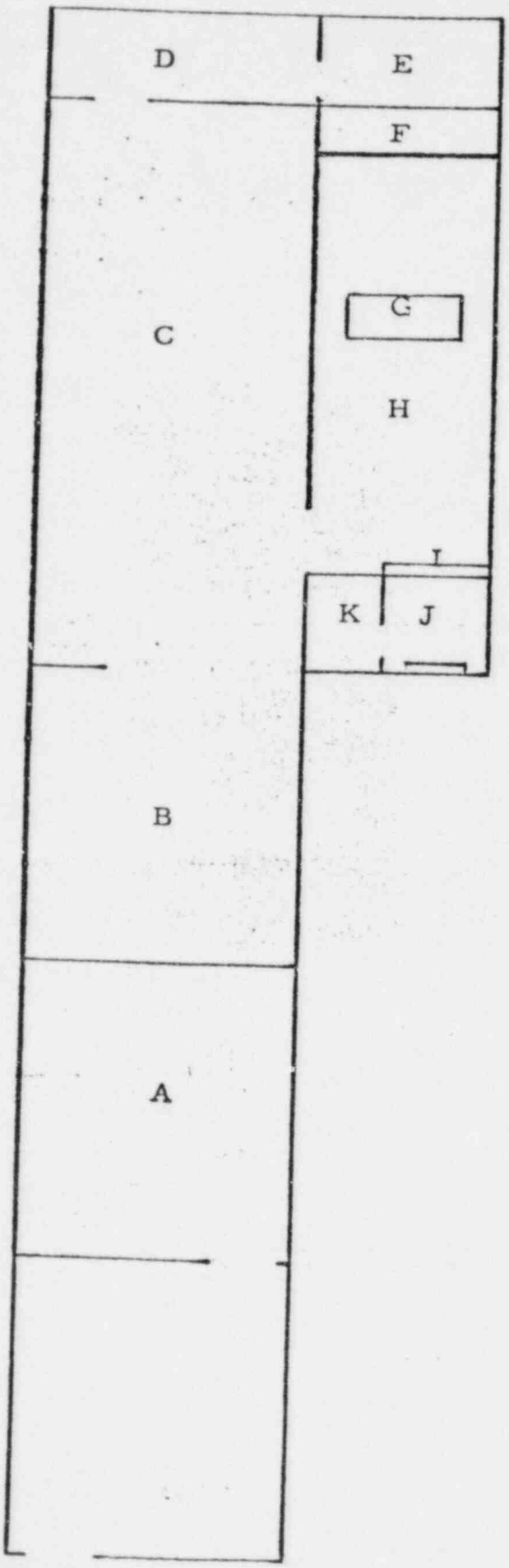
The isotope section is equipped with lead storage containers, portable lead bricks, stationary lead shields, high density concrete shields remote handling equipment, work benches, waste containers, and similar equipment.

A sketch of the facility is attached on fig. 1.

(B) DESCRIPTION OF RAD/IRID, SOURCE, TYPE - 1

Please see the attached sheet with title "Rad/Irid Source-Type 1" and fig. 2., for construction, pototype tests and quality controls.

(C) Iridium 192 seeds in nylon ribbons for interstitial implants are illustrated in fig. 3.



LEGEND

A=ADMINISTRATION OFFICE.
B=ADMINISTRATION OFFICE.
C=INACTIVE LAB.
D=INACTIVE STORAGE.
E=FURNACE.
F=WASTE AREA.
G=LOADING AREA.
H=UNPACKING AREA.
I=RECEIPT COUNTER.
J=RECEIVING AREA.
K=TOILET.

SCALE:1"=8'.

FIG. 1:SKETCH OF THE RAD/IRID, INC., FACILITY.

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A. Identification: Rad/Irid - 1

B. Proposed Use: For removable interstitial implant.

C. Radioisotope: Iridium 192 in form of a 30% Iridium - 70% platinum alloy wire of a 0.075 mm (0.003 inch in diameter up to 1.0 mc per wire, 2 to 4 Curies total.

D. Construction: Active material in 2 stainless steel capsules. The inner stainless steel capsules has an insi diameter of 0.225 mm (0.0009 inches) . Outer capsule has an outside diameter of 0.50 mm (0.020 inches), capsules are cold welded by shearing forces.

E. Prototype Tests: These sources have been in use for 22 years and no problems have been encountered in clinical practice.

Corrosion: Sources have been exposed to water and to cold and warm isotonic saline solutions (0.025% sodium Chloride by weight) for periods up to 6 months without any signs of corrosion or deterioration.

Prolonged exposure to concentrated "zepherin" (antiseptic solution) up to 6 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 noticed.

F. Quality Controls: Are provided routinely throughout the manufacture and use of the sources. The stainless steel tubing from which the capsules are made are certified by the manufacturer (Superior Tube Company) to be type 304 stainless steel hyperdemic 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 uniformity, 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.

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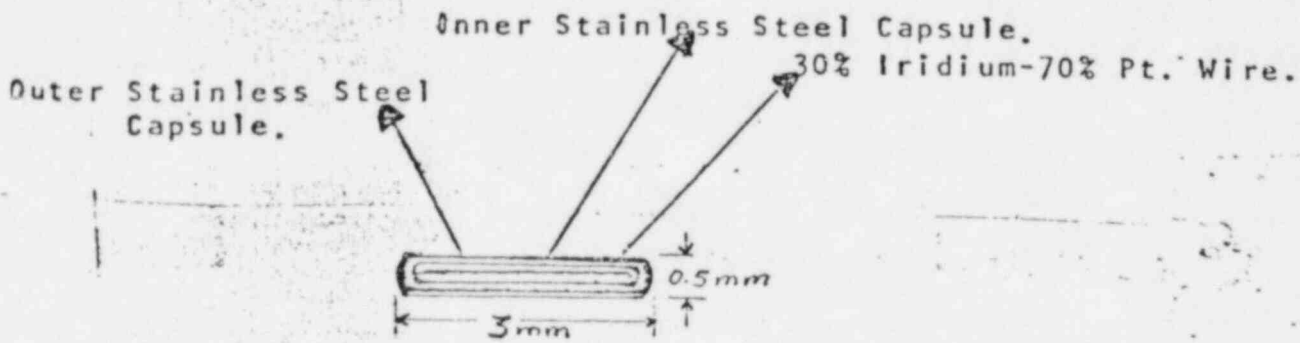

Fig. 2: Iridium - 192 Seed.

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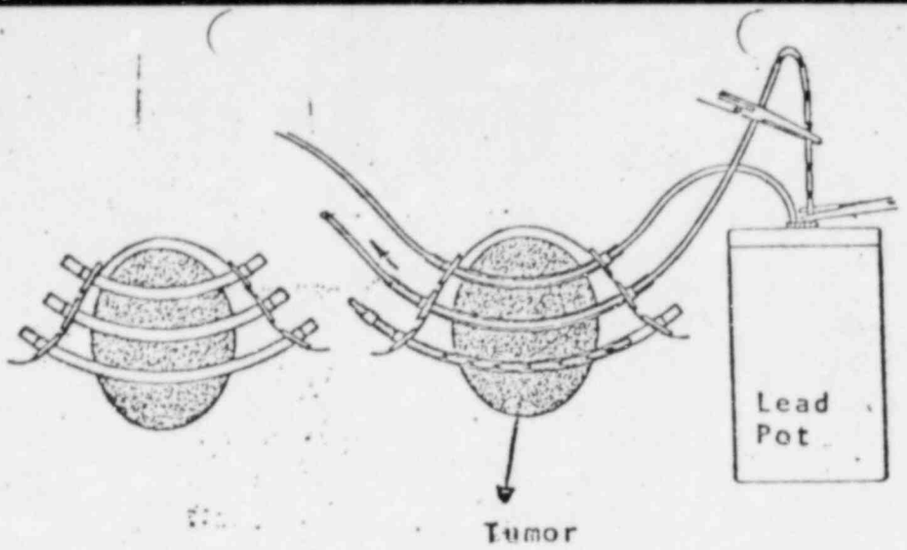


RIDIUM 192 SEEDS IN NYLON RIBBONS
for Interstitial Implants

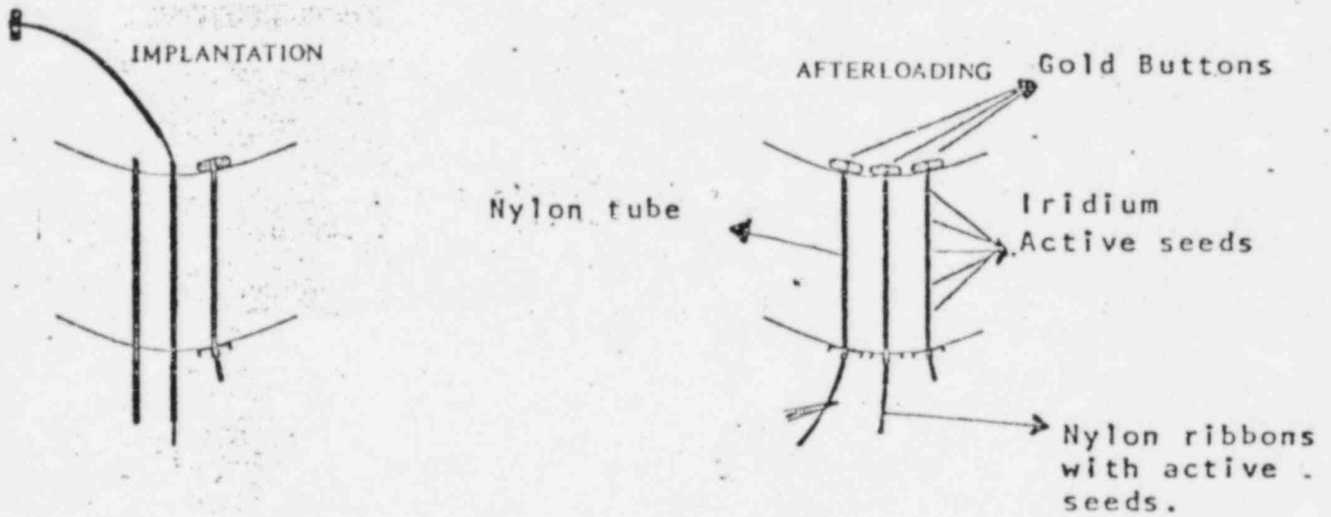


Fig.3b Description of Iridium Implant

RAD/IRID, Incorporated

2212 Georgia Ave. NW

Washington, D.C. 20001

(202) 387-2655

(A) RADIATION SAFETY OFFICER:

Mr. J. Rao Nibhanupudy is the radiation safety officer for Rad/Irid, Incorporated, and his resume is attached to this item. His responsibilites are to supervise each phase of operation from radiation safety point of view, conduct periodic training sessions, establish and supervise safety record keeping, maintain personnel exposure records, conduct periodic internal inspections.

In his absence, Dr. Mahan will perform the duties of radiation safety officer.

(B) PERSONNEL MONITORING:

Personnel monitoring is done by means of TLD- whole body and finger badges, supplied by Eberline Corporation, Santa Fe, New Mexico. The badges are changed monthly.

Self-reading pocket dosimeters are also assigned to laboratory personnel and the readings recorded daily.

(C) LABORATORY RADIATION CONTROL MEASURES:

Important control measures include;

1. Installed a gate just inside the lab. for the purpose of receiving materials and surveying on the spot and enter the reading in a ledger placed near the gate.

2. Procedures for opening and inspecting these materials are posted in the receiving area.

3. Any one leaving the Isotope area must survey himself and record results in the ledger.

4. A daily area survey of the restricted lab. must be carried out and record the results in the ledger.

5. All packages entering or leaving the lab must be surveyed and results recorded in the ledger.

(D) CUSTOMER'S LICENSES:

Letters are sent out to customers to verfy that they possess valid license for the Iridium shipments to be made.
Customers licenses are kept in a file.

(E) RADIATION PROFILES OF CONTAINERS:

Presently three types of lead containers each measuring 3" in diameter by 7" long are in use. Each container is packed in a corrugated container measuring 12" X 12" X 12" for shipping. Lead containers are designated as follows: (Drawings attached).

R/1, P-1 Maximum capacity 30 ribbons, 12 seeds each.
R/1, P-2 Maximim capacity 16 ribbons, 12 seeds each.
R/1, P-3 Maximum capacity 14 ribbons, 12 seeds each.

SOURCE CONTAINER'S RADIATION PROFILE

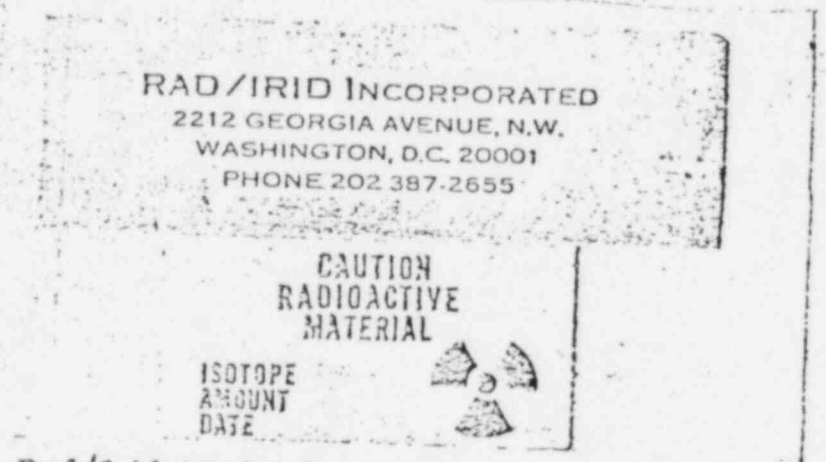
Maximum reading with maximum activity	R/1, P-1	R/1, P-2	R/1, P-3
Top	90 mR/hr	30 mR/hr	50 mR/hr
Bottom	40 mR/hr	60 mR/hr	35 mR/hr
Side	96 mR/hr	50 mR/hr	45 mR/hr

SHIPPING CONTAINER'S RADIATION PROFILE

Maximum reading with maximum activity	R/1, P-1	R/1, P-2	R/1,P-3
Top	20 mR/hr	8 mR/hr	20mR/hr
Bottom	15 mR/hr	25 mk/hr	15 mR/hr
SIDE	20 mR/hr	10 mR/hr	10 mR/hr

The basic container R/1, P-1 is designed so that the top plug is not removed in order to remove the active ribbons.

The following label is used on each container shipped.



Rad/Irid. Model 1 Ir-192 sources are licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 10CFR, sections 35.14 and 35.100 GroupVI or under equivalent licenses of agreement states.
For handling & storage instructions see package insert.

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Instructions for handling and storage of Iridium-192 seeds are sent out with containers. (This is attached to this item).

(F) LEAK TESTS:

Leak tests are done for every batch of new sources received, using " dry wipe test. The smears are taken by radiation safety officer and the contamination levels tested using a window less, gas flow, low background proportional counter having a minimum detectable activity levels of 3×10^{-5} microcuries for Sr - Y - 90 and 4×10^{-5} microcuries for Tc -99.

(G) CALIBRATION:

Calibration of the seeds is done using Capintech CRC-2 Calibrator. CRC-2 and other surveying, monitoring instruments are calibrated by using standard Cesium-137 source, every three months.

(H) PROTECTION SURVEYS:

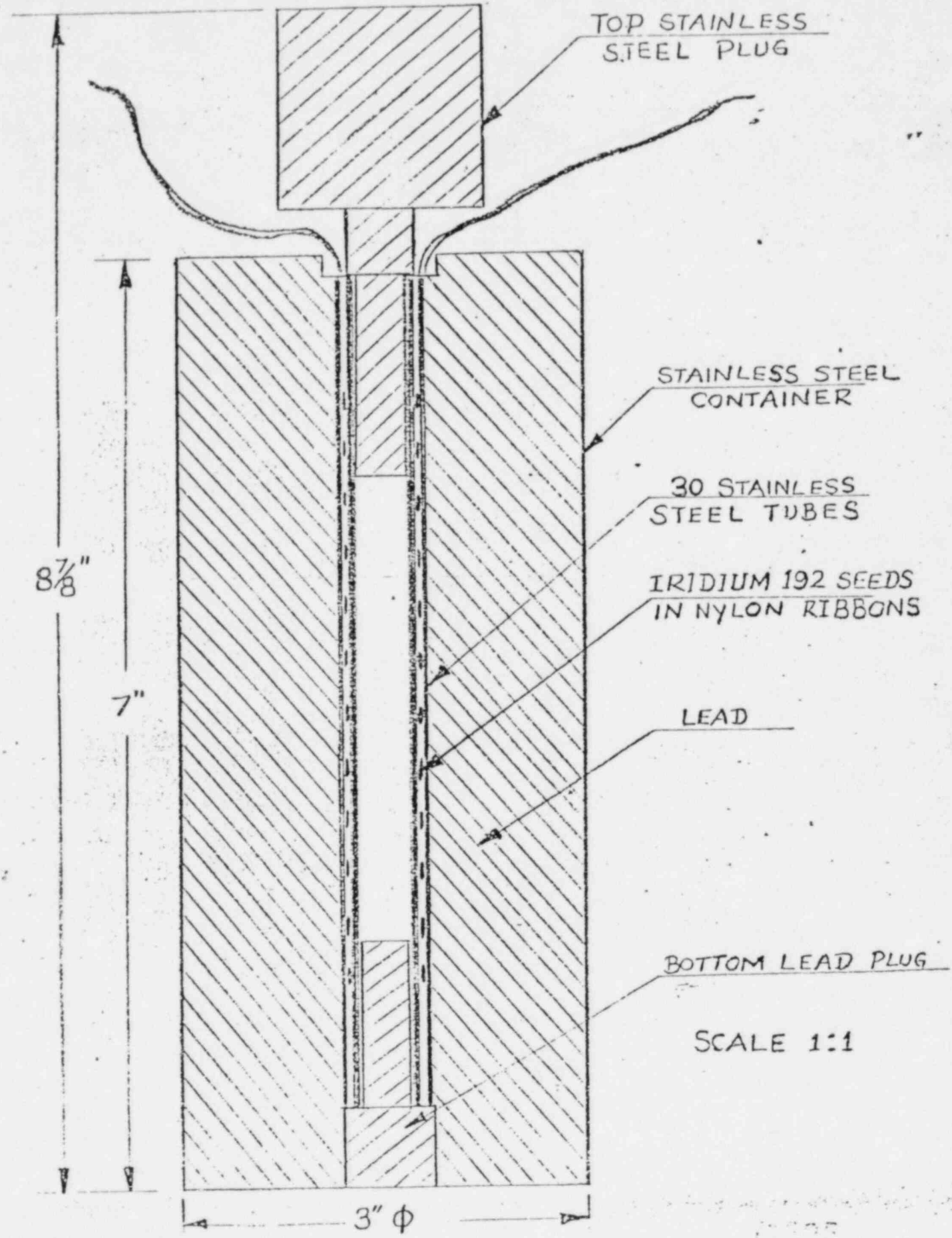
Radiation protection surveys are done using Victoreen model 440. Surveymeter once every three months inside and outside the building.

In addition, the survey of active lab is done daily and results recorded in a ledger.

(I) LICENSE FOR DISTRIBUTION FOR MEDICAL USE:

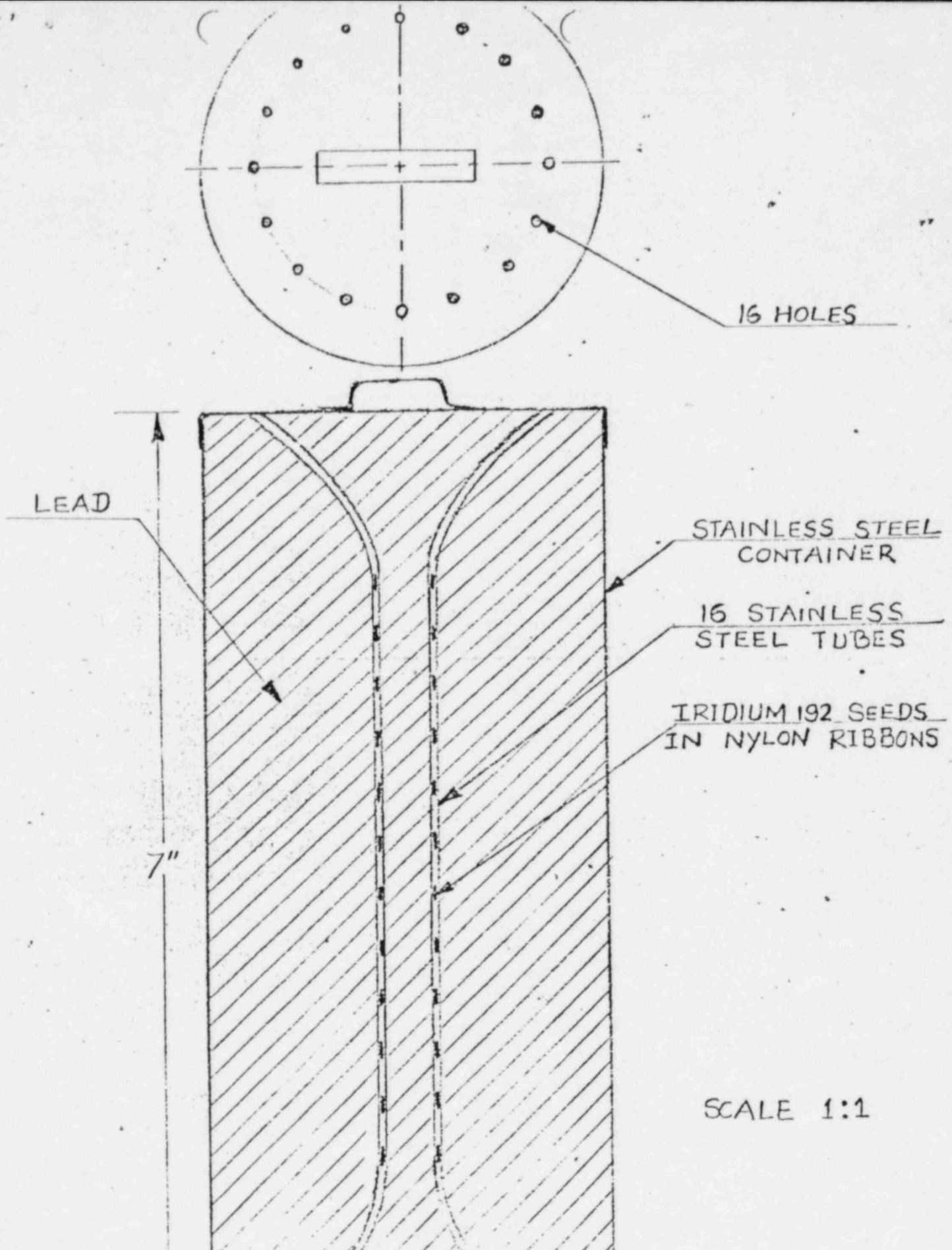
Rad/Irid, Inc. is authorized to distribute Iridium -192 seeds under USNRC license no. 08-14043-02 MD.

The expiration date for this license is January 31, 1981.



SCALE 1:1

R/I p-1



SCALE 1:1

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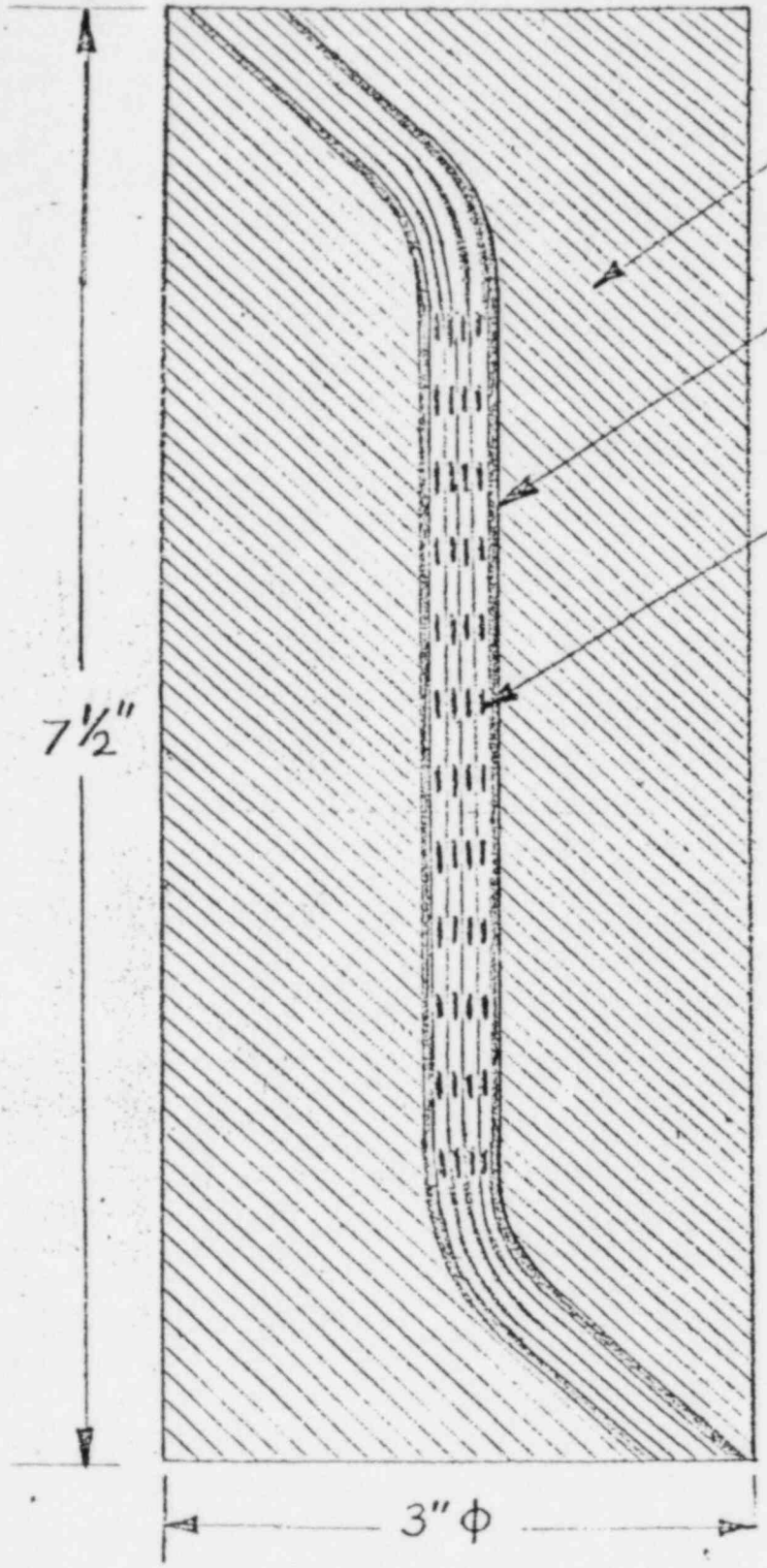
R/I 8-2



SCALE 1:1

R/I p-3

ONSTRUCTIONS FOR HANDLING AND STORAGE OF IRIDIUM-192 FOR RADIATION PROTECTION OF PERSONNEL:

A. PHYSICAL CHARACTERISTICS OF IRIDIUM-192

Iridium-192 decays to Osmium-192 by electron capture (4%) and decays to Platinum-192 by Beta emission (96%). This is branching decay process.

The physical half-life is 74.5 days.

The maximum energy of the Beta particle is 670 KeV.

The effective gamma ray energy is 340 KeV.

The half-value layer (50 percent attenuation) is about 4mm lead.

The specific gamma ray constant is 5.5 rh cm per mCi.

B. RADIATION SAFETY PRECAUTIONS:

With the data in item (A) in consideration, the radiation levels from the patient containing radioactive Iridium -192 seeds should be within the limits specified under 10 CFR part 20, using lead or other appropriate shielding material.

Nursing staff serving the patient with radioactive Iridium -192 seeds should be instructed accordingly by the radiation safety officer or a health physicist or the license, to keep radiation exposure to a minimum and within permissible limits.

CAUTION: This set should not be used after two (2) months from date of shipment.

Repeated autoclaving is not recommended.