NRC FORM 313 (8-2000) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 08/31/2002

Estimated burden per response to comply with this mandatory collection request: 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0000), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

03003327
X

'05 MAR 30 A10:01

RECEIVED REGION 1

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - ☐ A. NEW LICENSE
   - ☐ B. AMENDMENT TO LICENSE NUMBER 45-08482-01
   - ☒ C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*
   No. VA. Radiology
   8320 Old Courthouse Rd
   Ste. #150
   Vienna, VA. 22182

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED
   Same

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
   Peter Paras
   TELEPHONE NUMBER
   301 670-1095

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AEAS.
   App J

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES *(See 10 CFR 170 and Section 170.31)*
    FEE CATEGORY 7C
    AMOUNT ENCLOSED $2,300

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

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.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
V Panos Koutrouvelis - Director NVR	PK	3-28-2005

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	136679

NRC FORM 313 (8-2000) PRINTED ON RECYCLED PAPER

NMSS/RGNI MATERIALS-002

Application for Material License Renewal: 45-08482-01

Supplement to NRC Form 313 Page 1.

5. Radioactive Material.

We use I-125 and Pd-103 seeds, small sealed solid radioactive sources, of various activities: For I-125 0.30- 0.40 mCi.(0.37 average), on the day of implant, and
For Pd-103 1.5 mCi average on the day of implant.
We order the following models of seeds fro two companies:
Best Medical International, Inc. Model # 2301 for I-125, and Model #2335 for Pd-103
Amersham Inc. : Oncoseed I-125 Model # 6711 and Theraseed Pd-103 Model # 200
At any one time we will possess a Maximum amount of 2 Ci of radioactivity.

6. Purpose(e) for which licensed material will be used.

We have developed, implement, and maintain written procedures that meet the requirements of 10 CFR Part 35.400 for Interstitial Treatment of Cancer.

NOTE: The Stereotaxis, method developed by Dr Koutrouvelis using the PGK 3-D stereotactic system under CT guidance, is used for the accurate implantation of the radioactive seed in the entire target volume of the prostate is an example.
For more information see Appendix 1, "Protocol".

7. Individual(s) responsible for the RF Program and their Training.

The Radiation Safety Officer, Dr. Peter Paras serves under NRC License # 45-08482-01.
The recommendations of Appendix I, NUREG 1556 Vol.9 will be followed.
The delegation of authority has been signed.

Medical Physicists, Dr. Paras and Mr. Nibhanupudy will continue under NRC License # 45-08482-01.

The Authorized User Panos Koutrouvelis MD serves under NRC License # 45-08482-1.

8. Training for Individuals working in restricted areas.

The Model training program, Appendix J, NUREG 1556 Vol.9 will be followed.

9. Facilities and equipment.

Enclosed is the Facility diagram (Fig. 9.1) according to NRC NUREG 1556 vol.9 # 8.15 see Attachment 2.

8.16 The radiation monitoring instruments are calibrated by the A.M. Calibration Services Inc. 6290 Gaither Rd., Gaithersburg MD 20877, Tel. 301 926-9106.

8.17 and 8.18 are Not Applicable.
NOTE: Source activity (average in mCi/seed) and leak tests measurements are certified by the manufacturer. Data of spot checks of at least 10 seeds is included and filed in the patient's records.
8.19 Not Applicable.

10. Radiation Protection Program .

8.20 In general we adopt all the applicable to our operations guidance provided in NUREG 1556 Vol. 9 Apprentices I-Z: Model Procedures.

The radiation protection program that is implemented for each implant.

For confirmed prostate cancer patients a complete CT imaging procedure of the prostate is performed to determine the volume of the prostate. A preplan is prepared and the number of seeds to be implanted is estimated. An order is placed for the seeds to be delivered one working day prior to implant procedure (see also Attachment 1).

Seeds are delivered only during working hours and are placed in the storage room upon arrival. The package is monitored to verify background reading on contact and it is numbered and recorded in the log-book (name, date, activity/seed, and number of seeds).

On the day of the procedure the identity of the patient is verified by the receptionist and subsequently by the AU and the Anesthesiologist who are interviewing the patient prior to the procedure. The package is taken in the operating room, opened and the strands are monitored. The number of seeds is verified and Form 1 is filled out.
Under CT guidance the preplan is repeated and the number of needles/row and the number of seeds in each needle is estimated and recorded on a preliminary Form 3, row by row. The number of rows to cover the entire target volume (prostate, seminal vesicles, and some surrounding tissue) is determined and recorded see also Attachment 1.

During the procedure and under the supervision of the AU and the RSO the seeds are prepared and placed in the needles, which have been inserted in the target volume, in an orthogonal grid configuration. The position and depth of each needle is determined under CT guidance by a computerized program and is verified on the CT images. Due to possible edema during the insertion of the needles, and prostate movement during the procedure it is necessary to verify by CT the position of each needle in each transverse row and correct the needle position if necessary. After verification by CT of the correct position of the needles in each transverse row, the seeds in strands are implanted and the needles removed. This step is repeated for the next transverse row and so on until all transverse rows are implanted.

The Form 3 is filled out by the RSO during the implantation step by step. The number of seeds implanted is recorded for each row and each needle in the row until the implant is completed. The total number of seeds implanted is counted and recorded on Form 3 together with the estimated total activity implanted. The number of seeds not used are counted and returned to storage. Form 5 is filled out to verify that the number of seeds not used is equal to the number of seeds brought in the operating room (see Form 1) minus the number of seeds implanted (Form 3).

A detailed area and equipment survey is performed. All areas involved including the patient, hallways and storage are monitored and the Forms 4 and 5 are completed. In addition a summary, Form 6, is filled out.
The Written Directive Form 2 (blue) is then filled out and signed by the AU. All oral changes and corrections of the preplan are included.

All forms (see Attachment 2) and the source certificate(s) including pertinent dosimetry data are placed in the patents' records.
The patient is released after he is monitored according to NRC 10CFR 30.75.
The Model procedure in Appendix U of NUREG 1556 Vol. 9 is followed.

Lastly, pertinent data is recorded in the computerized inventory of seal sources.

(Item 10.) 8.21 Enclosed is a copy of the emergency procedures, see Attachment 3.

8.22 Occupational Dose.
All personnel are monitored including the receptionist. We have employed the services of the RDC an NRC approved Company.

Radiation Detection Company
8095 Camino Arroyo St.
Gilroy, California 95020
Tel. (408) 842-2700

We are operating under the ALARA Program. We have been able to maintain exposures less than 20% of the allowable level of occupational doses.

Unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR 20 for the following reasons:
a) The exposures on the outside walls of the operating room, during procedures, can not be detected (i.e. background).
b) Unmonitored individuals are not permitted in the operating room and restricted ares during implant procedures.
After the area surveys and the return of unused seeds in the storage room, the radiation exposure level in restricted areas is background.

The storage room is locket at all times. Access to it is restricted to the US, RSO, UMP and the Radiation Safety Technologist.

8.23 Area Surveys.
We have developed and will implement and maintain written procedures for area surveys in accordance with 10CFR 20.1101 that meet the requirements of 10CFR12501 and 10CFR35.70.

8.24, 8.25, 8.26, and 8.27 are not applicable.

11. Waste management.

8.28 "Statement": We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR20.1101, that also meet the requirements of the applicable section of Subpart K to 10CFR20 and 10CFR.3592".

We adopt the model procedures described in Appendix W of NRC NUREG 1556 Vol. 9.

12. License fees.

8.29 Attached is a copy of the NRC's invoice to NVR&NM dated 06/07/04 and a certified copy of the NRC Form 526 "Small entity status" together with a check of $2,300.00 according to NRC 10CFR171.16. See Attachment 4.

Attachments.

1. Protocol.
2. Facility Diagram.
3. Emergency Procedure.
4. License Fee and NRC Form 526, including a check of $ 2,300.00.

;

ATTACHMENT 1

Protocol: Prostate Implant

P R O T O C O L (revised 3/25/05)

Prostate cancer brachytherapy with the posterior pararectal method using a CT- guided 3-D stereotactic system

Introduction

Quality Control of the equipment is a prerequisite for any procedure including Biopsy, preplan, implant etc. The recommendations of the CT manufacturer and the AAPM (#39) are prerequisite to the good operation of the CT. Stricter limits must be observed for 3-D CT guided diagnostic and therapeutic procedures including Gantry calibration, PGK device calibration (in place), Scan localization light accuracy, Tilt error (between 0 and 26 degrees), and Table accuracy measurements.

Patient Selection

Indications: 1) Localized prostate adenocarcinoma including large volumes (60-180 cc)
2) Post TURP or external radiation treated reoccurring prostate cancer
3) Seminal vesicles cancer invasion and
4) Salvage brachytherapy after failed EBRT, Brachytherapy, or failed Radical Prostatectomy

Contraindications: 1) Metastatic cancer
2) Prostate volume grater than 180 cc
3) Medical conditions prohibiting spinal anesthesia

Patient pretreatment

Referred patients have consultation, signed consent Form, including a CT scan of the prostate and biopsies as indicated. Biopsies are taken from several locations within the target volume using the PKG 3-D stereotactic technique under CT guidance.

1. A pre-implant plan is prepared including prostate volume and dosimetry evaluation. Upon confirmation and staging of the cancer the proper radioactive seeds are ordered. The number and the activity of the seeds is estimated to deliver an average dose to the target volume of 144 Gy for I-125 or 120 Gy for Pd-104 seeds, using the Varian Variseed computer program and CT planning. The target volume depends on the prostate and cancer volume and may be extended 5-10 mm beyond the capsule into the connective tissue or fat including the seminal vesicles if involved.

2. Twenty-four hours prior to procedure, the patient begins bowel preparation and prophylactic antibiotic treatment as follows:

a) *Ciprofloxacin*, 500 mg, b.i.d. for 10 days beginning 24 hours prior to procedure.

Note- *in special cases an antibiotic is administered Via IV at the beginning of the Implant..*

b) *Flagyl,* 250-500 mg, one tablet every six hours for three days beginning 24 hours prior to implant. No alcohol while taking *Flagyl.*

c) Clear liquid diet 24 hours prior to implant.

d) Phospho-soda 1,5 ounces, 20 hours prior to procedure. Pour into one-half glass of cold clear liquid, drink and follow immediately with one full glass of water.

e) Forced fluids taken orally 20 hours prior to implant procedure.

f) Four *Dulcolax* tablets 12 hours prior to implant procedure.

g) *One Dulcolax* suppository and *Tannic acid* suppository 2 hours prior to implant procedure.

Implant Procedure

1. Identification of the patient is assured by technologist and secretary checking the name, SS number and date of birth.

2. Consultation and identification of patient with the radiation oncologist, anesthesiologist, and urologist including insertion of a catheter in the bladder.

3. Deliver of epidural spinal anesthesia with anesthesiologist.

4. Prepare the patient on the CT-Table and the PGK stereotactic Device.

5. Take a complete CT scan of the prostate and repeat the pre-treatment plan.

6. Insert the needles, under CT-guidance in an orthogonal array (4-6 needles 1 cm apart to form row in one direction and 4-7 rows also 1 cm apart in the other) using the template of the stereotactic PGK device.
   Note; a) The template has an orthogonal array of perforations, 32x40 holes 1 mm in diameter, and 2.5 mm apart in either direction.

7. Verification, with the CT, of the position of the needles of the **first row**. If needed apply corrections to assure that the needles are 1cm apart on the CT grid and cover the target.

8. Load radioactive seeds in each needle. The number of seeds and their activity is determined from the image of the prostate cut of the first row and the superimposed grid.

9. Insert the seeds into the prostate using a) the attachment to the PGK device for instant downloading and implantation of strands or loose with spacer seeds or 2) the Mick applicator for loose seeds.

10. Confirm position of seeds with CT and proceed to second row.

11. Repeat steps 6 to 9 for row 2.

12. Repeat steps 9 and 10 for the remaining rows (3-7).

13. Take a complete CT scan of the implant to determine the quality of the implant and to verify good coverage. If blank spots are found proceed to step 13, if not proceed to step 14.

14. Insert needles under CT guidance to blank spots and follow steps 5-9.

15. Take a complete CT study at 5 mm intervals for post implant CT dosimetry using Varian Variseed software.

16. Transfer the patient to recovery room and perform a detailed radiation survey of the operating room.

17. Remove Foley catheter and survey for radioactive seeds.

18. Repeat step 15, when possible, after 2 weeks when edema has subsided, for more accurate dosimetry.

Post-Implant Procedures

1. Verify that all seeds have been accounted for including seeds found in the operating room (CT-Table, counter, cart, floor, and in urine).

2. Perform radiation exposure survey around the patient.

3. Instruct patient to stay 6 feet away from other persons and particularly from pregnant women and children.

4. Post-Implant dosimetry and isodose distribution is determined from the data taken step 14 above.

Follow up

Patient consultation including PSA data and recently totesterone data determined at office visits every 3 months during the two years, 6-months up to the fifth year and yearly thereafter. The patients fill out questionnaires for GI and GU morbidity. In addition and whenever patients cannot make office visits, data are collected from direct telephone contact and patients responses to yearly written questionnaires.

Advantages of 3-D CT-Guided Pararectal Brachytherapy in Contrast to Transperineal Approach

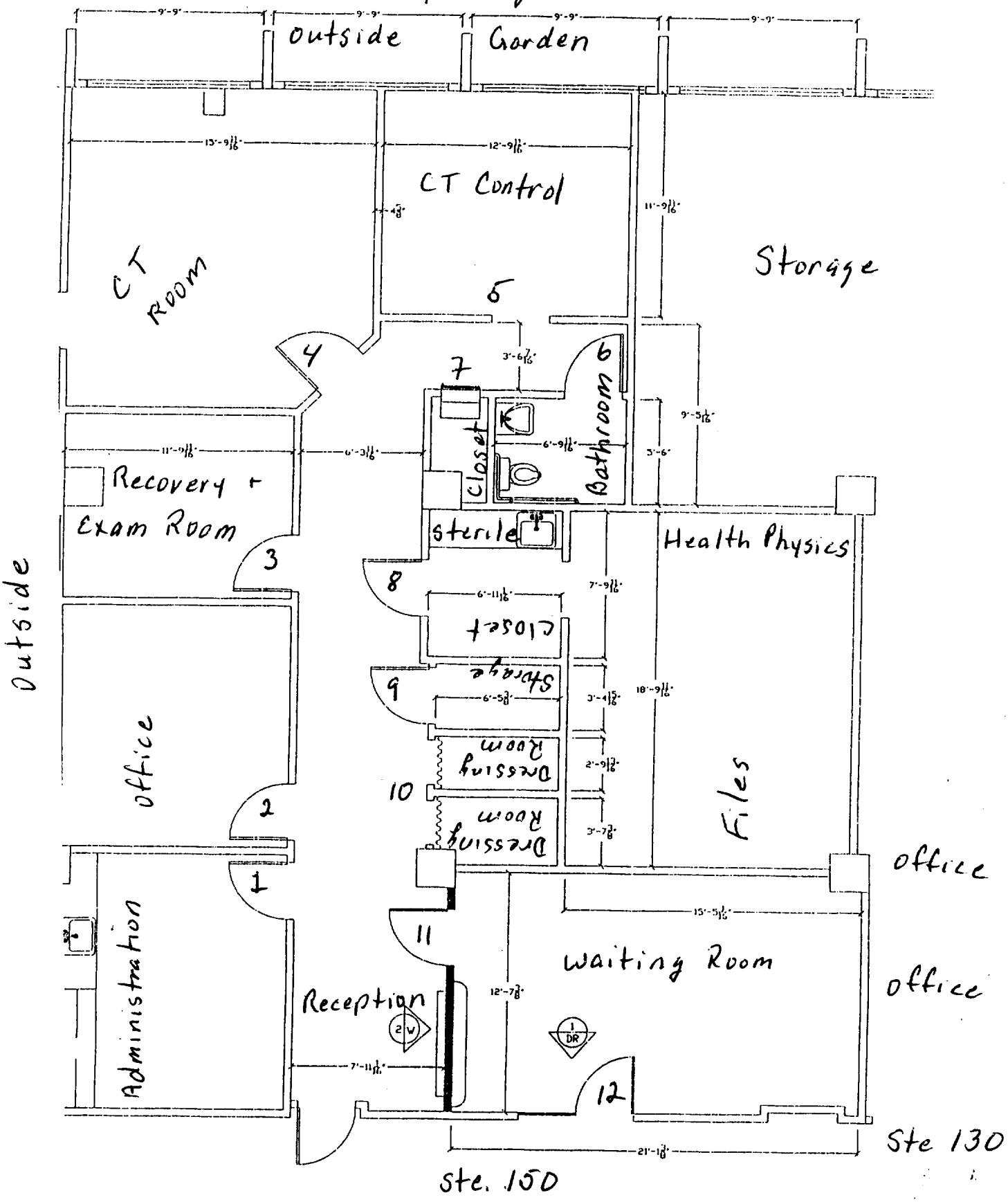
1) Patients without rectum; the rectum has been removed because of colorectal cancer or other causes.
2) Penile prosthesis.
3) Seminal Vesicle Invasion.
4) Large glands; Patients whose prostate size is ≥ 60 cm^3.
5) Protrusion of the prostate within the urinary bladder.
6) Pubic Arch Interference
7) Prior TURP defects; prior TURP is usually not performed with transperineal ultrasound-guided brachytherapy.
8) Large prostate calcification; large prostate calcification is usually not performed with transperineal ultrasound-guided brachytherapy.
9) Obese patients.
10) Urinary obstruction.
11) We performed CT-guided brachytherapy because the following vital structures are identified on CT images before and during the implant procedure.
    a) A Foley catheter is placed prior to the implant procedure and the urethra is clearly outlined on CT and avoided with the needles during the procedure.
    b) Contrast media is put into the bladder through the catheter to clearly outline the bladder during the implant procedure and we do not have to performed cystoscopy after the procedure to remove seeds from the urinary bladder (only one cystoscopy afterwards in 800 implants performed).
    c) The rectum is constricted with tannic acid and needles are placed to avoid the rectum.
    d) The internal sphincter is avoided.
    e) And the bulb of the penis is avoided.

ATTACHMENT 2

Facility Diagram

URPI Forms

Attachment 2
Facility Diagram Ste 150



Ste 130 MRI

Ste 230 offices

Uro-Radiology Prostate Institute
8320 Old Courthouse Road
Vienna, Virginia 22182
703-356-9674 (tel)703-356-9589(fax)

DATE _____ ID #_____
Pt. Phone #_____
Site of Treatment_____
Time Start _____Time End_____

FORM 2: TREATMENT PLANNING
SUMMARY CHART

Patient Name_____
Patient Age_____
Referring Physician _____
Initial PSA/Date_____
Prostate Volume/Date_____
Prostate CA: Right_____ Left_____
Grade: Gleason's_____
□Well Diff. ■ Moderate □ Poorly
Stage: □T1a, □T1b, □T1c, □T2a, □T2b,
□T3a, □T3b
Seminal Vesicle Biopsy:
□ Yes Date _____ Results_____ □ No
Erectile Dysfunction:
□ No □ Yes
Obstruction:
□ No □ Yes □ AUA #_____
TURP:
□ No ■ Yes Date_____
Hormone: ■ Yes_____ Date _____□ No
Radiation Oncologist_____
Urologist_____
Anesthesiologist_____

Number/Seeds _____mCi/Seed_____
Number/Seeds _____mCiSeed_____
Number/Seeds _____mCi/Seed_____

Avg mCi/seed_____
Total No of Seeds_____
Total Source Strength_____
Isotope_____No of Needles_____
Prescribed Dose_____

Signed by:_____
Radiation Oncologist

Base

LT *RT*

Couch													#,Seeds	#, Needles	Volume
#															
#															
#															
#															
#															
#															
													Total	Total	Total

Apex

Number above bold line segment represents number of seeds per needle. Number below represents depth of needle insertion from the surface of the template to the anterior portion of the target. Horizontal sequence of bold line segments represent the transverse row of needles at each CT couch position.

Uro-Radiology Prostate Institute
8320 Old Courthouse Road
Vienna, Virginia 22182
703-356-9674 (tel)
703-356-9589 (fax)
E-mail: pgk@prostate-ca.com

FORM 1: PRE-IMPLANT QA

Patient Name_____ Date_____

Date of Receipt_____

Isotope_____

1. # of Lead Cubicles or Trays _____
2. # of Strands _____
3. # of Seeds in each Strand _____
4. # of Loose Seeds _____
5. # of Seeds remaining in vial _____

Activity per seed/Date _____

Exposure Rate at Hand During Loading _____

Exposure Rate 1 Foot Away During Loading _____

Exposure on Lead Cubicle or Tray _____

Exposure on Working Surfaces _____

Survey Meter _____

Medical Physicist _____

Uro-Radiology Prostate Institute
8320 Old Courthouse Road
Vienna, Virginia 22182
703-356-9674 (tel)
703-356-9589 (fax)
E-mail: pgk@prostate-ca.com

FORM 3: PROSTATE IMPLANT CONTROL

Patient's Name _____ Date_____

Patient's Number _____

Patient's SS# _____

Patient's Age _____

Number of Seeds per Needle

	1st	2nd	3rd	4th	5th	6th	#, Needles	#,Seeds
Row I								
Row II								
Row III								
Row IV								
Row V								
Row VI								
Row VII								
Row VIII								
Row IX								
Row X								
Total								

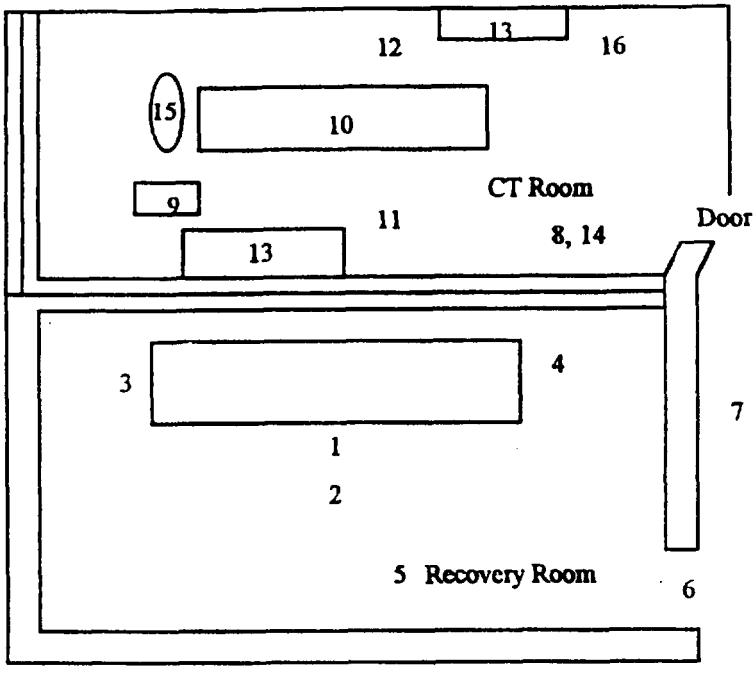
1st

Physicist_____

Radiation Oncologist_____

Uro-Radiology Prostate Institute
8320 Old Courthouse Road
Vienna, Virginia 22182
703-356-9674 (tel)703-356-9589(fax)
e-mail: pgk@prostate-ca.com

FORM 4: RADIATION SURVEY



DATE _____

PATIENT'S NAME _____

PATIENT NUMBER _____

RADIATION SOURCE _____

SURVEY METER _____

RECOVERY ROOM

1 One meter from Patient_____
2 Two meters fom Patient_____
3 Feet of Patient_____
4 Head of Patient_____
5 Insided Recovery Room_____
6 Doorway_____
7 Hallway_____

PROCEDURE ROOM

8 Catheter_____
9 Cart_____
10 CT Couch_____
11 Floor (left)_____
12 Floor (right)_____
13 Benches_____
14 Waste_____
15 Gantry_____
16 Doorway_____

Physicist_____

Uro-Radiology Prostate Institute
8320 Old Courthouse Road
Vienna, Virginia 22182
703-356-9674 (tel)
703-356-9589 (fax)
E-mail: pgk@prostate-ca.com

FORM 5: POST IMPLANT QA

Patient Name/ID_____ Date_____

Radioactive Material Used _____

# of Seeds Implanted _____

# of Seeds not Used _____

Number of Seeds Returned to Isotope Room Storage _____

Was Area Survey Around Patient Performed ? _____

Were Accessories Surveyed ? _____

Were Area Surveys Performed ? _____

Were Holding Surfaces and Containers Monitored ? _____

Were All Accessories Accounted For ? _____

Were Instructions Provided on:

a) Radiation control to family members/public _____
b) Urine collection for possible expelled seeds _____

Any Remarkable Observation(s)_____
_____
_____
_____

_____
Health Physicist

Uro-Radiology Prostate Institute
8320 Old Courthouse Road
Vienna, Virginia 22182
703-356-9674 (tel)
703-356-9589 (fax)
E-mail: pgk@prostate-ca.com

FORM 6: IMPLANT SUMMARY

Patient Name _____ Date _____

Patient Number _____

Radiation Oncologist _____

Prescribed Dose _____

Number of Seeds Ordered _____

Isotope/Activity per Seed (mCi) on Day of Procedure _____

Total Activity Used _____

Number of Seeds Implanted in Patient _____

Number of Seeds Recovered from Urine _____

Number of Seeds Remaining in Patient _____

Distance Between Needles 1.0 cm Distance Between Seeds 1.0 cm

Number of Needles Used _____

Following the implant procedure, a complete area survey of the procedure room was performed. A radiation survey around the implanted was also performed after the patient was transported to the recovery room. The patient's urine was monitored at regular intervals for any expelled seeds until the time of discharge. This monitoring included assay of the Foley catheter. Internal quality assurance was performed to account for all seeds: (a) number transported to the procedure room for implant, (b) number of seeds actually implanted, and (c) number of seeds returned to radioisotope room for disposal.

Medical Physicist _____

Radiation Oncologist _____

ATTACHMENT 3

Emergency Procedure

Access to Storage

Inspection Report

URPI **URO - Radiology Prostate Institute**

Northern Virginia Radiology and Nuclear Medicine, Inc.
8320 Old Courthouse Road, Suite 150
Vienna, Virginia 22182

Tel. 703-356-9674 **Fax 703-356-9589**

Emergency List

Call below for radiation theft emergency

Police	**Emergency 911** **Non-Emergency 703-556-7750**
Dr. Peter Paras, Physicist	**301-670-1095**
Dr. Panos Koutrouvelis, Director	**703-821-8283**
Nuclear Regulatory Commission, King of Prussia, PA	**1-800-432-1156**
Virginia Dept. of Health, Radiological Health	**1-800-468-0138**
Radiation Emergency	**1-800-468-8892**

Call below for radiation emergency:

Dr. Peter Paras, Physicist	**301-670-1095**
Dr. Panos Koutrouvelis, Director	**703-821-8283**
Nuclear Regulatory Commission, King of Prussia, PA	**1-800-432-1156**
Virginia Dept. of Health, Radiological Health	**1-800-468-0138**
Radiation Emergency	**1-800-468-8892**

Patient Immediate Emergency or Fire Emergency Call 911

URPI ***URO - Radiology Prostate Institute***

Northern Virginia Radiology and Nuclear Medicine, Inc.
8320 Old Courthouse Road, Suite 150
Vienna, Virginia 22182

Tel. 703-356-9674 **Fax 703-356-9589**

3 May 2001

These persons have authorized access to radioactive storage.

Dr. Panos Koutrouvelis, M.D.
Dr. Peter Paras, PhD.
Ms. Marcia Templeton, C.N.M.T.

Radioactive materials are delivered only when one of these named authorized access is available to receive the material (normally received by Ms. Marcia Templeton, C.N.M.T.)

Panos G. Koutrouvelis, M.D.
Director, Uro-Radiology Prostate Institute

FORM 591M PART 1
2003)
CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Northern Virginia Radiology and Nuclear Medicine, Inc. 8320 Old Courthouse Road, Suite 150 Vienna, Virginia 22182 REPORT NUMBER(S) 2004-001	REGION I US NUCLEAR REGULATORY COMMISSION 475 ALLENDALE ROAD KING OF PRUSSIA PA 19406-1415

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-03327	45-08482-01	09/21/04 and 10/08/04

LICENSEE:
The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

√ 1. Based on the inspection findings, no violations were identified.

√ 2. Previous violation(s) closed.

3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

non-cited violation(s) were discussed involving the following requirement(s):

4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE			
NRC INSPECTOR	Willie J. Lee	Willie J. Lee	10/14/2004

This is to acknowledge the receipt of your letter/application dated

3/28/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Renew 45-08482-01

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 136679.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader

	:	(FOR LFMS USE)
	:	INFORMATION FROM LTS
BETWEEN:	:	----------
	:	
License Fee Management Branch, ARM	:	Program Code: 02200
and	:	Status Code: 2
Regional Licensing Sections	:	Fee Category: 7C
	:	Exp. Date: 20050531
	:	Fee Comments: _____
	:	Decom Fin Assur Reqd: N
	::	

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED
   Applicant/Licensee: NORTHERN VA RADIOL.&NUCLEAR MED,INC
   Received Date: 20050330
   Docket No: 3003327
   Control No.: 136679
   License No.: 45-08482-01
   Action Type: Renewal

2. FEE ATTACHED
   Amount: /
   Check No.: /

3. COMMENTS

Signed Rebecca Hunt
Date 3/30/2005

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:
   Amendment _____
   Renewal _____
   License _____

3. OTHER _____
   _____

Signed _____
Date _____