ArnettCancerCare

US Nuclear Regulatory Commission
Region 3
Material Licensing Branch
2443 Warrenville Road, Suite #210
Lisle, IN 60532

License number 13-32087-01
Docket number 030-34812

Dear Gentleman:

The Oncology Institute of Greater Lafayette seeks to renew the above referenced license, which expires September 30, 2008. At the same time, it requests that the license be amended as described in the letter which follows.

As per the guidelines published 8.2.1 Timely Notification of Transfer Control from Regulations: 10 CFR 30.34(b) we hereby notify you that on October 15, 2008, the business known as Oncology Institute of Greater Lafayette will cease to exist. Clarian Health Partners, Arnett Clinic, LLC, and Oncology Institute of Greater Lafayette will merge to form a Joint Venture, Clarian Arnett Health.

In accordance to the Information Notice No. 89-25, details of the transfer of control are outlined below:

I. The name of the organization, if changed. Provide the new name of the licensed organization and if there is no change, so state.

Response: Arnett – Clarian Health System, LLC; d/b/a Clarian Arnett Health

II. Identification of any changes in personnel named in the license, including any required information of personnel qualification.

Response: No change in personnel

- Loubna Scally, M.D. will continue to serve as Authorized user
- Phil Dittmer, PhD. as Radiation Safety Officer
- Dr. Dittmer, Colleen DesRosiers, Ph.D., and Eric Slessinger, M.S. as Authorized Medical Physicists
- Dr. Scally is currently an Authorized User for 10 CFR 35.400 uses on the Materials License (Attachment 1) of Greater Lafayette Health Services, Inc., Drs. Dittmer and DesRosiers and Mr. Slessinger are

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qualified physicists on the manual brachytherapy permit (Attachment 2) of the Broad Scope License of Indiana University.

III. An indication of whether the seller will remain in business without the license.

Response: The seller will be merging to form the new business entity, Clarian Arnett Health, and will not remain in business.

IV. A complete, clear description of the transaction. The description should include any transfer of stocks or assets.

Response: Clarian Health Partners, Arnett Clinic, LLC, and Oncology Institute of Greater Lafayette are forming a Joint Venture called Clarian Arnett Health. The Joint Venture consists of a hospital and ambulatory practices. All assets, financial obligations, and personnel from Oncology Institute of Greater Lafayette will transfer into the new Joint Venture.

V. An indication of any planned changes in organization, location, facilities, equipment, procedures, or personnel. If such changes are to be made, they should be fully described.

Response: The new entity will maintain all current services at the existing location.

In addition, Dr. Loubna Scally plans to perform prostate seed implants (brachytherapy) at the new hospital location on 5165 McCarty Lane Lafayette, IN 47905. The nuclear material will be received and stored at the new hospital location.

Facilities: Attachment 3 is a diagram of the relevant portions of the new hospital, showing the hot lab where materials will be calibrated and stored.

Procedures: Attachment 4 describes the procedures for receipt of radioactive materials at this facility. Other procedures are as described in the original license application.

Equipment: As described in attachment 4, wipe tests will be read using a Capintec CRC ISW Well Counter. Calibration of sources will be performed using Standard Imaging HDR 1000 Plus Ionization Chamber, s/n A970135 in combination with one of two electrometers: PTW Unidos 10005 s/n 50072 or Keithley 35040 s/n 81182. Survey will be performed using Victoreen Model 450P serial number 4502 or Ludlum Geiger Counter Model 14C s/n 145035 with tube Model 44-7, s/n PR 147974.

VI. An indication of any changes in the use, possession, or storage of the licensed materials. If such changes are to be made, they should be described.

Response: As mentioned above, Dr. Scally wishes to perform prostate seed implants at 5165 McCarty Lane, Lafayette, IN 47905. We request that the license be amended to permit storage and use of byproduct material permitted by 10 CFR 35.400. As of April 2007, there were nineteen different seed types available with NIST calibrations.

In order to maintain maximum flexibility, each seed type can be listed on the license or a generic description can be used. The seed types are as follows:

Isotope	Manufacturer	Seed Model
^{125}I	North American Scientific	Prospera I-125 (MED3631-A/M)
^{125}I	International Brachytherapy	InterSource^{125} (1251L)
^{125}I	Bebig	IsoSeed I-125 (125.S06)
^{125}I	Best Medical International	Best I-125 (2301)
^{125}I	Implant Sciences	I-Plant (3500)
^{125}I	Bard Brachytherapy	BrachySource (STM1251)
^{125}I	Theragenics Corporation	I-Seed I-125 (125.S06)
^{125}I	GE Healthcare	OncoSeed (6711)
^{125}I	GE Healthcare	EchoSeed (6733)
^{125}I	Mills Biopharmaceuticals	ProstaSeed (125SL, 125SH)
^{125}I	IsoAid, LLC	Advantage I-125 (IAI-125A)
^{125}I	Isotron	selectSeed I-125 (130.002)
^{103}Pd	Theragenics Corporation	TheraSeed (200)
^{103}Pd	North American Scientific	Prospera Pd-103 (MED3633)
^{103}Pd	International Brachytherapy	OptiSeed^{103} (1032P)
^{103}Pd	Best Medical International	Best Pd-103 (2335)
^{103}Pd	RadioMed Corporation	Genetra
^{103}Pd	IsoAid, LLC	Advantage Pd-103 (IAPd-103A)
^{131}Cs	IsoRay Inc.	CS-1

A suggested limit for all 10 CFR 400 material in the clinic is one Curie, though it is expected that the total quantity in the clinic at any one time will be much less than this.

VII. An indication of whether all surveillance items and records, including radioactive material inventory and accountability requirements, will be current at the time of transfer. A description of the status of all surveillance requirements is records, e.g., calibration, leak tests, surveys, etc. should be provided.

Response: All surveillance items and records, including radioactive material inventory and accountability requirements, are current. These include records of source calibrations, leak tests and surveys conducted at the time of each HDR source exchange and at the time of receipt of any other sealed or

unsealed sources, and records of surveys conducted at the time of patient treatments. All of these records will be transferred to the new entity.

VIII. A description of the status of the facility. Specifically, the presence of absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?

Response: The new entity, Clarian Arnett Health, will assume full liability for decontamination of the existing facility at 420 N. 26th St. Decontamination requirements will be minimal as past procedures at the facility have, with a single solitary exception, involved only sealed sources. In the course of preparing this request, a survey was conducted of the hot lab in the existing facility, and no contamination was detected. A very small amount of contaminated waste from the single use of unsealed source material was found and returned to the vendor.

IX. A description of any decontamination plans, including financial assurance arrangements of the transferee, should be provided, as specified in 10 CFR Sections 30.35, 40.36, and 70.25. This should include information about how the transferee and transferor propose to divide the transferor's assets and responsibility for cleanup at the time of transfer.

Response: As discussed above, no contamination of the existing facility was detected in a recent survey; hence, there are no decontamination plans. If any contamination is discovered in the future, the new entity will assume full liability for decontamination.

X. An indication of whether the transferor and transferee agree to the change in ownership or control of the licensed material and activity. If so, documentation stating this should be provided.

Response: The assets and operations transfer, which is inclusive of all licensed material and activity, is set forth in the Clarian Arnett Health Joint Venture Definitive Agreement dated April, 2006.

XI. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its program to assure compliance with the license and regulations.

Response: As there were no changes in program operations, therefore, the constraints, conditions, requirements, representations and commitments of the existing license remain unchanged.

I look forward to receiving your response.

Sincerely,

Phil Dittmer
Radiation Safety Officer
Oncology Institute of Greater Lafayette

Dan Goodwin
Administrator
Oncology Institute of Greater Lafayette

Attachment 1

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 57

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with letter dated January 23, 2007,
1. Greater Lafayette Health Services, Inc. Nuclear Medicine Department 2. 2400 South Street Lafayette, IN 47904-3027	3. License number 13-09788-01 is amended in its entirety to read as follows:
	4. Expiration date November 30, 2013
	5. Docket No. 030-01642 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. As needed (not to exceed 1 curie of Iodine-131)
D. Any byproduct material permitted by 10 CFR 35.400	D. Any	D. One curie
E. Any byproduct material permitted by 10 CFR 35.500	E. Sealed sources (North American Scientific, Inc. Model MED 3601, Du Pont Merck Pharmaceutical Company Model NES-8412 or Isotopes Products Laboratories, Inc. Model A3410)	E. 0.3 curies per source and 2 curies total

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
13-09788-01

Docket or Reference Number
030-01642

Amendment No. 57

9. Authorized Use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.

B. Any imaging and localization study permitted by 10 CFR 35.200.

C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.

D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.

E. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

CONDITIONS

10. Licensed material listed in Sections 9.A. through 9.E. shall be used at the licensee's facilities located at Lafayette Home Hospital, 2400 [illegible] Street, Lafayette, In[illegible] and St. Elizabeth Medical Center, 1501 Hartford Street, Lafayette, Indiana.

11. The Radiation Safety Officer is P[illegible]andy L. Mu[illegible]

12. Licensed material is only authorized [illegible] supervision of [illegible]

A. Individuals permitted to [illegible] an authorized user in accordance with 10 CFR 35.13 and 35.14.

B. The following individuals are authorized [illegible] for the materials and uses indicated:

Authorized Users	Material and Use
David R. Schmidt, M.D.	CFR 35.[illegible]00 and 35.500.
Adel Yaacoub, M.D.	10 CFR 35.200 and 35.500.
Irene C. Gordon, M.D.	10 CFR 35.300, 35.400 and 35.500.
Debbie Wright, M.D.	10 CFR 35.200 and 35.500.
Robert Mehl, M.D.	10 CFR 35.100, 35.200, 35.300 (limited to sodium iodide I-131) and 35.500.
John F. Fiederlein, M.D.	10 CFR 35.100, 35.200, 35.300, and 35.500.
Steven B. Jones, M.D.	10 CFR 35.100, 35.200, and 35.300 **(for iodine-131, oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries)**, and 35.500.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
13-09788-01

Docket or Reference Number
030-01642

Amendment No. 57

Sam Hansen, M.D.	10 CFR 35.100, 35.200, and 35.500.
Timothy J. Lach, M.D.	10 CFR 35.100, 35.200, 35.300, and 35.500.
Alexander Boutselis, M.D.	10 CFR 35.100, 35.200, 35.300, and 35.500.
Paul E. Gandy, M.D.	10 CFR 35.100, 35.200 and 35.300.
William J. Miller, M.D.	10 CFR 35.100, 35.200, and 35.300.
Paul DesRosiers, M.D.	10 CFR 35.400.
Loubna T. Scally, M.D.	10 CFR 35.400

13. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

14. In addition to the possession limits in Item 8, the licensee shall not further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The NRC's regulations apply to those procedures that are required to be submitted in accordance with the NRC's regulations. This license condition does not limit the licensee's ability to make changes in the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the license application and correspondence are more restrictive than the regulations.

A. Application August 29, 2003; and

B. Letters dated November 25, 2003 and February 26, 2004.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date FEB 16 2007

By _____
James R. Mullauer, M.H.S.
Materials Licensing Branch
Region III

Attachment 2

INDIANA UNIVERSITY
SCHOOL OF MEDICINE

Radionuclide Use Permit

Authorization Number:	RONC01	**Issued To:**	Peter Johnstone, M.D.
Issued Date:	12/13/2005	**Expiration Date:**	12/31/2009
Amended Date:	09/19/2006		

In accordance with the statements and representatives made in your application for Project Approval, Project Admendment, and/or your Progress Report, an approval authorizing the below named individuals to order, possess, and use the materials or items designated below in accordance with NRC regulations, state regulations, University regulations, and such other conditions as are herein specified is hereby issued.

1. Personnel / Status

Approved

Joanna KurosZolnierczuk	Julie Wilson	Marvene Ewing
Vadim Moskvin	Robert Barriger, (RES)	Jeffrey Brabham, (RES)
Minsong Cao	Colleen DesRosiers	Phil Dittmer
Jeffrey Forquer, (RES)	Mark Henderson, (RES)	Xiaoyi Lu
Tracy Price, (RES)	Bedatri Sinha, (RES)	Eric Slessinger
Jennifer Zook, (RES)	Stephanie Frost,	

Authorized User

Mark Langer, MD	James Morphis, MD	Higinia Cardenes, MD
Achilles Fakiris, MD	Song-Chu Ko, MD	Peter Johnstone, M.D.

2. Locations of Use

Approved

RT	UH 0406 S	UH OR
UH ORAL SS		

3. Nuclides / Chemical Forms / Exp. Limit / Poss. Limit

Radionuclide Use Permit

Au-198SS	100	150		
seeds				
Cs-137SS	3000	3000		
brachytherapy sources				
I-125	300	400		
Iotrex				
I-125SS	1000	1000		
seeds				
Ir-192SS	350	400		
seeds				
Ir-192W	600	600		
wire				
Na-22PA	0.04	2	A	6/20/07
sources (A - 6/20/2007)				
Na-22SS	0.03	1		
sources (A)				
P-32	15	60		
colloidal chromic phosphate				
Pd-103SS	500	500		
seeds				
Sr-90SS	60	140		
Beta-Cath sources				

4. Authorized Use

P-32 chromic phosphate for treatment of malignant effusions.

Sealed sources, seeds, and wire for clinical radiation therapy.

Clinical protocol entitled, "A Phase II Study of Intraperitoneal P-32 and Vaginal Brachytherapy in the Treatment of Papillary Serous and Clear cell Adenocarcinomas of the Endometrium (HOG GYN97-1)"(CoPI - Gregory Sutton, MD) (app 9/9/97).

Clinical protocol entitled, "A Phase II Trial of pre-Operative Pelvic and Para-Aortic Radiotherapy and Radical Pelvic Surgery in Stages IIIB and IVA Carcinoma of the Cervix (HOG GYN97-2)"(CoPI - Gregory Sutton, MD)(app 9/9/97).

Clinical protocol entitled, "A Randomized Comparison of radiation vs. Radiation Plus Weekly Cisplatin vs. Radiation Plus PVI (Protracted venous Infusion) 5-FU in Patients with Stage II-B, III-B, and IV-A Carcinoma of the Cervix - GOG #165"(CoPI - Gregory Sutton, MD)(app 3/10/98).

Use of GliaSite RTS System" for intracacitary treatment in the brain following tumor reseaction (app 3/11/03).

5. Conditions of Authorization

Personnel monitoring (whole body and ring) required when handling sealed sources.

Proper log-in and log-out procedures for sealed sources shall be followed in accordance with 10CFR35.

A direct radiation survey and visual source count shall be made and documented upon removal of sealed sources from patients.

A direct radiation survey shall be made in teh room where sealed sources are implanted to assure no sources have been misplaced.

The Radiation Safety Office shall be notified when brachytherapy patients are to be loaded and transferred to hospital wards where the RSO would be responsible for direct radiation measurements.

A direct radiation surevy shall be taken at the time of loading and removal of seeds when implanted in an operating room or DS Oral Surgery Suite to ensure no sources are lost.

Radiation survey meter is required.

The total activity for all brachytehrapy sources shall not exceed 6000 mci.

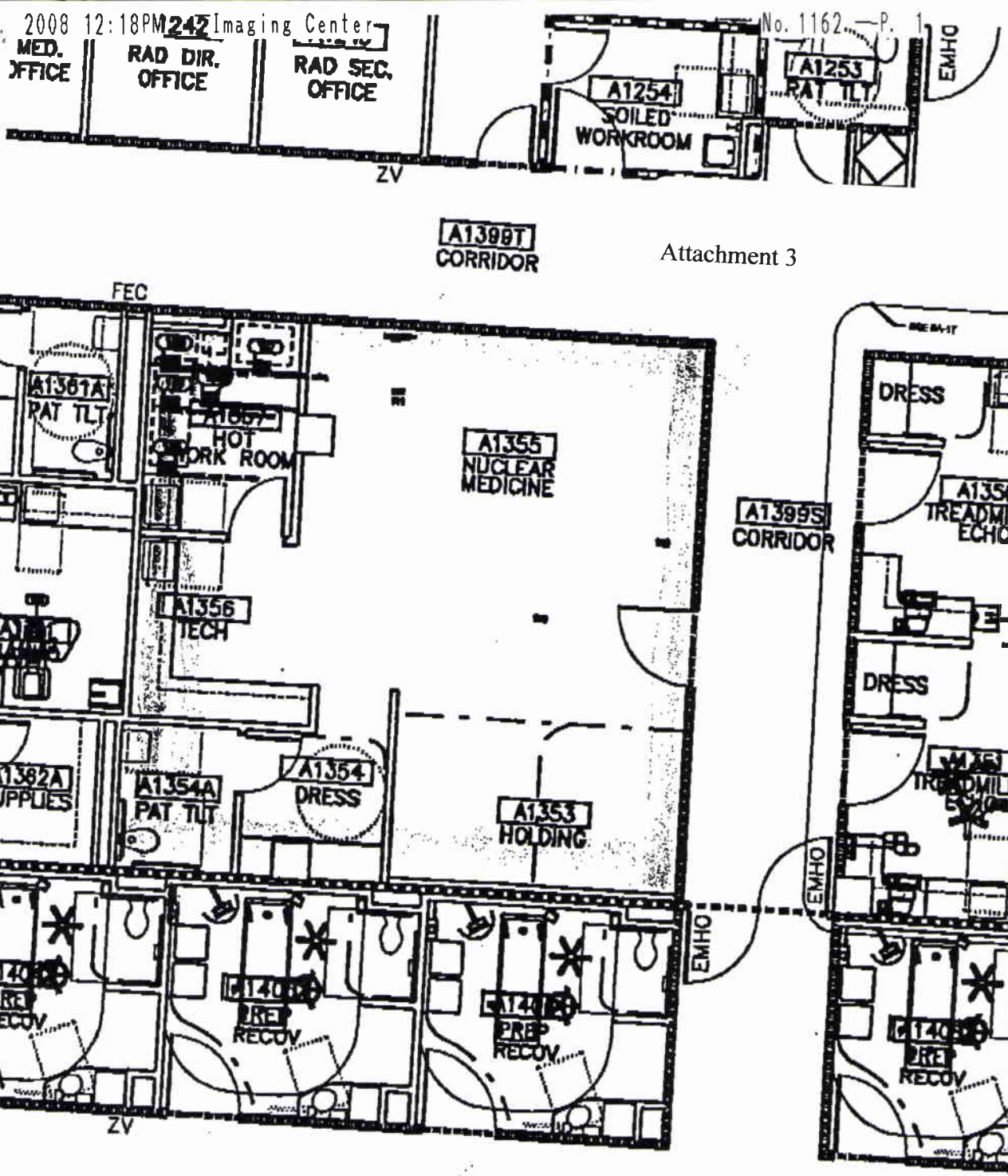
All equipment and areas utilized for cutting Ir-192 wire shall be wipe tested for removable contamination immediately following cutting procedures. Equipment and areas exceeding 200 dpm per 100 square centimeters shall be decontaminated, labeled and held for decay, or treated as radioactive waste.

This permit was originally under Ned Hornback, MD, Marcus randall, and James Morphis, MD.

All individuals involved in the delivery of standard brachytherapy shall review and follow the appropriate QMP.

Needles loaded with seeds may be stored in UH 0406 (OR Manager's Office) until they are used.

GliaSite Usage (3/11/03):
1. All inidviduals involved in GliaSite treatments shall receive vendor supplied training.
2. Written procedures for administration shall be modified and approved by the Radiation Safety Office following initial vendor supplied training.
3. Radiation Safety Staff members shall be present for administrations and removal of I-125 from GliaSite system for teh first 5 patients (completed 4 as of 11/5/04). Additional Radiation Safety Staff member participation after 5 patients shall be at the discretion of the RSO.



Attachment 3

To Phil Dittmer

FROM Dorcas Malcom

448-7632

Brachytherapy Procedure

1. Urology will schedule brachytherapy with OR Scheduler.

2. Urology will contact Oncology to order the seeds.

3. The radioactive seeds will be ordered through the radiation physicist under the supervision of the radiation oncologist.

4. Oncology will call Nuclear Medicine to expect delivery.

5. The radioactive seeds will be delivered to Nuclear Medicine.

6. A Nuclear Medicine Technologist will receive the package and perform a wipe test for surface contamination within the time limits specified in 10 CFR 20.1906. This test will be read with an instrument capable of detecting radiation quantities specified in 49 CFR 173.443. (The instrument currently used is a Capintec CRC 15W Well Counter.)

7. If contamination exceeds the specified limits, the technologist will immediately notify the final delivery carrier and the NRC Operations Center. If contamination levels are within limits, the technologist will place the sources in secure storage.

8. Nuclear Medicine will call Oncology when the sources are delivered.

9. The correct number, isotope, and strength of seeds will be verified and recorded in the Brachytherapy Log. Verification shall be done using manufacturer documentation and, where permitted by seed packaging, by independent measurement. (The instruments currently used are an HDR 1000 Plus Well Chamber and either a PTW Unidos 1005 or a Keithley 35040 Electrometer.)

10. The physicist will transport the seeds to surgery, maintain the seeds during the procedure, and return unused seeds to Nuclear Medicine.

11. The physicist will document all seed information in Brachytherapy Log as required per regulations.

Clarian Arnett Health
Kris Yoder, Clinic Manager
420 N. 26th St.
Lafayette, IN 47905

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7006 2760 0004 0877 1207

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RETURN RECEIPT REQUESTED

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