Bayhealth

Kent General Hospital | 640 South State Street | Dover, DE 19901 | 302.744.7000 | 302.744.7181 fax
Milford Memorial Hospital | 21 West Clarke Avenue | Milford, DE 19963 | 302.430.5942 | 302.430.5598 fax

Terence M. Murphy, FACHE
President and Chief Executive Officer
Mail Code: 1107

Br. 1

June 20, 2017

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Re: License No. 07-14850-01 03007565

To Whom It May Concern,

Bayhealth Medical Center, License Number 07-14850-01, wishes to amend our radioactive materials license to reflect the following:

- Please add Fan Zhang as an Authorized Medical Physicist for Iridium 192 High Dose Rate Remote Afterloader Unit for calibrations, spot-checks and training.
    - Please see the attached documentation.

If you have any questions regarding this amendment, please contact our radiation safety officer, Adam M. Henry at 1.866.755.2756 x703.

Sincerely,

Terry M. Murphy, FACHE
President and Chief Executive Officer

Enclosure:
Form 313a, RAM Licenses

Department of State Health Services

RADIOACTIVE MATERIAL LICENSE

Pursuant to the Texas Radiation Control Act and Texas Department of State Health Services (Agency) regulations on radiation, 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 radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Agency now or hereafter in effect and to any conditions specified below.

LICENSEE	This license is issued in response to an application
1. Name SCOTT AND WHITE MEMORIAL HOSPITAL AND SCOTT SHERWOOD AND BRINDLEY FOUNDATION DBA SCOTT AND WHITE MEMORIAL HOSPITAL ATTN DAVID M. JONES MS	Dated: May 19, 2015 Signed by: David Jones, RSO
2. Address 2401 SOUTH 31 ST STREET TEMPLE TX 76508	3. License Number L00331 / Amendment Number 101 PREVIOUS AMENDMENTS ARE VOID 4. Expiration Date June 30, 2024

RADIOACTIVE MATERIAL AUTHORIZED

5. Radioisotope	6. Form of Material	7. Maximum Activity	8. Authorized Use
A. Any radioactive material with an atomic number less than 84 and half-life less than 120 days	A. Any except sealed sources	A. 3 curies of any radioactive material, Total: 9 curies	A. Medical research, diagnosis and therapy, and instrument calibration
B. Mo-99	B. Tc-99m generators	B 18 curies	B. Production of technetium-99m.
C. Tc-99m	C. Any	C. 18 curies	C. Medical research, diagnosis, and shielding evaluations
D. Cs-137	D. Sealed source (Shepherd 6810; ORNL A-0096)	D. 1500 curies	D. Use in a J.L. Shepherd Model 143-45A blood irradiator.
E. Sr-90	E. Sealed sources (Tech/Ops M-1; Atlantic Research Corp. B-1)	E. No single source to exceed 60 millicuries, Total: 80 millicuries	E. Medical therapy.
F. Pd-103	F. Sealed source (seeds)	F. 1 curie	F. Medical therapy and diagnoses in radioactive seed localization (RSL) of non-palpable breast lesions.
G. I-125	G. Sealed source (seeds)	G. 1 curie	G. Medical therapy and diagnoses in radioactive seed localization (RSL) of non-palpable breast lesions.

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5. Radioisotope (continued)	6. Form of Material (continued)	7. Maximum Activity (continued)	8. Authorized Use (continued)
I. Ir-192	I. Sealed source (seeds in nylon ribbon)	I. 500 millicuries	I. Medical therapy.
J. Ir-192	J. Sealed source (Nucletron 105.002)	J. One source not exceed 13 curies at receipt and 12 curies at installation. One source not to exceed 8 curies Total: 21 curies	J. One source for treatment of humans with a Nucletron-HDR Model 105.999 or 106.990 – high dose rate afterloader (HDR) and the other source in its authorized shipping container during periods of source exchange.
K. Y-90	K. Sealed source (microspheres in solution)	K. 1 curie	K. Interstitial treatment of cancer as indicated in 25 TAC° §289.256(kk).
L. Cs-131	L. Sealed source	L. 2 curies	L. Medical therapy.
M. Ra-223	M. Radium-223 Dichloride (Xofigo)	M. 20 millicuries	M. Calibration and reference source; Medical therapy.
N. H-3	N. Any liquid or solid	N. 50 millicuries	N. Medical research
O. C-14	O. Any liquid or solid	O. 50 millicuries	O. Medical diagnosis and research
P. Co-57	P. Any except sealed sources	P. 2 millicuries	P. Medical diagnosis and research

° Texas Administrative Code (TAC)

9. Radioactive material shall be used only at:

A.

Site Number	Location
000	Temple – 2401 South 31st Street
002	Temple – 5701 Airport Road

B. The authorized place of use for the Scott & White mobile PET coach is at facilities within the Baylor Scott & White Healthcare network.

C. Temporary job sites throughout Texas in areas not under exclusive Federal jurisdiction for evaluation of structural shielding in medical facilities within the Baylor Scott & White Healthcare network.

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10. Each site shall maintain documents and records pertinent to the operations at that site. Copies of all documents and records required by this license shall be maintained for Agency review at Site 000, except those required by 25 TAC §289.201(d) that are directly related to radioactive materials for human-use and unsealed reference sources for instrument calibration, 25 TAC §289.202(nn), and 25 TAC §289.202(tt).

11. The licensee shall comply with the provisions (as amended) of 25 Texas Administrative Code (TAC) §289.201, §289.202, §289.203, §289.204, §289.205, §289.251, §289.252, §289.256 and §289.257.

12. A. Radioactive material shall only be used by, or under the supervision of, individuals designated by the Radiation Safety Committee (RSC), Matthew B. Crisp, M.D., Chair. Individuals authorized to serve on this committee are:

Matthew B. Crisp, M.D.	Chairman/Pediatric Radiology
C. Davis, B.S.	Children's Hospital
Niloyiyoti Deb, M.D.	Radiation Oncology
I.A. Hamilton, Ph.D.	Radiation Safety/Medical Physics
Andrey Hubbard, R.N.	Nursing
David M. Jones, M.S.	RSO/Medical Services/ex officio
Michael L. Middleton, M.D.	**Nuclear Medicine**
Timothy Mixon, M.D.	Cardiology
E.S. Rappaport, M.D.	Hematology/Clinical Pathology
Steven Ruiz, M.D.	Interventional Radiology
Wayne T. Stockburger, JD	Executive Director, Imaging
B.R. Trotter, M.D.	Diagnostic Radiology

B. For purposes of conducting meetings of the RSC, a quorum shall include but may not necessarily be limited to the Chair of the RSC, the RSO, and the representative from management.

13. The individual designated to perform the functions of Radiation Safety Officer (RSO) for activities covered by this license is David M. Jones.

14. The use of radioactive material in or on humans shall be by a licensed physician.

15. The licensee shall not open or remove sealed sources containing radioactive material from their respective source holders.

16. A. Sealed sources of radioactive material, Ni-63 foil, and/or plated alpha-emitting sources shall be tested for leakage and/or contamination in accordance with the provisions of 25 TAC §289.201(g).

B. Leak test analyses may be performed by, or under the supervision of, David M. Jones.

C. The periodic leak test required by 25 TAC §289.201(g) does not apply to sealed sources that are stored and exempted by that rule. The sources exempted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

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17. All radioactive material to be used in humans shall either be of radiopharmaceutical grade or shall be in the form of sealed sources, evaluated and approved for use in humans by the United States Nuclear Regulatory Commission (NRC) or the Agreement State in which they are produced.

18. Radioactive material shall not be used in humans until its pharmaceutical quality and assay have been established.

19. Research protocols which use procedures other than those specified in product labeling must be approved by a duly constituted Institutional Review Board.

20. Installation or exchange of sealed sources resident in an imaging scanner shall be performed only by the device manufacturer or other persons specifically authorized to perform such services by the Agency, U. S. Nuclear Regulatory Commission (NRC), another Agreement State, or a Licensing State. The licensee shall maintain a record of each installation or exchange for 3 years from the date of service. The record shall include the date of service, the name of the service provider, the number of the service provider's radioactive material license and identify the regulatory agency issuing the license to the service provider.

21. Experimental animals administered radioactive materials or their products shall not be used for human consumption.

22. A current copy of the licensee's radiation safety manual shall be provided to each person who uses radioactive material authorized by this license.

23. Proposed substantive changes in or additions to the licensee's radiation safety manual shall be submitted to the Agency for approval before being incorporated into that document.

24. Proposed new members to the licensee's Radiation Safety Committee shall be identified to the Agency by name and department, and their membership approved prior to their participation as full-voting members in the committee's deliberations. Interim appointments for replacements of departing members may be made by executive management, pending Agency approval, when the interim appointee has been identified to the Agency and represents the same department as did the departing member.

25. The licensee shall not open or remove sealed sources containing radioactive material from the blood irradiator.

26. The manufacturer's instruction manual for the Shepherd blood irradiator shall be followed when using the device. A copy of it shall be made available to all persons using the device.

27. The licensee shall maintain a current copy of the safety evaluation from "The Registry of Radioactive Sealed Sources and Devices" for each sealed source received under authority of this license, in excess of 1 millicurie of beta/gamma-emitting material or 10 microcuries of alpha-emitting material.

28. The licensee shall cease treatment of patients when any safety related system of a HDR unit is found inoperative, including the source drive mechanism, treatment timing system, safety interlocks and radiation field alarms. The licensee shall report to the Manager, Environmental Monitoring Group, any malfunction which requires the termination of patient treatments for more than 24 hours and shall submit a written report of the incident and corrective actions within seven calendar days.

Department of State Health Services

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29. The RSO or an authorized physician user (APU) shall review technologist handling of radioactive materials at least once per month to confirm proper radiation safety procedures.

30. The licensee shall comply with the requirements described in U. S. Nuclear Regulatory Commission's Order EA-07-305 (the Order). Not withstanding the time periods contained within the Order, the licensee shall comply with the following conditions in the time specified. The licensee shall complete implementation of said requirements by the first day that radionuclides in quantities of concern are possessed at or above the limits specified in "Table 1: Radionuclides of Concern" contained within the Order. The licensee shall notify DSHS - Radioactive Material Licensing Group, Manager when they have achieved full compliance with the requirements described in the Order. The notification shall be made within thirty (30) days after full compliance has been achieved. This notification shall include a certification that the Trustworthiness and Reliability (T&R) Official, and any subsequent T&R Official, is themselves deemed trustworthy and reliable by the Licensee as required in B.2. of the Order. The licensee shall notify the Manager, Radioactive Material Licensing Group, DSHS at (512) 834-6688, ext. 2206 within 24 hours if the results from a criminal history records check indicate that an individual is identified on the FBI's Terrorist Screening Data Base.

31. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material authorized by this license in accordance with statements, representations, and procedures contained in the following:

application dated May 30, 2014,
letters received May 5, 2015.

Title 25 TAC §289 shall prevail over statements contained in the above documents unless such statements are more restrictive than the regulations.

CCC: ccc

FOR THE DEPARTMENT OF STATE HEALTH SERVICES

Date May 28, 2015

J. Scott Kee, Program Coordinator
Medical and Academic Licensing Program

NRC FORM 313A (AMP)
(06-2016)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.51]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 06/30/2019

Name of Proposed Authorized Medical Physicist

Fan Zhang

Requested Authorization(s) (check all that apply)

- ☐ 35.400 Ophthalmic use of strontium-90
- ☐ 35.600 Teletherapy unit(s)
- ☑ 35.600 Remote afterloader unit(s)
- ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ **1. Board Certification**

a. Provide a copy of the board certification.

b. Go to the table in 3.c. and describe training provider and dates of training for each type of use for which authorization is sought.

c. Skip to and complete Part II Preceptor Attestation.

☐ **2. Current Authorized Medical Physicist Seeking Additional Authorization for use(s) checked above**

a. Go to the table in section 3.c. to document training for new device.

b. Skip to and complete Part II Preceptor Attestation

☑ **3. Education, Training, and Experience for Proposed Authorized Medical Physicist**

a. Education: Document master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

Degree	Major Field
Master of Science	Medical Physics

College or University

Duke University

b. Supervised Full-Time Medical Physics Training and Work Experience in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

☑ Yes. Completed 1 year of full-time training in medical physics (for areas identified below) under the supervision of Geethpriya Palaniswaamy, PhD who meets the requirements for an Authorized Medical Physicist.

AND

☑ Yes. Completed 1 year of full-time work experience in medical physics (for areas identified below) under the supervision of Geethpriya Palaniswaamy, PhD who meets the requirements for an Authorized Medical Physicist.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. **Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)**

b. Supervised Full-Time Medical Physics Training and Work Experience (continued)
If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility/Medical Devices Used+	Dates of Training*	Dates of Work Experience*
Medical Physics	Scott and White Memorial Hospital, Temple, TX/ L00331/Elekta Nucletron, Scott and White Waco Clinic/ L00845/ Varian Varisource iX,	7/1/2015-6/30 /2016	7/1/2016-6/30/2 017
Performing sealed source leak tests and inventories	Scott and White Memorial Hospital, Temple, TX/ L00331/Elekta Nucletron, Scott and White Waco Clinic/ L00845/ Varian Varisource iX,	7/1/2015-6/30 /2016	7/1/2016-6/30/2 017
Performing decay corrections	Scott and White Memorial Hospital, Temple, TX/ L00331/Elekta Nucletron, Scott and White Waco Clinic/ L00845/ Varian Varisource iX,	7/1/2015-6/30 /2016	7/1/2016-6/30/2 017
Performing full calibration and periodic spot checks of external beam treatment unit(s)			
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)			
Performing full calibration and periodic spot checks of remote afterloading unit(s)	Scott and White Memorial Hospital, Temple, TX/ L00331/Elekta Nucletron, Scott and White Waco Clinic/ L00845/ Varian Varisource iX,	7/1/2015-6/30 /2016	7/1/2016-6/30/2 017
Conducting radiation surveys around external beam treatment unit(s), stereotactic radiosurgery unit(s), remote after loading unit(s)	Scott and White Memorial Hospital, Temple, TX/ L00331/Elekta Nucletron, Scott and White Waco Clinic/ L00845/ Varian Varisource iX,	7/1/2015-6/30 /2016	7/1/2016-6/30/2 017

Supervising Individual**	License/Permit Number listing supervising individual as an authorized Medical Physicist
Geethpriya Palaniswaamy, PhD	L00845

for the following types of use:

☑ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

+ Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

* 1 year of Full-time medical physics training and 1 year of full time work experience cannot be concurrent.

** If the supervising medical physicist is not an authorized medical physicist, the licensee must submit evidence that the supervising medical physicist meets the training and experience requirements in 10 CFR 35.51 and 35.59 for the types of use for which the individual is seeking authorization.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

c. Describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Hands-on device operation	Scott and White Memorial Hospital 7/1/2015-6/30/2016		
Safety procedures for the device use	Scott and White Memorial Hospital 7/1/2015-6/30/2016		
Clinical use of the device	Scott and White Memorial Hospital 7/1/2015-6/30/2016		
Treatment planning system operation	Scott and White Memorial Hospital 7/1/2015-6/30/2016		

Supervising Individual *If training is provided by Supervising Medical Physicist. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)*	License/Permit Number listing supervising individual as an authorized Medical Physicist
Geethpriya Palaniswaamy, PhD	L00845

for the following types of use:

☑ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

If Applicable:

Authorization Sought	Device	Training Provided By	Dates of Training
35.400 Ophthalmic Use of strontium-90			

d. Skip to and complete Part II Preceptor Attestation.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section
Check one of the following:

1. Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized Medical Physicist
10 CFR 35.51(a)(1) and (a)(2).

OR

2. Education, Training, and Experience

☑ I attest that Fan Zhang has satisfactorily completed the 1-year of full-time
Name of Proposed Authorized Medical Physicist
training in medical physics and an additional year of full-time work experience as required by 10 CFR 35.51(b)(1).

AND

Second Section
Complete the following:

☑ I attest that Fan Zhang has training for the types of use for which authorization
Name of Proposed Authorized Medical Physicist
is sought that include hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

AND

Third Section
Complete the following:

☑ I attest that Fan Zhang has achieved a level of competency sufficient to
Name of Proposed Authorized Medical Physicist
function independently as an Authorized Medical Physicist for the following:

☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Teletherapy unit(s)
☑ 35.600 Remote afterloader unit(s) ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section
Complete the following for preceptor attestation and signature:

☑ I meet the requirements in 10 CFR 35.51, or equivalent Agreement State requirements for Authorized Medical Physicist for the following:

☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Teletherapy unit(s)
☑ 35.600 Remote afterloader unit(s) ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

Name of Preceptor	Signature	Telephone Number	Date
Geethpriya Palaniswaamy, PhD		(254) 724-6063	6/6/2017

License/Permit Number/Facility Name
L00331/Scott and White Memorial Hospital

Department of State Health Services

RADIOACTIVE MATERIAL LICENSE

Pursuant to the Texas Radiation Control Act and Texas Department of State Health Services (Agency) regulations on radiation, 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 radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Agency now or hereafter in effect and to any conditions specified below.

LICENSEE		This license is issued in response to a letter
1. Name	HILLCREST BAPTIST MEDICAL CENTER DBA BAYLOR SCOTT & WHITE MEDICAL CENTER HILLCREST ATTN AUDRA COKER MS LMP	Dated: November 18, 2016 Signed by: Audra L. Coker, M.S., LMP
2. Address	100 HILLCREST MEDICAL BLVD WACO TX 76712	3. License Number: L00845 / Amendment Number: 109 PREVIOUS AMENDMENTS ARE VOID 4. Expiration Date: March 31, 2019

RADIOACTIVE MATERIAL AUTHORIZED

5. Radioisotope	6. Form of Material	7. Maximum Activity	8. Authorized Use
A. Any radioactive material with a half-life < 120 days, except positron emitters	A. Any radiopharmaceutical, except gas and aerosol	A. As needed for diagnostic purposes	A. Any diagnostic use indicated in Title 25 TAC° §289.256(ff) and (hh).
B. Mo-99/ Tc-99m (FDA*-approved generators)	B. Solid or liquid	B. No generator to exceed 5 curies	B. Preparation of generator eluate and radiopharmaceutical reagent kits for use as indicated in 25 TAC §289.256 (hh).
C. F-18	C. Fluorodeoxyglucose (FDG) as a radiopharmaceutical	C. As needed for diagnostic purposes	C. Any diagnostic study involving imaging and tumor localization.
D. Xe-133	D. Any radiopharmaceutical	D. 150 millicuries	D. Pulmonary function studies and lung imaging.
E. I-131	E. Sodium iodide (in capsules only)	E. 300 millicuries	E. Treatment of hyperthyroidism and thyroid cancer in accordance with 25 TAC §289.256(kk).
F. Pd-103	F. Sealed sources (seeds)	F. 500 millicuries	F. Interstitial treatment of cancer in accordance with 25 TAC §289.256(rr).
G. I-125	G. Sealed sources (seeds)	G. 500 millicuries	G. Interstitial treatment of cancer in accordance with 25 TAC §289.256(rr).
H. Ir-192	H. Sealed sources (seeds in nylon ribbon)	H. 300 millicuries	H. Interstitial treatment of cancer in accordance with 25 TAC §289.256(rr).

° Texas Administrative Code (TAC) * U.S. Food and Drug Administration

Department of State Health Services

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5. Radioisotope	6. Form of Material	7. Maximum Activity	8. Authorized Use
I. F-18	I. Liquid	I. 100 millicuries	I. Calibration and reference source.
J. Ge/Ga-68	J. Sealed source (IPL A3407)	J. No single source to exceed 13 millicuries Total: 40 millicuries	J. Transmission scanning of patients with a GE Advance PET Imaging System.
K. Ge/Ga-68	K. Sealed source (IPL A3407)	K. No single source to exceed 2.5 millicuries Total: 4 millicuries	K. Calibration and reference source.
L. Ge/Ga-68	L. Sealed source (CTI LS Series)	L. No single source to exceed 6 millicuries Total: 30 millicuries	L. Instrument calibration and transmission scanning of patients with a CTI Positron Emission Tomography (PET) camera equipped with a model ECAT EXACT Series device.
M. Gd-153	M. Sealed line sources (NAS MED 3601; IPL HEGL 0037)	M. No single source to exceed 300 millicuries Total: 1 curie	M. Transmission scanning of patients with an ADAC gamma camera equipped with a Vantage device.
N. Sr-90	N. Sealed source (BEBIG SrO.SO3; AEAT SICW Series)	N. 208 sources not to exceed 5 millicuries each Total: 1040 millicuries	N. Intravascular brachytherapy (IVB) with a Novoste Beta-Cath System, Model A1000 Series in accordance with the FDA approved Pre-market Approval. Possession authorized for up to six devices in use and an additional six during device exchanges.
O. Ge-68/ Ga-68	O. Sealed source (CTI LS Series; Sanders PET-XXX/YY)	O. No single source to exceed 10 millicuries Total: 30 millicuries	O. Instrument calibration and transmission scanning of patients with a CTI Positron Emission Tomography (PET) camera equipped with model ECAT ACCEL Series device.
P. Ir-192	P. Sealed source (Varian VS 2000)	P. One source not to exceed 13 curies on receipt and 11 curies at installation, one source not to exceed 8 curies Total: 21 curies	P. One source for treatment of humans with a Varian Varisource iX high dose rate (HDR) afterloader and the other source in its authorized shipping container during periods of source exchange.

9. Radioactive material shall only be stored and used at:

Site Number	Location
001	Waco – 100 Hillcrest Medical Boulevard.

Department of State Health Services

RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER	AMENDMENT NUMBER
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10. Each site shall maintain documents and records pertinent to the operations at that site. Copies of all documents and records required by this license shall be maintained for Agency review at Site 001.

11. The licensee shall comply with the provisions (as amended) of Title 25 Texas Administrative Code (TAC) §289.201, §289.202, §289.203, §289.204, §289.205, §289.251, §289.252, §289.256 and §289.257.

12. Radioactive material may be used only under the direct supervision of, or by the physicians listed below for the use(s) specified.

A. All diagnostic uses authorized by the license; therapy with I-131 for hyperthyroidism and thyroid cancer.

William Lewis Dobie Jr. M.D. Daniel Kirzeder, M.D.

B. All diagnostic uses authorized by the license; therapy with I-131 for hyperthyroidism.

Henry J. Boehm, M.D.	Russell McClellan, M.D.	Jose V. Watson, M.D.
Jeffrey C. Gerik, M.D.	David O. Risinger, M.D.	Thomas B. White, M.D.

C. All diagnostic use authorized by license.

Greg Bathurrst, M.D. Adam Falcone, M.D.

D. Brachytherapy including the HDR.

Nancy Bednarz, M.D. Niloyiyota Deb, M.D. Dominic D. Nguyen, M.D.

E. Brachytherapy (not to include HDR).

Lewis G. Smith, III, M.D.

F. Diagnostic nuclear cardiology.

Sherwin F. Attai, M.D.	Donald S. Cross, M.D.	Charles A. Shoultz, Jr., M.D.
Brian Barnett, M.D.	Andrew K. Day, M.D.	Shawn Skeen, M.D.
Rodney A. Brown, M.D.	James Phillip Myatt, M.D.	

G. IVB may be performed by Authorized Physician Users (APU) who have completed the manufacturer's device training and are listed on this license for brachytherapy.

H. Calibration and quality control for the HDR.

Sunita Boddu, Ph.D.	Andrew Morrow, M.S.	Geethpriya Palaninswaamy, Ph.D.
Veera Rajesh Gutti, Ph.D.	Hannah Norris, M.S.	Dharanipathy Rangaraj, Ph.D.
Mohammad R. Islam, Ph.D.	Swetha Oddiraju, Ph.D.	Luis Vazquez, Ph.D.

Department of State Health Services

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13. The individual designated to perform the functions of Radiation Safety Officer (RSO) for activities covered by this license is Audra Coker, M.S., LMP.

14. The licensee shall not open sealed sources containing radioactive material.

15. Emergency instructions shall be posted at or around the storage container for sources used in a cardiac catherization lab where IVB is being performed. These instructions shall inform personnel of the procedure to be followed should the source(s) need to be retracted from the patient prior to the end of scheduled treatment and shall include specific instructions for:

    A. Locating and using readily available equipment needed to find and handle sources should the source(s) and catheter have to be retracted from a patient while taking note of the time.

    B. Securing the area against unauthorized entry if the sources cannot be placed in the shielded storage container

    C. Notifying the RSO, assessing exposures to personnel as well as in adjacent areas, and completing a report of the incident.

16. Installation or exchange of sealed sources resident in an imaging scanner shall be performed only by the device manufacturer or other persons specifically authorized to perform such services by the Agency, U. S. Nuclear Regulatory Commission (NRC), another Agreement State, or a Licensing State. The licensee shall maintain a record of each installation or exchange for 3 years from the date of service. The record shall include the date of service, the name of the service provider, the number of the service provider's radioactive material license and identify the regulatory agency issuing the license to the service provider.

17. The licensee shall maintain a current copy of the safety evaluation from "The Registry of Radioactive Sealed Sources and Devices" for each sealed source received under authority of this license, in excess of 1 millicurie of beta/gamma-emitting material or 10 microcuries of alpha-emitting material.

18. Injections of radiopharmaceuticals in patient care areas of the medical center which are outside of the authorized imaging areas shall be documented in a separate log to include the following:

    A. Time and date of each injection.

    B. Room number and injecting technologist's name.

    C. Removable contamination survey results based on a completed radiation safety survey of the injection area, to be performed immediately after the injection.

    D. Survey evaluation for authorizing release of the injection area for unrestricted use.

Department of State Health Services

RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER	AMENDMENT NUMBER
L00845	109

19. The licensee shall cease treatment of patients when any safety related system of an HDR unit is found inoperative, including the source drive mechanism, treatment timing system, safety interlocks and radiation field alarms. The licensee shall report to the Manager, Environmental Monitoring Group, any malfunction that requires termination of patient treatment for more than 24 hours and submit a written report of the incident and corrective actions within seven calendar days.

20. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material authorized by this license in accordance with statements, representations and procedures contained in the following:

application dated January 23, 2009,
letters dated January 29, 2009, February 3, 2009, March 31, 2009, April 8, 2009, June 8, 2009
October 4, 2013,
letters received March 25, 2009, and March 26, 2009.

Title 25 TAC §289 shall prevail over statements contained in the above documents unless such statements are more restrictive than the regulations.

ASH: ash

FOR THE DEPARTMENT OF STATE HEALTH SERVICES

Date November 22, 2016

J. Scott Kee, Program Coordinator
Medical and Academic Licensing Program

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee	Date
Terry M. Murphy President and Chief Executive Officer Bayhealth Medical Center 640 South State Street Dover, Delaware 19901	June 29, 2017
	License Number(s) 07-14850-01
	Mail Control Number(s) 599955
	Licensing and/or Technical Reviewer or Branch Medical Branch

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** June 20, 2017

The initial processing, which included an administrative review, has been performed.

☑ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf**

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, (610) 337-5239