ARIZONA DEPARTMENT OF HEALTH SERVICES
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIAL LICENSE

Pursuant to Chapter 4, Title 30, Arizona Revised Statutes, and Title 12, Chapter 1 of the Arizona Administrative Code, and in reliance on statements and representations made to the Department by the licensee, a license is hereby issued authorizing the acquisition, reception, possession, use and transfer of the radioactive material listed in this license for the purposes and at the places specified. This license is subject to all applicable rules and Department orders now or hereafter in effect and to the conditions specified. In accordance with letter dated February 20, 2018, signed by Paul Hanny, Ph.D., License Number 10-044, is hereby amended in its entirety to read as follows: ALL CHANGES ARE IN BOLD

LICENSEE

1. NAME: Banner Health
d/b/a Banner University Medical Center-Tucson

2. ADDRESS: 1501 N. Campbell Avenue
Tucson, Arizona 85724

3. a. LICENSE NUMBER: 10 - 044
   b. AMENDMENT NO.: 74

4. EXPIRATION DATE: September 30, 2018

5. CATEGORY: B1 - BROAD MEDICAL

6. Radioactive material (element and mass number)
   A. Any radioactive material with atomic number 3 through 83 inclusive
   B. Hydrogen-3
   C. Phosphorus-32
   D. Yttrium-90
   E. Yttrium-90
   F. Krypton-85
   G. Strontium-90
   H. Strontium-90
   I. Technicium-99
   J. Palladium-103

7. Chemical or physical form
   A. Any
   B. Any
   C. Source as approved in NRC SS&D for system authorized in 9(C)
   D. Yttrium-90 labeled Microspheres (TheraSphere)
   E. Yttrium-90 labeled Microspheres (SIR-Spheres)
   F. Gaseous or dissolved in saline solution
   G. Sealed sources
   H. Sealed sources
   I. Radiopharmaceuticals
   J. Seeds/Sealed sources

8. Maximum quantity licensee may possess at any time
   A. 37 GBq (1 curie) each nuclide
   B. 740 GBq (20 curies)
   C. 2 sources, no single source to exceed 22.2 GBq (600 millcuries)
   D. 74 GBq (2,000 millcuries)
   E. 37 GBq (1,000 millcuries)
   F. 74 GBq (2 curies)
   G. 37 GBq (1 curie)
   H. 37 GBq (1 curie); no single source in a source train shall exceed 185 MBq (5 millcuries)
   I. 74 GBq (2 curies)
   J. 185 GBq (5 curies)

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### RADIOACTIVE MATERIAL LICENSE

**SUPPLEMENTARY SHEET**

<table>
<thead>
<tr>
<th>K. Iodine-125</th>
<th>K. Seeds/Sealed sources</th>
<th>K. 37 GBq (1 curie)</th>
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<tr>
<td>L. Iodine-125</td>
<td>L. Liquid (lotrex)</td>
<td>L. 185 GBq (5 curies)</td>
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<tr>
<td>M. Xenon-133</td>
<td>M. Gaseous or dissolved in saline solution</td>
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<td>N. Cesium-137</td>
<td>N. Sealed sources</td>
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<tr>
<td>O. Holmium-166</td>
<td>O. Radiopharmaceuticals</td>
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<tr>
<td>P. Iridium-192</td>
<td>P. Sheathed wires or beads</td>
<td>P. 74 GBq (2 curies)</td>
</tr>
<tr>
<td>Q. Iridium-192</td>
<td>Q. Source as approved in NRC SS&amp;D for system authorized in 9(R)</td>
<td>Q. 2 sources, no single source to exceed 370 GBq (10 curies)</td>
</tr>
<tr>
<td>R. Gold-198</td>
<td>R. Seeds</td>
<td>R. 18.5 GBq (500 millicuries)</td>
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<td>S. Fluorine-18</td>
<td>S. Any</td>
<td>S. 37 GBq (1 curie)</td>
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<td>T. Radium-223</td>
<td>T. Radium chloride</td>
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<tr>
<td>U. Actinium-225</td>
<td>U. Any</td>
<td>U. 37 MBq (1 millicurie)</td>
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<tr>
<td>V. Cesium-131</td>
<td>V. Seeds/sealed sources</td>
<td>V. 370 GBq (10 curies)</td>
</tr>
</tbody>
</table>

### 9. Authorized Use:

A, B, F, G, I through K, M, N, O, P and R through V: Medical diagnosis, therapy and biomedical research and development.

C. For use in Guidant Corporation “Galileo” Intravascular Brachytherapy System (TX-1070-D-102-S).


Q. For use in Varian Medical Systems, Vari Source iX Brachytherapy Afterloader.

D. and E. Interstitial implants for the treatment of cancer.
CONDITIONS

10. Radioactive material may be possessed and used only at:
    Site 1: Banner University Medical Center - Tucson - 1501 North Campbell Avenue, Tucson, Arizona 85724
    Site 2: Banner University Medicine Medical Imaging - 4291 North Campbell Avenue, Tucson, Arizona 85719
    Site 3: University of Arizona Cancer Center - 1891 West Orange Grove Road, Tucson, Arizona 85704
    Site 4: Banner University Medical Center - South - 2800 East Ajo Way, Tucson, Arizona 85713
    Site 5: University of Arizona Waste Storage Facility - 1548-1 North Ring Road, Tucson, Arizona 85724

11. The licensee shall comply with the provisions of Title 12, Chapter 1, Arizona Administrative Code; Article 3, "Radioactive Material Licensing"; Article 4, "Standards for Protection Against Ionizing Radiation"; Article 7", Medical use of Radioactive Material" and Article 10, "Notices, Instructions and Reports to Radiation Workers; Inspections".

12. A. Radioactive material shall be used by, or under the supervision of, individuals designated by the Licensees Medical Radiation Safety Committee. The Radiation Safety Officer is: Daniel Silvain, MS, DABR.
    B. The use of radioactive material in, or on human beings shall be by, or under the supervision of authorized users, physicists, and nuclear pharmacists, if approved, as defined in A.A.C. R12-1-702.
    C. The Alternate Radiation Safety Officer is: Paul Hanny, Ph.D. The Alternate Radiation Safety Officer shall administer the Radiation Safety Program under the policy and procedure guidance of the Radiation Safety Officer.


14. The licensee shall perform a semiannual airflow direction check to verify a negative pressure differential within the Nuclear Medicine Department relative to surrounding areas. The licensee shall also perform annual ventilation flow rate measurements within the Department to ensure that radioactive gases in use are properly diluted and exhausted.

15. The licensee shall leak test sealed sources used for interstitial or intracavitary therapy implant in accordance with the requirements specified in each sealed source and device safety evaluation in the Nuclear Regulatory Commissions sealed source and device registration system.

16. A. The licensee shall ensure, in accordance with A.A.C. R12-1-419 (C), that an individual participates in a radiiodine bioassay if the individual:
    1. Is likely to receive an annual intake in excess 0.1 of the Annual Limits of Intake (ALI) specified in Table 1, Columns 1 and 2 of Appendix B in 12 A.A.C.1, Article 4;
    2. Is a minor or declared pregnant woman likely to receive an annual committed effective dose equivalent in excess of 50 mRem, or
    3. Has been involved in a spill, an incident, or other occurrence during which radiiodine may have been taken into the body either by inhalation, ingestion, or by absorption through the skin or a wound.

B. The licensee shall ensure that an individual who is directly involved in a radiiodine therapy, the handling of radiiodine stock solutions, or is involved in iodination’s, and meets, as a minimum, any one of the three criteria in Part A above, participates in a bioassay between 6 and 72 hours following the exposure to radiiodine. With Department approval, the licensee may perform I-131 bioassays up to 4 weeks and I-125 bioassays up to 12 weeks following radiiodine exposure.

C. For any individual whose cumulative annual intake is likely to exceed 0.1 ALI, the licensee shall perform a dosimetric determination based on the results of the bioassay performed under Part B. To assist in determining the total dose equivalent for the individual, the licensee shall add the obtained dose information to the committed dose equivalent information for the exposed individual. For the exposed individual whose bioassay exceeds 0.25 ALI, the licensee shall restrict the exposed individual from further radiiodine exposure until a bioassay indicates the individual’s exposure has dropped below 0.1 ALI.

D. For bioassays exceeding 0.1 ALI, the licensee shall investigate the circumstances surrounding the exposed individual’s uptake. Records of the investigation and all bioassay measurements shall be maintained as part of the licensee’s personnel dosimetry records and shall be available for inspection by the Department.

17. A. The licensee shall, in accordance with A.A.C. R12-1-419 (D), require an individual to participate in a Hydrogen-3 bioassay (urinalysis) whenever the individual is likely to receive, in one year, an intake in excess of 0.1 of the Annual Limits of Intake (ALI) specified in Table 1, Columns 1 and 2 of Appendix B in 12 A.A.C.1, Article 4.

B. The licensee shall initiate an individual’s bioassay following any operation involving, at any one time, more than 100 millicuries of Hydrogen-3 in a non-contained form, other than metallic foil. The bioassay shall be performed within one week following a single operation and at weekly intervals for continuing operations. If the average concentration for the individual is less than 10 μCi/liter for a calendar quarter, the bioassay rate may be reduced to monthly intervals.

C. Before an individual initiates work with hydrogen-3, the licensee shall require the individual participate in a baseline bioassay if the individual is to work with more than 100 millicuries of hydrogen-3.

D. For any individual whose cumulative annual intake is likely to exceed 0.1 ALI, the licensee shall perform a dosimetric determination based on the results of the bioassay performed under Part A. To assist in determining the total dose equivalent for the individual, the licensee shall add the obtained dose information to the committed dose equivalent for the exposed individual.

E. The licensee shall ensure occupationally exposed minors and declared pregnant women are monitored for hydrogen-3 intake, if they are likely to receive in one year, a committed effective dose equivalent in excess of 0.01 ALI.

F. For bioassays exceeding 0.1 ALI, the licensee shall investigated the circumstances surrounding the exposed individual’s uptake. Records of the investigation and all bioassay measurements shall be maintained as part of the licensee’s personnel dosimetry records and shall be available for inspection by the Department.

18. The licensee shall require the use of laboratory coats and gloves by laboratory personnel using unsealed radioactive material in greater than exempt quantities, unless it can be demonstrated that use of protective clothing compromises other safety aspects of the radioactive material use.
19. A. In addition to the possession limit in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10CFR 30.35, which is incorporated by reference in A.A.C. R12-1-323(C), in the absence of the Decommissioning Plan, attached to letter dated March 16, 2012, approved by the Department.

B. The licensee shall make available at the time of Department inspection an inventory control system that will ensure that the radionuclide’s possessed cannot exceed the regulatory limits in A.A.C. R12-1-323, in the absence of the Decommissioning Plan approved by the Department.

20. The following conditions of use apply to the GliaSite RTS brachytherapy system.

A. Users shall complete initial training by the manufacturer and participate in at least 3 patient therapies under the supervision of a manufacturer representative.

B. Prior to the administration of Iotrex the patient shall be administered a thyroid blocking agent.

C. Patients administered Iotrex in the GliaSite RTS system shall be monitored and handled as if undergoing a thyroid ablation.

D. A radioactive spill kit shall be available in the therapy room. Documentation of personnel training in the use of the kit shall be available for the Department inspection.

E. Each radiation therapy system shall be used for a single patient.

F. The licensee may perform brachytherapy GliaSite RTS system on an outpatient basis only after a determination has been made concerning the suitability of the patient’s release, and provided each patient is provided with information concerning the radiation safety aspects of his or her release.


A. General (For all intravascular therapy systems)

1. Training in the use of the intravascular system shall be provided by the manufacturer to the interventional cardiologist, authorized user, and medical physicist.

2. Emergency procedures for both stuck and detached sources shall be prominently posted and/or immediately available to operators.

3. Source output for all sources shall be independently measured by a medical physicist prior to the first patient treatment, using an instrument that has been calibrated in the previous 2 years by an NIST or AAPM accredited laboratory.

4. The therapy system shall only be used to treat vascular disease in the presence of the interventional cardiologist and the attending authorized user or the assisting qualified expert.

5. Radiation surveys with appropriate instrumentation shall be performed after each procedure to verify that the source has returned to safe storage.

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6. The licensee shall maintain records of all tests required under this condition for 3 years following completion of the tests.

7. The licensee shall maintain a Quality Management Program in accordance with R12-1-707.

8. Each therapy system shall be used in accordance with the manufacturer's specifications and the safety precautions addressed in the system's Sealed Sources and Devices Registry.

B. Guidant System (specific conditions of use):

1. The working life of the source approved for use under sub item C of Items 6, 7 and 8 shall be limited to 60 days or 650 cycles, whichever occurs first.

2. Each day of use, the following quality assurance tests shall be completed before the first patient treatment involving the system listed under 9 (C):
   a. Check of the operational status of the console and associated indicator lamps; and
   b. Check of source status indicators and the integrity of the source centering catheter and connectors; and source positioning accuracy.

3. Prior to the first patient use the licensee shall perform the following tests:
   a. A contact radiograph shall be performed to check integrity of welds, and source uniformity checked by autoradiography.
   b. Source positioning within +/- 1 mm.
   c. Battery backup for emergency source retraction.
   d. Source transit time and timer accuracy.

C. Novoste Beta-Cath System:

1. Radioactive sources listed under sub item H of Items 6, 7 and 8 shall be used in accordance with the safety precaution in SS&D No. GA-1115-D-101-S. The device authorized under 9(H) shall not be used after 6 months or 250 cycles whichever comes first.

2. Except when the Model A1730 and A1767 source trains are used, the device shall not be used for more than 125 cycles.

22. A. The licensee shall not participate in human research involving radioactive drugs as defined in 21CFR 361.1 unless the licensee has established a Radioactive Drug Research Committee (RDRC) approved by the FDA.

B. If the licensee did not provide evidence of a FDA approved RDRC at the time of application for license, the licensee shall provide evidence to the Department that an RDRC has been established and is approved by the FDA before initiating any human research as defined in Part A.
23. A. The licensee shall not change or modify a PET facility, or operations involving radioactive material, authorized under this license so that individuals exposed to radiation in or around the facility are exposed to radiation in excess of the levels in A.A.C. R12-1-408 and A.A.C. R12-1-416.

B. The licensee shall be informed at all times of activities in areas surrounding the PET facility to ensure that personnel occupancy does not change, resulting in radiation exposure in excess of the levels in A.A.C. R12-1-408 and A.A.C. R12-1-416.

C. As part of the annual ALARA review required under A.A.C. R12-1-407, the licensee shall review the PET patient workload to ensure that personal in unrestricted areas are not exposed to radiation in excess of the limits in A.A.C. R12-1-408 and A.A.C. R12-1-416.

D. The licensee shall not image more than 100 PET patients in a five day work week, at the Banner University Medicine Medical Imaging, located at 4291 North Campbell Avenue, Tucson, Az. 85719.

E. The licensee shall not image more than 40 patients in a five day work week, at the University of Arizona Cancer Center located at 1891 West Orange Grove Road, Tucson, Arizona 85704.

24. The licensee is authorized to release a patient in accordance with A.A.C. R12-1-717, in addition to the following conditions:

A. A patient may be released from licensee control without concern, if the activity administered is no greater than the activity in Column 1 of Table (U)(1) of NUREG 1556, Volume 9, Rev 2, available on the NRC website. The licensee shall maintain a record of the release in accordance with A.A.C. R12-1-717. A patient shall be given instruction as required in Part E below.

B. A patient may be released from licensee control if administered an activity amount greater than the activities in Part A above, provided the measured dose rate at 1 meter from the surface of the patient is no greater than the value in Column 2 of Table (U)(1), for the radionuclide administered to the patient. In addition to the record requirements in Part A above, the licensee shall survey the patient before release and record the reading, survey instrument used, and person performing the survey, as described in Section (U)(3)(1), NUREG 1556. A patient shall be given instructions, as required in Part E below.

C. If a licensee chooses to administer a radionuclide (i.e. Cs-131) not listed in Table (U)(1) and release the patient based on the measured dose rate, the licensee shall calculate the dose rate that corresponds to the 500 mRem dose limit, using the suggested method in Section (U)(1)(2) of NUREG 1556. If the measured dose rate is no greater than the calculated dose rate the patient may be released in accordance with Part B above. A patient shall be given instructions, as required in Part E below.

D. In lieu of the surveys required by this license condition, a licensee may perform a dose calculation using patient specific parameters in accordance with section (U)(1)(3) of NUREG 1556.

E. As applicable, the licensee shall provide the patient instructions in accordance with Section (U)(2)(3)(1) or (U)(2)(3)(2), NUREG 1556.
25. A. The licensee shall maintain a Decommissioning Plan.

B. The licensee shall re-examine the Decommissioning Plan described in Part A every two years to insure the estimates are current with regard to the scope of operation at the time of the review.

C. The licensee shall maintain on file for Department review, a letter signed by a representative of Banner Health management, documenting its approval of the most current decommissioning plan on file with Department.

26. For purposes of ending the principal activities authorized under this radioactive material license:

A. The license stays in effect beyond the license expiration date. Beyond the expiration date the licensee shall store radioactive material only, until the Department authorizes its use by license amendment, or the Department notifies the licensee in writing that the license is terminated.

B. The licensee shall ensure the timeliness of decommissioning of facilities where principal activities are conducted under this license in accordance with Department requirements.

C. The licensee shall continue to control public access into restricted areas and pay the annual licensing fee until the license is terminated.

27. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material described in Items 6, 7 and 8 of this license in accordance with the statements, representations and procedures contained in:


2. Letter dated May 2, 2016, signed by Daniel Silvain.

3. Letter with attachments dated February 20, 2018, signed by Paul Hanny, Ph.D.

The most recent statements, representations, and procedures shall govern if they conflict with previously submitted documents, unless otherwise specified by a license condition; and the Department’s rules shall govern the licensee’s statements in applications or letters.

BRIAN D. GORETZKI, BUREAU CHIEF

COLBY BOWER, ASSISTANT DIRECTOR

DATE ISSUED: MAR 4 2018

PRK:BDG:mjk

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