ARIZONA RADIATION REGULATORY AGENCY

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 Agency 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 Agency orders now or hereafter in effect and to the conditions specified. In accordance with letter dated December 12, 2016, signed by Daniel Silvain, License Number 10-044, is hereby amended in its entirety to read as follows: ALL CHANGES ARE IN BOLD

**LICENSEE**

1. **NAME:** University Arizona Health Network
da University of Arizona Medical Center and
Board of Regents dba University of Arizona
Office of Radiation, Chemical and
Biological Safety

2. **ADDRESS:** P.O. Box 245101
Tucson, Arizona 85724

3. **LICENSE NUMBER:** 10 - 044
   a. AMENDMENT NO.: 73

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

7. **Chemical or physical form**
   A. Any
   B. Any
   C. Source as approved in NRC
      SS&D for system authorized in
      9(C)

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 milllicuries)

This section redacted for security reasons.

F. Krypton-85
   F. Gaseous or dissolved in saline
      solution
   F. 74 GBq (2 curies)
G. Strontium-90
   G. Sealed sources
   G. 37 GBq (1 curie)
H. Strontium-90
   H. Sealed sources
   H. 37 GBq (1 curie); no single
      source in a source train shall
      exceed 183 MBq (5 milllicuries)
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<tbody>
<tr>
<td>I.</td>
<td>Technicium-99</td>
<td>Radiopharmaceuticals</td>
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<tr>
<td>J.</td>
<td>Palladium-103</td>
<td>Seeds/Sealed sources</td>
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<tr>
<td>K.</td>
<td>Iodine-125</td>
<td>Seeds/Sealed sources</td>
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<td>L.</td>
<td>Iodine-125</td>
<td>Liquid (iotrex)</td>
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<td>M.</td>
<td>Xenon-133</td>
<td>Gaseous or dissolved in saline solution</td>
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<tr>
<td>N.</td>
<td>Cesium-137</td>
<td>Sealed sources</td>
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<tbody>
<tr>
<td>P.</td>
<td>Holmium-166</td>
<td>Radiopharmaceuticals</td>
</tr>
<tr>
<td>Q.</td>
<td>Iridium-192</td>
<td>Sheathed wires or beads</td>
</tr>
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<td>R.</td>
<td>Iridium-192</td>
<td>Source as approved in NRC SS&amp;D for system authorized in 9(R)</td>
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<tr>
<td>S.</td>
<td>Gold-198</td>
<td>Seeds</td>
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<tr>
<td>T.</td>
<td>Plutonium-239</td>
<td>Sealed sources</td>
</tr>
<tr>
<td>U.</td>
<td>Americium-241</td>
<td>Sealed sources</td>
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<tr>
<td>V.</td>
<td>Depleted Uranium</td>
<td>Metal</td>
</tr>
<tr>
<td>W.</td>
<td>Fluorine-18</td>
<td>Any</td>
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<tr>
<td>X.</td>
<td>Radium-223</td>
<td>Radium chloride</td>
</tr>
<tr>
<td>Y.</td>
<td>Actinium-225</td>
<td>Any</td>
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<tr>
<td>Z.</td>
<td>Cesium-131</td>
<td>Seeds/sealed sources</td>
</tr>
<tr>
<td>AA.</td>
<td>Any radioactive material with atomic number 84 through 92</td>
<td>Enriched standard materials or standards</td>
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<tr>
<td>BB.</td>
<td>Any radioactive material with atomic number 93 through 95</td>
<td>Enriched standard materials or standards</td>
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9. Authorized Use:

A, B, F, G, I through K, M, N, P through S, T, U, W through Z:

Medical diagnosis, therapy and biomedical research and development.

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

This section redacted for security reasons.


R. For use in Varian Medical Systems, Varisource iX Brachytherapy Afterloader.

V. Depleted Uranium used as radiation shielding.

AA & BB. Research and development, as defined in A.A.C. R12-1-102.

CC & DD Interstitial implants for the treatment of cancer.

CONDITIONS

10. Radioactive material may be possessed and used only at:
Site 1: University of Arizona Medical Center - 1501 North Campbell Avenue, Tucson, Arizona
Site 2: University Medical Imaging - 4291 North Campbell Avenue, Tucson, Arizona 85719
Site 3: University Medical Center - Orange Grove 1891 West Orange Grove Road, Tucson, Arizona 85704
Site 4: University of Arizona Medical Center South Campus - 2800 East Ajo Way, Tucson, Arizona 85713
and at any site within the state of Arizona which is the property of, or under the control of, the University of Arizona or University Medical Center Corporation. For use of radioactive material on land not under the control of the University of Arizona or University Medical Center Corporation, the licensee shall request an amendment and shall provide to the Agency written permission from the land owner. Additionally, a documented review by the Medical Radiation Safety Committee shall be provided with each amendment request, showing their approval or radioactive material use at all sites, which are not the property of, or under the control of the University of Arizona, or University Medicine Center Corporation.
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 Ionizing 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 R12-1-702.

C. The Alternate Radiation Safety Officer is: Keith Carsten. The Alternate Radiation Safety Officer shall administer the Radiation Safety Program under the policy and procedure guidance of the Radiation Safety Officer.

13. Authorized users, physicists, and nuclear pharmacists, shall meet the training criteria established in R12-1-711, R12-1-712 and R12-1-719 through R12-1-723.

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) and (D), that an individual participates in a radioiodine 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 radioiodine 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 radioiodine therapy, the handling of radioiodine 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 radioiodine. With Agency approval, the licensee may perform I-131 bioassays up to 4 weeks and I-125 bioassays up to 12 weeks following radioiodine 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 Agency.

This section redacted for security reasons.
20. A. The licensee shall, in accordance with A.A.C. R12-1-419 (C) and (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 Agency.

21. 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.

22. 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 Agency.

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

23. 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.
23. Cont.

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 Agency 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.

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ARIZONA RADIATION REGULATORY AGENCY

RADIOACTIVE MATERIAL LICENSE
SUPPLEMENTARY SHEET

License Number: 10-044
Amendment Number: 73

This section redacted for security reasons.

25. 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 Agency that an RDRC has been established and is approved by the FDA before initiating any human research as defined in Part A.

26. The Licensee shall comply with the General Provision requirements set forth in Article 19, Pursuant to the:

A. Background investigations and access authorization program
B. Physical protection during use; and
C. Physical protection in transit.

This section redacted for security reasons.
28. 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. 12-1-408 and A.A.C. 12-1-416.

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. 12-1-408 and A.A.C. 12-1-416.

C. As part of the annual ALARA review required under R12-1-407, the licensee shall review the PET patient workload to ensure that personnel in unrestricted areas are not exposed to radiation in excess of the limits in A.A.C. 12-1-408 and A.A.C. 12-1-416.

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

E. The licensee shall not image more than 40 PET patients in a five day work week, at the University Medical Center at Orange Grove located at 1881 West Orange Grove Road, Tucson, Arizona 85704.

29. The licensee is authorized to release a patient in accordance with 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 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 NREG 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.
29. Cont.  
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.

30. 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 Agency authorizes its use by license amendment, or the Agency 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 Agency requirements.

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

31. A. The licensee shall maintain a Decommissioning Plan as described in attachment to letter dated March 16, 2012, signed by Leslie P. Tolbert, Ph.D.

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 Agency review, a letter signed by a representative of University management, documenting its approval of the most current decommissioning plan on file with Agency.

32. Each teletherapy machine shall be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism. This inspection and servicing must be performed by persons specifically authorized to do so by the Agency.

33. 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.

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 Agency’s rules shall govern the licensee’s statements in applications or letters.

DATE ISSUED: APR 25 2017

BRIAN D. GORETZKI, INTERIM DIRECTOR

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