

Roldan, Lizette

From: Roldan, Lizette
Sent: Tuesday, July 19, 2011 9:46 AM
To: 'timostac@sarmc.org'
Subject: REQUEST FOR ADDITIONAL INFORMATION REGARDING CONTROL 575427

License No.: 11-27306-01
Docket No.: 030-32263
Control No.: 575427

Dear Mr. Stack:

This is in reference to your letter dated June 13, 2011 requesting amendment to Nuclear Regulatory Commission License No. 11-27306-01. In order to continue our review, we need the following additional information:

1. In order to determine that Dr. Redward Coleman is qualified as a preceptor for Dr. Kimball Christianson, please submit a copy of the Agreement State license number 032-0247-4 from North Carolina where Dr. Coleman is explicitly named as an authorized user for 35.100, 35.200 and 35.300. Please keep in mind that if the license is a broad scope and doesn't explicitly name Dr. Coleman, you must also include a letter from the Radiation Safety Committee Chairman stating the authorizations for Dr. Coleman under that license.

We will continue our review upon receipt of this information. Please reply to my attention and refer to Mail Control No. 575427. If you reply via email, please attach a signed letter in PDF format or you may fax your response to (817) 860-8263. If we do not receive a reply from you by August 19, 2011, we will assume that you do not wish to pursue your application.

If you have any technical questions regarding this deficiency letter, please call me at (817) 276-6596.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Industrial, and Academic Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Sincerely,

Lizette Roldán-Otero, Ph.D.

Health Physicist
Nuclear Regulatory Commission
612 E. Lamar Blvd., Suite 400
Arlington, TX 76011
Office: 817-276-6596
Fax: 817-860-8263

Dear Ms. Roldan-Otero.

This fax is in response to your Request for Additional Information Regarding Control 575427 referenced in your deficiency letter that is attached. The faxed information requested as needed for license amendment. If there is more information that is needed please email at ericcola@sarmc.org.

Thanks

Eric Colaianni C.N.M.T

Authorization for Radioactive Material Use

Status: Active

**The Duke University Medical Center Radiation Safety Committee / Duke University
Radiation Safety Committee certifies that**

R. E. COLEMAN

Department: Radiology - DHN

**is authorized to possess and use radioactive materials or radiation sources under
Authorization Number MC-001A at Duke University.**

Authorized Radioactive Materials (Maximum Amount) (Date Last Modified):

Astatine 211 (2,000.0 mCi) [--]	Barium 133 (2,000.0 mCi) [--]
Bismuth 207 (2,000.0 mCi) [--]	Bromine 78 (2,000.0 mCi) [--]
Bromine 76 (2,000.0 mCi) [--]	Bromine 77 (2,000.0 mCi) [--]
Bromine 82 (2,000.0 mCi) [--]	Cadmium 109 (2,000.0 mCi) [--]
Cadmium 115 (2,000.0 mCi) [--]	Caesium 45 (2,000.0 mCi) [--]
Caesium 47 (2,000.0 mCi) [--]	Californium 252 (2,000.0 mCi) [--]
Carbon 11 (2,000.0 mCi) [--]	Carbon 14 (2,000.0 mCi) [--]
Carbon 14 (2,000.0 mCi) [--]	Cerium 137 (2,000.0 mCi) [--]
Chlorine 34 (2,000.0 mCi) [--]	Chlorine 36 (2,000.0 mCi) [--]
Cobalt 57 (2,000.0 mCi) [--]	Cobalt 60 (2,000.0 mCi) [--]
Copper 64 (2,000.0 mCi) [--]	Copper 67 (2,000.0 mCi) [--]
Curium 244 (2,000.0 mCi) [--]	Europlum 152 (0.001 mCi) [7/24/2009]
Fluorine 18 (2,000.0 mCi) [--]	Francium 223 (2,000.0 mCi) [--]
Gallium 67 (2,000.0 mCi) [--]	Germanium 68 (2,000.0 mCi) [--]
Gold 198 (2,000.0 mCi) [--]	Holmium 166 (6,000.0 mCi) [--]
Hydrogen 3 (2,000.0 mCi) [--]	Indium 111 (2,000.0 mCi) [--]
Indium 95 (2,000.0 mCi) [--]	Iodine 123 (2,000.0 mCi) [--]
Iodine 124 (2,000.0 mCi) [--]	Iodine 125 (2,000.0 mCi) [--]
Iodine 129 (0.001 mCi) [7/24/2009]	Iodine 131 (2,000.0 mCi) [--]
Iridium 192 (2,000.0 mCi) [--]	Iron 55 (2,000.0 mCi) [--]
Iron 59 (2,000.0 mCi) [--]	Krypton 85 (2,000.0 mCi) [--]
Lead 210 (2,000.0 mCi) [--]	Lawrencium 103 (2,000.0 mCi) [--]

RAM Authorization Certificate

Mercury 203 (2,000.0 mCi) [--]	Nickel 63 (2,000.0 mCi) [--]
Niobium 95 (2,000.0 mCi) [--]	Nitrogen 13 (2,000.0 mCi) [--]
Phosphorus 32 (2,000.0 mCi) [--]	Phosphorus 33 (2,000.0 mCi) [--]
Plutonium 239 (2,000.0 mCi) [--]	Polonium 209 (2,000.0 mCi) [--]
Potassium 42 (2,000.0 mCi) [--]	Rubidium 86 (2,000.0 mCi) [--]
Ruthenium 103 (2,000.0 mCi) [--]	Samarium 153 (2,000.0 mCi) [--]
Scandium 46 (2,000.0 mCi) [--]	Selenium 75 (2,000.0 mCi) [--]
Silver 110m (2,000.0 mCi) [--]	Sodium 22 (2,000.0 mCi) [--]
Sodium 24 (2,000.0 mCi) [--]	Strontium 85 (2,000.0 mCi) [--]
Strontium 90 (2,000.0 mCi) [--]	Sulfur 35 (2,000.0 mCi) [--]
Technetium 99 (2,000.0 mCi) [--]	Technetium 99m (2,000.0 mCi) [--]
Thallium 201 (2,000.0 mCi) [--]	Thulium 204 (2,000.0 mCi) [--]
Tin 113 (2,000.0 mCi) [--]	Tungsten 185 (2,000.0 mCi) [--]
Tungsten 187 (dup) (2,000.0 mCi) [--]	Tungsten 187 (2,000.0 mCi) [--]
Uranium 238 (2,000.0 mCi) [--]	Xenon 133 (2,000.0 mCi) [--]
Yttrium 90 (2,000.0 mCi) [--]	Zinc 65 (2,000.0 mCi) [--]

Authorized Locations (Date Last Modified):

ANCILLARY BUILDING Room 1401B [1/8/2008]	ANCILLARY BUILDING Room 1402C4 [1/8/2008]
ANCILLARY BUILDING Room 1402C5 [1/8/2008]	ANCILLARY BUILDING Room 1402C6 [1/8/2008]
ANCILLARY BUILDING Room 1402C7 [1/8/2008]	ANCILLARY BUILDING Room 1411B1 [1/8/2008]
ANCILLARY BUILDING Room 1411B2 [1/8/2008]	ANCILLARY BUILDING Room 1411B2A [4/4/2001]
ANCILLARY BUILDING Room 1411B2B [4/4/2011]	ANCILLARY BUILDING Room 1411B3 [1/8/2008]
ANCILLARY BUILDING Room 1411B4 [1/8/2008]	ANCILLARY BUILDING Room 14 patient care area [--]
DUKE HOSPITAL AND ADDITION Room 0401/0405 [1/8/2008]	DUKE HOSPITAL AND ADDITION Room 0404 [1/8/2008]
DUKE HOSPITAL AND ADDITION Room 0405 [1/8/2008]	RESEARCH PARK BUILDING #2 Room 0118 [9/2/2008]

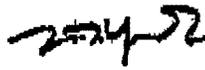
Conditions

- A. This Authorization expires with cessation of faculty appointment or by order of the Committee.
- B. Amendment to this Authorization shall be made only by the Authorized User, with the approval of the Radiation Safety Officer. Changes in use locations, radionuclides and possession limits shall be submitted to the Radiation Safety Officer in writing or via electronic mail, and shall not be implemented until approval by the Radiation Safety Officer, or by his/her designee, has been documented.
- C. Radioactive material shall be used by or under the direct supervision of R. E. COLEMAN.
- D. Radioactive material shall be possessed and used in accordance with statements, representations and procedures in the User's most recent application and the Duke University Radiation Safety Manual.
- E. Radioactive materials shall not be administered to humans, except for explicitly described medical uses as found in the application.

RAM Authorization Certificate

P. Individuals utilizing radioactive iodine shall have thyroid monitoring performed in accordance with procedures described in the Duke University Radiation Safety Manual.

7/29/2011



Date Printed

Terry T. Yoshizumi, Radiation Safety Officer



**RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES**

RADIOACTIVE MATERIALS LICENSE

Pursuant to North Carolina Regulations for Protection Against Radiation and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer, and import radioactive materials listed below; and use such radioactive material for the purpose(s) and at the place(s) designated below. This License is subject to all applicable rules and regulations of the North Carolina Department of Environment and Natural Resources now and hereafter in effect and to any conditions specified below.

1. Licensee Name: Duke University Medical Center	3. License No: 032-0247-4										
2a. Mailing Address: P.O. Box 5155 Durham, NC 27710	4. Expiration Date: May 31, 2012										
b. Physical Address: Erwin Road Durham, NC 27710	<table border="1"> <tr> <td>New License</td> <td><input checked="" type="checkbox"/></td> <td>Routine</td> <td><input type="checkbox"/></td> <td>Corrected Copy</td> </tr> <tr> <td>Renewal</td> <td><input type="checkbox"/></td> <td>Administrative</td> <td><input type="checkbox"/></td> <td>Termination</td> </tr> </table>	New License	<input checked="" type="checkbox"/>	Routine	<input type="checkbox"/>	Corrected Copy	Renewal	<input type="checkbox"/>	Administrative	<input type="checkbox"/>	Termination
New License	<input checked="" type="checkbox"/>	Routine	<input type="checkbox"/>	Corrected Copy							
Renewal	<input type="checkbox"/>	Administrative	<input type="checkbox"/>	Termination							
c. Radiation Safety Officer: Terry T. Yashizumi, Ph.D.	5a. Amendment No.: 158										
	b. Issuance Date: October 6, 2010										

6. Radioactive Material (element and mass no.)	7. Chemical and/or Physical Form	8. Maximum Amount of Radioactivity and/or Quantity of Radioactive Material which Licensee May Possess at Any One Time.
A. Any radioactive materials with atomic numbers 3-98, except as listed below.	A. Any Form	A. As needed
B. Any radioactive materials with atomic numbers 3-98 with half-life less than 120 days, except as listed below.	B. Any Form	B. As needed
C. Any radioactive materials with atomic numbers 3-98 with half-life greater than 120 days, except as listed below.	C. Any Form	C. 100 millicuries
D. Carbon 14	D. Any Form	D. 250 millicuries
E. Hydrogen 3	E. Any Form	E. 1 curies
F. Radon 222	F. Any Form	F. 50 millicuries
G. Strontium 90/Yttrium 90	G. Medical Applicator	G. 100 millicuries
H. Cesium 137	H. Sealed Sources	H. 2.2 curies
I. Iodine 125	I. Seeds	I. 2 curies
J. Strontium 82	J. Generator	J. 200 millicuries
K. Radium 226	K. Sealed Source	K. 2 millicuries
L. Polonium 210	L. Sealed Source	L. 5 millicuries (No single source to exceed 0.5 millicuries)
M. Cesium 137	M. Sealed Source	M. 2,160 curies



**RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES**

Page 2 of 9
License No.: 032-0247-4

RADIOACTIVE MATERIALS LICENSE

6.	Radioactive Material (element and mass no.)	7.	Chemical and/or Physical Form	8.	Maximum Amount of Radioactivity and/or Quantity of Radioactive Material which Licensee May Possess at Any One Time.
N.	Cesium 137	N.	Sealed Sources	N.	10,000 curies
O.	Nickel 63	O.	Custom Plated Source	O.	30 millicuries (No source to exceed 15 millicuries)
P.	Americium 241	P.	Sealed Source	P.	25 millicuries
Q.	Cesium 137	Q.	Sealed Sources (chloride)	Q.	530 millicuries
R.	Gadolinium 153	R.	Line Source	R.	4 millicuries
S.	Iridium 192	S.	Sealed Source	S.	21 curies (No single source to exceed 15 curies)
T.	Uranium 238 (depleted)	T.	Solid Form	T.	4.1 millicuries
U.	Cesium 137	U.	Sealed Source	U.	No single source to exceed 1,700 curies
V.	Cesium 137	V.	Sealed Source	V.	100 millicuries
W.	Germanium 68	W.	Sealed Source	W.	100 millicuries
X.	Strontium 85	X.	Liquid	X.	1 curie
Y.	Yttrium 90	Y.	Micro-Spheres	Y.	2 curies
Z.	Iodine 125	Z.	Sealed Sources	Z.	2.64 curies
AA.	Cesium 137	AA.	Calibration Source	AA.	5 curies total activity
BB.	Palladium 103	BB.	Sealed Source	BB.	No single source to exceed 10 Curies
CC.	Cesium 131	CC.	Sealed Sources (as described in Registry of Radioactive Sealed Sources and Devices No. (WA-1220-S-101-S)	CC.	400 millicuries
DD.	Zinc 62 / Copper 62	DD.	Sterile Generator	DD.	200 millicuries
EE.	Palladium 103	EE.	Sealed Sources	EE.	300 millicuries
FF.	Cobalt 57	FF.	Sealed Source	FF.	150 millicuries
GG.	Iridium 192	GG.	Sealed Source/Seeds	GG.	1 curie
HH.	Phosphorus 32	HH.	Sealed Source	HH.	200 millicuries

9. Authorized Use:

A. For medical use in humans as described in 15A NCAC 11 .0361.

B, D, E, F. For use in biomedical research and development (non-human applications).



**RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES**

Page 3 of 9
License No.: 032-0247-4

RADIOACTIVE MATERIALS LICENSE

9. Authorized Use:

- C. For use in biomedical research, development, calibration and training.
- G-J. For use in biomedical research, diagnosis and therapy.
- K. To be used for calibration, research and development.
- L. To be used in a static eliminator.
- M. To be used in an AECL Gamma Cell 1000 Irradiator for the irradiation of blood and blood cell components.
- N. To be used in a J. L. Shepherd Mark I Irradiator for non-human radiation studies.
- O. To be used in Electron Capture Detector as a part of Gas Chromatograph System.
- P. To be used for calibration, research and development.
- Q. To be used for medical research, diagnosis and therapy, and research by the Department of Radiation Oncology.
- R. To be used in Hitachi SPECTRA V210BSP, Elscint Cardinal and Tricor Triad SPECT cameras for calibration, research and development by the Nuclear Medicine Department.
- S. To be used in a GammaMedplus iX HDR for the treatment of cancer in humans and medical research.
- T. To be used as shielding in a GammaMedplus iX HDR and as pinhole inserts for use with a Triad SPECT unit.
- U. To be used in an IBI 437C Blood Irradiator.
- V&W. To be used for geometric characterization of gamma and positron imaging devices.
- X. No specific use. Isotope is an obligate impurity of a Cardio-Ged 82 Strontium 82/Rubidium 82 Generator (See item J. under 6., 7., 8. and 9.)
- Y. To be used in a Sirtex Medical Limited brachytherapy afterloader for treatment of malignant hepatic tumors in humans.
- Z. To be used as directed by the manufacturer for the application of low dose rate intracavitary brachytherapy in humans for the treatment of malignant brain tumors.
- AA. To be used in a Hopswell Designs, Inc. Model G10-2-12 dual source irradiator for calibration, research, and development.
- BB. To be used in Theragonics Therasight Model 5000 Ocular Brachytherapy System for treatment of ocular malignancies in humans (SSDR Number GA-0645-D-103-S)
- CC. To be used for biomedical research, calibration, and training.
- DD. For use in biomedical research, diagnosis and therapy.
- EE. To be used for biomedical research, calibration, and training.
- FF. To be used for calibration, research and development.
- GG. To be used for medical research, diagnosis and therapy.



**RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES**

Page 4 of 9
License No.: 032-0247-4

RADIOACTIVE MATERIALS LICENSE

9. Authorized Use:

HH. To be used as directed by the manufacturer for the application of brachytherapy for the intraoperative treatment of irregularly-shaped or superficial malignant tumors in humans.

CONDITIONS

10. A. Radioactive material may be received and used anywhere on Duke University Campus, Duke University Medical Center, Duke Center for Living, 3475 Erwin Road, Durham, N.C. 27705, Duke Regional Clinical Laboratories, 4425 Ben Franklin Road, Durham, NC 27704, Hook Plaza, 2424 Erwin Road, Durham, NC 27705, and OESO Radiation Safety Office 2214 Elder Street, Durham, NC, 27705.
- B. Radioactive materials also may be used at Duke University owned facilities throughout the State of North Carolina in areas not under exclusive Federal jurisdiction (Federal installations such as military bases, VA hospitals, etc). Authorization for the use of radioactive materials at temporary jobsites under exclusive Federal jurisdiction shall be obtained either by (1) filing an NRC Form 241 [10 CFR 150.20(b)], or (2) applying for reciprocity, or (3) applying for a specific license from the NRC if the length of the job is to exceed six (6) months.
- C. The licensee may transport licensed material or deliver licensed material to a carrier for transport, in accordance with the provisions of Section 71.5, Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material For Transport."
- D. The licensee shall retain records of each use of radioactive material under Condition No. 10.B. above. The records shall, at a minimum, include the following information:
1. A copy of the bill of lading and/or other documents used in the transportation of the radioactive materials;
 2. The person or persons who transported and/or used the radioactive material;
 3. The purpose for which the radioactive material was used;
 4. Surveys which demonstrate compliance with 15A NCAC 11 .1627; and
 5. Exit surveys of the temporary jobsite which demonstrate that no contamination from the licensee owned radioactive material remains at the facility.
- E. If the licensee orders the radioactive material(s) to be delivered directly to the temporary jobsite, the licensee is responsible for ensuring compliance with 15A NCAC 11 .1627.
11. The licensee shall comply with the provisions of 15A NCAC 11 .1600, "Standards for Protection Against Radiation," and 15A NCAC 11 .1000, "Notices, Instructions, Reports and Inspections." (The North Carolina Regulations for Protection Against Radiation are contained in 15A NCAC 11.)
12. A. Radioactive material shall be used by, or under the supervision of individuals authorized by the Radiation Safety Committee and Radioactive Drug Research Committee.
- B. The Radiation Safety Officer for the activities authorized by this license shall be Terry T. Yoshizumi, Ph.D.
13. A. Each sealed source containing radioactive material, other than Hydrogen 3, with a half-life greater than thirty (30) days, and in any form other than gas shall be tested for leakage and/or contamination at the interval prescribed in the respective Registry of Radioactive Sealed Sources and Devices sheet. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested.
- B. Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma-emitting material or 10 microcuries or less of alpha-emitting material.



**RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES**

Page 5 of 9
License No.: 032-0247-4

RADIOACTIVE MATERIALS LICENSE

CONDITIONS (continued):

13. C. The periodic leak test required by this condition does not apply to the Cesium 131 listed in Subitem CC. of Items 6., 7., and 8. & 9.
- D. The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage at intervals not to exceed three (3) years and prior to any use or transfer to another person unless they have been leak tested within six (6) months prior to the date of use or transfer.
- E. Notwithstanding Condition No. 13.A., the Cesium 137 listed in Subitem H. of Items 6., 7., and 8. & 9. shall be tested for leakage and/or contamination at intervals not to exceed three (3) years. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency.
- G. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Agency regulations. A report shall be filed within five (5) days of the test with the Radioactive Materials Branch, Radiation Protection Section, Department of Environment and Natural Resources, 1645 Mail Service Center, Raleigh, NC 27699-1645, describing the equipment involved, the test results, and the corrective action taken.
- H. Tests for leakage and/or contamination shall be performed by the licensee, or by other persons specifically authorized by the Agency to perform such services.
14. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 15A NCAC 11.1625(a)(1), the licensee is hereby authorized to label detector cells and cell baths, containing radioactive material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.
15. Experimental animals administered radioactive materials or their products shall not be used for human consumption.
16. A. Individuals involved in operations which utilize, at any one time, more than 100 millicuries of Hydrogen 3 in a non-contained form, other than metallic foil, shall have bioassays performed within one (1) week following a single operation and at weekly intervals for continuous operation. The urine specimen shall be collected on the same day of the week insofar as possible.
- B. Notwithstanding the bioassay at weekly intervals for continuous operations required by the preceding paragraph, bioassay may be performed at monthly intervals on any individual for the following calendar quarter, if the average concentration of Hydrogen 3 in the urine of the individual during a calendar quarter was less than 10 microcuries per liter. Bioassay may continue at monthly intervals so long as the average concentration remains below 10 microcuries per liter.
- C. Hydrogen 3 shall not be used in such a manner as to cause any individual to receive a radiation exposure such that the urinary excretion rates exceed 28 microcuries of Hydrogen 3 per liter when averaged over a calendar quarter.
- D. A report of an average concentration in excess of the limit specified in the preceding paragraph for any individual shall be filed, in writing, within thirty (30) days of the end of the calendar quarter with the Radioactive Materials Branch, Radiation Protection Section, Department of Environment and Natural Resources, 1645 Mail Service Center, Raleigh, NC 27699-1645. The report shall contain the results of all urinalysis for the individual during the calendar quarter, the cause of the excessive concentrations and the corrective steps taken or planned to assure against a recurrence.



**RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES**

Page 6 of 9
License No.: 932-0247-4

RADIOACTIVE MATERIALS LICENSE

CONDITIONS (continued):

17. The foil may be removed from the electron capture cell for cleaning only, in accordance with procedures contained in the manufacturer's operating manual.
18. The Nickel 63 Electron Capture Detectors designated in this license shall be used in conjunction with a properly operating temperature limiting device as specified by the manufacturer.
19. Provided that the licensee has been authorized in Items 5, 7, 8, & 9 of this license for the use of agency approved radioactive gases, gases-in-solution, or aerosols, the licensee shall:
 - A. Procure radioactive gases as free gas or gas-in-solution, to be administered to humans, from a supplier who distributes the product in accordance with the Federal Food, Drug, and Cosmetic Act, and
 - B. Comply with the applicable provisions of 15A NCAC 11 .0361(e)(1) - (5).
20. Radioactive material shall not be used in humans until its pharmaceutical quality and assay have been established.
21.
 - A. The licensee shall establish written procedures for performing use and calibration of dose calibrator(s) used to determine the quantity and quality of radiopharmaceuticals in accordance with 15A NCAC 11 .0359
 - B. Records of the results of the tests outlined in Condition A, above shall be maintained for a minimum of three (3) years following the completion of the test for inspection by the agency.
 - C. The licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (0.37 MBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.
22. The licensee is authorized to conduct a decay-in-storage program in accordance with 15A NCAC 11 .0362.
23. The licensee shall comply with the provisions of 15A NCAC 11 .0700, "Use of Sealed Radioactive Sources in the Healing Arts."
24.
 - A. Patients administered either diagnostic or therapeutic quantities of unsealed radioactive material, or therapeutic quantities of permanently implanted sealed radioactive materials may be released in accordance with the provisions of 15A NCAC 11 .0358.
 - B. Patients administered therapeutic quantities of temporary implanted sealed radioactive materials shall remain hospitalized until the implants are removed.
 - C. Notwithstanding Condition 24, B., above, patients being treated with eye plaques or other surgically secured temporary implanted sealed radioactive materials may be released from the hospital in accordance with 15A NCAC 11 .0358, provided the attending physician has determined the seeds are secured and are not likely to be dislodged and/or lost by the patient.
 - D. The licensee shall retain all records associated with the release of patients containing radioactive materials, when applicable, for a minimum of three (3) years following the administration.
25. The licensee shall perform and document radiation surveys of patients receiving implants in accordance with the applicable provisions of 15A NCAC 11 .0702(c).
26. The licensee shall maintain accountability for all brachytherapy sources in storage or in use. Records of source accountability shall be maintained in accordance with the applicable provisions of 15A NCAC 11 .0702(e) & (f).



**RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES
RADIOACTIVE MATERIALS LICENSE**

Page 7 of 9
License No.: 032-0247-4

CONDITIONS (continued):

27. Patients containing implants shall remain hospitalized until the implants are removed, except that patients containing Iridium 192, Palladium 103, Cesium 131 or Iodine 125 seeds or other licensed radioactive material in encapsulated form, may be released from the hospital provided:
- A. the attending physician has determined the seeds are secured and are not likely to be lost by the patient; and
 - B. The patient has been released in accordance with 15A NCAC 11.0358.
 - C. The licensee shall retain all records associated with the release of patients containing radioactive materials, when applicable, for a minimum of three (3) years following the administration.
28. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.
29. Sealed sources containing radioactive material shall not be opened.
30. The licensee shall not transfer possession and/or control of materials or products containing radioactive materials except:
- A. by transfer of waste to an authorized recipient; or
 - B. by transfer to a specifically licensed recipient.
31. This license does not authorize commercial distribution of licensed material.
32. In addition to the possession limits specified in item 8 above, the licensee shall further restrict possession of licensed material with a half-life greater than 120 days as follows:
- A. Unsealed radioactive material possession shall be maintained at or below the limits specified in 15A NCAC 11.0353(b)(31); and,
 - B. Sealed radioactive material possession shall be maintained at or below the limits specified in 15A NCAC 11.0353(c)(2).
33. In accordance with the provisions of 15A NCAC 11.0353(j), the licensee shall maintain documentation of information important to the safe and effective decommissioning of the facility. The records shall, at a minimum, contain the following: records of spills or other unusual occurrences, facility drawings showing modifications, and records of the cost estimates for decommissioning.
34. In addition to the requirements of Condition No. 32, the licensee shall make or cause to be made an evaluation of the licensee's current financial assurance status whenever one of the following occurs:
- A. The license is in renewal with the agency; or,
 - B. When the Radiation Safety Committee approves the first use any new radioactive material in unsealed or sealed form with a half-life greater than 120 days; or,
 - C. The licensee formally requests a license amendment for increase in possession limits or the addition of any radioactive materials to the license.
35. In addition to the requirements of Condition No. 33, above, any changes in financial assurance status which results from that evaluation shall be provided in writing to the agency within thirty (30) days of the change.



**RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES
RADIOACTIVE MATERIALS LICENSE**

Page 3 of 9
License No.: 032-0247-4

CONDITIONS (continued):

36. The licensee shall annually review its Radiation Protection Program for content and implementation [Reference 15A NCAC 11 .1603(c)]. Documentation of the Radiation Protection Program reviews shall be retained for inspection by the agency [Reference: 15A NCAC 11 .1636].
37. The licensee shall institute the provisions of 15A NCAC 11 .1610 when an occupationally exposed woman voluntarily informs her supervisor, in writing, of the pregnancy and the estimated date of conception.
38. The licensee shall ensure that no individual "member of the public" [Reference: 15A NCAC 11 .0104(64)] receives a radiation dose in excess of the limits specified in 15A NCAC 11 .1611(a) while conducting licensed activities.
39. This license may be subject to amendment, revision, modification, suspension, or revocation in accordance with the provisions of 15A NCAC 11 .0344.
40. The licensee shall comply with the requirements described in the Agency letter dated October 24, 2005 and attached document entitled "Increased Controls for Licensees that Possess Sources Containing Radioactive Materials Quantities of Concern." The licensee shall complete implementation of said requirements within 6 months from the issuance of the license amendment or the first day that radionuclides in quantities of concern are possessed at or above the limits specified in Table 1 of the attachment, whichever is later. Within twenty-five (25) days after the implementation of the requirements of this condition, the licensee shall notify the Agency in writing that it has completed the requirements of this condition:
41. A. In addition to Condition No. 40., of this license, the licensee shall comply with the requirements described in Agency letter with attachments dated March 20, 2008 and Agency document entitled "Fingerprinting and Criminal Background Check Requirements for Unescorted Access to Certain Radioactive Material" (hereinafter the "Fingerprinting Requirements"). The agency document may be found at http://www.ncradiation.net/rms/rmsic_toolbox.htm.
- B. The licensee shall achieve full compliance not later than September 22, 2008. The licensee shall notify the Agency in writing within 25 days of achieving full compliance with the requirements noted in Condition A. above.
- C. The licensee shall notify the Agency via telephone and writing 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.
- D. In addition to the notification requirements in Condition B. & C. above, the licensee shall notify the agency at other intervals specified in the "Fingerprinting Requirements" Document. Unless otherwise specified, written notifications shall be made using the agency form "Certificate of Compliance."
42. The licensee shall report to the Radioactive Materials Branch, Radiation Protection Section, 3825 Barrett Drive, Raleigh, NC 27609, by March 1st each year their low-level radioactive waste disposal, management and storage information utilizing the North Carolina Low-Level Radioactive Waste Survey form found at www.ncradiation.net.
43. The licensee shall comply with the provisions of 10 CFR 20.2207 regarding the reporting of transactions involving nationally tracked sources, as defined in 10 CFR 20.1003 and Appendix E of 10 CFR Part 20.
44. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6., 7., and 8. of this license in accordance with statements, representations and procedures and attachments listed below. The North Carolina Regulations for Protection Against Radiation shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application with attachments dated April 16, 2007, signed by Michael Cuffe, MD, VP for Medical Affairs.
- B. Administrative amendment in accordance with US Nuclear Regulatory Commission mandate requiring "Fingerprinting and Criminal Background Check Requirements for Unescorted Access to Certain Radioactive Material."
- C. Letter dated May 12, 2008, signed by Terry Yoshizumi, Ph.D., Radiation Safety Officer.



**RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES**

Page 9 of 9
License No.: 032-0247-4

RADIOACTIVE MATERIALS LICENSE

CONDITIONS (continued):

- 44. D. Application for amendment with attachment dated May 14, 2008, signed by Terry Yoshizumi, RSO.
- E. Application for amendment with attachments dated June 16, 2008, with electronic mail dated July 25, 2008, both signed by Terry Yoshizumi, RSO.
- F. Application for amendment dated November 19, 2008, signed by Terry Yoshizumi, RSO.
- G. Administrative amendment dated January 28, 2009, to implement National Source Tracking System requirements and to reference leak test frequency to the interval prescribed in the respective Registry of Radioactive Sealed Sources and Devices sheet.
- H. Letter with attachments dated January 13, 2009, signed by Terry Yoshizumi, Ph.D., RSO.
- I. Application for amendment with attachment dated April 28, 2009, signed by Terry Yoshizumi, RSO, and an e-mail dated May 12, 2009, signed by Terry Yoshizumi, RSO, and an Administrative amendment to correct a reference in Condition 41.
- J. Email with attachment dated June 6, 2009, sent by Terry Yoshizumi, Ph.D., RSO.
- K. Corrected Copy issue based on an email received July 14, 2009 from Ann Hunter-Paschall.
- L. Letter with attachments dated September 28, 2009, signed by Terry Yoshizumi, Ph.D., RSO.
- M. Application for Amendment with attachments dated April 9, 2010, signed by Terry Yoshizumi, Ph.D., RSO.
- N. Application for Amendment with attachments dated October 4, 2010, signed by Terry Yoshizumi, Ph.D., RSO.


For: W. Lee Cox, III
Chief, Radiation Protection Section

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