THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

K-3

January 10, 2008

37-13919-01
03003207

Michelle Simmons
U.S. Nuclear Regulatory Commission
Region I Office
475 Allendale Road
King of Prussia, PA 19406

RE: Letter of Verification for Janis O'Malley, M.D.

Dear Ms. Simmons:

In accordance with your request received by telephone yesterday, I am sending you this letter in order to verify that Janis O'Malley, M.D., who is the head of the Nuclear Medicine Division here at the University of Alabama at Birmingham (UAB), is specifically listed as an Authorized Physician User on the Nuclear Medicine Division radioactive material license # 313 issued by the Radiation Safety Program in Occupational Health & Safety at UAB. I am enclosing a copy of the Nuclear Medicine Division radioactive material license # 313, with amendments. This documentation verifies that Dr. Janis O'Malley is an Authorized Physician User for 10 CFR 35.100 (use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required), 10 CFR 35.200 (use of unsealed byproduct material for imaging and localization studies for which a written directive is not required), and 10 CFR 35.300 (use of unsealed byproduct material for which a written directive is required) administrations of radioactive materials to humans at the University of Alabama at Birmingham. UAB is licensed for the possession, use, and storage of radioactive material by license # 266 issued by the Alabama Department of Public Health, Office of Radiation Control, which is a broad-scope radioactive material license. A copy of license # 266 was sent to you by the U.S. Postal Service as part of a letter dated January 3, 2008, which you should receive shortly. Please do not hesitate to contact me if you have any questions or need any additional information.

Sincerely,

Bradley S. Brinkley

Bradley S. Brinkley, M.S., M.B.A.
ABR Certified
Radiation Safety Officer
University of Alabama at Birmingham

Enclosures

Occupational Health and Safety
445 Community Health Services Building
933 19th Street South
205.934.2487
Fax 205.934.7487
www.healthsafe.uab.edu

Mailing Address:
CH19 445
1530 3RD AVE S
BIRMINGHAM AL 35294-2041

141260

NMSS/RGN1 MATERIALS-002

RADIOACTIVE MATERIAL LICENSE
UNIVERSITY OF ALABAMA AT BIRMINGHAM

Pursuant to the Alabama Regulations for control of Radiation and to the UAB Radiation Safety Procedures Manual and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, possess, and transfer radioactive material listed below. This license is subject to all applicable rules and regulations of the Alabama State Department of Public health and UAB Radioisotopes and Radiation Safety Committee now or hereafter in effect and to any conditions specified below.

LICENSE AND CONDITIONS OF LICENSURE

1. Name: Nuclear Medicine Division
Diagnostic Radiology Department

2. License Number: 313

3. Campus Mailing Address:
Second Floor, Quarterback Tower
UAB Medical Center

4. Amendment Number: 42
Amended in its entirety

3A. Campus Telephone: 4-2140

5. Expiration Date: September 30, 2005

6. Radioactive Material:	7. Chemical and/or Physical Form and Authorized Use:	8. Maximum Radioactivity and/or Quantity Which Licensee May Possess at Any One Time:
See Page 2	See Page 2	See Page 2

9A. The licensee may also use and store radioactive materials in Room 537 of Spain Rehabilitation Center and in the Pulmonary Laboratory on the second floor of the Kracke Building, and in Room M-806 of the West Pavilion Building. Room 537 in the Zeigler Research Building may be used as an additional imaging area. When clinically necessary, the licensee may perform diagnostic studies with radiopharmaceuticals on human patients within the patients' rooms. Therapeutic administration of radiopharmaceuticals to human patients may also be performed within the patients' rooms; however, these are limited to private rooms when doses exceed 30 millicuries in activity.

B. Room 427B of the Dental Research Building is authorized for use of radioactive material listed in Subitem AE of Conditions 6, 7, and 8, and Room 110 of the Wallace Tumor Institute for radioactive material listed in Subitems AF and AH of Conditions 6, 7, and 8.

10A. Radioactive materials listed herein, except Subitems 6U, 6W, 6AE, 6AF, and 6AH may be used by, or under the supervision of the following personnel:

Eva V. Dubovsky, M.D.
Charles D. Russell, M.D., Ph.D.
Johnny Scott, M.D., Ph.D.
Ami Iskandrian, M.D.
Gerald Pohost, M.D.
Robert C. Bourge, M.D.
James Mountz, M.D., Ph.D.
Elmer San Pedro, M.D.

6. Radioactive Material	7.	Chemical and/or Physical Form and Authorized Use:	8.	Maximum Quantity
6A. Group I of the schedule of Groups of Diagnostic Uses Listed in Schedule D of Section 420-3-26.07 Of the Alabama Regulations	7A.	Group I studies in humans which involve measurements of uptake, dilution and excretion for which an NDA and IND has been issued by the Food and Drug Administration (FDA)	8A.	As Needed
6B. Group II of the schedule of Groups of Diagnostic Uses Listed in Schedule D of Section 420-3-26.07 Of the Alabama Regulations	7B.	Group II studies in humans which involve imaging and tumor localizations for which an NDA and an IND has been issued by the Food and Drug Administration (FDA)	8B.	As Needed
6C. Group III of the schedule of Groups of Diagnostic Section 420-3-26.07 Of the Alabama Regulations	7C.	Group III studies in humans which involve use of generators and reagent kits for preparation and use of radiopharmaceuticals employed for which an NDA and IND has been issued by the FDA	8C.	As Needed
6D. Molybdenum-99	7D.	Generators (NEN Model NRP-196F, Squibb Minetec J3-389L, Union Carbide Model 3503 and Mallinckrodt Ultratechnecoll FM) for ^{99m}Tc Production	8D.	4 Curies
6E. Technetium-99m	7E.	Pertechnetate of MDP for Group I, II and III Diagnostic Studies	8E.	4 Curies
6F. Xenon-133	7F.	Gas and saline solution for Group II Diagnostic Studies	8F.	2 Curies
6G. Iodine-131	7G.	Sodium Iodide for treatment of hyper-thyroidism and thyroid cancer in humans	8G.	700 mCi
6H. Iodine-131	7H.	Clinical "In Vitro" Procedures	8H.	200 uCi
6I. Cobalt 57	7I.	Clinical "In Vitro" Procedures	8I.	200 uCi
6J. Iodine-125	7J.	Clinical "In Vitro" Procedures	8J.	200 uCi

6K. Iron-59	7K.	Clinical "In Vitro" Procedures	8K. 200 uCi
6L. Selenium-75	7L.	Clinical "In Vitro" Procedures	8L. 200 uCi
6M. Hydrogen-3	7M.	Clinical "In Vitro" Procedures	8M. 200 uCi
6N. Carbon-14	7N.	Clinical "In Vitro" Procedures	8N. 200 uCi
6O. Iodine-129/Am-241	7O.	Mock Iodine reference Am-241	8O. 0.05/.005 uCi. respectively
6P. Cesium-137	7P.	Sealed Source (NEN Model NES-356) for instrument calibration	8P. 250 uCi
6Q. Cobalt-57	7Q.	Sealed Source (NEN Model-206) for instrument calibration	8Q. 25 mCi
6R. Cobalt-57	7R.	Sealed Source (NEN Model NES-297 NES-391 or NES-8009) for instrument calibration	8R. 5 mCi
6S. Barium-133	7S.	Sealed Source (NEN Model NES-358) for instrument calibration	8S. 500 uCi
6T. Cobalt-60	7T.	Sealed Source (NEN Model NES-360) for instrument calibration	8T. 100 uCi
6U. Sodium-24	7U.	Sodium Chloride in water for hypertension research studies	8U. As Needed
6V. Phosphorus-32	7V.	Sodium Phosphate for treatment of polycythemia vera, blood dyscrasias, malignant disease metastatic to bone and for localization of melanomas of the eye	8V. 20 mCi
6W. Technetium-99m	7W.	Labeled antimony trisulfide colloid for cancer detection management	8W. As Needed
6X. Technetium-99m	7X.	Labeled trimethybromo HIDA for hepatobiliary imaging	8X. As Needed
6Y. Technetium-99m	7Y.	Labeled anti-melanoma monoclonal antibody foe cancer studies	8Y. As Needed
6Z. Indium-111	7Z.	Labeled anti-CEA monoclonal antibody for cancer studies	8Z. As Needed

6AA. Gadolinium-153	7AA.	Gulf Nuclear Model GD-1, Amersham Model GDC-CY1, NEN Model NER-430 Or Biosources Limited Model OS-213-A Sealed source for human use of bone Absorptiometry units manufactured by Novo Diagnostics Systems (Model BMC-Lab 22A) Or Lunar Radiation Corp. (Model DP-3), both designed for bone mineral measurements	8AA. 1.5 Curies
6AB. Indium-111	7AB.	Labeled antibody to PSA for detection of prostate carcinoma	8AB. As Needed
6AC. Cobalt-57	7AC.	Flood source for quality assurance checks on gamma cameras	8AC. 3.0 mCi
6AD. Iodine-131	7AD.	Labeled Chimeric IgG4 B-72.3 monoclonal antibody for use in treating patients with advanced colorectal carcinoma	8AD. As Needed
6AE. Technetium-99m	7AE.	As pertechnetate for use in quality assurance of dose calibrators and gamma cameras	8AE. 200 mCi
6AF. Iodine-125	7AF.	Labeled Chimeric 17-1A monoclonal antibody for use in treating patients with advanced colorectal cancer	8AF. 500 mCi
6AG. Iodine-131	7AG.	Sodium Iodide for labeling murine M_0Ab D612 antibodies and for therapeutic administration and evaluation of ^{131}I labeled monoclonal antibody D612 in patients having metastatic gastrointestinal cancer according to Study UAC-192 (IND. 3854)	8AG. 30 mCi
6AH. Strontium-89	7AH.	Strontium chloride for use in evaluation of ^{89}Sr-therapy in patients with metastatic cancer of the prostate	8AH. 40 mCi
6AI. Iodine-131	7AI.	Labeled MIBG for use in a diagnostic study of pheochromocytoma and neuroblastoma	8AI. 500 uCi
6AJ. Iodine-131	7AJ.	Labeled orthohhippurate for use in measuring effective renal plasma flow in patients	8AJ. 1.0 mCi

6AK. Technetium-99m	7AK.	Labeled DTPA for use in measuring glomerular filtration rates in patients	8AK. 75.0 mCi
6AL. Iodine-131	7AL.	^{131}I-labeled EPB-2 murine IgG antibody for theropeutic use in patients with non-Hodgkin's lymphoma	8AL. 100 mCi
6AM. Strontium-89	7AM.	^{89}Sr Metastron for use in cancer therapy	8AM. 100 mCi
6AN. Iodine-131	7AN.	labeled murine monoclonal antibody HD 37/dg ricin A chain immunotoxin for Therapeutic use in patients with chemo-Therapy-resistant B-cell lymphoma (Reference IND 3960)	8AN. 500 mCi
6AO. Iodine-131	7AO.	Labeled monoclonal antibodies for human administration in study titled "Radioimmune Imaging and Comparative Radiolocalization of Intravenously Administered Monoclonal Antibodies Directed to the Tag-72 Antigen In Non-Small Cell Lung Cancer (NSCLC)." (UAC-097)	8AO. 29.0 mCi
6AP. Iodine-125	7AP.	Labeled monoclonal antibodies for human administration in study titled "Radioimmune Imaging and Comparative Radiolocalization of Intravenously Administered Monoclonal Antibodies Directed to the Tag-72 Antigen In Non-Small Cell Lung Cancer (NSCLC)." (UAC-097)	8AP. 10 mCi
6AQ. Technetium-99m	7AQ.	Labeled monoclonal antibodies for human administration in study titled "Radioimmune Imaging and Comparative Radiolocalization of Intravenously Administered Monoclonal Antibodies Directed to the Tag-72 Antigen In Non-Small Cell Lung Cancer (NSCLC)." (UAC-097)	8AQ. As Needed
6AR. Fluoroine-18	7AR.	Labeled fluorodeoxyglucose for use in performing PET imaging of the brain, heart and tumors as proposed in the study entitled "Metabolic Rate of Glucose Utilization Measured by ^{18}F-fluoro-deoxyglucose Positron Emission Tomography in Brain, Heart and Tumor"	8AR. As Needed

6AS. Technetium-99m	7AS.	Labeled sodium pertechnetate and hexamethylpropyleneamine oxime for use in performing SPECT brain scans in epileptic patients as proposed in the study entitled "Performance of Ictal State Tc-99m HM PAO SPECT Scans in Epilepsy"	8AS. 200 mCi
6AT. Americium-241	7AT.	Sealed source (Amersham Model AMC.24) for use as a point source for motion detection during nuclear imaging procedures	8AT. 1 mCi
6AU. Germanium-68	7AU.	Sealed sources (as ^{68}Germanium tetrachloride solution) for use in a Super PETT II PET Scanner, Model SP 3000-E	8AU. 10 mCi
6AV. Indium-111	7AV.	labeled Oncoscint (monoclonal Ab) for ovarian and colonrectal and colorectal cancer	8AV. 10 mCi
6AW. Indium-111	7AW.	Penetetrotide for use in a study titled "Compassionate use of ^{111}In Penettreotide in patients with known or suspected neuroendocrine tumors containing somatostatin receptors"	8AW.6 mCi
6AX. Technetium-99m	7AX.	Exametazime kit (HMPAO) for use in a study entitled "Localization of epileptic foci in SPECT brain studies using a stabilized form of ^{99m}Tc Exametazime (HMPAO)"	8AX. 75 mCi
6AY. Gadolinium-153	7AY.	Sealed source, Isotope Products Laboratories Model 3409, Capsule No. A3409 for use in a Picker Triple Head Camera	8AY. 75 mCi
6AZ. Technetium-99m	7AZ.	^{99m}Tc labeled HMPAO and ECD for use in thetotal protocol entitled "Ictal and and late-ictal Tc-99m bicisate (ECD) SPECT brain imaging: Comparison of the accuracy of the late ictal study to identify the epileptogenic focus"	8AZ. 60.0mCi

6BA. Gadolinium-153	7BA.	Sealed sources Model No. MED3601 MED 3601 Manufactured By North American Scientific, for use as Line Sources in an ADAC Vantage Non-Uniform Attenuation Correction Camera	8BA. Two Sources of 250 to to 300 mCi each.
6BB. Cesium-137	7BB.	Sealed sources, Isotope Products Laboratories Model HEG-137) for use In an ADAC Laboratories Gamma Camera as Attenuation Correction Devices	8BB. 120 mCi Total: no source to exceed 30 mCi
6BC. Uranium-238	7BC.	Depleted Uranium for use as shielding for attenuation correction device	8BC. 60 Kg total
6BD. Fluorine-18	7BD.	Labeled 2-fluorodeoxyglucose for use in various nuclear medicine studies	8BD. 100 mCi
6BE. Fluorine-18	7BE.	Labeled 2-fluorodeoxyglucose for use in protocol entitled "Role of FDG-PET, Proton MR Spectroscopy and Magnetic Source Imaging in Epilepsy Surgery"	8BE. 100 mCi
6BF. Iodine-123	7BF.	Labeled Metaiodobenzylguanidine (MIBG) for use in the protocol entitle "Cardiac Sympathetic Innervation in Diabetes"	8BF. 15 mCi
6BG Carbon-14	7BG.	Labeled Erythromycin for use in the protocol entitled "Degree and Time Course of Induction and De-induction Of CYP3A4."	8BG. 500 uCi

B. The radioactive material listed herein may be used by Michael Yester, Ph.D. and Gary Barnes, Ph.D. for quality assurance tests and radioactivity determinations and radiation surveys to include the leak testing of sealed sources.

C. The radioactive materials listed in Subitems AF and AH of Conditions 6, 7, and 8 may be used by or under the supervision of Ruby Meredith, M.D., Ph.D.

D. Cardiac imaging and function studies using Tc-99m and/or Tl-201 may be performed by or under the supervision of Thomas D. Payne, M.D. and Mark Lawson, M.D.

E. The material listed in 6BI, 7Bi and 8BI is to be used only under supervision of James Mountz, M.D.

11A. Each sealed source with a half life greater than thirty days and in any form other than a gas shall be tested for leakage and/or contamination at intervals not to exceed six months or at intervals otherwise authorized by the State of Alabama, an Agreement State, or the Nuclear Regulatory Commission. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the sealed source shall not be put to use until tested.

B. The beta or beta/gamma emitting standards used for quality assurance of dose calibrations are exempt from leak testing.

C. 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 surface of the device in which the sealed source is permanently mounted or stored, where one might expect contamination to accumulate. Records of leak tests shall be kept in units of microcuries and maintained for inspection by the Radiological Health Branch of the Alabama Department of Public and the UAB Radiation Safety Division.

D. 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 notify the Radiation Safety Division.

E. Notwithstanding the periodic leak test required by Subitem 11A., any licensed sealed source containing radioactive material is exempted from periodic leak tests provided that the quantity of radioactive material contained in the source does not exceed ten times the quantity specified for the radioactive material in the attached Schedule B.

12. Radioactive Materials listed in Condition 6 may be used in Room 544 of the Bevill Biomedical Research Building, Room N112 of the Emergency Department, and in the Nuclear Medicine Department located on the second floor of Quarterback Tower.

13. Radioactive materials shall not be used in humans until their pharmaceutical quality and assay have been established.

14. Patients containing Iodine-131 for the treatment of cancer shall remain hospitalized until the residual activity is 30 millicuries or less or the maximum dose rate at a distance of one meter from the surface of the patient's body is 5 millirem per hour or less.

15. Technetium-99m pertechnetate shall be procured in separated, prepackaged, precalibrated form from a pharmaceutical supplier who manufactures the products under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility, and pyrogenicity. Notwithstanding the foregoing requirement, technetium-99m pertechnetate may be eluted and prepared from a Molybdenum-99/Technetium-99m generator.

16. Radioactive material prepared by the licensee may be used in humans, provided the product is produced under pharmaceutical controls related to assay, identity, quality, purity, sterility and nonpyrogenicity.

17. Any adverse reactions or occurrences following administration of radiopharmaceuticals to patients shall be reported to the Radiation Safety Officer. Any acute life-threatening reaction or occurrence shall be reported immediately; other adverse reactions or occurrences shall be reported within two weeks.

18. It is the responsibility of the investigative user to immediately report to the Radioactive Drug Research Committee via the Radiation Safety Officer as soon as it is known that an approved human use research project will involve more than 30 subjects or will involve a research subject under 18 years of age. In either case, the investigator will be required to immediately submit a special summary report to the FDA.

19. It is the responsibility of the investigative user to report quarterly the activity of any approved research project to the Radioactive Drug Research Committee. Form RD (See APPENDIX M) must be completed and sent to the RSD no later than two weeks following each calendar quarter. Reports of inactivity of unterminated research studies must also be submitted.

20. It is the responsibility of the investigative user to report annually the results of the approved research project to the Radioactive Drug Research Committee which will forward the report to the FDA. Form FD 2915 (See Appendix L) must be completed and sent to the RSD no later than two weeks after December 31 of each calendar year. Reports of inactivity of unterminated research studies must also be submitted.

21. The generator or reagent kits authorized by the Group III Schedule must be used and the radiopharmaceuticals prepared according to the instructions given in the brochure from the manufacturer specified on the container labeling.

22A. Before administration to patients, each elution of technetium-99m from the generator is to be tested to determine Molybdenum-99 concentration. This testing shall be conducted according to written procedures and by personnel who have been specifically trained to perform these tests. Elutions containing more than 0.15 microcurie of Molybdenum-99 per millicurie of technetium-99m shall not be used. Maintain for three years records of the Molybdenum-99 test conducted on each elution from generators.

B. The Nuclear Medicine Division shall prohibit the administration to patients of technetium-99m solutions containing 2.5 microcuries or more Molybdenum-99 per administered dose.

C. The Nuclear Medicine Division shall determine that the percent of binding activity of any technetium-99m labeled compound is not less than ninety percent of the total radioactivity.

D. The Nuclear Medicine Division shall prohibit further administration to patients if the radioactivity of other chemical forms in the label exceed ten percent of the total radioactivity at the time it is labeled.

E. Technetium-99m labeled sulfur colloid preparations which are flocculaent or aggregated shall not be used in humans.

23. Radiation monitoring requirements for personnel working with radioisotopes are as follows:

A. Radiation monitoring to measure whole body exposure and/or skin of whole body exposure is required for personnel working with stock solutions of radioisotopes of types and in the millicurie activities given below:

Radionuclide	Activity (mCi)
Iodine-131	10
Iron-59	2
Potassium-42	10
Sodium-24	0.5
Technetium-99m	20
Molybdenum-99	10

B. Finger monitors to measure extremity radiation exposure are required for personnel handling stock solutions of radiopharmaceuticals of the types and in the millicurie activities given below:

Radionuclide	Activity (mCi)
Iodine-131	10
Iron-59	0.5
Phosphorus-32	1
Potassium-42	0.15
Sodium-24	0.5
Technetium-99m	20
Molybdenum-99	10

24. A. The licensee may perform floor surveys for radioactive contamination, using the procedure and equipment described in the memo-randum dated October 30, 1987.

B. The licensee is required to perform package surveys of therapeutic quantities of radioiodine (greater than 30 millicuries) received directly from radiopharmaceutical distributors, utilizing a portable ionization chamber survey meter capable of measuring the radiation levels surrounding such packages. Records of surveys of packages received directly from these distributors must be maintained for inspection at least five years following the safe disposal of these radiopharmaceuticals.

25. When personnel monitors are required, these monitors must be worn in all areas where any occupational exposure to ionizing radiation may occur from its use.

26A. Radioactive waste known or suspected to contain infectious material must be effectively treated with a chemical disinfectant prior to disposal in radioactive waste receptacles.

B. Radioactive waste packages know to contain gaseous products (i.e., tritium water vapor, iodine, carbon dioxide) in microcurie quantities (or more) must be visibly labeled CAUTION RADIOACTIVE GAS.

C. Radioactive waste must not be capable of generating and/or releasing toxic gases, vapors, or fumes harmful to persons transporting, handling or disposing of the waste.

D. Liquid radioactive wastes must be adjusted in their ion concentration to a pH range of 5.0 to 9.0 and otherwise treated to make them non-reactive (with respect to reactions with water or other chemicals or biological constituents of the waste solution).

27. If the radiolabeled materials used are infectious, they will have to be handled as Class II infectious agents, and will require the approval of the UAB Biosafety Committee.

28. Adequate shielding must be provided while working with gamma emitters because of the medium to high electromagnetic radiation.

29. Appropriate shielding of low atomic number should be provided when working with high-energy beta emitters.

30. Laboratory personnel are required to wear outer protective clothing (i.e., gloves and lab coat).

31. Bioassays shall be performed at a frequency determined by the Radiation Safety Officer. A baseline study for each individual is required during the first month of radioisotope work, and shall be scheduled with the Radiation Safety Officer. When required, specific routine monitoring requirements are give in Supplementary Sheet entitled "Bioassay Schedule: which becomes a part of this license.

32A. Hoods or enclosures approved by the Radiation Safety Officer must be used while working with dusty forms or volatile forms of radioisotopes (such as during radioiodination procedures).

B. Prior to using any hood or enclosure for radioisotope work, approval must be obtained from the Radiation Safety Officer. Any hood used must be ducted to the outside of the building.

C. Hoods used for procedures involving the use of radioiodine will require the following:

a. An average face velocity of 150 linear feet per minute. At no point in the plane of sash should the flow rate be less than 80 linear feet per minute.

b. New or existing prefilters must be changed at such intervals as to meet the above airflow requirements.

c. Activated charcoal filters must be used in addition to prefilters. Both types of filters must be accessible and easily removed.

d. The Radiation Safety Division must be notified when a radioisotope hood is suspected or known to have a lower than required airflow rate.

e. Planning for emergency situations (i.e., fume hood failure) is essential. The use of a designated alternate fume hood must be given prior consideration.

f. An alternate fume hood must be designated for storage during an emergency situation (i.e., fume hood failure or hood low-flow alarm).

D. Radioisotopes must be placed in sealed containers during autoclaving procedures in such a manner that no breach of primary containment will allow volatile emissions from the container to occur.

E. No radioisotope effluent release via the hood or sewer in each experiment is allowed except that small quantity which might escape during normal operation. A trap must be provided initially during a procedure to collect radioactive effluents. This is to provide date for the determination of releases during radioisotope work. The amount of release must be determined (in microcurie quantities), documented and then sent to the Radiation Safety Division for review for each procedure where an effluent release is likely.

33. Contaminated articles must be properly decontaminated or disposed through the Hazardous Materials Facility.

34. Handling of laboratory animals and animal waste will be done only by personnel directly involved with this research.

35. Appropriate instrumentation should be provided in the laboratory for conducting radiation surveys.

36. Adequate space should be provided for storage of radioactive materials and for working areas when utilizing these same materials.

37A. Surveys for contamination and/or radiation levels are to be performed daily (when used) except where otherwise provided in Subitem B of this condition, in areas designed for radioactive material use. Wipe samples should be taken from work surfaces and counted to determine contamination levels. These surveys must be documented at least on a weekly basis. It is recommended that these surveys be performed just before the daily lunch break and at the end of each day in which these isotopes are used.

B. In any laboratory where "Deminimus Levels of Radioactivity" (use defined and prescribed in Revision 1 of Section XIII, of the UAB Radiation Safety Procedures Manual) are used, area surveys of radiation levels and/or contamination are required to be performed and documented at weekly intervals if it is used there during any portion of a week.

38A. Records of radioactive material transfer to and from the laboratory are to be maintained in a log. These records must reflect the following:

Date of Transfer (Receipt or Disposition)
Type of Radioisotope
Amount
Chemical Form
Name of Person making the Record Entry

B. Radioactive material wastes that are generated by the licensee necessitate special records to accurately account for their removal from the laboratory (either through decay or transfer). A log book must be maintained to indicate how the radioactive waste was removed and must provide the following information:

Control Number
Date of Disposal of Container*
Type of Radioisotope
Activity**
Physical Form
Chemical Form***
pH (if liquid material)
Name of Person Making the Record Entry

*Radioactive waste must be packaged according to Radiation Safety Division Policy.

**The licensee must have documentation supporting estimates of the radioactivity in the various forms of waste. Disposals by decay must indicate the radiation rates that were measured at the time of disposal and these may not exceed background exposure rates.

***Chelates that are in the waste must be identified and if the volume of chelates is suspected to exceed 0.1% of the material, its volume is to be estimated.

C. Radioactive materials are authorized for decay to twice background levels, provided that they are properly surveyed, and subsequent disposal are properly documented to:

Date of Disposal
Physical Form of Radioisotopes
Type of Radioisotope
Serial Number of Survey Meter
Meter Reading
Background Reading
Name of Individual Documenting Disposal

D. Except for diagnostic kits for "in vitro" medical studies, Radioactive Material Use Records must be maintained to accurately account for the disposition of radioisotopes while in the laboratory. These records must reflect the following information at the time of use:

Control Number
Date of Use
Specific Activity (mCi/ml or mCi/gm)
Amount Used (ml volume or gm weight)
Calculated Activity Used
Residual Activity in Original Container
Name of Person Making the Record Entry

39. Laboratory personnel having neither formal radiation safety training nor experience in radioisotope techniques are required to take the UAB Radiation Safety Training Course. Personnel who have had a formal safety training course in radiation and who have had some experience must take the third day of the UAB safety procedure and policy.

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

Nuclear Medicine Procedures Manual, 2000 edition
UAB Radiation Safety Procedures Manual, where applicable, and
Radioactive Materials Application, dated July 31, 1978 and July 27, 1983
Letters of correspondence dated December 14 and 19, 1984; April 10, 1985; June 16, 1987 and January 8, 1988.

William B. Bass, M.S., MBA (date) 11/15/00
Director of Radiation Safety

Gary T. Barnes, Ph.D. (date) 11/16/00
Chair, Radioisotope & Radiation
Safety Committee

OC/F/k Nuc. Med Div

UNIVERSITY OF ALABAMA AT BIRMINGHAM
RADIOACTIVE MATERIAL LICENSE
SUPPLEMENTARY SHEET

License Number: 313
Amendment Number: 53
Amended In Its Entirety By: 42
Expiration Date: September 30, 2010

Nuclear Medicine Division
c/o Janis O'Malley, M.D.
Director of Nuclear Medicine
Department of Radiology
260 Jefferson Towers-6835

In accordance with amendment request dated March 9, 2006, Radioactive Materials License Number 313 is hereby revised as follows:

Subitem A of Condition 10 is changed as follows:

TO CHANGE:

10A. Radioactive materials listed herein, except Subitems 6U, 6W, 6AE, 6AF and 6AH may be used by, or under the supervision of the following personnel:

Janis O Malley, M.D.
Eva V. Dubovsky, M.D.
Robert C. Bourge, M.D.
Johnny Scott, M.D., Ph.D.
Ami Iskandrian, M.D.
Jaekyeong Heo, M.D.
Jon A. Baldwin, D.O.
Leland W. Eaton, M.D.
Sibyll Goetze, M.D.

William B. Bass, M.S., MBA (date) 6/29/06
Director of Radiation Safety

Gary T. Barnes, Ph.D. (date) 6/29/06
Chair, Radioisotope and
Radiation Safety Committee

20285