



Washington University in St. Louis

Environmental Health & Safety

Radiation Safety Office

September 30, 2009

Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352

Attn: Kevin G. Null

Subject: Application – New Accelerator Production License

Enclosed in Attachment 1 are two copies of the Washington University in St. Louis new license application for accelerator production of radioactive material. Our license application is being submitted in accordance with the NRC regulations regarding the expanded byproduct material definition and the second phase of waiver terminations. Enclosed in Attachment 2 is a completed NRC Form 629 authorizing credit card payment of \$6,500 for our new license application fee in accordance with 10 CFR 170.31 Materials License Category 3.S.

Washington University in St. Louis has also submitted on September 30, 2009:

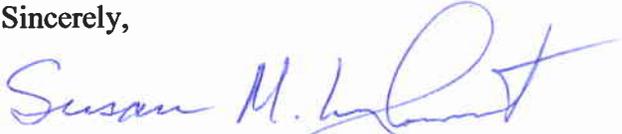
- amendment request for its broad scope license (License No. 24-00167-11) to incorporate additional information needed to coordinate license coverage with this new production license application; and
- updated decommissioning funding plan and self-guarantee to incorporate decommissioning of the University's cyclotron facilities and update decommissioning cost estimates for the University's broad scope license activities.

Please note that Washington University is not part of a consortium, as described in 10 CFR 30.32(j), and does not supply radiopharmaceuticals to other licensees.

RECEIVED OCT 01 2009

I appreciate your review of our new production license application. Please contact me at (314) 362-2988 or at langhors@wustl.edu if you have any questions.

Sincerely,



Susan M. Langhorst, Ph.D., CHP
Radiation Safety Officer

Cc: Bruce D. Backus, P.E., Environmental Health & Safety
Barry A. Siegel, M.D., Radiation Safety Committee Chairman
Christopher W. Goddard, Assistant General Counsel

Attachment 1

Accelerator Production License
Application Document
(Original + Copy)

NRC FORM 313
(3-2009)
10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 3/31/2012

APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
612 E. LAMAR BOULEVARD, SUITE 400
ARLINGTON, TX 76011-4125

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- A. NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER _____
- C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Washington University in St. Louis
660 S. Euclid Avenue, Campus Box 8053
St. Louis, MO 63110-1093

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

See attached

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Susan M. Langhorst, Ph.D., CHP

TELEPHONE NUMBER

(314) 362-2988

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

- a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time. **See attached**

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED. **See attached**

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE. **See attached**

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. **See attached**

9. FACILITIES AND EQUIPMENT. **See attached**

10. RADIATION SAFETY PROGRAM. **See attached**

11. WASTE MANAGEMENT. **See attached**

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY **3.S.** AMOUNT ENCLOSED \$ **6,500.00**

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE

Larry J. Shapiro, M.D., Exec Vice Chancellor Med Affairs

SIGNATURE



DATE

09/30/2009

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

Attachment to NRC FORM 313

Application for New Accelerator Production License

Information for Items 5 – 11

Introduction

The following information is submitted to address NRC FORM 313 Items 5, 6, 7, 8, 9, 10 and 11 for the new license application for an NRC Accelerator Production License to be issued to Washington University in St. Louis. This license covers the production and storage of byproduct material in three separate cyclotron vaults. When this licensed byproduct material moves outside of its cyclotron vault, it is transferred to the Washington University in St. Louis Broad Scope Medical Use Type A License No. 24-00167-11. Radioactive material brought into the cyclotron vaults remains on the University's broad scope license. Washington University does not provide radiopharmaceuticals for commercial or non-commercial transfer to other licensees.

We have utilized the check list from the following NUREG-1556 Volume to provide the application information requested by this NRC guidance document for an accelerator production license issued under 10 CFR 30:

NUREG-1556, Vol. 21, "Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator," dated October 2007, Appendix C

See Accelerator Production License (ACC)

Due to the integrated features of this production license with the University's broad scope license, sections of the broad scope license application are repeated in this production license application and noted by "[from NRC License No. 24-00167-11]".

Definitions

To clarify understanding of the descriptions provided in this production license application, we use the definitions and associated discussions provided below.

Facilities

The University's two cyclotron facilities are located in buildings at the Washington University Medical Center. This accelerator production license covers radioactive materials produced in these cyclotron vaults.

Barnard Cyclotron Facility (BCF)

JSW Vault
CS-15 Vault

East Building Cyclotron Facility (ECF)

RDS Vault

Time Frames (except for Dosimetry Program) [from NRC License No. 24-00167-24]

Daily – unless otherwise defined, to occur sometime during the calendar day

Weekly – to occur sometime during the calendar week, Sunday through Saturday

Monthly – to occur sometime during the calendar month

License year – calendar year

Quarterly – to occur sometime during the calendar quarter:

First Quarter – January 1 to March 31
Second Quarter – April 1 to June 30
Third Quarter – July 1 to September 30
Fourth Quarter – October 1 to December 31

Semi-annually – to occur sometime during the half-year

First half-year – January 1 to June 30
Second half-year – July 1 to December 31

Annually – to occur sometime during the license year

Dosimetry Program Time Frames [from NRC License No. 24-00167-24]

In 10 CFR 20.1003, NRC defines year as follows:

“Year means the period of time beginning in January used to determine compliance with the provisions of this part. The licensee may change the starting date of the year used to determine compliance by the licensee provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.”

Dosimetry Program Time Frames [cont.]

Since before 1990, we have operated with a mid-month change out of our dosimeters with our dosimetry processor. We plan to continue this practice because it allows our dosimetry processor to process our many dosimeters in a more timely manner. Based on NRC's definition of "year," our offset of time for our dosimetry program is allowed under the regulations, and we will use the following definitions for our dosimetry program.

Dosimetry year – January 15 to January 14 of the following year

Dosimetry Quarter –

First Quarter –	January 15 to April 14
Second Quarter –	April 15 to July 14
Third Quarter –	July 15 to October 14
Fourth Quarter –	October 15 to January 14 of the following year

Dosimetry Month –

January –	January 15 to February 14
February –	February 15 to March 14
March –	March 15 to April 14
April –	April 15 to May 14
May –	May 15 to June 14
June –	June 15 to July 14
July –	July 15 to August 14
August –	August 15 to September 14
September –	September 15 to October 14
October –	October 15 to November 14
November –	November 15 to December 14
December –	December 15 to January 14 of the following year

**ACCELERATOR PRODUCTION
LICENSE (ACC)**

Item No.	Suggested Response	Agree to Use	Description Attached
5.	<p>RADIOACTIVE MATERIAL (Cont.)</p> <p>Unsealed and/or Sealed Sources (Cont.)</p> <ul style="list-style-type: none"> • For sealed radioactive materials and discrete sources of radium-226: <ul style="list-style-type: none"> – Identify each radionuclide (element name and mass number) that will be used in each source; – Provide the manufacturer’s (distributor’s) name and model number for each sealed source and device and discrete source of radium-226 requested; – Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State; – Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State; and – If the above information cannot be provided for the discrete source of radium-226, describe the discrete source. <p>Financial Assurance and Recordkeeping for Decommissioning</p> <p>If a DFP or FA is required, submit the required documents as described in NUREG-1757, Vol. 3, “Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness,” dated September 2003.</p>	<p>N/A</p> <p>X</p>	<p>ACC 5.3</p>
6.	<p>PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED</p> <p>For accelerator-produced radionuclides, applicants should state that radioactive materials will be possessed and stored incident to their production by an accelerator in accordance with the regulations. For sealed sources that are not produced, specify their proposed use (e.g., calibration of instruments). Use of the format in Table 8.1 will facilitate the review of the application.</p>	<p>X</p>	<p>ACC 6.</p>

Item No.	Suggested Response	Agree to Use	Description Attached
9.	<p>FACILITIES AND EQUIPMENT</p> <p>Describe the facilities and equipment to be made available at each location where radioactive material will be produced, possessed, and/or used. Include the following information:</p> <ul style="list-style-type: none"> • Provide a description of the areas assigned for the production of radioactive materials, which includes transfer of produced material, storage, preparation, shipping, security, and measurement; • Provide a description and diagrams showing the locations of delivery lines, shielded areas and equipment (e.g., hot cells, waste), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety (see Figures 8.6 and 8.7); • Provide a diagram and a description of the ventilation system, including representative equipment such as hot cells, glove boxes, or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials that have the probability of becoming airborne; and • Provide verification that ventilation systems ensure that effluents are within the dose limits of 10 CFR 20.1301, and the ALARA constraints for air emissions established under 10 CFR 20.1101(d) are ALARA. <p><i>Note:</i> Mark drawings and diagrams that provide the exact location of materials or depict the specific location of safety or security equipment as: “Security-Related Information – Withhold Under 10 CFR 2.390.”</p>	X	ACC 9.

Item No.	Suggested Response	Agree to Use	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont.)</p> <p>Material Accountability</p> <ul style="list-style-type: none"> • “We have developed, and will implement and maintain written procedures for licensed material accountability and control to ensure that: <ul style="list-style-type: none"> – license possession limits are not exceeded; – licensed material in storage is secured from unauthorized access or removal; – licensed material not in storage is maintained under constant surveillance and control; and – records of production, transfer, and disposal of licensed material are maintained.” <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • “We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months.” <p>Occupational Dose</p> <p>“We have developed and will implement and maintain written procedures for monitoring occupational dose that meet the requirements in 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.2106, as applicable.”</p> <p><i>Note:</i> Alternative responses will be reviewed using the criteria listed.</p> <p>Public Dose</p> <p>Initially, a response is not required from the applicant.</p>	<p>X</p> <p>N/A</p> <p>X</p> <p>N/A</p>	<p>N/A</p> <p>N/A</p> <p>N/A</p> <p>N/A</p>

Item No.	Suggested Response	Agree to Use	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont.)</p> <p>Safe Handling of Radionuclides and Emergency Procedures</p> <p>Develop and maintain procedures for safe handling of radionuclides and emergencies. State that such procedures will be developed and documented before production of licensed material.</p> <p>The applicant should state that procedures will be revised only if:</p> <ul style="list-style-type: none"> • The changes are reviewed and approved by licensee management and the RSO; • Licensee staff is trained in the revised procedures before they are implemented; • The changes are in compliance with NRC regulations and the license; and • The changes do not degrade the effectiveness of the program. <p>If an emergency response plan is needed, submit it as a separate part of the application.</p>	<p>X</p> <p>X</p> <p>N/A</p>	<p>ACC 10.6</p> <p>ACC 10.6</p>

Item No.	Suggested Response	Agree to Use	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont.)</p> <p>Surveys</p> <p>“We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix L to NUREG-1556, Vol. 21. If applicable, state: “We will perform contamination checks on all manufactured sealed sources prior to distribution.” Leak tests of sealed sources will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State, to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer’s (distributor’s) and kit supplier’s instructions. As an alternative, we will implement the model leak test program published in Appendix N to NUREG-1556, Vol. 21.”</p> <p style="text-align: center;">OR</p> <p>Submit a description of alternative equipment and/or procedures to evaluate a radiological hazard and for determining whether there is radioactive leakage from sealed sources or plated foils.</p> <p>Maintenance</p> <p>No response is required in the application process.</p> <p>Transportation</p> <p>No response is needed from applicants during the licensing phase.</p>	<p><input type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p>N/A</p> <p>N/A</p>	<p>N/A</p> <p>ACC 10.7</p> <p>N/A</p> <p>N/A</p>

Item No.	Suggested Response	Agree to Use	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont.)</p> <p>Minimization of Contamination</p> <p>The applicant does not need to provide a response to this item under the following condition:</p> <p>NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: Section 8.5.1, "Radioactive Material – Sealed Sources and Devices or Unsealed Radioactive Material," Section 8.9, "Facilities and Equipment," Section 8.10.6, "Radiation Safety Program – Safe Handling of Radionuclides and Emergency Procedures," Section 8.10.7, "Radiation Safety Program – Surveys and Leak Tests," and Section 8.11, "Waste Management."</p>	N/A	N/A
11.	<p>WASTE MANAGEMENT</p> <p>Provide procedures for waste collection, storage, and disposal by any of the authorized methods described in this section. Applicants should contact the appropriate NRC Regional Office for guidance and obtain advance approval of any method(s) of waste disposal other than those discussed in this section.</p> <p><i>Note:</i> Alternative responses will be reviewed using the criteria listed above.</p>	X	ACC 11.

ACCELERATOR PRODUCTION LICENSE (ACC)

ACC Item 5.

Radioactive Material

ACC 5.1 Unsealed and/or Sealed Sources

Byproduct Source and/or Special Nuclear Material	Chemical/Physical Form	Maximum Possession
A. Any byproduct material with Atomic Number between 1 through 83 inclusive	A. Any	A. 1 curie of each radionuclide with total possession limit of 10 curies, except as specifically listed below: Bromine-76 3 curies Bromine-77 3 curies Carbon-11 20 curies Copper-64 5 curies Fluorine-18 50 curies Nitrogen-13 3 curies Oxygen-15 10 curies Yttrium-86 3 curies
B. Any byproduct material with Atomic Number between 1 through 83 inclusive	B. Incidentally activated products	B. 1 curie of each radionuclide with total possession limit of 3 curies

ACC 5.2 Radiological Emergency Plan

The inventory for radionuclides in unsealed form will be maintained so that possession will not exceed the quantities in §30.72, "Schedule C – Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release."

ACC 5.3 Financial Assurance and Recordkeeping for Decommissioning

We are required to have a Decommissioning Funding Plan (DFP) in accordance with 10 CFR 30.35(a) and based on the quantities of radionuclides we are allowed to possess. On September 30, 2009, Washington University submitted an updated DFP and the certificate of financial assurance for decommissioning of this license and University's Broad Scope Type A Medical Use License, No. 24-00167-11.

ACCELERATOR PRODUCTION LICENSE (ACC)

ACC Item 6.

Purpose For Which Licensed Material Will Be Used

- A.** Production and possession of radiochemicals for transfer to NRC License 24-00167-11.
- B.** Possession and storage incident to production activities, and for transfer to NRC License No. 24-00167-11.

ACCELERATOR PRODUCTION LICENSE (ACC) SECTION

ACC Item 7.

Individuals Responsible for Cyclotron Production Radiation Safety Program

ACC 7.1 Executive Management

Executive responsibility and authority for administration of Washington University in St. Louis is assigned to the Chancellor. The Chancellor has delegated the responsibility and authority to oversee the implementation and management of this accelerator production license to the Executive Vice Chancellor for Medical Affairs. This individual ultimately supervises the individuals responsible for the safe production, possession and transfer of radioactive materials from the University's cyclotron facilities to the University's Broad Scope Type A Medical Use License (No. 24-00167-11). The Chancellor appoints the RSO. See the radiation safety program organizational chart in ACC Schedule 1.

ACC 7.2 Radiation Safety Officer (RSO)

The Radiation Safety Officer and Radiation Safety Staff responsible for this production license are also responsible for the University's Broad Scope License. Many of the responsibilities and duties listed below are maintained under the Broad Scope License.

ACC 7.2-1 Radiation Safety Officer Identified

See ACC Schedule 2 for name, training and experience of the Radiation Safety Officer named for this production license.

ACC 7.2-2 Responsibilities and Duties of the Radiation Safety Officer and Staff

- a. Ensure that licensed material possessed by the licensee is limited to the types and quantities of licensed material listed on the license;
- b. Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in 10 CFR 20.1301;
- c. Ensure security of radioactive material;
- d. Oversee proper transfer of radioactive material to NRC License No. 24-00167-11 (see Section ACC 9.1), including transfer for radwaste disposal (see Section ACC 11.);

- e. Ensure that licensed material is transported in accordance with applicable NRC and DOT requirements;
- f. Post documents as required by 10 CFR Parts 19.11 and 21.6;
- g. Ensure that radiation exposures are ALARA;
- h. Oversee all activities (licensed and unlicensed) involving radioactive material, including monitoring and surveys of all areas in which radioactive material is possessed;
- i. Act as liaison with NRC and other regulatory authorities;
- j. Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to 10 CFR Parts 19 and 20, and any other applicable regulations;
- k. Distribute and process personnel radiation monitoring equipment, determine the need for and evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching established limits, and recommend appropriate remedial action;
- l. Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to possession or possession and use, both at periodic intervals (refresher training), and as required by changes in procedures, equipment, or regulations;
- m. Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records (see Section 11.);
- n. Oversee the storage of radioactive material not in current use, including waste;
- o. Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments;
- p. Maintain an inventory of all radionuclides possessed under the license and limit the quantity to the amounts authorized by the license;
- q. Immediately terminate any unsafe condition or activity that is found to be a threat to public health and safety or property;
- r. Supervise decontamination and recovery operations;

- s. Maintain other records not specifically designated above (e.g., records of production, transfers, and surveys as required by 10 CFR 30.51 and 10 CFR 20, Subpart L, "Records");
- t. Hold periodic meetings with, and provide reports to, licensee management;
- u. Ensure that all users are properly trained;
- v. Perform periodic audits of the Radiation Safety Program to ensure that the licensee is complying with: all applicable NRC regulations, the terms and conditions of the license (e.g., inventories and possession to trained, approved users), the content and implementation of the Radiation Safety Program to achieve occupational doses and doses to members of the public that are ALARA in accordance with 10 CFR 20.1101, and the requirement that all records be properly maintained;
- w. Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for at least 3 years) and provided to management for review; ensure that prompt action is taken to correct deficiencies;
- x. Ensure that the audit results and corrective actions are communicated to all personnel who possess or possess and use licensed material;
- y. Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or 10 CFR Part 20 limits are investigated and reported to NRC and other appropriate authorities, if required, within the required time limits; and
- z. Maintain an understanding of, and up-to-date copies of, NRC regulations, the license, and revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to NRC during the licensing process.

ACC 7.2-3 Radiation Safety Officer Delegation of Authority

See ACC Schedule 3 for the RSO Delegation of Authority signed by the Chancellor of Washington University in St. Louis.

ACC 7.3 Authorized Users for Cyclotron Production (AU)

ACC 7.3-1 Authorized Users Identified

See ACC Schedules 4 and 5 for names of the Authorized Users for this cyclotron production license and their training and experience. Each of these individuals has nearly 20 years or more of experience with cyclotron production of radioactive material, and has had

training in Radiation Protection Principles, Characteristics of Ionizing Radiation, Units of Radiation Dose and Quantities, Radiation Detection Instrumentation, Biological Hazards of Exposure to Radiation (appropriate to the types and forms of byproduct material to be used), and Handling of Radioactive Materials Relevant to Accelerator Activities.

ACCELERATOR PRODUCTION LICENSE (ACC)

ACC Item 8.

Training for Individuals Working in or Frequenting Restricted Areas (Instructions to Radiation Workers and Ancillary Personnel)

ACC 8.1 Initial Training for Authorized Users and Radiation Workers [from NRC License 24-00167-11]

The term "Radiation Worker" used in this license use section is defined to mean those workers who in the course of employment or study utilize licensed materials under the supervision of an Authorized User. Authorized Users and Radiation Workers receive instruction in accordance with 10 CFR 19.12 prior to being allowed to handle licensed materials without direct supervision of another Authorized User or Radiation Worker. Direct supervision means that the Authorized User or Radiation Worker responsible for maintaining radiation safety remains in direct verbal and visual contact with the individual being trained. Instruction on the overall radiation safety program is provided by the Radiation Safety staff in written form and understanding is confirmed by written exam. This instruction includes the following subjects:

- a. Applicable regulations and license conditions.
- b. Areas where licensed material is allowed to be produced and stored.
- c. Potential hazards associated with licensed material
- d. Appropriate radiation safety procedures.
- e. Cyclotron production and licensed materials handling procedures, as applicable to job responsibilities.
- f. Individual's obligation to report unsafe conditions to their supervisor, Authorized User or Radiation Safety Office.
- g. Appropriate response to emergencies or unsafe conditions.
- h. Workers right to be informed of occupational radiation exposure and bioassay results.
- i. Locations where copies of pertinent regulations, licenses, and other material required by regulations are posted or made available.

In addition, Authorized Users are responsible for ensuring their Radiation Workers receive specific instruction regarding the proper use, storage and disposal of licensed material, and

potential hazards associated with the licensed materials as approved under the authorization and commensurate with the Radiation Workers' responsibilities.

Radiation Workers are required to follow conditions approved for the authorization under which they use licensed material, written radiation protection procedures established for this license, NRC regulations and license conditions with respect to the research use¹ of licensed material. Authorized Users are responsible for the acts and omissions of Radiation Workers working under their authorization.

Authorized Users and Radiation Workers will be required to complete radiation safety training annually or whenever there is a significant change in duties, regulations, or the terms of the license that are related to their use of licensed materials.

ACC 8.2 Training for Individuals Working in or Frequenting the Cyclotron Vaults

The Cyclotron Facilities Director and the Manager of Cyclotron Operations are responsible for ensuring only trained individuals are granted unescorted access to the cyclotron vaults. The Manager of Cyclotron Operations and the Cyclotron Supervisors and Operators are granted unescorted access to the vaults when the cyclotron is off. Other individuals may be granted unescorted access to the cyclotron vaults (e.g., Cyclotron Engineers, Radiation Safety staff, radiochemists, etc.). Since the RDS vault houses a self-shielded cyclotron, other cyclotron facility staff may have unescorted access to the RDS vault at times when the cyclotron shield is closed.

In addition to the training already described in Section ACC 8.1, individuals granted unescorted access to any or all of the cyclotron vaults will also receive training on the following topics for each applicable cyclotron vault prior to being granted unescorted access.

- Vault and equipment description
- Vault security and safety systems during cyclotron operation
- Vault entry and safety procedures
- Typical radiation exposure rates
- Escorting other individuals into the vault
- Other vault procedures applicable to the individual's duties

An individual's training will be assessed and documented by the trainer through performance-based questioning on the individual's comprehension of the applicable training topics prior to granting the individual unescorted access. Individuals granted unescorted access will review these training topics as part of their annual radiation safety training.

The initial training for cyclotron vault unescorted access will be conducted by an individual who has had unescorted access for at least one year and who is approved by the

¹ This use would be with respect to production and storage under this license, and the subsequent use for radiochemical or radiopharmaceutical production.

Cyclotron Facilities Director, the Manager of Cyclotron Operations or the Radiation Safety Officer to do this training.

ACC 8.3 Training for Ancillary Workers

The term "Ancillary Worker" used in this license is defined to mean those workers who in the course of employment or study enter a cyclotron vault. Ancillary Workers entering a cyclotron vault will be escorted at all times by an individual who has unescorted access to the cyclotron vault. This escorting individual will have the responsibility for maintaining radiation safety for the escorted Ancillary Worker. If an Ancillary Worker's duties require frequent access to a cyclotron vault, the Ancillary Worker will be trained in the topics listed in Section ACC 8.2 and may be granted unescorted access.

ACCELERATOR PRODUCTION LICENSE (ACC)

ACC Item 9.

Facilities and Equipment

ACC 9.1 Cyclotrons and Vaults

Washington University owns and operates three cyclotrons located in two cyclotron facilities. This accelerator production license covers the byproduct material produced within three cyclotron vaults, either by the purposeful production of radioactive materials or by incidental activation of materials within the vaults. When byproduct material is physically transferred to outside of a cyclotron vault, then it is also transferred from the University's accelerator production license to the University's broad scope license. No byproduct material is transferred from this accelerator production license to any other byproduct material license. Byproduct material brought into a cyclotron vault continues to be possessed under the University's broad scope license.

ACC 9.1-1 Barnard Cyclotron Facility (BCF)

The older of the two cyclotron facilities, established in 1963, is located in the basement of the Barnard Hospital Building. The Barnard Cyclotron Facility (BCF) is shown in ACC Schedule 6, and contains the CS-15 vault and the JSW vault.

The CS-15 vault was constructed as a sub-basement of the BCF with 5 feet thick concrete walls with rebar reinforcement surrounded by terra firma (see ACC Schedule 7). This vault contains a Cyclotron Corporation Model CS-15 cyclotron used to accelerate protons (15 MeV).

The JSW vault is constructed with 4 feet of concrete reinforced with rebar (see ACC Schedule 8). When the JSW was installed in the vault additional concrete was poured at the external wall to increase the thickness of the West side of the vault to 6 approximately feet. To increase the shielding in the JSW vault a maze was constructed with 3 layers of 15.75 x 5.75 x 2" cinder blocks providing a shielding thickness of 27.25" of concrete on the east end of the vault. On a portion of the south vault wall, a 2" thick lead wall constructed with interlocking bricks held in place with 1/8" steel plates was placed on the exterior of the vault and 7.5" polypropylene was added on the interior of the vault. In addition to the vault shielding a 4" thick shield constructed with 5% borated polypropylene was placed around the targets of the JSW. The other walls are adjacent to terra firma and the CS-15 vault. This vault contains a Japan Steel Works (JSW) Model 168 cyclotron used to accelerate both protons (16 MeV) and deuterons (8 MeV).

ACC 9.1-2 East Building Cyclotron Facility (ECF)

The newer of the two cyclotron facilities, established in 2001, is located in the basement of the East Building. The East Building Cyclotron Facility (ECF) is shown in ACC Schedule 9, and contains the RDS vault.

The RDS vault, originally constructed to house a prototype Tandem Cascade Linear accelerator, has walls constructed with 1 foot thick solid filled concrete blocks with a ¼" sheet of lead on exterior walls (see ACC Schedule 10). This vault contains a self-shielded CTI Model RDS111 cyclotron that has been upgraded to an RDS Eclipse used to accelerate protons (11 MeV).

ACC 9.2 Cyclotron Vault Security and Radiation Controls

Unescorted access to the cyclotron vaults is granted only to trained personnel under the supervision of an Authorized User, his designee or the RSO. Other individuals accessing the cyclotron vaults will be escorted by one of the trained personnel. The first entry by these trained personnel into a cyclotron vault following the operation of the cyclotron requires the use of a survey meter to identify any remaining high radiation areas and to evaluate what ALARA techniques should be used for the task the individual needs to do. All cyclotron vault entries by trained personnel require the use of immediate reading dosimetry, e.g., pocket chamber, electronic dosimeter, etc., unless documented survey is performed which demonstrates dose rates are not likely to exceed 5 mrem in any one hour for the planned work or radioactive material handling. All individuals working in a cyclotron vault will be issued personal dosimetry. All individuals entering a cyclotron vault will be issued personal dosimetry or immediate reading dosimetry.

ACC 9.2-1 CS-15 Vault

Two retracting and interlocking doors, which are 36"-thick made of steel filled with polypropylene, are used to control access to the CS-15 vault (see ACC Schedule 7). This entryway is posted with warning signs indicating the presence of a high radiation area when the CS-15 cyclotron is operating. A red warning light is visible above the entryway when the CS-15 cyclotron is running. An audible alarm sounds when the CS-15 vault doors are closing. There is an automatic machine shut-off (beam kill) if the steel doors open while the CS-15 cyclotron is running.

ACC 9.2-2 JSW Vault

A wooden door, and then a 5.5"-thick steel door filled with polypropylene, are used to control access to the JSW vault (see ACC Schedule 8). The polypropylene steel door also supports 0.5" of lead shielding. The door is posted with warning signs indicating the presence of a high radiation area when the JSW cyclotron is operating. A red warning light is visible above the entryway when the JSW cyclotron is running. There is an automatic machine shut-off (beam kill) if the steel door opens while the JSW cyclotron is running.

ACC 9.2-3 RDS Vault

The RDS vault has two entryways (see ACC Schedule 10). Two wood doors control the north entryway to the RDS vault from the adjacent corridor. A sliding 7.5" polypropylene steel shield blocks these two wood doors during cyclotron operation. A single 7.5"-thick steel door filled with polypropylene is used to control the south entryway to the RDS vault from the ECF. Both entryways are posted with warning signs indicating the presence of a radiation area when the RDS cyclotron is running. Each entryway has a "Cyclotron in Use" sign above the entryway which lights up when the RDS cyclotron is running. An audible alarm sounds when the RDS cyclotron is powering up. There is an automatic machine shut-off (beam kill) if the RDS cyclotron shielding or if the north vault doors are opened while the RDS cyclotron is running. The south vault door is allowed to be opened while the RDS cyclotron is running because the cyclotron self-shielding maintains dose rates below 100 mrem in any one hour.

ACC 9.3 Production and Transfer of Cyclotron-Produced Radioactive Materials

Target materials used to produce radioactive materials may be in the form of gas, liquid or solid. General descriptions of these target forms and their transfer from the cyclotron vaults to the University's broad scope license is described here.

ACC 9.3-1 Gas Targets

Gas targets irradiated in the cyclotrons may be transferred from the cyclotron vault through gas transfer lines to hot cell equipment within the cyclotron facility or may be transferred through gas transfer lines directly to equipment housed at other Medical Center authorized areas. Gas line tubing materials and location criteria are described in the University's Broad Scope License Application.

ACC 9.3-2 Liquid Targets

Liquid targets irradiated in the cyclotrons are transferred from the cyclotron vault through liquid transfer lines to hot cell equipment within the cyclotron facility. Liquid transfer line tubing materials and location criteria are described in the University's Broad Scope License Application.

ACC 9.3-3 Solid Targets

Solid targets may be in the form of pressed powders or plated materials. Solid targets irradiated in the cyclotrons may be transferred from the cyclotron vault by an automated mechanical transfer system delivering the solid target to hot cell equipment within the cyclotron facility or by vault entry after the cyclotron is turned off by trained personnel to physically remove the solid target using proper shielding. Descriptions of the movement of solid sources and handling criteria are described in the University's Broad Scope License Application.

ACC 9.4 Storage of Cyclotron-Produced Radioactive Materials

Obviously, each cyclotron vault is used to store all of the equipment and vault building materials which become radioactive incidental to radioactive material production activities. Each cyclotron vault has designated radioactive material storage areas where usable parts and tools, and used targets can be stored to allow for decay or to shield until used again. Radioactive materials which are brought into the cyclotron vaults remain under the University's broad scope license and also may be stored in these designated areas.

ACC 9.5 Facilities and Equipment used under Broad Scope License

The portions of the University's cyclotron facilities and equipment located outside of the cyclotron vaults are covered by the University's broad scope license. See the Washington University in St. Louis NRC Broad Scope Type A Medical Use License (No. 24-00167-11) application for information on the areas used for the preparation and measurements of radiochemicals and radiopharmaceuticals, transfer of produced material from the cyclotron facilities to use areas, and description of the ventilation system, including representative equipment such as hot cells, glove boxes, or fume hoods.

ACCELERATOR PRODUCTION LICENSE (ACC)

ACC Item 10.

Radiation Safety Program

ACC 10.1 Audit Program

No response is required.

ACC 10.2 Radiation Monitoring Instruments [from NRC License No. 24-00167-11]

ACC 10.2-1 Radiation Monitoring Instrumentation Evaluation

Authorized Users are required to have or have access to appropriate radiation monitoring instruments prior to receiving licensed material under their authorization. Instrumentation is evaluated during the Radiation Safety Staff review of the authorization application based on the licensed material and quantity being requested. The following table outlines typical instrumentation deemed appropriate for most authorizations. The RSO can require different or additional types of instruments or monitoring devices on a case-by-case basis.

Radiation Type/Examples of Licensed Materials	Contamination Assessment	Meter Assessment
Low-Energy Beta/ H-3	LSC	None
Moderate to High-Energy Beta/ C-14, P-33, P-32, etc.	LSC	GM, Beta Scintillator
Low-Energy Gamma/ I-125, etc.	LSC or Gamma Counter	GM, NaI-thin crystal, Ion Chamber
Medium to High-Energy Gamma/ Tc-99m, Cr-51, Co-60, etc.	LSC or Gamma Counter	GM, NaI-thick crystal, Ion Chamber

ACC 10.2-2 Instrument Calibration

The Radiation Safety Office will maintain a listing of survey instruments assigned to each authorization. Survey instruments will be calibrated at a frequency not to exceed one year and following repairs that affect the instrument calibration. Authorized Users and Radiation Workers will not be allowed to use survey instruments past their calibration date for radiation safety surveys required under their authorization.

Survey instruments will be calibrated by a vendor who is licensed by NRC or an Agreement State to perform instrument calibrations or by the Radiation Safety Office. The Radiation Safety Staff will use the following survey instrument calibration procedure:

a. Survey meters

i. Measuring dose rate:

- 1) Use J.L. Shepherd and Associates Series 28 Calibrator
- 2) Decay correct the source
- 3) Using the inverse square law, check the response at approximately 1/3 and 2/3 of full scale and on each scale (or each decade for logarithmic readout instruments.)
- 4) The scale is considered calibrated when the response at both points is within +/- 10% of actual dose rate value.
- 5) If the instrument cannot be adjusted to provide less than 10% difference between the observed response and the actual value, but the difference is less than +/- 20%, the scale is considered calibrated if a chart with the correction factors is completed and attached to the unit.
- 6) Survey instruments with one or more ranges that cannot be adjusted to achieve the +/- 20% agreement are removed from service for repair.
- 7) Readings above 1 R/hr are not calibrated, but are sent for vendor calibration if required surveys require the instrument to measure these levels.

ii. Measuring contamination

- 1) Use calibrated source(s) emitting radiation(s) similar to the licensed materials to be detected.
- 2) At a designated distance from the source, record the instrument response.
- 3) Calculate the efficiency factor(s) and record on the calibration label affixed to the instrument.

b. Other radiation detecting instruments used for required surveys

- i. Approximate the geometry of the samples to be analyzed
- ii. Approximate the same energy and type of radiation for required surveys
- iii. Calibration must produce readings within $\pm 20\%$ of the actual values over the range required for required surveys
- iv. For liquid scintillation counters, include quench correction
- v. Alternately, the Radiation Safety Office may allow use of calibration efficiencies that are conservative estimates for the instrument and licensed material being counted.

ACC 10.2-3 Instrument Calibration

Instruments used to quantitatively measure the radioactivity in the radioactive material products and process, and the procedures followed to ensure accuracy of those measurements are discussed in the University's broad scope license application.

ACC 10.3 Material Accountability

No additional response is required.

ACC 10.4 Occupational Dose

No additional response is required.

ACC 10.5 Public Dose

No response is required.

ACC 10.6 Safe Handling of Radionuclides and Emergency Procedures

Cyclotron production procedures will be developed and maintained for the safe handling of radionuclides covered by this production license and for associated emergency responses. These procedures and revisions will require review and approval by the Cyclotron Facilities Director and the RSO. Review will assure that the procedure provides continued compliance with NRC regulations and this license and does not degrade the effectiveness of the radiation safety program. Staff will be trained in revised procedures prior to implementation.

ACC 10.7 Surveys

Description of cyclotron vault surveys for personnel entry is presented in ACC 9.2. Maintenance work performed on external parts of the cyclotron, or loading/unloading targets are done when the ambient radiation exposure rates in the vault are ALARA. When working on internal cyclotron components (ie. ion source), the time individuals spend working in the maximum dose area is limited, and personnel wear an immediate reading dosimeter and check the accumulated dose reading frequently. In most cases, personnel are able to limit their accumulated dose to less than 20 mrem per procedure.

Radioactive materials removed from a cyclotron vault are surveyed to determine the approximate activity unless the radioactive material is from a known target and irradiation

protocol. Evaluation for irradiation of new types of target materials is required. Prior to irradiation, the following information should be provided:

- Chemical and physical form of the target material
- Enrichment of target material
- Excitation function for the production of the intended radionuclide to be produced
- Properties of the intended radionuclide to be produced with regard to radiation types and energies emitted
- Anticipated radionuclide purity
- Irradiation conditions (beam type, current and irradiation time)
- Anticipated production yield per irradiation
- Anticipated incidental activation of other radioactive materials

Low level test irradiations may be used to determine and/or confirm this information.

Radiation surveys are made of public access areas surrounding the cyclotron vaults to ensure compliance with public dose limits as required by 10 CFR 20.1302. These surveys are repeated as necessary when there is significant change in cyclotron operation, irradiation protocols or shielding.

ACC 10.8 Maintenance

No response is required.

ACC 10.9 Transportation

No response is required.

ACC 10.10 Minimization of Contamination

No response is required.

ACCELERATOR PRODUCTION LICENSE (ACC)

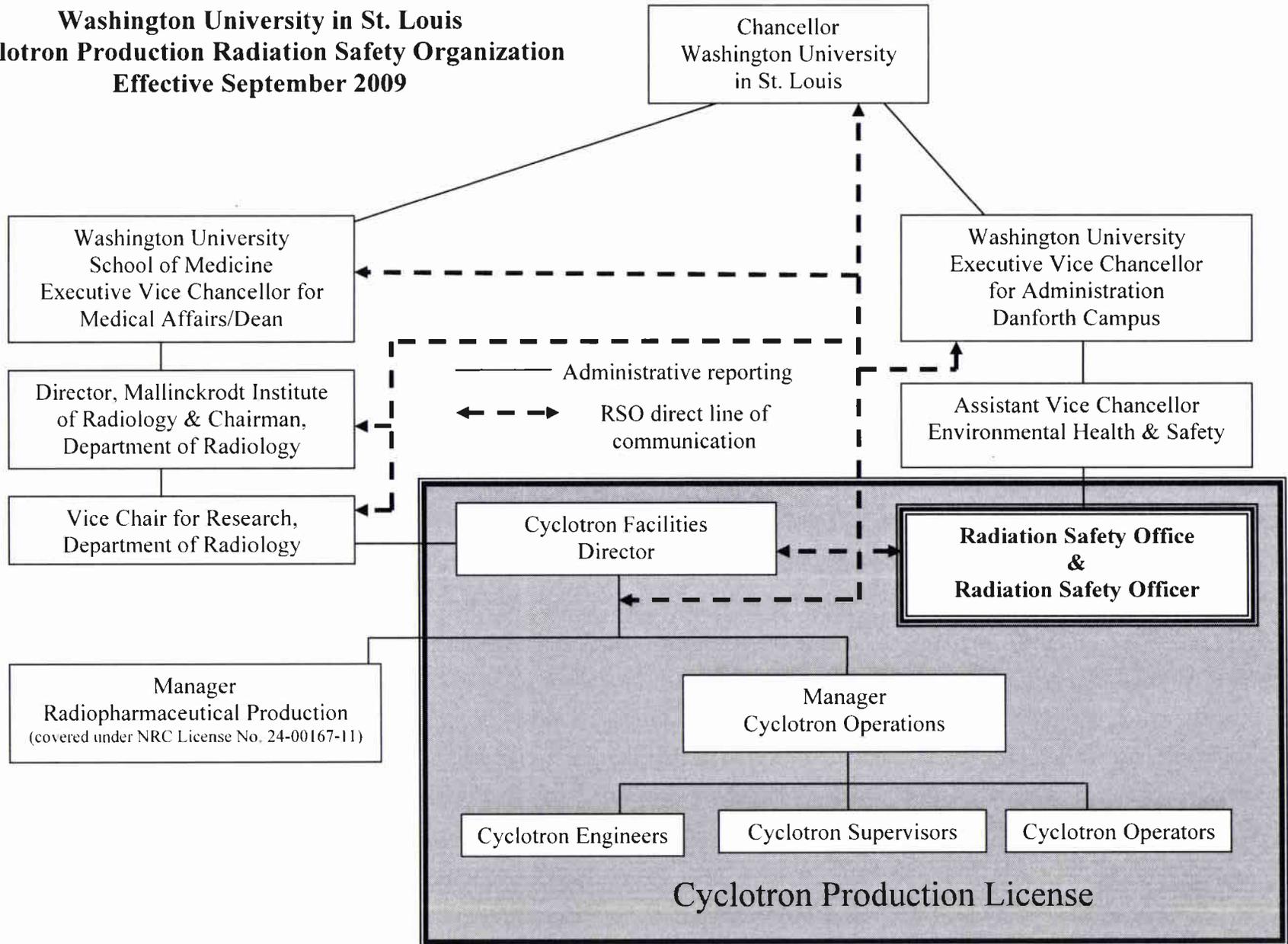
ACC Item 11.

Waste Management by Transfer to Broad Scope License

All radioactive material possessed under the production license will ultimately be removed from the cyclotron vault and transferred to Washington University in St. Louis Broad Scope Medical Use Type A License No. 24-00167-11. No radioactive waste will be disposed directly from this production license.

ACC Schedule 1

**Washington University in St. Louis
Cyclotron Production Radiation Safety Organization
Effective September 2009**



ACC Schedule 2

SUSAN M. LANGHORST, Ph.D., CHP
Washington University School of Medicine
Radiation Safety Office
WUSM Campus Box 8053
660 S. Euclid Avenue
St. Louis, MO 63110
Phone: (314) 362-2988
Fax: (314) 362-6666
e-mail: langhors@wustl.edu

EDUCATION:

Ph.D., Nuclear Engineering/Health Physics Option, University of Missouri-Columbia, 1982
M.S., Nuclear Engineering/Health Physics Option, University of Missouri-Columbia, 1979
B.S., Nuclear Engineering, University of Missouri-Rolla, 1976

PROFESSIONAL EXPERIENCE:

Radiation Safety Officer and Assistant Director; Radiation Safety Office in Environmental Health & Safety, Washington University School of Medicine; December 2000 to present; RSO on NRC broad scope Type A medical license (License No. 24-00167-11)

Assistant Professor; Radiology, Washington University School of Medicine; January 2001 to present

RSO Member; NRC Advisory Committee on Medical Use of Isotopes (ACMUI); July 2009 to present

Scientific Vice President; National Council on Radiation Protection and Measurements; Chairman of Scientific Committee 46, *Operational Radiation Safety*, September 2002 to December 2005 (Committee Member, May 1995 to December 2005); Council Member, April 1999-present; Member of Scientific Committee 46-15, *Radiation Safety Program for Astronauts in Low Earth Orbit*; Chairman of Scientific Committee 46-17, *Radiation Protection in Educational Institutions*.

National Academy of Sciences: Member, Board on Radioactive Waste Management, January 2004 to November 2005; Member, Nuclear and Radiation Studies Board, December 2005 to December 2006.

Radiation Safety Officer and Assistant Director; Environmental Health & Safety, University of Missouri-Columbia; March 1994 to December 2000; RSO on NRC broad scope Type A medical license (License No. 24-00513-32).

Assistant Professor; Nuclear Engineering Program, University of Missouri-Columbia; August 1983 to December 2000.

Faculty Research Fellow; Committee on Interagency Radiation Research and Policy Coordination, Office of Science and Technology Policy, Executive Office of the President; January 1993 to February 1994.

Manager, Reactor Health Physics; Research Reactor, University of Missouri-Columbia; April 1987 to February 1994 (on leave from January 1993 to February 1994); Reactor Health Physics Manager for NRC research reactor license (License No. R-103).

Report Committee Member; ANSI/ANS-15.11: *American National Standard for Radiation Protection at Research Reactor Facilities* (1993)

Certified Health Physicist, (Comprehensive); American Board of Health Physics; September 1985-recertified through 2009.

ACC Schedule 3



Mark S. Wrighton
Chancellor

TO: Susan M. Langhorst
Radiation Safety Officer

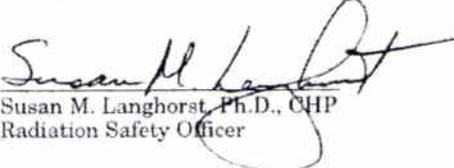
FROM: Mark S. Wrighton
Chancellor 

DATE: September 22, 2009

RE: Updated Delegation of Authority

You have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation under our NRC Broadscope Type A Medical Use License (No. 24-00167-11) and under our new NRC Accelerator Production License (new license application submitted September 2009). You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by individuals who do not meet the necessary requirements and shutting down operations where justified to maintain radiation safety. You are required to notify management if individuals do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at anytime.

I accept the above responsibilities.


Susan M. Langhorst, Ph.D., CHP
Radiation Safety Officer

MSW:se

cc: Larry J. Shapiro, Executive Vice Chancellor for Medical Affairs and Dean
Henry S. Webber, Executive Vice Chancellor for Administration
Richard J. Liekweg, President, Barnes-Jewish Hospital
Lee F. Fetter, President and Senior Executive Officer, St. Louis Children's Hospital
Anne Schmitt, Manager of Administrative Services, Howard Hughes Medical Institute
Robin M. Feder, Executive Director, Central Institute for the Deaf
Bruce D. Backus, Assistant Vice Chancellor for Environmental Health & Safety

Washington University in St. Louis, Campus Box 1192, One Brookings Drive, St. Louis, Missouri 63130-4899
(314) 935-5100, Fax: (314) 935-4744, wrighton@wustl.edu, www.wustl.edu

ACC Schedule 4

BIOGRAPHICAL SKETCH

NAME Robert H. Mach, Ph.D. rhmach@wustl.edu, Campus Box 8225		POSITION TITLE Professor of Radiology, Cell Biology & Physiology, and Biochemistry & Molecular Biophysics Director of Cyclotron Facilities	
EDUCATION/TRAINING			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
State University of New York-College at Potsdam	B.A.	1978	Chemistry
State University of New York at Buffalo	Ph.D.	1985	Medicinal Chemistry

A. Positions and Honors

Positions and Employment

1983-1985	NIH Predoctoral Fellow, Department of Medicinal Chemistry, SUNY at Buffalo, NY
1985-1986	Research Instructor, Department of Nuclear Medicine, SUNY at Buffalo, NY
1986-1987	Research Assistant Professor, Department of Nuclear Medicine, SUNY at Buffalo, NY
1987-1992	Research Assistant Professor, Department of Radiology, University of Pennsylvania
1988-1992	Research Assistant Professor, Department of Neurology, University of Pennsylvania
1992-1995	Assistant Professor, Departments of Radiology and Physiology & Pharmacology, Wake Forest University School of Medicine, Winston-Salem, NC
1995-2000	Associate Professor, Departments of Radiology and Physiology & Pharmacology, Wake Forest University School of Medicine, Winston-Salem, NC
2000-2002	Professor, Departments of Radiology and Physiology & Pharmacology, Wake Forest University School of Medicine, Winston-Salem, NC
2000-2002	Vice Chairman for Research, Department of Radiology, Wake Forest University School of Medicine, Winston-Salem, NC
2002-present	Professor, Division of Radiological Sciences, Mallinckrodt Institute of Radiology, Washington University School of Medicine, St. Louis, MO
2003-present	Professor, Department of Cell Biology and Physiology, Washington University School of Medicine, St. Louis, MO
2008-present	Professor, Department of Biochemistry & Molecular Biophysics, Washington University School of Medicine, St. Louis, MO

Professional Memberships

American Chemical Society

Society for Neuroscience

Academy for Molecular Imaging

Society of Nuclear Medicine

Society of Radiopharmaceutical Chemistry and Biology

Society for Molecular Imaging

B. Selected peer-reviewed publications (from a total of 109):

1. Tu Z, Dence CS, Ponde DE, Jones L, Wheeler KT, Welch MJ, Mach RH. Carbon-11 labeled σ_2 receptor ligands for imaging breast cancer. *Nucl. Med. Biol.* 2005; 32: 423-430.
2. Tu Z, Chu W, Zhang J, Dence CS, Welch MJ, Mach RH. Synthesis and In Vivo Evaluation of [^{11}C]PJ34, A Potential Radiotracer for Imaging the Role of PARP-1 in Necrosis. *Nucl. Med. Biol.* 2005; 32: 437-443.
3. Mach RH, Gage HD, Buchheimer N, Huang Y, Kuhner R, Wu L., Morton TE, Ehrenkaufer RL.. [^{18}F]4'-Fluorobenzyl-4-(2-fluorophenyl)acetamide ([^{18}F]FBFPA): A Potential Fluorine-18 Labeled PET Radiotracer for Imaging Sigma-1 Receptors in the CNS, *Synapse* 2005; 58: 267-274.
4. Xu J, Tu Z, Jones LA, Wheeler KT, Mach RH. [^3H]N-[4-(3,4-dihydro-6,7-dimethoxyisoquinolin-2(1H)- γ l)butyl]-2-methoxy-5-methylbenzamide: a Novel Sigma-2 Receptor Probe. *Eur. J. Pharmacol.* 2005; 525: 8-17.
5. Hou C, Tu Z., Mach RH, Kung HF, Kung M-P. Characterization of a novel iodinated sigma-2 receptor ligand as a cell proliferation marker. *Nucl. Med. Biol.* 2006; 33: 203-209.
6. Rowland DJ, Tu Z, Xu J, Ponde D, Mach RH, Welch MJ. Synthesis and evaluation of two high-affinity ^{76}Br -labeled sigma-2 receptor ligands. *J. Nucl. Med.* 2006; 47: 1041-1048.
7. Mintun MA, LaRossa GN, Sheline YI, Dence CS, Lee SY, Mach RH, Klunk WE, Mathis CA, DeKosky ST, Morris JC. [^{11}C]PIB in a nondemented population: potential antecedent marker of Alzheimer disease. *Neurology* 2006; 67: 446-452.
8. Zhou D, Chu W, Rothfuss J, Zeng C, Xu J, Jones L, Welch MJ, Mach RH. Synthesis, radiolabeling, and in vivo evaluation of an ^{18}F -labeled isatin analog for imaging caspase-3 activation in apoptosis. *Bioorg Med. Chem. Lett.* 2006; 16: 5041-5046.
9. Lee H, Finck BN, Jones LA, Welch MJ, Mach RH. Synthesis and evaluation of a bromine-76 Labeled PPAR γ antagonist, 2-bromo-5-nitro-N-phenyl-benzamide. *Nucl. Med. Biol.* 2006; 33: 847 - 854.
10. Jost SC, Wanebo JE, Song SK, Chicoine MR, Rich KM, Woolsey TA, Lewis JA, Mach RH, Garbow JR. In vivo imaging in a murine model of glioblastoma. *Neurosurgery* 2007; 60: 360 - 371.
11. Mach RH and Wheeler. Imaging the proliferative status of tumors with PET. *J. Labelled. Compds. Radiopharm.* 2007; 50: 366 - 369.
12. Lee BC, Lee KC, Lee H., Mach RH, Katzenellenbogen JA. Synthesis and Binding Affinity of a fluorine-substituted peroxisome proliferator-activated gamma (PPAR γ) ligand as a potential positron emission tomography (PET) imaging agent. *Bioconjugate Chemistry* 2007; 18: 507 - 513.
13. Lee BC, Lee KC, Lee H., Mach RH, Katzenellenbogen JA. Strategies for the labeling of halogen-substituted Peroxisome Proliferator-Activated Gamma (PPAR γ) ligands: potential positron emission tomography and single photon computed tomography imaging agents. *Bioconjugate Chemistry* 2007; 18: 514 - 523.

14. Tu Z, Xu J, Jones LA, Li S, Dumstorff C, Vangveravong S, Wheeler KT, Welch MJ, Mach RH. Fluorine-18 labeled benzamide analogues for imaging the σ_2 receptor status of solid tumors with positron emission tomography. *Journal of Medicinal Chemistry* 2007; 50: 3194-3204.
15. Mach RH, Zeng C, Tu Z, Jones L, Wheeler KT. Molecular probes for imaging the sigma-2 receptor: a receptor-based biomarker of cell proliferation. In *Recent Advances of Bioconjugate Chemistry in Molecular Imaging*, Research Signpost, Kerala, India. In press.
16. Mach RH, Wheeler KT. Development of molecular probes for imaging sigma-2 receptors in vitro and in vivo. *Current Medicinal Chemistry – CNS Agents*, in press.
17. Zhou D, Chu W, Chen DL, Wang Q, Reichert DE, Rothfuss J, D'Avignon A, Welch MJ, Mach RH. [^{18}F]- and [^{11}C]-Labelled N-benzyl-isatin sulfonamide analogues as PET tracers for apoptosis: synthesis, radiolabeling mechanism, and in vivo imaging of apoptosis in Fas-treated mice. *Organic & Biomolecular Chemistry* 2009; 7: 1337-1348.
18. Chu W, Xu J, Zhou D, Zhang F, Jones LA, Wheeler KT, Mach RH. New N-substituted 9-azabicyclo[3.3.1]nonan-3 α -yl phenylcarbamate analogs as σ_2 receptor ligands: synthesis, in vitro characterization, and evaluation as PET imaging and chemosensitization agents. *Bioorg. Med. Chem.* 2009; 17: 1222-1231.
19. Tu Z, Efang SMN, Xu J, L, S, Jones L, Parsons S, Mach RH. Synthesis and evaluation in Vivo and Vitro of F-18 labeled PET Ligands for Imaging the Vesicular Acetylcholine Transporter. *J. Med. Chem.* 2009; 52: 1358-1369.
20. Zhou D, Lee H, Rothfuss J, Chen D, Ponde D, Welch MJ, Mach RH. Design and synthesis of 2-amino-4-methylpyridine analogues as inhibitors for inducible nitric oxide synthase and in vivo evaluation of [^{18}F]6-(2-fluoropropyl)-4-methyl-pyridin-2-amine as a potential positron emission tomography tracer for inducible nitric oxide synthase. *J. Med. Chem.* 2009; 52: 2443-2453.
21. Xu J, Chu W, Tu Z, Jones LA, Luedtke RR, Perlmutter JS, Mintun MA, Mach RH. [^3H]4-(Dimethylamino)-N-[4-(4-methoxyphenyl)piperazin-1-yl]butyl]benzamide, a selective radioligands for dopamine D₃ receptors. I. In vitro characterization. *Synapse* 2009; 63: 717-728.
22. Chen DL, Zhou D, Chu W, Herrbrich PE, Jones LA, Rothfuss JM, Engle JT, Geraci M, Welch MJ, Mach RH. Comparison of radiolabeled isatin analogs for imaging apoptosis with positron emission tomography. *Nucl. Med. Biol.* 2009; 36: 651-658.
23. Mach RH, Dehdashti F, Wheeler KT. PET radiotracers for imaging the proliferative status of solid tumors. *PET Clinics* 2009; 4:1-15.

Selected Book Chapters

1. Mach RH, Brown-Proctor C, Vangveravong S, Blair JB, Buchheimer N, Bottoms J, Wheeler KT. Receptor-based radiotracers for imaging the proliferative status of breast tumors. *Synthesis and Applications of Isotopically Labelled Compounds Volume 8*; 2004: 157-160.
2. Mach RH, Gage HD, Buchheimer N, Morton TE, Bottoms J, Ehrenkauf RL. [^{18}F]4-Fluorobenzyl iodide as a useful precursor in PET research: application in the development of dopaminergic and cholinergic radiotracers. *Synthesis and Applications of Isotopically Labelled Compounds Volume 8*; 2004: 183-186.
3. Dence CS, Herrero P, Schwarz SW, Mach RH, Gropler RJ, Welch MJ. Imaging myocardium enzymatic pathways with carbon-11 radiotracers. *Methods in Enzymology* 2004; 385: 286-315.

C. Research Support

Ongoing Research Support

- P01 HL13851 (RA Gropler) 12/22/03 - 11/30/08 (No cost extension)
NIH/HLBI
Cyclotron Produced Isotopes in Biology and Medicine
Project 1: Chemistry Studies
The major goal of Project 1 is to develop radiotracers that can be used to study change in cardiovascular function in Type 1 and Type 2 diabetes using PET.
Role: P.I. of Project 1
- P30 NS048056 (MA Mintun) 9/30/04 – 6/30/10 (no cost extension)
NIH/NINDS
NINDS Center Core for Brain Imaging
The goal of this Center will be to enhance the quality, the efficiency, and the diversity of neuroimaging research at our institution.
Role: P.I. of PET Core
- R21 CA121952-01 (RH Mach) 09/01/05-08/31/09
NIH/NCI
Radiolabeled Probes for Imaging Caspase 3 Activation
The goal of this project is to develop PET imaging agents possessing a high affinity and selectivity for caspase-3.
- R01 AG025826-04 (RH Mach) 6/15/05 – 5/31/10
NIH/NIA
Neurovascular Mechanisms of Brain Function and Disease
The goal of this project is to develop radiolabeled beta amyloid peptides in order to image beta amyloid deposits in the brain vasculature.
- R33 MH081281-03 (RH Mach) 07/01/07 – 6/30/12
NIH/NIMH
Dopamine D₂ Selective Imaging Agents for PET
The goal of this project is to synthesize and evaluate PET and SPECT-based radiotracers having a high affinity and selectivity for the dopamine D₂ receptor.
Role: Principal Investigator
- R01 DA023957-01 (RR Luedtke) 9/30/07 – 8/31/12
NIH/NIDA
D₃ Receptor Compounds for the Treatment of Psychostimulant Abuse
The goal of this project is to synthesize and evaluate in vivo compounds having a high affinity and selectivity for the dopamine D₃ receptor as potential treatments of psychostimulant abuse.
Role: Principal Investigator of Subcontract to Washington University

Pending Research Support

S10 RR029450-01 (RH Mach)

NIH/NCRR

GE PETtrace Cyclotron

The goal of this high end instrumentation grant is to provide the funds for the purchase of a GE PETtrace cyclotron.

Role: Principal Investigator

Completed Research Support

R33 DA16181 (RH Mach)

7/01/02 – 6/30/07

NIH/NIMH/NIDA

Dopamine D₃ Receptor Imaging Agents for PET and SPECT

The goal of this project is to synthesize and evaluate PET and SPECT-based radiotracers having a high affinity and selectivity for the dopamine D₃ receptor.

Role: Principal Investigator

R33 CA 102869 (RH Mach)

9/01/03 – 8/31/07

NIH/NCI

PET Imaging of Breast Cancer via Sigma-2 Receptors

The goal of this project is to synthesize and evaluate PET radiotracers having a high affinity and selectivity for σ_2 receptors as potential breast cancer imaging agents.

Role: Principal Investigator

ACC Schedule 5

BIOGRAPHICAL SKETCH

Greg G. Gaele	POSITION TITLE Cyclotron Facility Manager & Senior Research Engineer
gaehleg@wustl.edu, Campus Box 8225	

EDUCATION/TRAINING			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Tulane University, New Orleans, LA	B.S.	1989	Biomedical Engineering
Washington University, St. Louis, MO	M.A.	1995	Biology/Biotechnology

A. Positions held at Washington University Cyclotron Facility with job positions listed in chronological order previous positions, concluding with present position:

Scientific Coordinator: 1990-1996 Managed and developed automation systems used to safely process F-18, C-11, O-15, N-13 and Ga-68 into PET radiopharmaceuticals

Research Engineer: 1996-2001 Managed and maintained a prototype Tandem Cascade Accelerator used to produce O-15 Oxygen, O-15 Carbon Monoxide and O-15 water. Operated CS-15 Cyclotron and JSW168 as needed

Senior Research Engineer: 2001- present Responsible for designing and implement numerous system upgrades for the Radiochemistry Laboratory at Mallinckrodt institute of Radiology including the installation of a Radio pharmacy designed around a 11MeV RDS cyclotron (Siemens)

Cyclotron Facility Manager: 2006 – present Manage two cyclotron facility supervisors, three cyclotron operators, a network engineer, a senior research engineer and two research engineers; operating, designing, programming, improving, testing, and maintaining systems used in the production of radioisotopes, Processing of radioisotopes into PET radiopharmaceuticals and the delivery of these radiopharmaceutical to the end user.

B. Sampling of Projects

Coordinated the installation and helped design a PET pharmacy. This 2.6 million dollar project began with the decommissioning of a tandem cascade accelerator and the installation of a CTI RDS111 cyclotron. This project included a cold reagent lab, a quality control facility and a radiopharmaceutical production area capable of producing over 15 PET radiopharmaceuticals on a routine basis

Tested various target systems and upgraded the terminal high voltage system of the prototype tandem cascade accelerator in an effort to improve reliability

Integrated various standard and solid target systems on both a CS-15 and JSW168 cyclotron

Designed and constructed a robotic system, using a CRS M1A arm and various purchased and in house designed chemistry stations to synthesize a variety of ^{11}C and ^{18}F -radiopharmaceuticals.

C. Selected peer-reviewed publications (in chronological order).

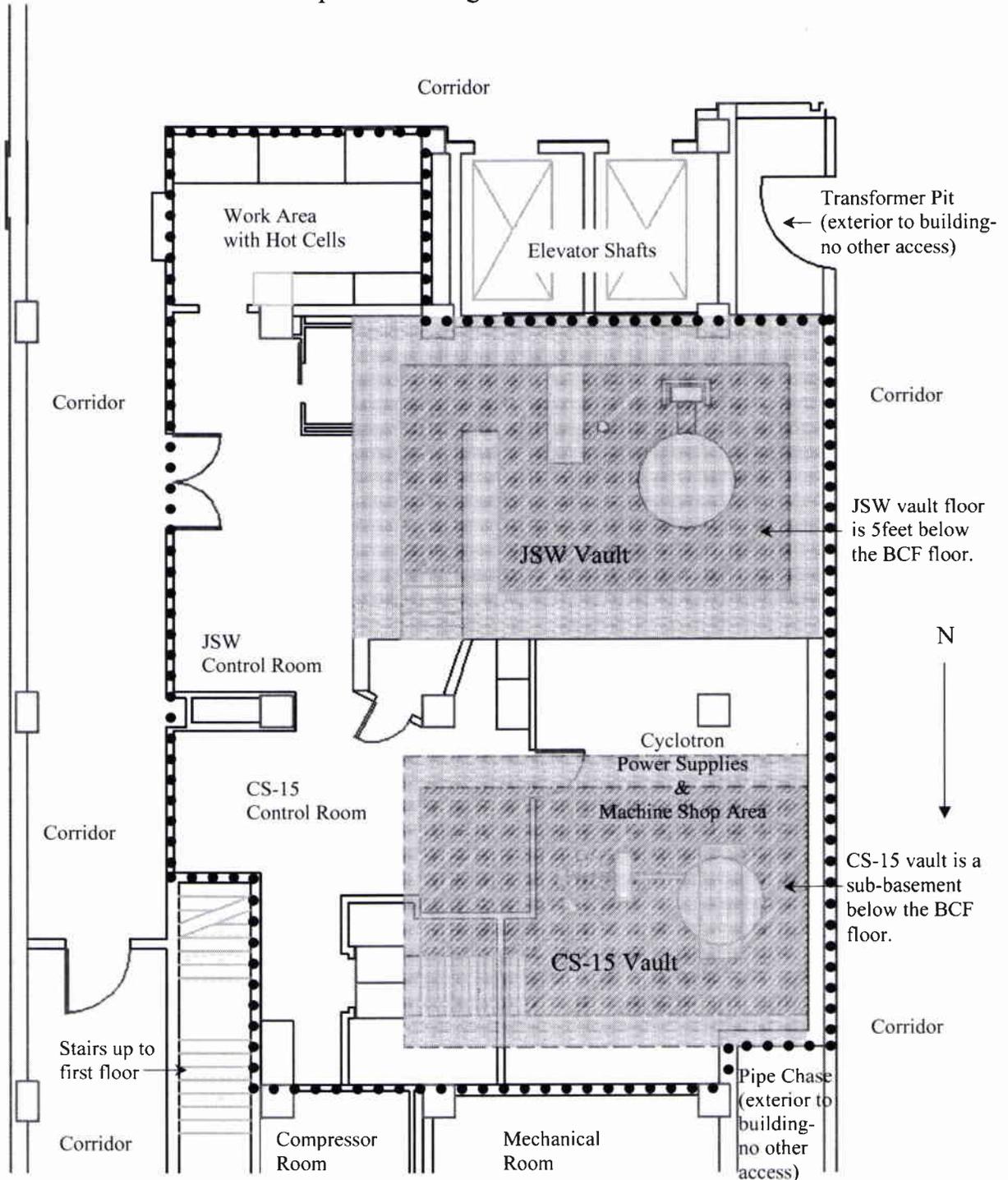
Moerlein, Stephen M.; Gaehle, Gregory G.; Welch, Michael J. , Robotic preparation of Sodium Acetate C- 11 Injection for use in clinical PET, *Nuclear Medicine and Biology* (2002), 29(5), 613-621

Gaehle, G.; Margenau, P.; McCarthy, D.; Rowland, D.; Hughey, B.; Klinkowstein, R.; Shefer, R.; Dart, A.; Ledoux, R.; Welch, M. The installation of a solid target system produced by Newton Scientific on a 168 JSW baby cyclotron capable of loading and delivering multiple solid targets with a single setup *AIP Conference Proceedings* (2003), 680(Application of Accelerators in Research and Industry), 1106-1108

Gaehle, G., Schwarz S., Mueller M., Margenau B. and Welch M.J., The Installation of a P.E.T. Pharmacy at Washington University, *AIP Conference Proceedings* (2003), 680 (Application of Accelerators in Research and Industry), 785-787

ACC Schedule 6

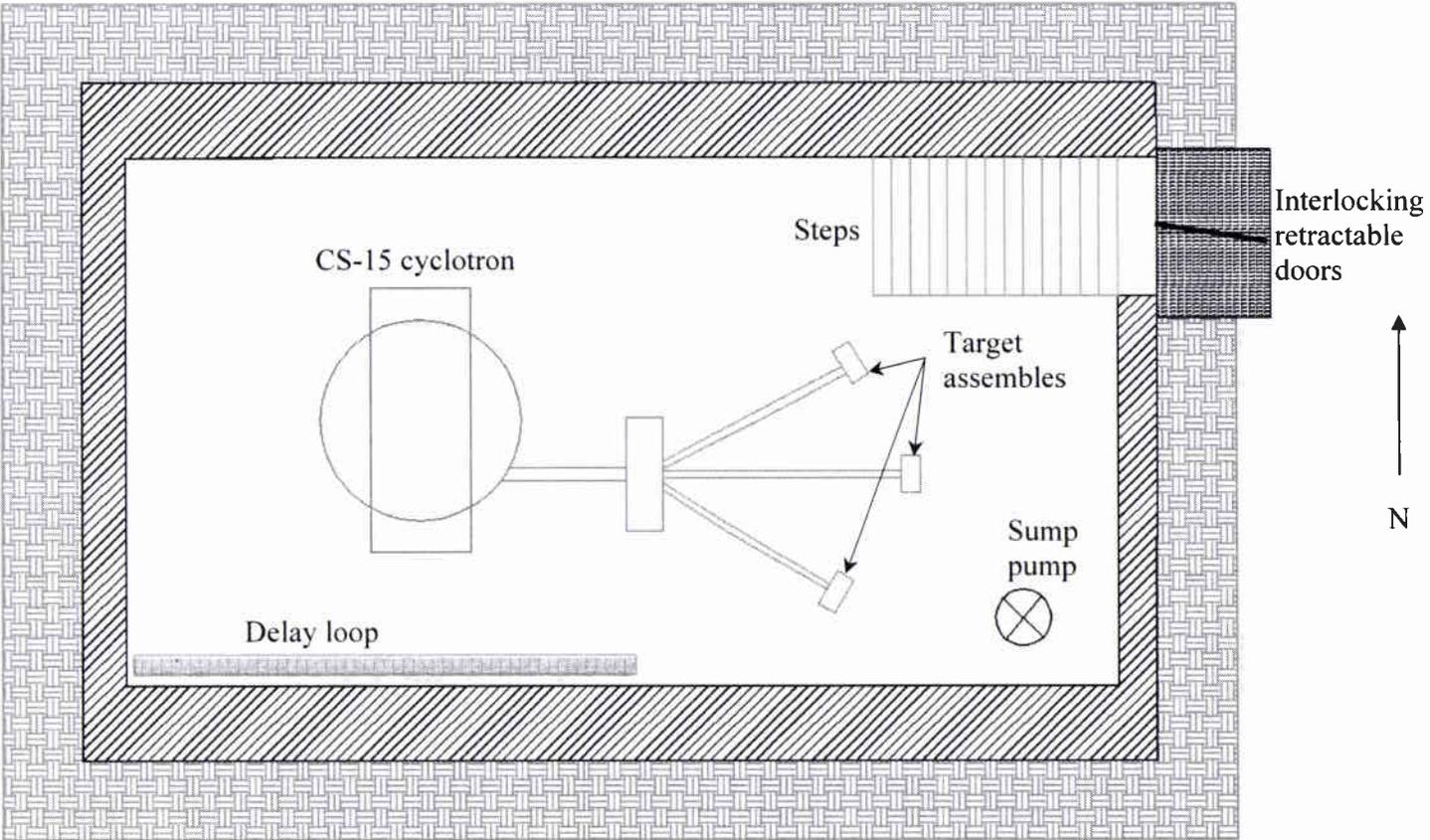
**Portion of Barnard Cyclotron Facility (BCF) Containing Cyclotron Vaults
Barnard Hospital Building Basement Floor**



ACC Schedule 7 CS-15 Vault

The CS-15 vault is a sub-basement below an area within the BCF used to house cyclotron power supplies and a cyclotron machine shop.

-  Polypropylene
-  Concrete
-  Earth



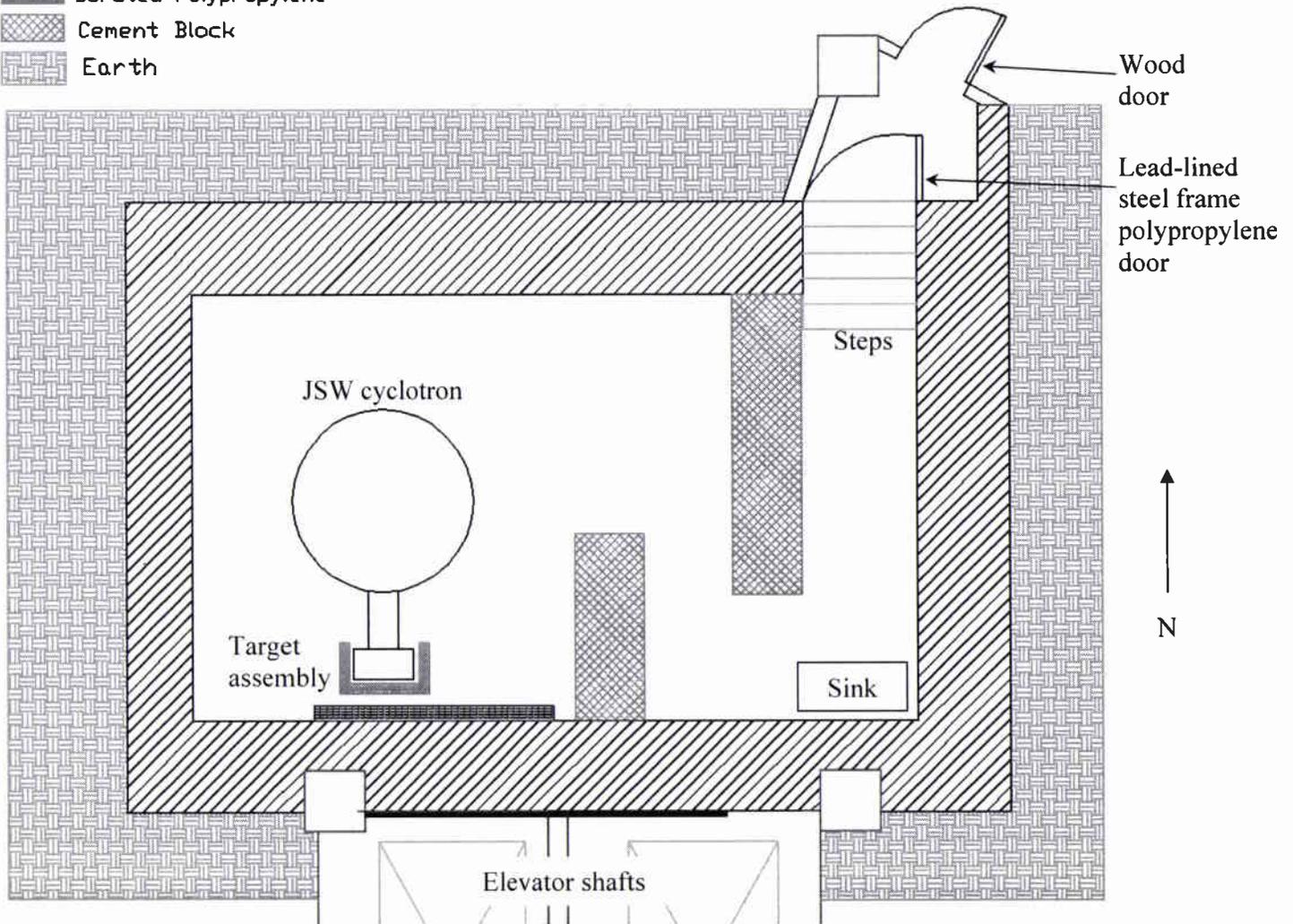
SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390

SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390

ACC Schedule 8 JSW Vault

-  Concrete
-  Lead
-  Polypropylene
-  Borated Polypropylene
-  Cement Block
-  Earth

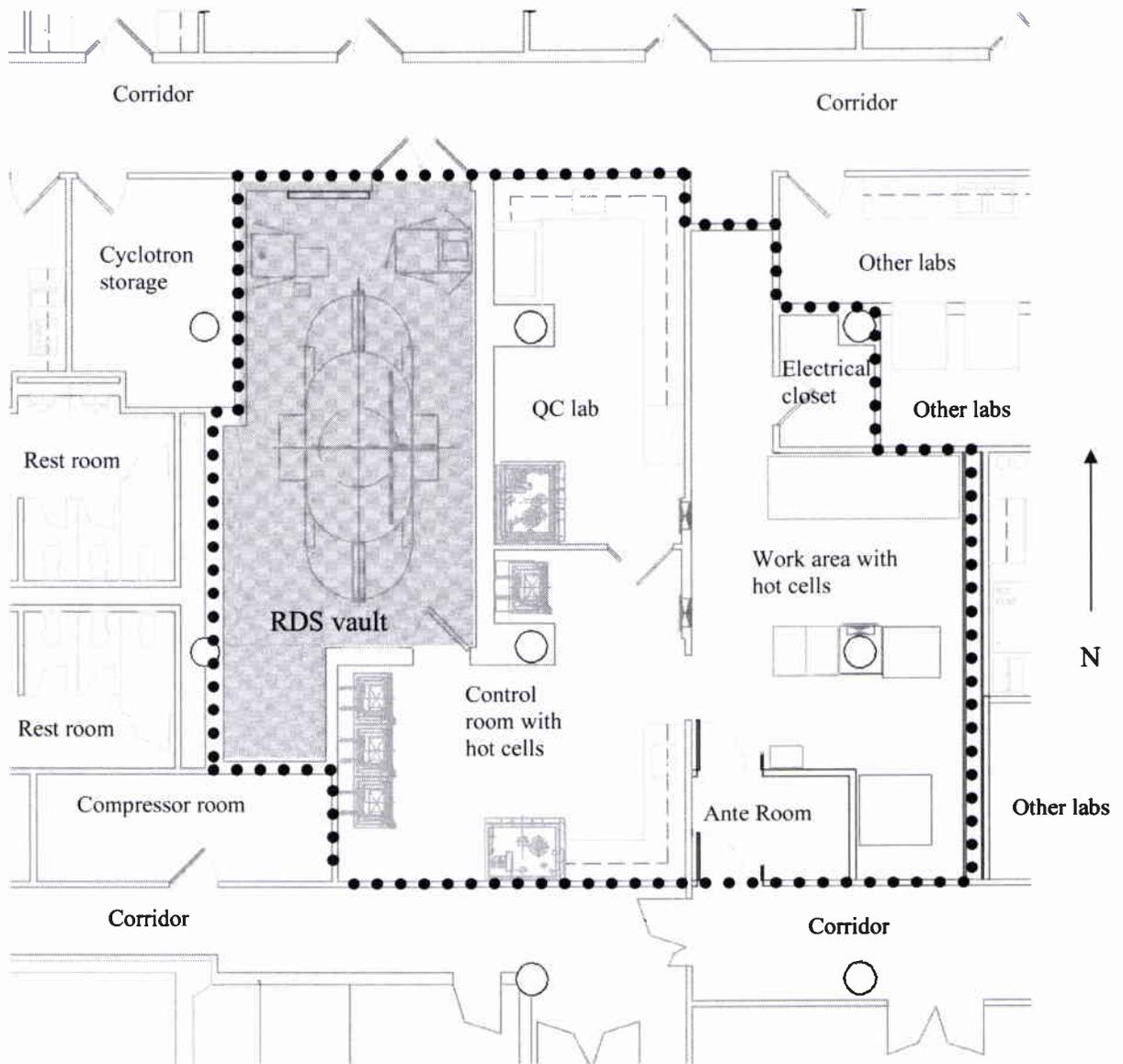
The floor of the JSW vault is 5' below the BCF floor. The top of the vault is 3'8" below the BCF ceiling allowing space for additional localized shielding. The area directly above the JSW vault, on the first floor of Barnard Hospital, houses the cyclotron engineer's offices



SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390

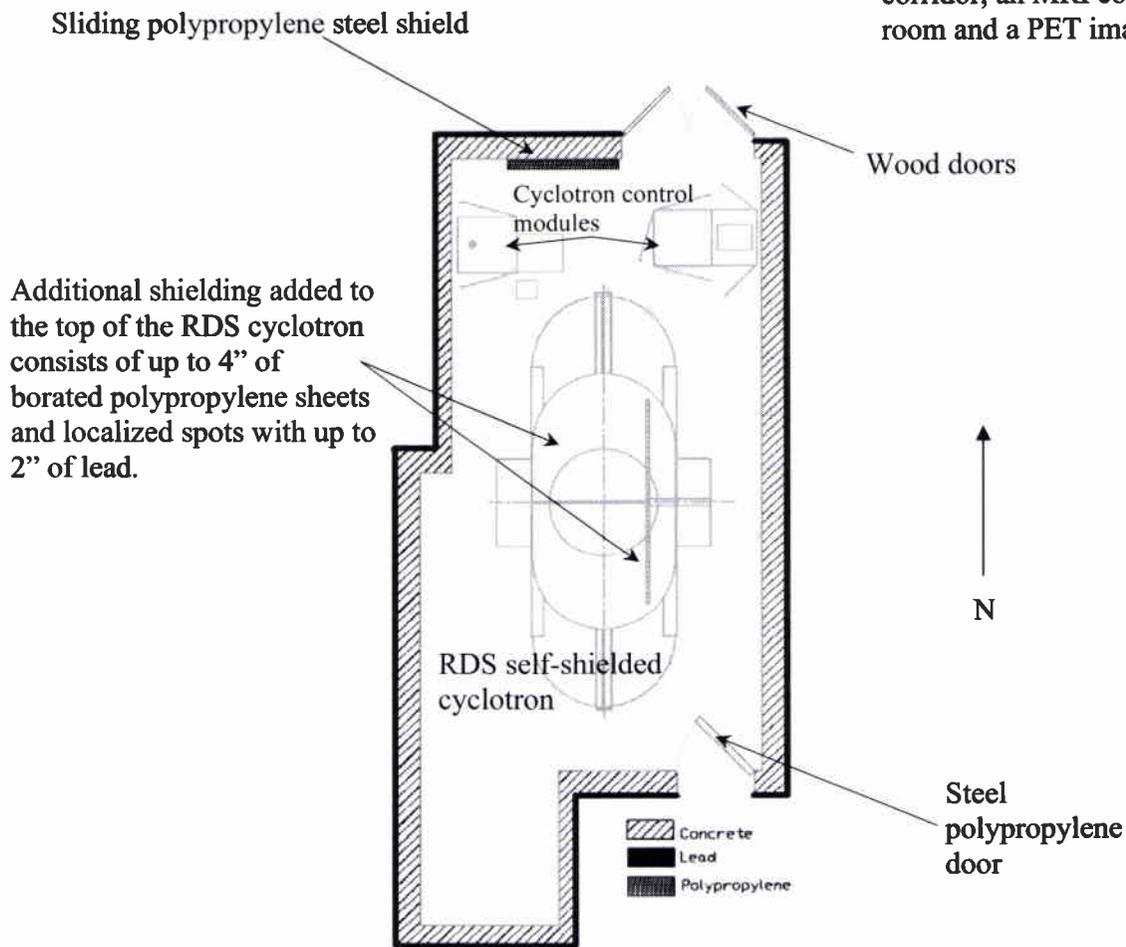
SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390

ACC Schedule 9
East Building Cyclotron Facility (ECF)
East Building Basement Floor



ACC Schedule 10 RDS Vault

Above the RDS vault, on the first floor of East Building, is a corridor, an MRI computer room and a PET imaging lab.



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* To meet locations. ** To meet locations.

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