NRC FORM 313 (10-2005) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 10/31/2008**

Estimated burden per response to comply with this mandatory collection request: 4.4 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@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:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
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, MISSISSIPPI, 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, 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
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

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 24-15595-1
- ☐ C RENEWAL OF LICENSE NUMBER

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

Aptuit, Inc.
10245 Hickman Mills Drive
Kansas City, Missouri 64134-0708

3 ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Aptuit, Inc.
10245 Hickman Mills Drive
Kansas City, Missouri 64134-0708

4 NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Clint Gregg

TELEPHONE NUMBER

(816) 767-6000

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

6 PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7 INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

8 TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9 FACILITIES AND EQUIPMENT

10 RADIATION SAFETY PROGRAM

11 WASTE MANAGEMENT

12 LICENSE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY | AMOUNT ENCLOSED $

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	SIGNATURE	DATE
Pam Barton, Facilities North America Director	Pamela Barton	4/1/2008

FOR NRC USE ONLY

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

NRC FORM 313 (10-2005) PRINTED ON RECYCLED PAPER

RECEIVED APR 0 2 2008

aptuit

March 31, 2008

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
Attn:Kevin G. Null
Materials Licensing Branch

Response: Additional Information to Control Number 316804

Dear Mr. Null:

We have completed our response to your NRC Deficiency letter dated February 20, 2008. Please find our response in bold print below:

Financial Assurance

As a result of Aptuit's request to increase its possession limit of hydrogen-3 from 1 curie to 5000 curies, and carbon-14 from 2 curies to 500 curies, Aptuit will need to resubmit financial assurance in the form of a decommissioning funding plan (DFP), as required in 10 CFR Part 30, Section 30.35.

Upon receipt of the DFP we will review it for adequacy to supply funds for future decommissioning, as applicable.

Per telephone conversation between you and Pam Barton on January 28, 2008, and your visit to Aptuit on March 14, 2008, Aptuit is revising requested possession limits for hydrogen-3 to 100 curies and carbon-14 to 100 curies. These revised lower limits are in accordance with your suggestion for phasing in radiosynthesis operations and establishing operational history at the lower levels. We understand that future requests to increase the limits can be expedited once safe operations at the lower levels have been demonstrated.

The revised possession limits still exceed the threshold for using prescribed financial assurance amounts. A Decommissioning Funding Plan has been written and has been submitted to the NRC with a letter of credit. A revised Attachment 1 – "Radioactive Material, chemical/physical form, maximum amount possessed, and purpose for which licensed material will be used" is attached.

10245 Hickman Mills Drive • Kansas City, Mo 64137 • Tel: (816) 767-6000 • Fax (816) 767-0266 • www.aptuit.com

Programmatic Changes

From our review of your application it appears that you are requesting that Aptuit's license be upgraded to a broad scope program. Evidence of this appears in Attachment 7 to the Radiation Protection Program where reference was made to Radiation Safety Committee (RSC) duties and responsibilities that include, for example, approval of users and uses of license material, and modifications of facilities and equipment.

Given Aptuit's request to significantly increase possession limits of hydrogen-3 and carbon-14, expand its authorized use from research and development (R&D) to radiosynthesis, and the recent change in the Radiation Safety Officer (RSO), the NRC feels very strongly that at this time Aptuit's license should continue to be written as a limited scope R&D.

During telephone conversations that we held on January 18 and 28, 2008, you stated your agreement with our proposal. Therefore, it will be necessary for Aptuit to review its October 25, 2007, application in its entirety and make the necessary modifications to the application in accordance with the enclosed NUREG-1556, Volume 7, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope", and submit the revisions for our review.

The Radiation Protection Program Manual (RPPM) has been revised to follow the guidance for a limited scope R&D license. Wording was changed as appropriate; specifically sections V. "Responsibilities" and IX. "Procedures for Working with Radioactive Materials" to reflect that the NRC will approve users and uses of license material, and modifications of facilities and equipment. A revised Attachment 2, Item 7, "Individuals responsible for radiation safety program", and Attachment 7, "Radiation Protection Program Manual" are enclosed.

Authorized Use

Describe the purpose for conducting radiosynthesis, and confirm that you will not be engaged in commercial distribution of end product.

Radiosynthesis will be performed on a client request basis. These materials will be distributed to our clients and agreement state or NRC licensed facilities; but will not be for commercial distribution.

Describe the types of radiosynthesis studies that will conducted. Include nuclides involved, frequency of studies performed, and typical quantities of each radionuclide that will be used at any one time.

Custom chemical radiosynthesis will be performed per contract with our clients in the Active Pharmaceutical Ingredients (API) area of B2 (refer to the Synthesis Area Floor Plan in Attachment 5). Custom chemical radiosyntheses are usually contracted only once and work is not repeated, therefore there is no single defined product that is made on a regular basis. The B-2 area was designed incorporating several of Aptuit's principles of "designing a better drug process."

The radiochemistry area of B-2 consists of a change room, a Nuclear Magnetic Resonance (NMR) laboratory, a non-GMP radiosynthesis laboratory, a radioanalytical laboratory, and several Current Good Manufacturing Practice (CGMP) suites. The radiochemistry area will utilize radioisotopes including C-14, H-3 and S-35. B2 is located on the ground floor of the B-building. The radiochemistry area has a dedicated air handling system (refer to AC-B01 HVAC Schematic in Attachment 5).

- **The change room will be used to don and doff PPE and for staging new PPE and equipment. This area has a sink for hand washing and a frisking area for personnel exiting the laboratory. This area is designated as the entry point for the radiochemistry laboratories. A set of double doors exists in the synthesis area for entry of equipment too large to fit through the change room doors. An emergency exit is located at the opposite end of the radiochemistry area for exit in emergency situations.**
- **The NMR lab will consist of the Nuclear Magnetic Resonance spectrometer (console and magnet), as-well-as containers for liquid nitrogen and helium and other equipment depending on needs.**
- **The non-GMP radiosynthesis laboratory contains eleven bench top hoods and one walk-in hood. This lab will be utilized for custom chemical synthesis and development of processes using mCi up to one curie quantities of C-14, H-3 and S-35. These processes consist of bench scale chemistry utilizing organic solvents. All operations are performed in hoods or isolated enclosures. Emissions will be controlled at the source through the use of traps and chemists experience.**
- **The radioanalytical laboratory will provide analytical support for the radiosynthesis laboratories consisting of analysis of intermediates and products for purity and impurity profiling to satisfy our clients needs. The radioanalytical lab contains two bench top hoods.**
- **The radio-CGMP area consists of four isolated suites. Each suite has a hood and is isolated to prevent cross contamination between product lines. These suites are designed to ensure the integrity of the compound and each suite has a designated airlock. Additional PPE will be utilized to ensure the integrity of the product.**

Authorized Users

Your current license authorizes the Radiation Safety Officer (RSO) to approve users of licensed material. As we discussed during our telephone conversation on January 18, 2008, the NRC feels that given the recent change in Aptuit's RSO, request for a significant increase in possession limits for hydrogen-3 and carbon-14, and a programmatic change from research and development to radiosynthesis, Aptuit's license should be modified to list the authorized users. Therefore, please provide a complete list of authorized users with a description of radionuclides that you would like each to be approved to use. Also, include a description of their experience in using each nuclide (include maximum quantities used per study and types of studies conducted).

A revised Attachment 2, Item 7, "Individuals responsible for radiation safety program" is enclosed. Attachment 2 contains the name of each proposed authorized user with the type of use and information demonstrating that the users are qualified for the proposed use by appropriate training and experience.

Training Program

Item 8, Attachment 3 to your October 25, 2007, amendment request states that "new employees with limited experience must work under supervision of an Authorized User." Provide more detail on the criteria that will be used to evaluate new employees in order to assess their ability to work safely with licensed material.

The following criteria will be used to evaluate new employees with limited experience with radioactive materials:

- **Completed Aptuit radiation safety training**
- **Read and understood Aptuit's Radiation Protection Program Manual**
- **Follows good contamination control procedures**
- **Observes postings**
- **Dons and doffs PPE correctly**
- **Frisks and performs surveys correctly and as required**
- **Follows waste minimization methods**

Attachment 3, Item 8 and Section VI of the RPPM have been revised and are enclosed.

Provide us with the name of the instructor(s) for your training program, and include their qualifications to provide the training.

Current radiation safety trainers are:

Clint Gregg

- **Twelve years experience in radiation safety at a radiosynthesis laboratory including nine years as the Radiation Safety Officer.**
- **Seven years in the U.S. Navy working in nuclear propulsion plant chemistry and radiological controls.**
- **Specialized training in radiological controls, operational water chemistry, hazardous and radioactive materials handling and transportation.**
- **Radiation safety instructor for initial and annual refresher training at a radiosynthesis laboratory.**

Rick Greene

- **Certified Health Physicist with 30 years experience in DOE and commercial facilities including six years at a national laboratory, two years at a DOE weapons facility, and 22 years at commercial laboratories and testing facilities.**
- **Twenty years experience as a Radiation Safety Officer in laboratories.**
- **Developed and presented training in numerous areas including: radiation safety, radiation detection and measurement, health physics technician**

training, regulation of radioactive materials, transportation of radioactive materials, laboratory safety, chemical hygiene plan, etc.

- **Consultant in many areas including: radiation surveys and site investigations, D&D, licensing, and program assessments.**

Facilities and Equipment

Please describe in detail all modifications that were made to your facility, and submit a list of radiation safety equipment that will be used to ensure that radiosynthesis operations are conducted safely. Include any changes in ventilation systems, air/water effluent monitoring programs/equipment, etc. Submit diagrams and locations of all synthesis labs, and include the location of any specialized safety-related equipment for each lab, e.g., fume hoods, glove boxes, waste storage areas, etc.

Describe equipment used to filter radioactively contaminated air/water before effluents are released to the environment. Include a description of the methods that will be used to evaluate these filtration systems for saturation.

Identify the location of all areas that are dedicated for the storage of radioactive waste. Include a description of provisions taken to ensure that these areas will be secured from unauthorized access.

A dedicated air-handling unit serves the CGMP Radio Labs, Radioanalytical Lab and Non-GMP Radio Lab portions of the facility (refer to AC-B01 HVAC Schematic in Attachment 5). The supply fan motor for the unit is equipped with a variable frequency drive and HEPA filters are installed on the downstream side of the supply fan. The supply fan motor is on emergency power. Individual rooms connected to the air-handling unit have lab supply air terminals with heating hot water reheat coils to maintain the space temperature set points and space pressurization.

Two exhaust fans are installed on grade to the west of Building "B" and serve the CGMP Radio Labs, Radioanalytical Lab and Non-GMP Radio Lab portions of the facility. The exhaust fans are redundant fans and are connected to a common exhaust stack. The exhaust stack is 30 inches in diameter and 60 feet tall. The exhaust stack extends 20 feet above the roof and the exhaust velocity of the exhaust stack is greater than 3000 feet per minute. There are two grade level outside air intake louvers below the stack. The nearest louver is approximately 50 feet away from the stack discharge and the other louver is approximately 75 feet away. There are multiple roof mounted air handling units on the roofs of the buildings within the site. The nearest outside air intake for one of these roof mounted air handling units is 80 feet away from the stack discharge. All other outside air intakes for the multiple roof mounted air handling units are over 145 feet away from the stack discharge.

The exhaust fan motors have variable frequency drives and are connected to emergency power. Exhaust ductwork is routed from the exhaust fans through a heat recovery coil and then into the west side of Building "B". The exhaust ductwork is then routed through a HEPA filter housing and then to lab exhaust air terminals that

are connected to fume hoods and exhaust grilles within the labs to maintain space pressurization. New low airflow fume hoods with two position control are installed within the new labs. Each fume hood is connected to a lab exhaust air terminal that controls the exhaust airflow for each fume hood.

The HEPA filters for the systems are 99.99% efficient on 0.3 micron size particles and are tested bi-annually for HEPA certification. In addition, the differential pressure across the HEPA filters is continuously monitored by the Siemens Building Management System and an alarm is generated when the differential pressure is at level as indicated by the HEPA filter manufacturer for the filters to be replaced. The filter housing for the exhaust HEPA filters is a bag-in/bag-out system.

The radiochemistry area is under a negative pressure in relationship to the surrounding areas and there is security card reader access only to the radiochemistry area. Door pressurization is continuously monitored by the Siemens Environmental Monitoring System for all perimeter doors for the radiochemistry area. In addition when the pressure differential between the radiochemistry area and the surrounding area is less than -0.02"wc for a set amount of time, an alarm is generated and a flashing strobe in the area is activated.

There are no floor drains within the radiochemistry area and the fume hoods do not have cup sinks or drains within the hoods. There are only hand sinks within the radiochemistry area.

Frisker stations are located at the control point. Personnel leaving the radiochemistry area are required to frisk prior to leaving the controlled area.

A schematic of the HVAC system and a lab floor plan for area are included in Attachment 5.

Unauthorized access to licensed material is accomplished by the use of multiple security features.

A chain link fence with barbed wire and gated entrances surrounds the perimeter of the Marion Park Campus, which includes the entire Aptuit KCM facility. The perimeter is patrolled by Security. There are two gate entrances. The entrances are manned by security personnel during normal working hours (6 AM-6 PM). During non-working hours the gates are closed and the campus can only be accessed with an electronic badge system. The gates and entrances are monitored by remotely operated closed-circuit television (CCTV) with viewing monitors located in the security console. The CCTV is recorded.

Building Entry: All entrances to the buildings are controlled by electronic badge readers. After hour entry requires a PIN in addition to the electronic badge. Building entrances are monitored by CCTV.

Areas where radioactive materials are used or stored have restricted access by badge readers.

Radiation Monitoring Instruments

Please address Item 8.10.2 of the enclosed NUREG-1556, Volume 7, and submit a more detailed description of the radiation monitoring instruments that Aptuit will possess and use.

A list and description of instruments used at Aptuit to perform radiation surveys is presented below and is included in Section IX of the RPPM (Attachment 7). These instruments meet the radiation monitoring instrument specifications published in Appendix M to NUREG-1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Laboratory Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary.

Type of Instrument	Radiation Detected	Sensitivity Range	Window Thickness	USE
Survey meter with pancake G-M detector (PGM)	beta, gamma	X.1, X1, X10 0-5K cpm or 0-5 mR/hr	1.7 +/-.03 mg/cm²	Contamination surveys
Alarm Ratemeter with PGM	Beta , gamma	0 - 500 cpm, X1, X10, X100, X1k	1.7 +/-.03 mg/cm²	Personnel contamination monitoring
Inspector (G-M)	beta, gamma	0-300K cpm .001-1000 mR/hr	1.5-2.0 mg/cm²	Contamination surveys
Liquid Scintillation Counter	beta	NA	NA	Removable contamination, waste and product assays
Ion chamber or microR meter	gamma	0 – 5000 mR/hr	NA	Exposure rate, package surveys
Low energy gamma detector	Low energy gamma	0 - 500 cpm X1, X10, X100, X1000	18.4 mg/cm²	I-125 surveys
Large area gas proportional detector	Alpha, beta	X1, X10, X100, X1000 0 - 500 cpm,	0.4 – 0.8 mg/cm²	Contamination surveys

Occupational Dose

Please address occupational dose by submitting a response to Item 8.10.4 of the enclosed NUREG-1556, Volume 7.

We will monitor individuals in accordance with the criteria in the section entitled 'Radiation Safety Program - Occupational Dose' in NUREG-1556, Vol. 7, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope,'" dated December 1999. External dosimetry will provided by a vendor approved by the

National Voluntary Laboratory Accreditation Program (NVLAP). The RPPM has been revised to reference NUREG-1556, Vol. 7.

Bioassay Program

The discussion in your application regarding monitoring for internal dose states that a "bioassay program may be implemented at the discretion of the RSO." With the increase in possession limits of both hydrogen-3 and carbon-14 and authorization to conduct radiosynthesis, you must be more definitive in your statement and develop a strict bioassay program with clear criteria for implementation. Therefore, please review the enclosed Regulatory Guides 8.9 and 8.32, and submit a comprehensive bioassay for monitoring internal dose from the intake of radionuclides.

Employees who routinely work in radiosynthesis will submit a weekly urine sample. Employees working in other areas will submit bioassay samples in accordance with the guidelines in Table 1 - General guidelines for internal dose monitoring, of the RPPM. The "Internal Dose Monitoring" section of the RPPM has been revised (Attachment 7).

Survey Program

The survey frequency described in your application for conducting contamination surveys is significantly higher than the frequencies recommended in NUREG-1556, Volume 7. For example, your program requires daily surveys for contamination when quantities of hydrogen-3 used are greater than, or equal to, 1000 curies. Volume 7 recommends daily surveys for contamination be conducted where quantities used are greater than or equal to 1.0 Annual Limit on Intake (ALI). The smallest ALI for hydrogen-3 is 80 millicuries. Please modify your criteria for frequency of conducting contamination surveys to be in accordance with Appendix Q to Volume 7, NUREG-1556.

Describe in greater detail the criteria that the RSO will use to determine the types, frequencies, and locations of routine surveys.

Surveys for contamination will be performed in locations where individuals are working with an unsealed form of radioactive material. Weekly routine surveys will be performed in and adjacent to radiosynthesis areas and monthly in R&D areas. In addition, users will perform daily surveys in radiosynthesis areas and at project completion in radio R&D areas. The "Radiation Safety Survey" section of the RPPM has been revised (Attachment 7).

Waste Management

Describe your monitoring program for air and liquid effluents that you will implement to verify that concentrations of radioactive materials do not exceed 10 CFR Part 20 limits.

Also, describe how you will test and confirm that effluents released to the environment are within 10 CFR Part 20 limits.

Air effluents from the radiochemistry area go through HEPA filters prior to release to the environment. The Comply code is used to demonstrate compliance with 10

CFR Part 20 limits based on possession limits and/or material balance calculations. The synthesis area does not contain floor drains or hood cup sinks to reduce the potential for release to the sanitary sewerage system.

Environmental Assessment

10 CFR Part 51, Section 51.22, describes criterion for categorical exclusion (CATX) of licensing actions that would not require an environmental assessment (EA). Section 51.22(c)(14)(v) provides a CATX for the use of radioactive materials for research and development purposes.

Research and development licensees that release radioactive material to the environment will normally not need an EA and are covered under this CATX, **provided**:

- All releases originating on-site to the environment, such as air and liquid effluents, direct radiation from deposition of radioactive materials from the release (e.g., groundshine), comply with as low as reasonably achievable (ALARA) and 10 CFR Part 20 requirements.

  Releases from the radiochemistry area are through a common stack and HEPA filters. Releases are reduced to ALARA through use of traps at the point of generation. There are no floor drains or cup sinks in hoods to eliminate the possibility of inadvertent releases to the sanitary sewer. Liquids generated in the controlled area (e.g. mop water) are collected and analyzed prior to release to the sewer.

- To assist in demonstrating compliance with the requirements of 10 CFR Part 20, please set ALARA goals for air effluents at a modest fraction of the values in Appendix B, Table 2, Columns 1 and 2, to 10 CFR Part 20, Sections 20.1001-20.2401. Experience indicates that values of about 10 millirems per year from all radioactive air effluents should be practicable for almost all materials facility licensees (see Regulatory Guide 8.37). Therefore, as a first step toward demonstrating compliance with ALARA for radioactive air effluents, please demonstrate that the nearest member of the general public will receive no more than 10 millirems per year from all of Aptuit's radioactive air effluents (i.e., please demonstrate how Aptuit will meet the requirements of 10 CFR 20.1101(d)).

  Gaseous effluents are trapped/scrubbed at the point of generation. Particulates are captured in the HEPA filters. Projects are evaluated to determine if yields would be low (which would result in the potential for higher emissions). Projects with low yields are rejected. Possession limits and/or material balance calculations are used to demonstrate compliance with the public dose limit and the constraint on air emissions.

- All releases on-site comply with all applicable decommissioning requirements (e.g., decommissioning recordkeeping requirements pursuant to 10 CFR 30.35(g)) and current decommissioning policies.

  In accordance with 10 CFR 30.35(g) Aptuit will retain:

  1. **Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. The records will**

include any known information on identification of involved nuclides, quantities, forms, and concentrations.

2. **As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination.**
3. **A list contained in a single document and updated every 2 years, of the following:**
   - **All areas designated and formerly designated restricted areas**
   - **All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning**
   - **Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.**

In order to demonstrate that your program qualifies for a CATX, please demonstrate how Aptuit meets the above criterion.

As demonstrated above, Aptuit meets the criterion for a categorical exclusion from the requirement to perform an environmental assessment.

As was discussed during your visit on March 14, 2008, we have revised and are enclosing with this submittal, the entire license amendment request with attachments. We appreciated the opportunity to show you the radiosynthesis facility and to better explain the proposed activities.

Please let me know if additional information is needed.

Sincerely,

Clinton Gregg

Radiation Safety Officer

Enclosure

Aptuit, Inc.
NRC License Number 24-15595-01
Amendment Request
March 31, 2008
Control Number 316804

Table of Contents

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Attachment 1
Radioactive Material, chemical/physical form, maximum amount possessed, and purpose for which licensed material will be used

Item No.	5. a. Radioactive Material	5. b. Chemical/Physical Form	5. c. Maximum Amount Possessed
	A. H-3	Any	100 curie
	B. C-14	Any	100 curie
	C. S-35	Any	1.5 curie
	D. I-125	Any	70 millicurie
	E. I-131	Any	30 millicurie
	F. Ba-133	Sealed source	20 millicurie
	G. Cs-137	Sealed source	90 microcurie total, no single source to exceed 30 microcurie
6. Use	A. through C.	To be used for research and development as defined in 10 CFR 30.4 and to be used in the synthesis of radio-labeled organic chemicals.	
	D. and E.	To be used for research and development as defined in 10 CFR 30.4.	
	F.	To be used with Perkin Elmer liquid scintillation counter.	
	G.	To be used with Beckman Model 100C, 3801, LS6000L or equivalent liquid scintillation counter.	

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Attachment 2
Individuals responsible for radiation safety program
Item 7

Employee name	Isotope	Maximum Amount	Where experience was gained	Duration of experience	Type of use	Relevant Education & Training
Clint Gregg, RSO	C-14 H-3 MAFP EU Co-60 Cs-137 sources	60 Ci 100 Ci various	Aptuit, Inc. ChemSyn/EPPS US Navy	2007-08 1996-07 1989-1995	RSO, Safety & Environmental Compliance, shipping, waste packaging Radiological controls, primary system operational water chemistry, calibration & testing	Nuclear Power School and Nuclear Prototype Training Unit Machinist's Mate Nuclear Field "A" School Engineering Laboratory Technician School Operational Water Chemistry and Radiological Controls School IATA - Federal Express Air Transportation of Dangerous Goods Training HAZWOPER - Hazardous Materials Technician Course for Chemical Spill and Release Response DOT - Lion's Department of Transportation Hazardous Materials Training

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Employee name	Isotope	Maximum Amount	Where experience was gained	Duration of experience	Type of use	Relevant Education & Training
Scott Peterson	C-14	< 100 mCi	Aptuit, Inc. Quintiles-MMD Deserett Polymer Research	2006-08 1985-2006 1984-85	Analytical operations	McCrone Research Institute-working on certification in Applied Chemical Microscopy Avila University-currently working on Secondary Education Certification in Science University of Cincinnati, Ohio, 18 credit hours towards M.S. Degree in Chemistry B.S. in Chemistry and Biology, Wilmington College, Wilmington, Ohio
Andrew Damon	C-14 TC-99 Cu-64/67	<575 mCi < 10 mCi < 25 mCi	Aptuit, Inc. Quintiles ABC UMKC	2006-08 2004-05 1997-02 1991-97	Analytical –HPLC, LSC, TLC (E-Fate studies)	Graduate School, Department of Chemistry-Inorganic Chemistry, 1997, and conducted research on radiopharmaceuticals, University of Missouri, Columbia, Missouri. 1991 B.S., Chemistry, Southwest Baptist University, Bolivar, Missouri. 1992

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Employee name	Isotope	Maximum Amount	Where experience was gained	Duration of experience	Type of use	Relevant Education & Training
Michael Sadick	C-14 H-3 S-35 I-125	1.0 mCi 1.0 mCi 1.0 mCi 5.0 mCi	Aptuit, Inc. Eli Lilly & Co. Genetech Completed Aptuit Radiation Training 2008;Annual refresher	2007- 2001-2007 1991-2001	Analytical –HPLC, LSC, TLC (E-Fate studies)	Ph.D., Immunology, University of Washington, Seattle, Washington.1985 M.S., Immunology, University of Washington, Seattle, Washington.1982 B.A. Biology, Johns Hopkins University, Baltimore, Maryland.1979

Employee name	Isotope	Maximum Amount	Where experience was gained	Duration of experience	Type of use	Relevant Education & Training
Mike Marx, Ph.D.	C-14 H-3	Up to 3 Ci Transfer of 10 Ci	Aptuit, Inc. ChemSyn/EPPS Completed initial ChemSyn Radiation Training 1991; Annual refresher	2007-08 1987-2007	Custom chemical synthesis	B.A., Chemistry, Avila College, Kansas City, Missouri. 1979 B.S., Medical Technology ,Avila College, Kansas City, Missouri. 1980 Board of Registry, American Society of Clinical Pathology.1980 M.S., Medicinal Chemistry, University of Kansas, Lawrence, Kansas. 1983 Ph.D., Medicinal Chemistry , University of Kansas, Lawrence, Kansas. 1985 Visiting Instructor, Research Assoc., University of North Carolina, Chapel Hill. 1985-87

Employee name	Isotope	Maximum Amount	Where experience was gained	Duration of experience	Type of use	Relevant Education & Training
John Goehl	C-14 H-3	Up to 4 Ci Up to 3 Ci	Aptuit, Inc. ChemSyn/EPPS Completed initial ChemSyn Radiation Training 1991; Annual refresher	2007-08 1990-2007	Custom chemical synthesis	B.S., Chemistry, Barry University, Miami Shores, Florida, 1987 M.S., Chemistry, Mount Allison University, Sackville, New Brunswick, Canada, 1990
David Leuck	C-14 H-3	Up to 2 Ci Up to 1 Ci	Aptuit, Inc. ChemSyn/EPPS Completed initial ChemSyn Radiation Training 1991; Annual refresher	2007-08 1989-2007	Custom chemical synthesis	B.S., Chemistry/Biochemistry, Oklahoma State Univeristy, 1982 M.S., Orgainic Chemistry, Iowa State University, "Organopalladium Approaches to Cyclic Compounds,", 1987

Employee name	Isotope	Maximum Amount	Where experience was gained	Duration of experience	Type of use	Relevant Education & Training
Rocky Gipson	C-14 H-3	Up to 2 Ci Up to 1 Ci	Aptuit, Inc. ChemSyn/EPPS ViTrax Radiochemicals Completed initial EPPS Radiation Training 2004; Annual refresher	2007-2008 2004-2007 2003-2004	Custom chemical synthesis	Ph.D. in Chemistry, University of California, Irvine, 2003. B.S. in Chemistry, California State University Fresno, 1992.
Patrick Kirchhoefer	C-14	Up to 3 Ci	Aptuit, Inc. ABC Laboratoires University of Missouri-Research Assistant Completed initial EPPS Radiation Training; Annual refresher	2007-2008 2003-2007 1997-2003	Custom chemical synthesis	Ph.D. , Organic Chemistry, 2004, University of Missouri, Columbia, Missouri B.S., Chemistry, 1997, Truman State University, Kirksville, Missouri

Employee name	Isotope	Maximum Amount	Where experience was gained	Duration of experience	Type of use	Relevant Education & Training
David Ebert	C-14	Up to 1 Ci	Aptuit, Inc. ChemSyn/EPPS Completed initial ChemSyn Radiation Training 1991; Annual refresher	2007-08 1986-2007	Custom chemical synthesis	B.S., Chemistry, 1073, Kansas State University A.A. 1967,Kansas City, Kansas Junior College
Brad McKinnis	C-14 H-3	Up to 1 Ci Up to 1 Ci	Aptuit, Inc. ChemSyn/EPPS Monsanto/Pfizer Completed initial EPPS Radiation Training 2006; Annual refresher	2007-08 2006-2007 1992-2006	Custom chemical synthesis	Ph.D. Organic Chemistry 1992, University of Missouri, Columbia, Missouri B.S. Chemsitry,1986, Central State University, Warrensburg, Missouri

Employee name	Isotope	Maximum Amount	Where experience was gained	Duration of experience	Type of use	Relevant Education & Training
Jim Windels	C-14 H-3	> 100 mCi up to 2 Ci Up to 3 Ci	Aptuit, Inc. ChemSyn/EPPS Completed initial ChemSyn Radiation Training 1991; Annual refresher	2007-08 1987-07	Analytical operations	B.S., Chemistry, Kansas State University, 1970, Manhattan, Kansas Army Medical Department Officer Basic Course, Fort Sam Houston, Texas, 1971 Orientation to Medical Department Laboratories Course, Fort Sam Houston, Texas, 1971
John Davidson	C-14 H-3	< 10 mCi < 10 mCi	Aptuit, Inc. EPPS Completed initial EPPS Radiation Training 2005; Annual refresher	2007-2008 2002-2007	Analytical operations	B.S., Chemistry, Biology Minor, Buena Vista College, Storm Lake, Iowa 1988 Gas Chromatography workshop, Virginia Tech University, Blacksburg, VA, June 1993 Pharmaceutical Technical Exchange Association Meeting, Kansas City, MO, October 1999 Pharmaceutical Technical Exchange Association Meeting, Kansas City, MO, April 2002

Employee name	Isotope	Maximum Amount	Where experience was gained	Duration of experience	Type of use	Relevant Education & Training
Paul Robert Goddard	C-14 H-3	< 10 mCi < 10 mCi	Aptuit, Inc. ChemSyn/EPPS Completed initial ChemSyn Radiation Training 2006; Annual refresher	2007-2008 2006-2007	Analytical operations	B.S. Chemistry, University of Kansas, Lawrence Kansas
Peter Swan	C-14 H-3	Up to 100 mCi Up to 100 mCi	Aptuit, Inc. ChemSyn/EPPS Completed initial ChemSyn Radiation Training 2002; Annual refresher	2007-2008 2001-2007	Analytical synthesis	B.S., Biology, Southwest Missouri State University, Springfield, Missouri, 1998

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Employee name	Isotope	Maximum Amount	Where experience was gained	Duration of experience	Type of use	Relevant Education & Training
Hari Pennaka	C-14 H-3	Up to 2 Ci Up to 1 Ci	Aptuit, Inc. EPPS ViTrax Radiochemicals Completed initial EPPS Radiation Training 1991; Annual refresher	2007-2008 2006-2007 2005-2006	Custom chemical synthesis	Ph.D. , Organic Chemistry, Sri Venkateswarea University, Tirupati, India M.S., Industrial Chemistry, Barkatullah University, Bhopal, India B.S. Chemistry & Biology, Sri Venkateswara University, Tirupati, India
Murali Ukkalam	C-14 H-3	Up to 500 mCi Up to 500 mCi	Aptuit, Inc. Shire Pharmaceuticals Completed initial EPPS Radiation Training 2007; Annual refresher	2007-2008 2006-2007	Custom chemical synthesis	Ph.D. Synthetic Orgainc Chemistry, 1996, Indian Institute of Chemical Technology, Hyderabad, India. MS. Organic chemistry, S.V. University, Tirupati, India. 1990

Aptuit purchased EaglePicher Pharmaceutical Services LLC in August of 2007. ChemSyn Science Laboratories changed their name to Eagle Picher Pharmceutical Services LLC in 2003.

Quintiles refers to time worked as Quintiles, Hoechst Marian Rousell, Marion Merrell Dow, & Merrell Dow.

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Attachment 3
Training for individuals working in or frequenting restricted areas

Item 8.	RPP Section VI, "Training"

Occupationally Exposed Workers
Prior to beginning work with radioactive materials, employees must complete a formal radiation safety training program commensurate with their assigned duties. The training program will consist of the following topics:

- Radiological Fundamentals
- Biological Effects
- Radiation Detection and Measurement
- Principles of Radiation Protection
- Regulatory Requirements
- Aptuit Radiation Safety Program

Radiation safety training will be followed by a quiz. A score of 80% is required for successful completion of the training program.

In addition, employees will be given on-the-job training in safe handling procedures specific to their work areas. This training will be documented.

New employees with limited experience must work under the supervision of an authorized user. An initial evaluation of the employee's ability to work safely with radioactive materials will be conducted after three months of supervised work. Evaluations will continue monthly thereafter or until the authorized user is confident of the new employee's ability and understanding of NRC regulations, license provisions and Aptuit-specific safety procedures. The following criteria will be used to evaluate new employees with limited experience with radioactive materials:

- Completed Aptuit radiation safety training
- Read and understood Aptuit's Radiation Protection Program Manual
- Follows good contamination control procedures
- Observes postings
- Dons and doffs PPE correctly
- Frisks and performs surveys correctly and as required
- Follows waste minimization methods

Refresher training is conducted whenever major changes are made in the RPP or in regulations which affect the radiation protection aspects of the work. Refresher training is conducted at least annually.

The Aptuit Radiation Protection Program Manual will be available to all employees working with radioactive materials or radiation-producing machines.

	Ancillary Personnel Ancillary personnel such as maintenance, housekeeping and security whose duties require them to enter posted radioactive materials areas must receive radiation awareness training prior to entering the labs. This training will cover locations of use, health risks, and elements of radiation protection. This training will be provided under the direction of the RSO. Refresher training for ancillary personnel will be required at least every two years.

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Attachment 4
Facilities and Equipment

Item 9.	No laboratory or area at Aptuit will be used for the storage or use of radioactive materials without review by the RSC and prior approval by the NRC. Facilities and equipment must be sufficient to ensure the safe use of the isotopes, quantities, and activities planned. All research and development laboratories used for radioactive materials conform to minimum standards that require impervious lab bench tops and laboratory ventilation with one pass air. Fume hoods or other containment will be available as needed. Laboratory flooring is constructed for easy decontamination, i.e. either made of impervious material or is designed for easy removal of small sections. The RSC will review and submit to the NRC for approval significant modifications in facilities or equipment that may impact the radiation safety of employees, the public, or the environment. In evaluating areas for consideration for use or storage of radioisotopes, the RSC will consider the isotopes, quantities and procedures to be used and the administrative and engineering controls needed to work safely with the materials. Radiosynthesis operations will take place in a portion of the second floor of B Building. This area includes restricted access, a change room, and an isolated laboratory exhaust system with HEPA filtration which exhausts through a single stack. The synthesis area is at a negative air pressure with respect to surrounding areas. Diagrams of Aptuit laboratory areas are included in Attachment 5. Also see RPP Section IX, "Procedures for Working with Radioactive Materials", subsection "Authorized Facilities"

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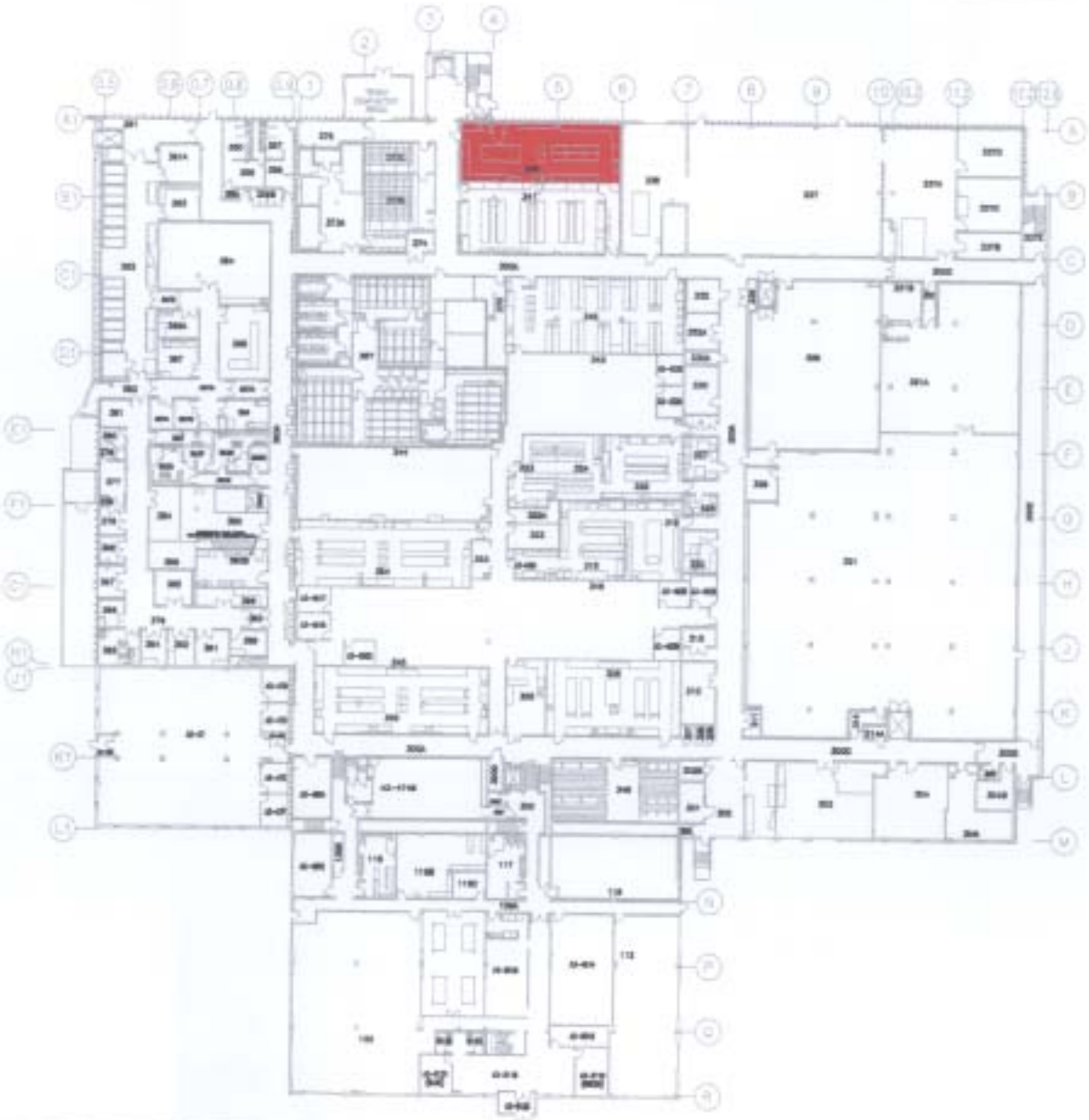
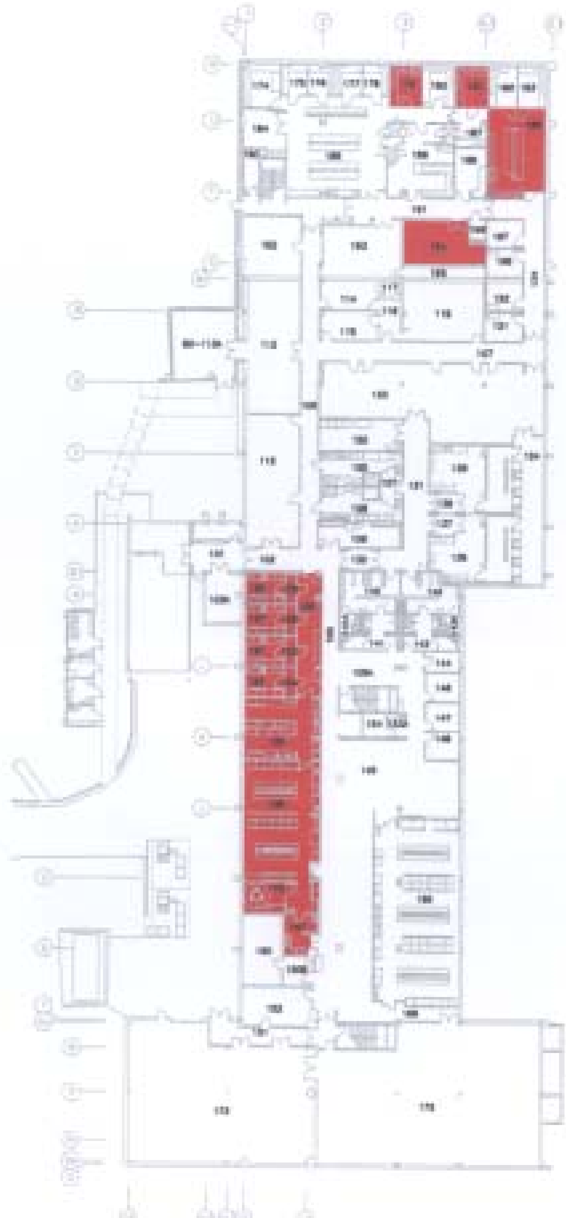
Attachment 5
Facility Diagrams[1]

RD-101	Building A – Level Three - current radioactive material areas
RD-102	Building B – Level Two – current and proposed radioactive material area
RD-103	Buildings B & E – Level Three –current radioactive material areas
AC-B01 HVAC Schematic	Building B – Level Two – Synthesis area HVAC schematic drawing
Synthesis area floor plan	Building B – Level Two – Synthesis area floor plan

[1] Red shaded areas are current radioactive material use areas with the exception of the some of the areas on drawing RD-102. Labs 155-167 and 170 on drawing RD-102 comprise the proposed synthesis area. The addition or removal of radioactive material use and storage areas will be done in accordance with Aptuit's USNRC Materials License.



aptuit	Aptuit 13248 Hickman Mills Drive Kansas City, MO 64137
RADIATION DRAWING BUILDING A - LEVEL THREE	
NONE	S.W. KELLER RDHLDGA-L3-1
1	RD-101



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RADIATION DRAWING
BUILDING B - LEVEL TWO

NONE	S.W. KELLER	RD-BLDG-B-L2-1
2	RD-102	

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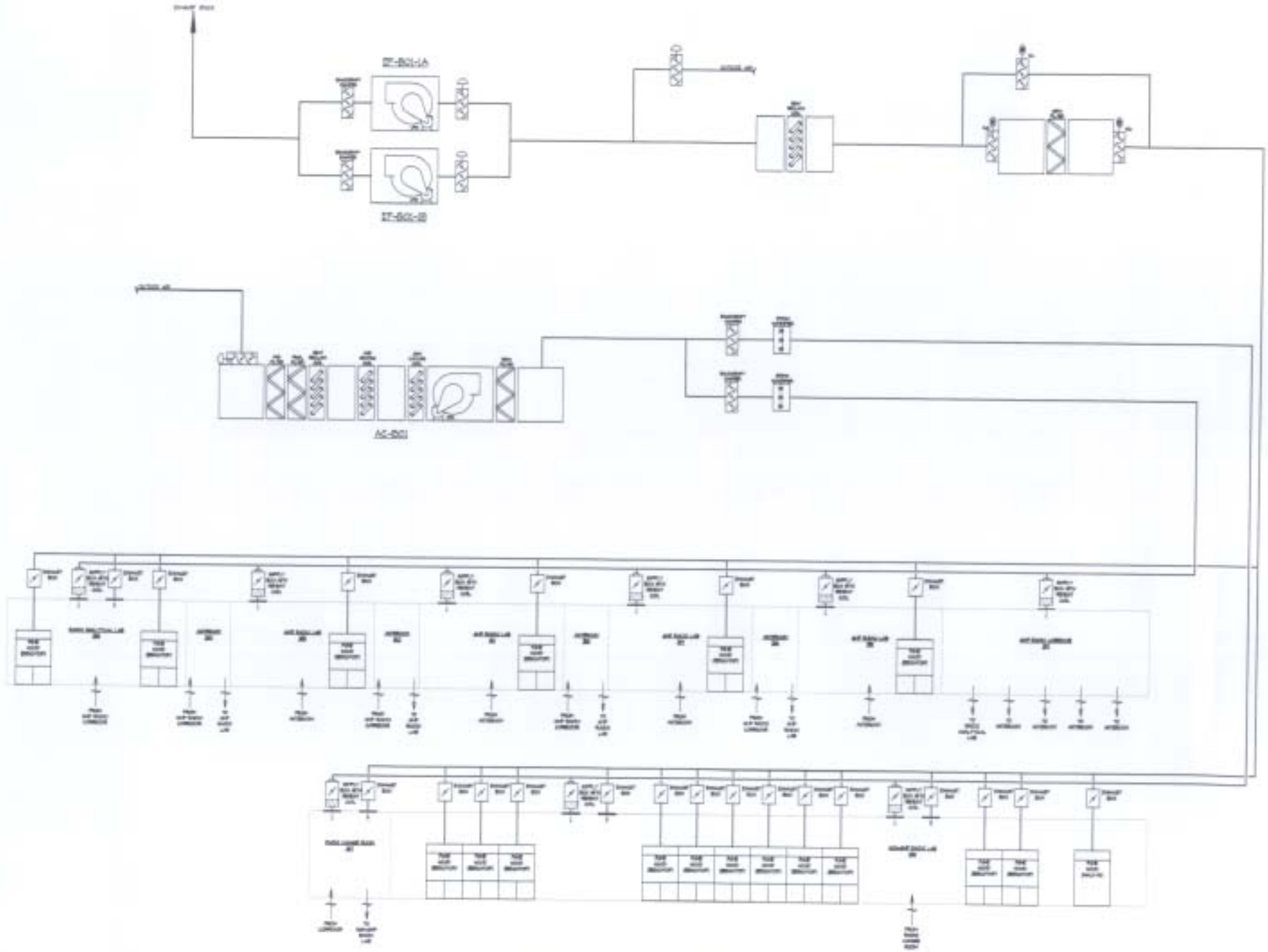
Aptuit
10245 Hickman Mills Drive
Kansas City, MO 64137

RADIATION DRAWING
BUILDING B & E - LEVEL THREE

NONE	B.W. KELLER	RD-BLDG-BE-L3-1
3	RD-103	



① AC-B01 HVAC SCHEMATIC

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Attachment 6
Radiation Safety Program and Waste Management

Item 10.	The Aptuit Radiation Protection Program Manual (Revision 4) is included as Attachment 7. The RPP may be revised only if: a) The changes are reviewed and approved by the RSC and the NRC; b) The affected staff is provided training in the revised procedures prior to implementation; c) The changes are in compliance with NRC regulations and the license; and d) The changes do not degrade the effectiveness of the program.
Item 11.	Waste management procedures are found in Section X of the Aptuit Radiation Protection Program Manual. The RPP is included as Attachment 7.

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Attachment 7
Radiation Protection Program Manual

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APTUIT RADIATION PROTECTION PROGRAM MANUAL

I. PURPOSE

This Radiation Protection Program (RPP) establishes safe work practices for protection against ionizing radiation hazards. Adherence to this program will ensure compliance with Federal and State regulations and provide for the radiological safety of employees, the general public, and the environment.

II. POLICY

It is the policy of Aptuit to perform all work involving radioactive materials in accordance with applicable Nuclear Regulatory Commission (NRC), Environmental Protection Agency (EPA), Missouri Department of Natural Resources (MDNR), and Department of Transportation (DOT) regulations, as well as any site license requirements. All work involving radiation-producing machines is to be performed in accordance with MDNR regulations.

It is the policy of Aptuit to ensure that exposures to personnel and the environment are maintained below the applicable standards and to a point that is as low as reasonably achievable (ALARA).

III. SCOPE

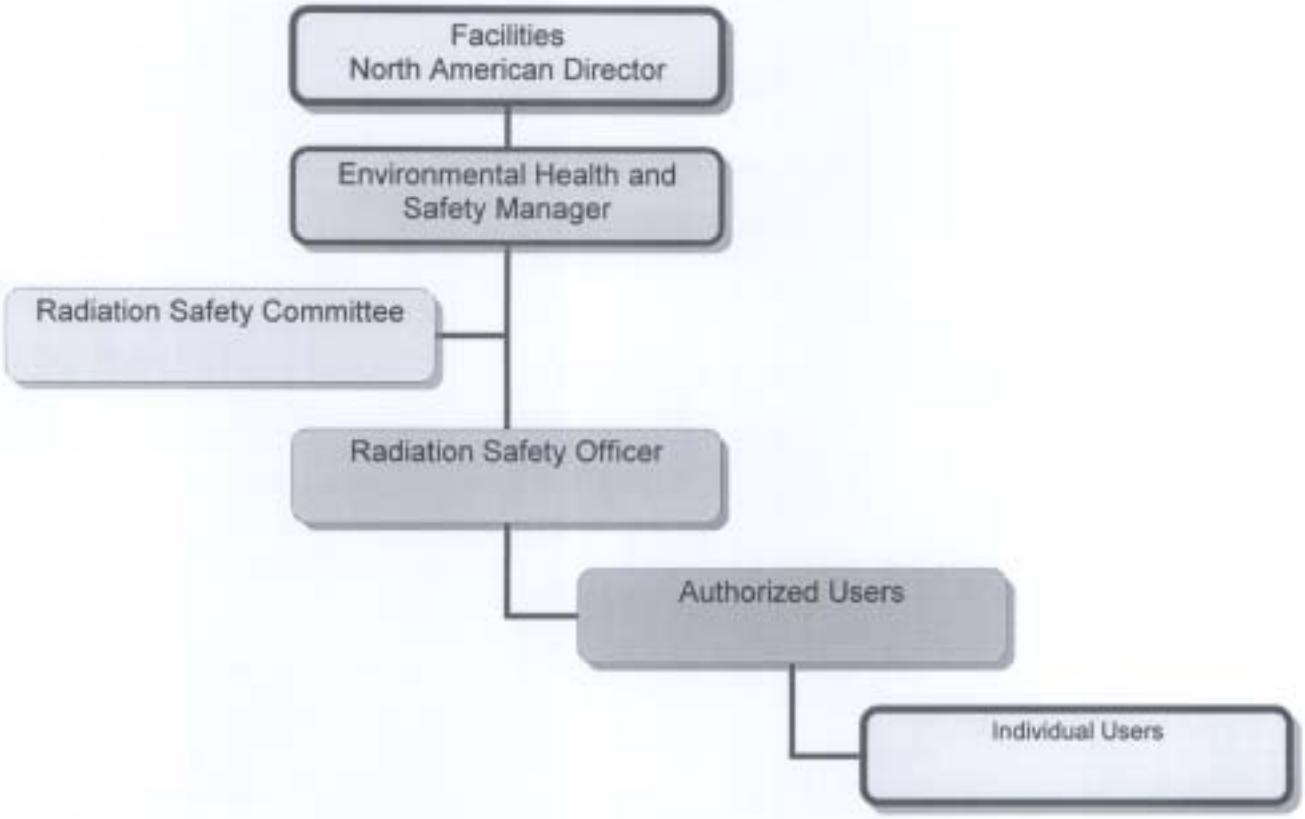
This RPP applies to all individuals who use radioactive materials at the Kansas City, Missouri (KCM) site.

IV. TABLE OF CONTENTS

V. RESPONSIBILITIES

Radiation Safety Organization

Aptuit operates the KCM radiation safety program under the guidance of the Facilities North America Director and the Environmental Health and Safety (EH&S) Manager. The Radiation Safety Officer (RSO) reports to the EH&S Manager. A Radiation Safety Committee (RSC) oversees the uses of radioactive materials at the KCM facilities. The radiation safety organization is represented in the following diagram:



Radiation Safety Officer (RSO)

The RSO is approved by the NRC and is responsible for the overall management of the radiation protection program, including implementation of ALARA principles. The RSO is responsible for:

a) Recommending policies for the control of radiation sources and determining compliance with procedures, rules, regulations, and license conditions through periodic audits.

b) Maintaining an accurate and up-to-date radioactive materials license and all required records including records that demonstrate compliance with limits on dose to the public.

c) Providing consultation to personnel on all aspects of radiation protection, including overseeing the radiation safety training program.

d) Maintaining personnel monitoring program, including the maintenance of exposure records and notification of employees, their supervisors, and Health Services.

e) Coordinating periodic surveys, monitoring of all sources and working areas where radionuclides are used or stored and maintaining records of all such surveys. Ensuring all radiation detection instruments are calibrated.

f) Coordinating order, receipt, storage, processing, shipping, disposal, and recordkeeping for all radionuclides, including sealed sources to ensure that licensed material is limited to the types and quantities of byproduct material authorized by the license.

g) Maintaining an inventory of all radioisotopes possessed under the license and maintaining the security of such.

h) Registering and tracking sealed sources. This includes coordinating leak tests on all sealed sources and recordkeeping for all such tests.

i) Coordinating the waste disposal program, with the assistance of the Environmental Specialist, including the maintenance of waste storage and disposal records.

j) Reviewing radiation incidents and providing advice on decontamination procedures. Instituting corrective actions to prevent similar incidents.

k) Serving as the point of contact and providing assistance in case of emergency (e.g., fire, etc.) to ensure that proper authorities are notified promptly in case of accident or other incidents that may involve the release or loss of licensed material.

l) Terminating any unsafe condition or activity that is found to be a threat to public health and safety or property.

Radiation Safety Committee

The RSC consists of the Facilities Director, the EH&S Manager, the RSO, and senior managers from each group using radioactive materials. Additional members may be assigned to serve by the RSC. The EH&S Manager serves as the committee chairman. Four members, including the RSO, must be present to constitute a quorum.

The responsibilities of the RSC include:

a) Perform, or cause to be performed, the annual review of the content and implementation of the radiation protection program.

b) Review proposed uses of radioactive materials and radiation producing equipment, radioactive material use and disposal procedures, and license amendment requests.

c) Review significant modifications in facilities or equipment that may impact the radiation safety of employees, the public, or the environment prior to submittal to the NRC for approval.

d) Review and recommend proposed users of radioactive material based on the training and experience requirements described below.

e) Provide technical advice to the Radiation Safety Officer (RSO).

f) Provide input for radiation safety training.

g) Review employee exposures and the ALARA program.

h) Review incident reports and reports of violations of radiation safety procedures and regulatory requirements.

Users

All employees using radioactive materials, working in areas where radioactive materials are used, or handling such materials are to be knowledgeable of appropriate safety and handling procedures.

Attendance at Aptuit Radiation Safety Training will be mandatory regardless of prior experience, as a prerequisite for approval to handle radiation sources.

There are two classes of users: Authorized and Individual.

Authorized Users: Those employees who have been officially authorized to use radioisotopes by the NRC. Authorized users must meet minimum requirements including an undergraduate degree with major coursework in the sciences, or equivalent work experience, and a combination of 40 hours training and hands-on experience working with radioactive materials. Employees qualified to be authorized users will submit the appropriate supporting information and documentation to the RSC prior to approval.

Individuals Users: Individuals who do not have the education, experience, and training required to be an authorized user may perform studies utilizing radioisotopes only when the studies are conducted under the supervision of an authorized user and with the prior approval of the RSO.

Authorized users are responsible for:

a) Ensuring that the RPPM and guidelines for the safe use of radioisotopes and radiation-producing machines are adhered to within their areas of responsibility.

b) Planning for radiation safety prior to beginning an experiment or procedure. This may include: outlining the procedure, identifying appropriate safety precautions to be taken to keep exposures and releases ALARA, and, when appropriate, perform a "dry run" of the procedure using non-radioactive materials.

c) Instructing those employees, for whom they are responsible, in the use of safe techniques and in the application of approved radiation safety practices and ensuring attendance at required radiation safety courses.

d) Notifying the RSO whenever major changes in operational procedures, new techniques, or new operations might lead to personnel exposure.

e) Complying with regulations governing the use of radioactive materials or radiation-producing machines.

f) Notifying the RSO prior to the purchase of any radioactive material, device containing radioactive material, or radiation-producing machine.

g) Report any incidents involving radionuclides or radiation-producing machines to the RSO in a prompt manner.

h) Preparing and updating, on a biennial basis, a *Background and Experience Handling Radioactive Materials* form (example as Attachment A).

All users (Authorized and Individual Users) are responsible for:

a) Understanding and abiding by all posted notices and safety regulations, for utilizing all appropriate protective measures, and for keeping exposure to radiation as low as possible.

b) Wearing prescribed monitoring devices and participating in bioassay procedures as directed by the RSO.

c) Completing Initial Radiation Safety Training prior to working with radioisotopes or a radiation-producing machine.

d) Maintaining good personal hygiene and keeping the laboratory neat and clean.

e) Labeling and isolating radioactive waste and equipment. Once used for radioactive substances, equipment should not be used for non-radioactive work until demonstrated free of contamination (see **Contamination Limits**).

f) Ensure area/equipment is free of contamination[1] (see Table 3) when requesting maintenance work.

g) Reporting any incident involving a radioactive material or radiation producing machine to his/her supervisor and the RSO.

h) Carrying out decontamination procedures when necessary, and taking the necessary steps to prevent the spread of contamination to other areas.

Health Services

Health Services is responsible for:

a) Implementing the long-range health program.

b) Scheduling the annual physical examinations for personnel working with radioactive materials.

c) Scheduling exit physicals for employees who have been in the personnel monitoring program upon termination of employment or transfer to other duties, when practicable.

d) Reviewing personal monitoring reports, keeping copies of exposure records as part of the employee's medical file and investigating any abnormal exposure.

VI. TRAINING

Occupationally Exposed Workers

Prior to beginning work with radioactive materials, employees must complete a formal radiation safety training program commensurate with their assigned duties. The training program will consist of the following topics:

- Radiological Fundamentals
- Biological Effects
- Radiation Detection and Measurement
- Principles of Radiation Protection
- Regulatory Requirements
- Aptuit Radiation Safety Program

Radiation safety training will be followed by a quiz. A score of 80% is required for successful completion of the training program.

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[1] For C-14 and normal laboratory conditions using a pancake Geiger-Mueller (PGM) detector, an instrument reading of 2X the background count rate would indicate that contamination is present. See footnote "a" to Table 3.

In addition, employees will be given on-the-job training in safe handling procedures specific to their work areas. This training will be documented.

New employees with limited experience must work under the supervision of an authorized user. An initial evaluation of the employee's ability to work safely with radioactive materials will be conducted after three months of supervised work. Evaluations will continue monthly thereafter or until the authorized user is confident of the new employee's ability and understanding of NRC regulations, license provisions and Aptuit-specific safety procedures. The following criteria will be used to evaluate new employees with limited experience with radioactive materials:

- Completed Aptuit radiation safety training
- Read and understood Aptuit's Radiation Protection Program Manual
- Follows good contamination control procedures
- Observes postings
- Dons and doffs PPE correctly
- Frisks and performs surveys correctly and as required
- Follows waste minimization methods

Refresher training is conducted whenever major changes are made in the RPP or in regulations which affect the radiation protection aspects of the work. Refresher training is conducted at least annually.

The *Aptuit Radiation Protection Program Manual* will be available to all employees working with radioactive materials or radiation-producing machines.

Ancillary Personnel

Ancillary personnel such as maintenance, housekeeping and security whose duties require them to enter posted radioactive materials areas must receive radiation awareness training prior to entering the labs. This training will cover locations of use, health risks, and elements of radiation protection. This training will be provided under the direction of the RSO.

Refresher training for ancillary personnel will be required at least every two years.

VII. RADIOACTIVE MATERIAL ACCOUNTABILITY AND CONTROL

Aptuit will maintain accountability and control of licensed material sufficient to ensure that:

a) License possession limits are not exceeded;

b) Material balance can be used for emission calculations;

c) Licensed material in storage is secured from unauthorized access or removal;

d) Licensed material not in storage is maintained under constant surveillance and control;

e) Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.

f) Records of receipt, transfer, and disposal of licensed material are maintained by the RSO.

Procurement of Radionuclides

a) All purchase order requests for radioactive materials will be submitted to the RSO. Such requests should contain the name of the radioisotope, chemical form, activity in appropriate units (e.g. millicuries (mCi) or curies (Ci)), supplier, and person responsible for its use. The RSO must approve the order before it can be placed.

b) The RSO ensures the amount of radioactive material does not exceed amounts specified by the NRC License. For a copy of the NRC license, contact the RSO.

c) All shipments of radionuclides will be directed to the RSO or designee.

Security of Licensed Material

Unauthorized access to licensed material is accomplished by the use of multiple security features.

a) A chain link fence with barbed wire and gated entrances surrounds the perimeter of the Marion Park Campus, which includes the entire Aptuit KCM facility. The perimeter is patrolled by Security. There are two gate entrances. The entrances are manned by security personnel during normal working hours (6 AM-6 PM). During non-working hours the gates are closed and the campus can only be accessed with an electronic badge system. The gates and entrances are monitored by remotely operated closed-circuit television (CCTV) with viewing monitors located in the security console. The CCTV is recorded.

b) Building Entry: All entrances to the buildings are controlled by electronic badge readers. After hour entry requires a PIN in addition to the electronic badge. Building entrances are monitored by CCTV.

c) Areas where radioactive materials are used or stored have restricted access by badge readers.

Receipt of Packages Containing Radioactive Materials

a) All packages containing radioactive materials are picked up by the RSO (or designee) at the designated dock.

b) The RSO (or designee) will examine, survey, and open each package containing radioactive materials in accordance with established procedures.

c) Packages will be opened as soon as possible after receipt in accordance with established procedures.

Storage and Transportation of Radioactive Materials

a) All radioactive materials shall be stored in suitably shielded containers. The exposure to radiation, 3 inches from the walls of any container shall not exceed 1 mrem per hour.

b) All stock sources, when not in use, shall be stored in designated control storage areas of the Radioisotope Laboratories and shall be secured from unauthorized access or removal.

c) The transportation of all radioactive materials between laboratories or buildings must be done in a primary and secondary container. When transporting solutions, the cases must be leak proof and should contain sufficient absorbent material to absorb the entire solution.

d) All containers of radioactive material must be appropriately labeled with the isotope, compound name, activity, user's name, and any other relevant information available. Containers should be identified as containing radioactive material by the words "Radioactive Material", "Radioactive", or the radiation symbol.

Off-Site Shipping

a) All off-site shipping of radioactive materials will be done under the guidance and approval of the RSO (or designee).

b) The shipment will be packaged to meet U. S. Department of Transportation (DOT) or International Air Transportation Association (IATA) regulations. Packages must be surveyed and swiped to ensure that radiation and contamination levels are within acceptable limits prior to shipment. The RSO will provide guidance on the shipping requirements on a case-by-case basis.

c) The RSO (or designee) will contact the receiving site to notify them of the shipment. The RSO (or designee) will ensure that the shipment is in compliance with all applicable DOT and/or IATA regulations.

d) A Material Safety Data Sheet (MSDS) for the cold drug substance must be shipped with all samples of radio-labeled drug substance.

e) The RSO must possess a copy of the license, or otherwise verify that the receiving facility is authorized for receipt of the type, form and quantity of material being transferred, prior to shipment.

VIII. OCCUPATIONAL DOSE

Occupational Dose Limits

Radiation exposure limits have been established by the NRC as an upper limit on doses to which workers may be exposed. Assuming that all radiation exposure carries some risk, Aptuit has adopted the policy of maintaining all exposures as far below these upper dose limits as is reasonably achievable. This policy is known as ALARA.

Occupational exposure limits are found in Title 10 Part 20.1201 of the Code of Federal Regulations (10 CFR 20.1201). Exposure limits for adults and for the embryo/fetus of a declared pregnant woman are given below:

OCCUPATIONAL ANNUAL DOSE LIMITS

THE LESSER OF THE TOTAL EFFECTIVE DOSE EQUIVALENT	5 REM (0.05 SV) OR
THE SUM OF THE DEEP-DOSE EQUIVALENT AND THE COMMITTED DOSE EQUIVALENT TO ANY INDIVIDUAL ORGAN OR TISSUE	50 REM (0.5 SV)
EYE DOSE EQUIVALENT	15 REM (0.15 SV)
SHALLOW DOSE EQUIVALENT TO THE SKIN OR ANY EXTREMITY	50 REM (0.5 SV)
DOSE TO THE EMBRYO/FETUS OF A DECLARED PREGNANT WOMAN	0.5 REM (0.005 SV) DURING ENTIRE PREGNANCY

Declared Pregnant Worker

The NRC limits fetal radiation dose received as a result of a pregnant worker's occupational exposure to 500 mrem in the gestation period. For this limit to apply, the regulation requires the woman to declare pregnancy in writing and give the estimated date of conception. If a woman chooses not to declare her pregnancy, the normal occupational dose limit of 5,000 mrem per year would be in effect with the provision to maintain occupational radiation exposure ALARA.

A radiation worker who decides to declare a pregnancy would do so by submitting a Declaration of Pregnancy form or equivalent (Attachment B) to the RSO, Health Services, and her immediate supervisor. The Declaration of Pregnancy form and any dose records to the embryo/fetus are maintained with those of the declared pregnant worker (DPW). When pregnancy is declared in writing, an evaluation will be

performed by the RSO to determine the potential for the employee to exceed the regulatory exposure limit during the nine-month gestation period. The individual's potential exposure and their job functions will be reviewed by Health Services, Environmental Health and Safety (EH&S), and management. Recommendations on minimizing radiation exposure may be made on an individual basis after this evaluation. A DPW may revoke her declaration of pregnancy by submitting a letter to the RSO; however the lower dose limit for the embryo/fetus will no longer apply.

External Dose Monitoring

The RSO will determine the need for and type of personnel dosimetry in accordance with applicable NRC regulations and guidance documents (e.g. NUREG-1556, Vol. 7, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope). The personnel dosimetry program shall be conducted through a dosimetry provider that is accredited by the National Voluntary Laboratory Accreditation Program (NVLAP).

It is the responsibility of employees who are assigned personnel dosimetry devices to wear and store them in accordance with the instructions of the RSO. Dosimetry reports will be reviewed by the RSO. Monitoring records will be maintained as part of the employee's health file. Employees will be notified of any exposures recorded above the dosimeter's minimum measurable quantity. A summary of the annual results will be provided to each employee participating in the personnel monitoring program.

Internal Dose Monitoring

Employees who routinely work in radiosynthesis will submit weekly urine samples. Other employees using ^{3}H, ^{14}C, ^{35}S, ^{125}I, or ^{131}I, at the levels indicated in Table 1 will be required to participate in the bioassay program as determined by the RSO. The RSO will determine participation in the bioassay program based on the amount and form of the isotope, type of use, control methods and in accordance with applicable NRC Regulatory Guides. Users are required to notify the RSO before using radionuclide form/activity combinations exceeding those in Table 1. Scheduling of bioassay tests will be coordinated through the RSO. In addition, appropriate bioassay may be performed whenever an internal exposure to radioactive materials is suspected.

Records of all monitored employee exposures are maintained by the RSO and also as part of the employee's permanent health record.

Table 1 - General guidelines for internal dose monitoring

Nuclide	Form	Use Level[2]	Frequency	Method
^{3}H	HTO and tritiated compounds	>100 mCi at one time	Within 4 to 72 hours following use	urinalysis
^{14}C	Monoxide	>50 Ci[3]	Within 24 to 72 hours following use	urinalysis
	Dioxide	> 5 Ci[3]		
	Compounds	> 50 mCi[3]		
^{35}S	vapor	>250 mCi[3]	Within 24 to 72 hours following use	urinalysis
^{125}I, ^{131}I	Volatile	>1 mCi open room or bench >10 mCi in fume hood >100 mCi in glove box	Within 24 to 72 hours following use	Thyroid count
	Bound to nonvolatile agent	>10 mCi open room or bench >100 mCi in fume hood >1000 mCi in glove box		

Public Dose

NRC regulations (10 CFR 20.1302) require demonstration of compliance to the 100 millirem (mrem) annual dose limit to the public. In addition, 10 CFR 20.1101(d) establishes a constraint on air emissions such that the individual member of the public likely to receive the highest dose shall not be expected to receive a total effective dose equivalent from air emissions in excess of 10 mrem per year.

Aptuit will demonstrate compliance with the public dose limit and the constraint on air emissions on an annual basis using methods described in NRC regulatory guidance documents. These methods may include calculation or measurement of emissions. In addition, Aptuit will establish and maintain levels for gaseous and liquid effluents ALARA.

IX. PROCEDURES FOR WORKING WITH RADIOACTIVE MATERIALS

Standard Laboratory Practices

[2]The quantities also apply to the cumulative amount handled during a one month period.

[3] Based on handling 25 times the ALI at one time or cumulative over 1 month.

The following standard laboratory practices will be followed for work with radioactive materials in the absence of procedures for specific operations and/or areas. Specific procedures that are developed shall be sufficient to maintain exposures ALARA. Specific procedures shall be approved by the RSC.

a) The areas and equipment within a laboratory where radioactive materials are used should be clearly marked, (i.e., with radioactive material warning tape at the work site) or labeled.

b) Secondary containment and/or absorbent paper should be used with radioactive materials that have the potential to cause contamination. After the completion of an experiment, the paper will be removed for appropriate disposal (i.e. disposal as radioactive waste if it is contaminated).

c) After completion of the experiment and removal of potentially contaminated disposable material (e.g. absorbent paper), the area will be surveyed for possible radioactive contamination using appropriate survey procedures (e.g. a Geiger counter equipped with a pancake-probe (PGM) for ^{14}C, a thin-window scintillation crystal for ^{125}I, or by collecting and counting wipe samples for ^{3}H). The results of the survey will be documented on the Survey Log (Attachment C).

d) If contamination is found on surfaces or equipment greater than the limits in Table 3, decontamination must be performed and the area resurveyed after decontamination.

e) Glassware that may have been in contact with radioactive material must be appropriately labeled and decontaminated or discarded in the radioactive waste at the completion of the experiment.

f) Disposable gloves must be worn when handling radioactive materials or wiping areas.

g) Laboratory coats must be worn at all times when using radioactive materials and should not be worn outside the radioisotope laboratory area.

h) Mouth pipeting is strictly prohibited in all laboratories.

i) Smoking, eating, drinking, and applying makeup or contact lenses is prohibited in all areas where radioisotopes are used or stored.

j) Applications that use volatile radioisotopes or are likely to produce aerosols will be restricted to approved enclosed areas, i.e., fume hoods, metabolism cages, or biobubbles. Volatile radioisotopes should not be used in a biological safety cabinet without prior approval by the RSO.

k) Gloves must be removed and discarded prior to handling uncontaminated items, such as drawer pulls, telephones, door handles, Geiger counters, etc.

l) All solid radioactive waste will be double bagged and placed in **Clearly Labeled Containers.** Also, liquid waste will be stored in appropriate **Clearly Labeled Containers.**

m) The need for shielding and/or remote handling devices must be determined prior to the start of a project. Consult with the RSO for guidance on shielding or remote handling devices.

n) After completion of work with radioactive materials (with the exception of ^{3}H), personnel must frisk with an appropriate instrument (e.g. PGM or thin NaI) for possible contamination prior to leaving the laboratory.

o) All employees must wash their hands prior to leaving the laboratory.

p) The Survey Log will be filled out after completion of contamination surveys. The Survey Log must be sent to the RSO at the end of each month.

q) Employees shall use the principles of time, distance and shielding wherever possible to keep external doses ALARA.

Procedures for work with radioactive materials may be revised only if:

a) The changes are reviewed and approved by the RSC;

b) The affected staff is provided training in the revised procedures prior to implementation;

c) The changes are in compliance with NRC regulations and the license; and

d) The changes do not degrade the effectiveness of the program.

Radiological Areas and Posting

Radiological area definitions and posting/labeling requirements throughout Aptuit facilities will be as described in 10 CFR 20.1003 and 10 CFR 20, Subpart J--Precautionary Procedures. All personnel permitted unescorted access to the radiologically restricted areas of the facilities are trained in recognition of posting/labeling during radiation safety training.

NRC Form 3, "Notice to Employees", shall be posted in prominent locations where it may be seen by those engaging in licensed activities. The "Notice to Employees" form will include a notice stating that "Copies of the regulations in 10 CFR 19 and 20; the license, license conditions, or documents incorporated into the license by reference, and amendments thereto; and operating procedures applicable to licensed activities are available from the RSO."

Authorized Facilities

No laboratory or area at Aptuit will be used for the storage or use of radioactive materials without review by the RSC and prior approval of the NRC. Facilities and equipment must be sufficient to ensure the safe use of the isotopes, quantities, and activities planned. All research and development laboratories used for radioactive materials conform to minimum standards that include impervious lab bench tops and laboratory ventilation with one pass air. Fume hoods or other containment will be available as needed. Laboratory flooring is constructed for easy decontamination, i.e. either made of impervious material or is designed for easy removal of small sections.

In evaluating areas for use or storage of radioisotopes, the RSC will consider the isotopes, quantities and procedures to be used and the administrative and engineering controls needed to work safely with the materials.

Approved laboratories will be conspicuously identified by distinctive signs supplied by the RSO. These signs will bear the standard radiation symbol and appropriate wording as required by regulation (see **Radiological Areas and Posting**). Any specific entry requirements or restrictions will be posted (e.g. Shoe covers and lab coats required for entry, Authorized Personnel Only, etc.) at the entrance to laboratories and areas approved for radioactive material use or storage. These signs will not be affixed or removed from any area without the permission of the RSO.

Once a laboratory or area has been approved for radioactive material use it becomes subject to the survey requirements found in **Radiation Safety Surveys** of this RPP. If the use of a laboratory for radioactive materials is to be terminated, prompt notification of the RSO is required. Area and equipment surveys may be required by the RSO prior to an area being decommissioned as a radioisotope use or storage area as described in **Contamination Surveys**. Contamination limits for areas and equipment are found in Table 3.

Radiation Monitoring Instruments

Aptuit will maintain an adequate number of calibrated instruments for the types and levels of radiation present.

Table 2 - Radiation detection instruments available at Aptuit

Type of Instrument	Radiation Detected	Sensitivity Range	Window Thickness	USE
Survey meter with pancake G-M detector (PGM)	beta, gamma	X.1, X1, X10 0-5K cpm or 0-5 mR/hr	1.7 +/-.03 mg/cm²	Contamination surveys

Type of Instrument	Radiation Detected	Sensitivity Range	Window Thickness	USE
Alarm Ratemeter with PGM	Beta , gamma	0 - 500 cpm, X1, X10, X100, X1k	1.7 +/-.03 mg/cm²	Personnel contamination monitoring
Inspector (G-M)	beta, gamma	0-300K cpm .001-1000 mR/hr	1.5-2.0 mg/cm²	Contamination surveys
Liquid Scintillation Counter	beta	NA	NA	Removable contamination, waste and product assays
Ion chamber or microR meter	gamma	0 – 5000 mR/hr	NA	Exposure rate, package surveys
Low energy gamma detector	Low energy gamma	0 - 500 cpm X1, X10, X100, X1000	18.4 mg/cm²	I-125 surveys
Large area gas proportional detector	Alpha, beta	X1, X10, X100, X1000 0 - 500 cpm,	0.4 – 0.8 mg/cm²	Contamination surveys

Portable survey instruments are calibrated annually or after repair by persons authorized by the NRC, an Agreement State, or a licensing State to perform that service. Calibration records are maintained in the radiation safety files. Fixed laboratory instruments used for analysis of samples are checked for satisfactory performance pursuant to vendor instruction manuals.

Instruments used for radiation detection/measurement may be upgraded as necessary at the discretion of the RSO.

Radiation Safety Surveys

Aptuit will perform radiation safety surveys that are sufficient in scope to assess the radiation hazards to workers and the public. These surveys will consist of dose-rate and contamination surveys, as appropriate, in and adjacent to locations where radioactive materials are used or stored. The RSO will determine the types, locations and frequency of radiation safety surveys in accordance with current guidance documents (e.g. NUREG-1556, Vol. 7, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope). The RSO maintains records of radiation safety surveys. General guidelines for performing surveys are presented below.

Dose-rate Surveys

Dose-rate surveys may be performed in areas where external exposure hazards are present. In general, dose-rate surveys should be performed if radiation levels

could result in doses in excess of 500 mrem per year or where the dose rate in the area could exceed 2.5 mrem per hour. The frequency of dose-rate surveys will depend on the type, quantity and use of radioactive materials, as well as the controls that are in place to protect workers and members of the public from external exposure to radiation.

Contamination Surveys
Contamination surveys are performed to evaluate radioactive contamination that could be present on building surfaces, fixtures, laboratory furniture, equipment and personnel. Contamination surveys may consist of measurements of total contamination by direct reading instruments and/or removable contamination by wipe survey.

Routine contamination surveys are performed in and adjacent to areas where radioactive materials are used or stored. The RSO will determine the type, locations, and frequency of routine surveys depending on the radionuclides, quantities and type of use. Wipe tests will be performed in the immediate areas of benches, hoods, doors, equipment, etc. where radioactive material is handled. Storage areas, waste disposal areas, floors, and other locations where inadvertent contamination is likely to occur will also be wiped. Sufficient wipes will be collected to provide an accurate profile of the area.

Guidelines for the frequency for performing routine contamination surveys are below.

- Weekly routine surveys will be performed in and adjacent to radiosynthesis areas and monthly in R&D areas.

- Users will perform daily surveys in radiosynthesis areas and at project completion in R&D areas.

Results will be recorded on the Survey Log. If contamination is found on surfaces or equipment greater than the limits in Table 3, the user responsible for the laboratory will carry out corrective measures as recommended by the RSO. The area will be resurveyed after decontamination. If decontamination is not possible, the area shall be clearly marked and the RSO notified.

Sealed sources, such as the ^{63}Ni foils contained in electron capture detector of gas chromatographs, will be tested for leakage at the interval specified in the license.

Contamination Limits
Acceptable surface contamination limits for equipment and for building surfaces are found in Table 3. Contamination found in unrestricted areas should be promptly decontaminated to background levels. If background levels are not achievable then the contamination level must not exceed the limits in Table 3.

Potentially contaminated facilities and equipment must be decontaminated to levels below those in Table 3 to be acceptable for unrestricted release. In

addition, contamination levels should be reduced to ALARA prior to release. Facilities that are to be decommissioned and removed from the NRC license must meet the requirements of 10 CFR 20, Subpart E--Radiological Criteria for License Termination.

Table 3 - Acceptable Surface Contamination Levels (based on NUREG-1556, Vol. 11)

Nuclide	Average[a, b]	Maximum[a, c]	Removable[a, d]
^{3}H, ^{14}C, ^{32}P, ^{35}S	5,000 dpm/100 cm^2	15,000 dpm/100 cm^2	1,000 dpm/100 cm^2
^{131}I	1,000 dpm/100 cm^2	3,000 dpm/100 cm^2	200 dpm/100 cm^2
^{125}I	100 dpm/100 cm^2	300 dpm/100 cm^2	20 dpm/100 cm^2

[a] As used in this table, dpm (disintegration per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation. For example for ^{14}C, using published efficiency for a PGM detector (5%) with a 15 cm^2 probe and a background count rate of 40 cpm, it is possible to detect <5000 dpm/100 cm^2 with the probe stationary and <13,000 dpm/100 cm^2 while scanning. Under these conditions, a reading of 2X background is approximately 5000 dpm/100 cm^2.

[b] Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

[c] The maximum contamination level applies to an area of not more than 100 cm^2.

[d] The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

Airborne Radioactivity Surveys

Air sampling and/or monitoring is performed based on the potential for release of significant quantities of airborne radioactive materials into the workplace. The need for and type of air monitoring is determined on a case-by-case basis using current guidance documents.[4]

Emergency Procedures

In the event of an accident involving the release of significant quantities of radioactive material, the objectives of all remedial actions are:

a) Minimizing personal exposure to radioactive materials, including surface contamination, absorption through the skin, ingestion, inhalation, or through any wounds.

[4] Current guidance as of this RPP revision include Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992, and NUREG-1400, "Air Sampling in the Workplace," dated September 1993.

b) Removing any radioactive contamination on personnel.

c) Preventing the spread of contamination from the area of the accident.

d) Decontamination and clean up of the spilled material.

Personnel Decontamination

The following procedures should be followed if contamination is detected on an individual, his/her clothing, or belongings.

a) The individual who detects the contamination should immediately advise his coworkers, supervisor, and the RSO.

b) Any contaminated clothing must be removed before determining the level of skin contamination.

c) Contaminated areas of the skin must be washed thoroughly with copious amounts of water, being careful not to abrade skin. Any area of the body found to have significantly higher levels of contamination will be initially spot cleaned with soap and water to prevent the spread of contamination. Care should be taken to ensure that localized contamination is not spread to other areas during the washing process. Hands should be washed with soap and water with special attention to the areas between fingers and around fingernails.

d) All affected areas will be monitored after washing. The above procedures will be repeated if monitoring indicates the presence of skin contamination.

e) If the radiation is still excessive, more powerful decontamination procedures will be initiated after consultation with the RSO and Health Services.

ALL incidents involving personnel contamination must be reported to Health Services and the RSO.

Minor Spills

Most spills in the laboratory will involve only minor quantities of radioactivity (microcurie to millicurie quantities). In these cases, the person responsible for the spill will follow the procedure outlined below:

a) Notify persons in the area that a spill has occurred.

b) Wash hands if they are contaminated as a result of the accident. Put on disposable gloves to prevent contamination of the hands.

c) Cover liquid spill with absorbent material to limit the spread of contamination. If solids are spilled, dampen the paper and then cover the spill.

d) Notify maintenance to shut off ventilation equipment if airborne contamination is suspected. This can be done by calling Security at extension 1500.

e) Mark off contaminated area and restrict traffic to the area.

f) Do not allow anyone to leave contaminated area without first being monitored to be sure they are not contaminated.

g) Notify the RSO of the incident.

h) Start decontamination procedures as soon as possible. Cleaning agents normally used in the lab should be adequate. Start at the periphery of the contaminated area and work inward, systematically reducing the contaminated area.

i) Place all contaminated disposal materials into doubled, plastic bags for disposal.

j) Assign a person equipped with an appropriate survey meter to follow the work and to watch for the accidental spread of contamination. Survey the area around the spill and check hands, clothing, and shoes for contamination.

Major Spills or Releases

a) In the event of fire, explosion or other incident resulting in a major release of airborne radioactivity, all affected personnel in the immediate area will be notified to evacuate. After reaching a safe location, report the event by calling Security at extension 1500. The RSO will be notified by Security.

b) Notify the laboratory supervisor.

c) Block off or isolate the incident area.

d) Notify maintenance to shut off ventilation equipment. Radioactive hoods with isolated exhaust systems and equipped with exhaust filters can remain in operation.

e) Survey all persons involved in the emergency. Follow decontamination procedures for any personnel found to be contaminated.

f) Survey the area to determine protective devices needed for decontamination.

g) Decontamination will be conducted under the direction of the RSO.

h) A detailed report of any incident involving radioactive materials will be prepared by the laboratory supervisor using the site accident report form. An

incident investigation will be conducted under the direction of the RSO to identify causes and take corrective actions to prevent recurrence.

After-Hours Incidents Involving Radioactive Materials

In the event that radioactive material is spilled or found leaking after-hours, the following steps will be taken:

a) Security will immediately notified to block or close off the area involved to prevent the spread of contamination.

b) The RSO and the employee responsible for that lab will be contacted by Security.

c) No attempt to clean up the spill will be made by unauthorized personnel. The RSO and the authorized user will be responsible for defining decontamination procedures.

X. WASTE MANAGEMENT

Authorized users are responsible for the initial identification and segregation of waste.

The packaging, storage and disposal of radioactive waste will be conducted under the supervision of the RSO and/or the Environmental Specialist. The user will label all waste for pick-up with the following information:

a) Radioisotope
b) Total activity in appropriate units (e.g. microcuries, millicuries, curies, etc.)
c) Authorized user's name

Waste that does not contain this information will not be picked up and the user will be notified.

Current waste streams and disposal methods are described below. However, waste streams and/or disposal options may change and the disposal methods may be revised if:

a) The changes are reviewed and approved by the RSC;
b) The affected staff is provided training in the revised methods prior to implementation;
c) The changes are in compliance with NRC regulations and the license.

Disposal guidelines are contained in Attachment D.

Waste Types

Solid Waste

Dry solid waste, such as gloves, paper towels, dry test tubes, etc., are collected in plastic bags or metal cans which are kept in hoods. Activity assigned to the bag or should agree with that on the close-out sheets. When these bags or cans are full they are placed into appropriate, lined containers for pick-up. **NOTE: No free liquids or tubes with liquids can be placed into this container!** ^{3}H, ^{14}C, and short lived isotopes ($T_{1/2} \leq 120$ days) are segregated from all other isotopes. The log form is completed indicating radioactive material and activity added.

Liquid Waste

The RSO and/or Environmental Specialist should be contacted for pick-up of liquid waste. Upon pouring the waste into the container, the user will assign an activity based on assay or through process knowledge and keep a running total of the waste input until the container is full or otherwise ready for disposal. Liquid wastes generated at Aptuit falls into several categories with each having specific disposal options.

Liquid Scintillation Media (LSM): This includes biodegradable, nonhazardous LSM and flammable LSM. LSM is further classified for disposal based on the concentration of ^{3}H and ^{14}C. LSM containing ≤ 0.05 μCi ^{3}H or ^{14}C per gram of medium may be disposed without regard to the radioactive content. LSM that is flammable or that contains ≥ 0.05 μCi of ^{3}H or ^{14}C per gram of medium is collected in a DOT–approved, 55 gallon steel drum with 4 mil plastic liner in alternating 6 inch layers of vials and vermiculite. LSM that is nonhazardous and contains ≤ 0.05 μCi of ^{3}H or ^{14}C per gram of medium are collected in a DOT-approved, 55-gallon drum with a plastic liner. The LSM must be clearly identified as to classification.

Tritiated Water: ^{3}H water waste (tritiated water) may be solidified with Portland cement or other solidification agents for disposal.

Aqueous Liquid Waste: Water-based radioactive wastes (with the exception of tritiated water) will be transferred to the RSO and/or Environmental Specialist for proper disposal.

Non-aqueous Liquid Waste: EPA listed liquids containing radioisotopes will be accumulated in appropriate containers depending on the waste characteristics. The waste may be segregated by isotope and by waste type (e.g. ^{3}H pump oil) as directed by the RSO and/or Environmental Specialist. When the waste container is full it is then transferred for proper disposal.

Other Radioactive Wastes

Contact the RSO or the Environmental Specialist for information on collection of waste streams not identified above.

Waste Disposal

Decay-in-Storage

a) Waste material with a physical half-life of less than 120 days may be held for decay-in-storage before being disposed of as non-radioactive waste. Each isotope must be collected separately.

b) All material held for decay-in-storage will be allowed to decay a minimum of 10 half-lives.

c) Prior to disposal, radioactivity will be monitored with an appropriate survey meter to ensure activity at container surface is indistinguishable from background radiation levels. All radiation labels will be removed or defaced prior to disposal. Dry waste can be placed into medical waste containers.

Accumulation of Wastes for Transfer to Off-Site Disposal Facility or Extended Interim Storage Pending Off-Site Disposal

a) Contaminated wastes and LSM with isotopes with physical half life $\geq$ 120 days, are accumulated in suitably marked waste containers and stored in the radioactive waste storage area.

b) Records are maintained for each disposal drum showing the category of material, the isotope(s), and total activity.

Disposal by Release into Sanitary Sewerage Systems

Sanitary Sewer discharge will only be done by the RSO (or designee). Sink disposal logs will be maintained. The date, initials, radioactive material, and quantity disposed (in appropriate units such as μCi), must be recorded at the time of any sink disposal.

Attachment A

APTUIT, INC.

BACKGROUND AND EXPERIENCE HANDLING RADIOACTIVE MATERIALS

Please print or type:

Name: _____ ID:_____ SSN:_____ DOB:_____
Gender: _____ Department: _____ Cost Center: _____
Job Title: _____Supervisor:_____
Extension: _____ Mail Stop: _____ Email: _____

Please list training received in radioactive materials handling and/or protection:

Topic	Location	Duration	Formal or On-the-Job?

Please list your experience working with radioactive materials:

Radionucleide	Amount (mCi)	Chemical or Physical Form	Procedure or Technique*

Please list radionuclides you plan on working with and the procedures which will be used:

Radionuclide	Amount (mCi)	Chemical or Physical Form	Procedure or Technique*

*General category of experiment (e.g., RIA, DNA sequencing, etc.)

Signature: _____ Date:_____

Radiation Safety Use Only

Reviewed by: _____ Date: _____

Attachment B

FORM LETTER FOR DECLARING PREGNANCY

This form letter is provided for your convenience. To make your written declaration of pregnancy, you may fill in the blanks in this form letter or you may write your own letter.

DECLARATION OF PREGNANCY

To: Radiation Safety Officer

Health Services

_____ (Immediate supervisor)

In accordance with the NRC regulation at 10 CFR 20.1208, "Dose to an Embryo/Fetus," I am declaring that I am pregnant. I believe I became pregnant in _____(month and year).

I understand the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 0.5 rem (unless that dose has already been exceeded between the time of conception and submitting this letter). I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

_____,
(Your signature)

_____,
(Your name printed)

_____,
(Date)

Attachment C

SURVEY LOG

MONTH/YEAR: _____ LAB No. _____

DATE	ISOTOPE USED	METER ID	METER (CPM)	WIPES (DPM)	USER	AREA

Post in Laboratory. Send to RSO at the end of the month.

Attachment D

DISPOSAL GUIDELINES FOR RADIOACTIVE MATERIALS

To track isotope usage and disposal, waste disposal logs will be posted on all containers used to dispose of radioactive material. Isotope users are responsible for recording:

1. The date waste was added to the container.
2. The initials of the person disposing of the waste.
3. The isotope(s) and the material disposed of.
4. The activity of the waste (in μCi, mCi, or Ci) disposed of at each location.

Amounts of waste can be estimated by the following procedures:

DRAIN DISPOSAL: If the binding percentage of a radioassay is known, the total bound radioactivity can be subtracted from the total isotope used. For example, in a binding assay where 10% of the isotope is bound to the substrate, 90% of the total isotope added is disposed of by an appropriate means. If 10 μCi of isotope are added, 9 μCi remain unbound and are disposed of into the waste container.

SCINTILLATION VIALS: To estimate the activity in scintillation vials in μCi, use the following conversion equation:

$$\frac{(\text{CPM} \div \text{Efficiency}) \times \text{Number of Vials}}{2.22 \times 10^6}$$

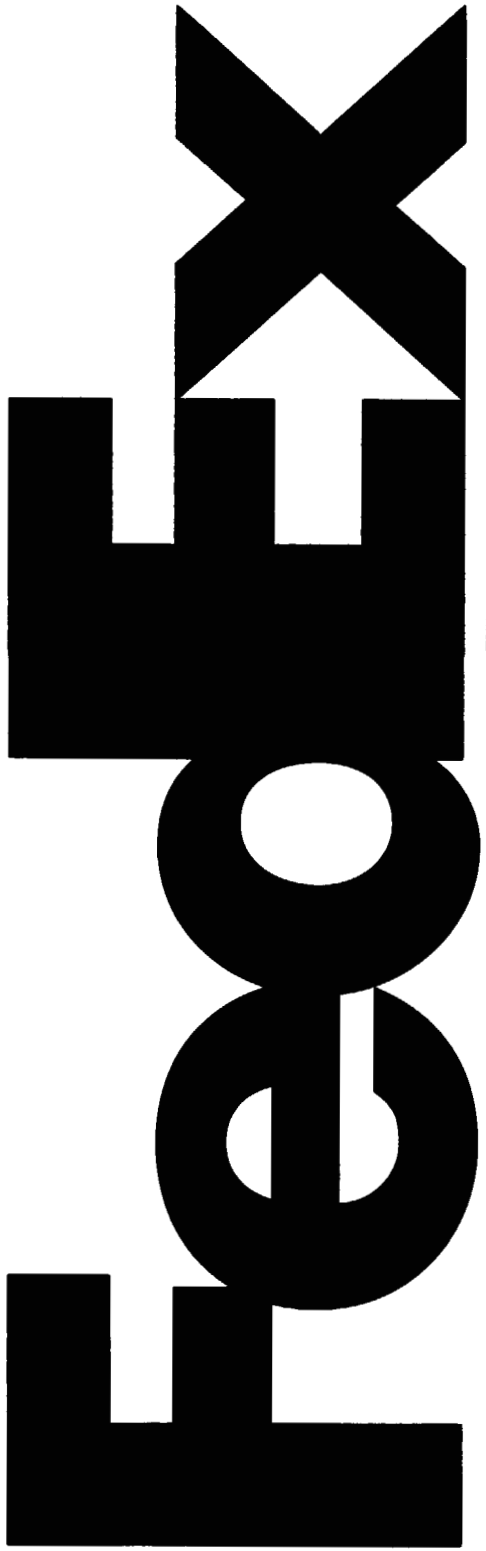
CPM = average counts per minute of vials
Efficiency = efficiency of counter (used to convert CPM to DPM)

If 96 vials with an average of 12000 CPM on a counter with 40% efficiency, the conversion to μCi is shown below.

$$((12000 \div 0.40) \times 96) \div 2.22 \times 10^6 = 1.3\ \mu\text{Ci}$$

NOTE – Vials containing more than 0.05 μCi/g are regulated and must be segregated into a separate drum. A vial containing 0.05μCi/g in 10-mL of scintillation fluid will have a count of approximately 1,111,000 DPM. A vial containing 0.05 μCi/g in 5-mL of scintillation fluid will have a count of approximately 555,000 DPM. Contact the RSO prior to generating large quantities of vials containing >0.05 μCi/g.

AQUEOUS LIQUIDS: A log of liquid radioactive waste must be kept for each container or jug. The log may be attached to or associated with the jug. Information to be included on the log includes: location of jug, name of radioactive material & isotope, activity of waste, and the initials of the person adding the waste.



The World On Time.

Small Box

For FedEx Express® Shipments Only

Align bottom of **Peel and Stick Airbill** or **Pouch** here.