



PHILIP MORRIS USA

P.O. BOX 26603, RICHMOND, VIRGINIA 23261 TELEPHONE (804) 274-2000

NMSB2

April 5, 2007

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

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030 37449
03620*

(45-00385-07)

RECEIVED
REGION 1
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SUBJECT: Application for new materials license

Dear Sirs:

Enclosed is a materials license application from Philip Morris USA for a new research facility. This facility will be called the Philip Morris USA Center for Research and Technology and will be situated at 706 East Leigh Street, Richmond, VA 23219.

Pursuant to NUREG-1556, Vol.7, Philip Morris USA desires a Limited Scope license for Research and Development. Also enclosed is a check for \$3,400 to process this amendment. Your expeditious attention to this license request is appreciated.

Please call me at (804) 274-2946 if you have questions.

Sincerely,

Joseph N. Tenhet
Radiation Safety Officer

140364

NMSS/RGN1 MATERIALS-002

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

U.S. NUCLEAR REGULATORY COMMISSION

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, NEOF-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.

APPLICATION FOR MATERIAL LICENSE

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

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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.

<p>1. THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input checked="" type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)</p> <p>Philip Morris USA, Inc. 615 Maury Street Richmond, VA 23224</p>
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<p>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p> <p>Philip Morris USA Center for Research and Technology 706 East Leigh Street Richmond, VA 23219</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>Joe Tenhet</p> <p>TELEPHONE NUMBER</p> <p>(804) 274-2946</p>
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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.

<p>5. RADIOACTIVE MATERIAL</p> <p>a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.</p>	<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>
<p>9. FACILITIES AND EQUIPMENT.</p>	<p>10. RADIATION SAFETY PROGRAM.</p>
<p>11. WASTE MANAGEMENT.</p>	<p>12. LICENSE FEES (See 10 CFR 170 and Section 170.31)</p> <p>FEE CATEGORY 3M AMOUNT ENCLOSED \$ 3,400.00</p>

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.

<p>CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE</p> <p>Charles L. Stiff, Director RD&E Administration</p>	<p>SIGNATURE</p> 	<p>DATE</p> <p>4/4/07</p>
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FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$	DATE	140364
APPROVED BY					

5. RADIOACTIVE MATERIAL

Radioisotope	Chemical/Physical Form	Maximum Possession Limit
H-3	Any	20 millicuries
C-14	Any	20 millicuries
P-32	Any	10 millicuries
P-33	Any	10 millicuries
S-35	Any	10 millicuries
Cr-51	Any	10 millicuries
I-125	Any / Bound, non-volatile	10 millicuries

6. PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

Licensed materials will be used in biomedical research and development. Examples of the types of research utilizing licensed materials include radioimmune assays, receptor binding studies, and biotransformation studies.

7. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

RADIATION SAFETY OFFICER

Mr. Joseph N. Tenhet will serve as the Radiation Safety Officer (RSO) on this license.

Mr. Tenhet is currently the RSO of specific license 45-00385-06 for sealed sources and fixed gauges. His training and experience are described in his attached resume (Attachment A).

The RSO will perform all applicable duties and responsibilities as outlined in NUREG – 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999.

AUTHORIZED USERS

In addition to the RSO, the following individuals will be Authorized Users, i.e., authorized to work unsupervised and to supervise others with radioactive materials:

Dr. Marc W. Farris
Dr. Mohammad R. Hajaligol
Dr. David B. Kane
Dr. Chengalrayan Kudithipudi
Dr. Diana McKinney
Dr. Michael J. Oldham
Dr. Ali. A Rostami
Dr. Rutger Van der Hoeven

These individuals, along with the RSO, will be responsible for the research performed under this license. Copies of their resumes (partial) are provided in Attachment A, emphasizing experience with the types of research proposed under this license. Absent appropriate training and experience, prior to requesting status as an AU, newly proposed AUs will sit for radiation safety training which will cover the following topics:

- Radiation Protection Principles
- Characteristics Of Ionizing Radiation
- Units Of Radiation Dose And Quantities
- Radiation Detection Instrumentation
- Biological Hazards Of Exposure To Radiation
- Review Of Procedures Describing Work With Licensed Materials

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Authorized Users and other laboratory personnel will occupy the laboratories and other areas where licensed material will be utilized and stored.

As described in item 7 above, the RSO will have received, at a minimum, 40-hours of radiation safety officer training. Authorized Users named on the license will have demonstrated radiation safety training and experience working with comparable types of radioactive materials as those proposed in this application. Other individuals with access to the posted areas will have previously had or will be provided initial radiation safety training by either the RSO or arranged for by the RSO. The training will be held prior to initiating work with licensed materials and will be commensurate with the individual's potential for work with and exposure to radioactive materials. Training will cover the same topics noted in Item 7 for authorized users, and will include a review of specific procedures including contamination control techniques, disposal of radioactive waste, and other appropriate topics related to the utilization of radioisotopes in biomedical research.

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Training will be provided prior to an individual's work with licensed material. Annual refresher training will also be provided. Documentation of training will be maintained by the RSO.

Radiation "Awareness" training will be made available to ancillary personnel who may have occasion to spend time in posted laboratories. The training will provide basic radiation safety instructions such that individuals will be capable of complying with appropriate elements of the radiation safety program.

9. FACILITIES AND EQUIPMENT

When completed, the Philip Morris USA Center for Research and Technology (CRT) will be a modern, multi-storied research facility employing several hundred persons. Work with radioactive materials will be limited to a relatively small fraction of those employees with the training and experience described in items 7 and 8 above. As shown on the floor sketches (Attachment B), licensed materials will be used in laboratories located on floors 4, 5, and/or 6. In addition to selected rooms in those areas, the Shipping and Receiving area and portions of the adjacent Employee Health and Safety (EHS) areas on the Lower Level of the CRT will be posted with CAUTION RADIOACTIVE MATERIALS. Packages containing radioactive materials will enter the CRT through the Shipping and Receiving area, and EHS will maintain a laboratory for counting samples (liquid scintillation counters) and a radioactive waste storage room.

The door to any laboratory utilized to store or work with licensed materials will be posted with a 'CAUTION RADIOACTIVE MATERIALS' posting. The NRC 'Notice To Employees' will be posted on a centrally located official bulletin board. At least one posted laboratory will contain a fume hood located in the portion of the lab designated for radioisotope work. It, too, will be labeled 'CAUTION RADIOACTIVE MATERIALS' and will be considered a part of the restricted area. Personal belongings such as coats, lunches, etc. will not be allowed in these areas. All research with licensed material will be done in the posted laboratories. Work surfaces will be covered with absorbent paper whenever licensed materials are used. Vials and other materials posing external radiation hazards will be shielded, as appropriate, with lead or other suitable materials. Philip Morris USA reserves the right to post additional laboratories as appropriate without submission of a license amendment. Laboratories will only be posted when requested by an Authorized User in an application to use radioactive materials following approval by the RSO.

Access to the restricted, or posted, areas will be limited to authorized persons. Employees will be provided card key access to the CRT, which will be staffed around the clock by security personnel. Access to the laboratories on floors 4, 5, and 6 will be limited to persons authorized to work in those rooms. Only approved persons will have card keys programmed to unlock doors to those areas. The doors to the EHS laboratory and the posted waste storage room will be locked when the rooms are unoccupied. Room key access will be provided only to persons authorized by the RSO or an AU.

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Packages with licensed materials will be delivered to Philip Morris USA at the address indicated on this license application. All packages will be delivered to the Shipping and Receiving dock. Shipping and Receiving personnel will be provided radiation safety awareness training such that they are able to recognize packages with licensed material. They will be instructed to immediately notify the RSO or the AU who ordered the material upon arrival of a package containing licensed material. Within not more than three business hours of receipt of licensed material, the RSO or his/her designee will perform the required package survey measurements detailed in the Radiation Safety Manual package receipt procedure. Following the survey, the package will be delivered to an appropriate, posted, storage area. The licensed material will be placed in an appropriately labeled, locked refrigerator, freezer, or cabinet.

Dry radioactive waste (e.g., lab diapers, gloves, paper towels, etc.) generated in the posted laboratories will be placed in labeled waste containers lined with plastic bags for either decay-in-storage or transfer to a licensed radioactive waste broker. When waste containers are full, waste will be transferred for storage to the posted waste storage area on the Lower Level (see attached sketch). Soluble liquid radioactive waste will be collected in plastic containers known as "carboys." When approximately $\frac{3}{4}$ full, carboys will be transferred to the waste storage area and held for either decay-in-storage, discharge to the sanitary sewer, or transfer to a licensed radioactive waste broker.

Given the radionuclides and activities requested in this application, the facility as constructed will be sufficient to ensure that the dose to individual members of the public from licensed operations will not exceed the limits of 10 CFR 20.1301 (0.1 rem in a year and no more than 0.002 rem in any one hour).

10. RADIATION SAFETY PROGRAM (see attached Radiation Safety Manual)

A. Audit Program.

Philip Morris USA will maintain a radiation safety program as outlined in NUREG – 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. As a part of the safety program, the licensee will review the content and implementation of its radiation safety program annually to ensure:

- a) compliance with NRC and DOT regulations and the terms and conditions of the license,
- b) occupational doses and doses to members of the public are ALARA, and
- c) records of audits and other reviews of program content are maintained for 3 years.

Audits will be conducted annually according to the outline of Appendix L, NUREG – 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999.

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B. Instruments

Philip Morris USA will use instruments that 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 Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary.

Several types of radiation detectors will be routinely used. Contamination monitoring will be performed with pancake GM detectors (Ludlum model 43-9 or equivalent) or thin window, thin crystal NaI detectors (Ludlum model 44-3 or equivalent) coupled to a ratemeter (Ludlum model 3 or equivalent). Dose rates will be determined with NaI detectors (Ludlum model 44-2 or equivalent) or energy compensated GM detectors coupled to appropriately calibrated ratemeters, or with portable ion chambers, pressurized ion chambers, or tissue equivalent plastic scintillators.

Detector/ratemeter pairs will be calibrated at intervals not to exceed 12 months at a licensed calibration facility. Calibration records will be maintained by the RSO.

The CRT will contain at least one liquid scintillation counter (LSC), to be obtained from Perkin Elmer, Beckman, or another reputable vendor. The LSC will be maintained by the RSO, assisted via a preventive maintenance contract with the manufacturer or qualified vendor. The LSC will be used to count wipe samples collected during contamination surveys of posted rooms. To support licensed activities at other PM USA locations, the CRT LSC may be used for leak test analysis of sealed source samples collected from these facilities.

If any need for contamination monitoring is warranted in the case of fire, accident, or incident involving licensed materials, additional instruments and procedures will be obtained as appropriate from facilities such as the Radiation Safety Academy and RSO, Inc., located in Gaithersburg, MD and Laurel, MD, respectively.

C. Material Receipt and Accountability

Philip Morris USA will maintain comprehensive records of all receipts, transfer, or disposal of licensed material to ensure cradle to grave accountability. Licensed materials will be maintained in secured areas, such as a posted laboratory with access limited via card keys issued only to authorized personnel. Material record-keeping will enable the RSO to demonstrate compliance with the license activity limits at all times. Physical inventories of sealed sources (should any be obtained in the future following receipt of an appropriate license amendment) will be conducted at intervals not to exceed six months. Inventory records will ensure that the possession limits stated in the license are not exceeded.

Inventory records will include:

1. Quantities of licensed material in source vials for each Authorized User.
2. Activity present in samples and labeled cells.
3. Activity in storage in the waste storage area.

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4. Date of the inventory.
5. RSO Signature.

D. Occupational Dose

Philip Morris USA 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.

Appropriate dosimeters will be procured from a National Voluntary Laboratory Accreditation Program (NVLAP) approved dosimetry vendor. They will be furnished to the RSO who will issue dosimeters to the appropriate personnel performing work with licensed materials. We anticipate providing both whole body and extremity dosimeters (ring badges) to personnel.

If internal exposure to any licensed material is suspected because of fire or other incident, then bioassay samples will be collected. Estimates of committed effective dose equivalent (CEDE) will be based on the urinalysis data. If responding to suspected intake of radioiodine, thyroid scanning may be implemented instead of urinalysis. Routine bioassay monitoring will not be required.

E. Safe Use Of Radionuclides and Emergency Procedures

Philip Morris USA has developed and will implement and maintain operating procedures for the safe use of licensed materials, including security of materials and emergency response procedures. Procedures are consistent with guidance contained in Appendix P, NUREG – 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Procedures may be revised only if 1) the changes are reviewed and approved by Philip Morris USA management and the RSO in writing; 2) Philip Morris USA staff is provided training in the revised procedures prior to implementation; 3) the changes are in compliance with the NRC regulations and the license; and 4) the changes do not degrade the effectiveness of the program.

F. Surveys

We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG – 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. No sealed sources will be listed on the license; therefore, leak tests will not be required. Should any sealed sources be added to our inventory in the future, leak tests will be conducted in compliance with the requirements stipulated on the appropriate sealed source and device registration certificates.

11. WASTE MANAGEMENT

We will use the Decay-In-Storage model waste procedures that are published in Appendix T to NUREG – 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999.

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**ATTACHMENT A
TRAINING AND EXPERIENCE OF THE PROPOSED RADIATION SAFETY
OFFICER AND AUTHORIZED USERS**

Joseph N. Tenhet - TRAINING AND EXPERIENCE

Formal Education:

Bachelor of Science, Civil Engineering, Virginia Military Institute, 1970, Lexington, Virginia

Master of Public Administration, Virginia Commonwealth University, 1983, Richmond, Virginia

Master of Public Health, Virginia Commonwealth University, 1998, Richmond, Virginia

Professional Courses and Seminars:

Radiation Safety Program Seminar, one day, Oct 1993, GPS Technology Inc.

Radiation Safety Officer's Course, one week, Nov 1-5, 1993, University of Texas Health Center

Radiation Safety Officer's Course, three day, Mar 28-30, 1994, Englehardt & Associates

Transportation of Radioactive materials – Packaging and Transportation of Excepted and Type A packages, four days, Hazardous Materials Advisory Council - Jun 1994 & Sep 2001

Work Related Experience:

RSO of Philip Morris USA Virginia operations since March, 1995.

Twenty years experience as an environmental engineer.

ABBREVIATED RESUME

Name: Marc W. Fariss, Ph.D.

Education: B.S. Biology, Lynchburg College, 1973

Ph.D. Pathology, Medical College of Virginia, Virginia Commonwealth University, 1980

Postdoctoral Fellow, Department of Biochemistry, Oregon State University, 1980-1984.

Laboratory and Radionucleotide Experience:

1976-1980 Graduate Student in Pathology, MCV/VCU, laboratory and radionucleotide experience including radiation safety course.

1980-1984 Postdoctoral Research Experience, Oregon State University, laboratory and radionucleotide experience.

1984-1995 Faculty member in Department of Pathology, MCV/VCU, laboratory and radionucleotide experience including radiation safety course.

1995-2003 Tenured faculty member in Department of Pharmaceutical Sciences, Washington State University, laboratory and radionucleotide experience.

2003-2006 Tenured faculty member in Department of Pharmaceutical Sciences, University of Colorado Health Sciences Center, laboratory experience.

MOHAMMAD R. HAJALIGOL
Exposure Group

EDUCATION MASSACHUSETTS INSTITUTE OF TECHNOLOGY, Cambridge, MA.
Ph.D. in Chemical Engineering, February 1981.

EXPERIENCE
2/88-present Sr. Principal Scientist, Philip Morris, Research Center, Richmond, VA.
Have various multi-disciplinary and cross-functional responsibilities. Activities included research on exposure and combustion physics/chemistry of ligno-cellulosic materials and bio-polymers. R&D and process commercialization for production of a composite heating substrate from energetic materials; synthesis and processing of ceramic materials; development and commercialization of a unique high temperature oxidation and corrosion resistant inter-metallic (FeAl) for structural application.

9/85-2/88 Research Engineer, MIT, Energy Lab, Cambridge, MA.
Conducted basic research on the combustion and pyrolysis of coals and biomass; thermal and catalytic destruction of poly-aromatic hydrocarbons (PAH); sulfur removal from flue gases for its environmental effects; kinetic/heat/mass transfer modeling of pyrolysis and combustion processes; health effects of biomass tars.

1/81-9/85 Faculty, Teheran, Iran.
Taught courses in thermo-fluids, heat and mass transfer, separation processes, petroleum refining engineering; supervised thesis in applied thermodynamics; coordinated university and industry relations.

Lab Skills Experimental research design; process design, development, and optimization at both pilot and commercial plants scales; familiar with the various analytical/thermal/ structural testing techniques such as GC/MS, TOFMS, HPLC, GPC, X-ray, SEM, TG/TD/DSC, gas adsorption, and tensile/creep/fatigue.

David B. Kane

Contact Information:

Work

Address: Research Development and Engineering
Philip Morris, USA
4201 Commerce Rd.
Richmond, VA 23234

Phone: 804-274-5778
Fax: 804-274-2468
E-mail: david.b.kane@pmusa.com

Education:

- Ph.D.**, Chemical Physics, Virginia Commonwealth University, 1997
Advisor: M. Samy El-Shall
Title of Dissertation: "Application of Resonant Enhanced Multiphoton Ionization to the Study of Ion Nucleation in Supersaturated Vapors "
- M.S.**, Physics, Virginia Commonwealth University, 1993
Advisor: M. Samy El-Shall
Title of Thesis: "Homogeneous Nucleation of Hydrogen Bonding Liquids"
- B.S.**, Physics, University of Richmond, 1986

Laboratory Work Experience:

- 2004 to present **Research Scientist**, Philip Morris USA, provided expertise in aerosol physics and aerosol characterization to support health science research, understand airway deposition of smoke and aerosols and determine exposure to smoke components.
- 2002 to 2004 **Research Associate**, Philip Morris USA Postdoctoral Research Program, developed and applied methods to study the dynamics of high concentration aerosols that exist over short time scales. Applied the principles of aerosol physics and chemistry to the development of reduced harm cigarettes.
- 1998 to 2001 **Postdoctoral Research Associate** with Dr. Murray Johnston, University of Delaware, developed instrumentation and methods to characterize nanoparticles with aerosol mass spectrometry. Utilized ^{210}Po and ^{85}Kr in aerosol neutralizer, trained in the use and handling of these radioactive sources.
- 1994 to 1997 **Graduate Research Assistant**, Virginia Commonwealth University, made measurements of nucleation rates and critical supersaturation for vapor phase nucleation using a diffusion cloud chamber. Developed experimental instrumentation and techniques to study the role of molecular properties of ions in ion-induced nucleation using multiphoton ionization in a diffusion cloud chamber.
- 1987 **Laboratory Technician**, Commonwealth Laboratories, Inc., Richmond, VA, used standard analytical methods to test waste water samples, and assisted in the collection of samples from industrial smoke stacks.

CHENGALRAYAN KUDITHIPUDI

Associate Research Scientist

Philip Morris USA

4201 Commerce Road

Richmond, VA 23234

Telephone: 804-274-5521

Email: Chengalrayan.Kudithipudi@pmusa.com

PROFESSIONAL EXPERIENCE

- 2006 – Present : Associate Research Scientist, Tobacco Research, PMUSA, Richmond, Virginia
- 2004 – 2006 : Post Doctoral Fellow, Tobacco Research, PMUSA, Richmond, Virginia
- 2000 – 2004 : Post Doctoral Fellow, Agronomy Department, University of Florida, Gainesville, Florida
- 1998 – 1999 : Post Doctoral Fellow, Botany Department, National Taiwan University, Taiwan

SKILLS

Radiation: Radiation training, hands on experience with ^{32}P and ^{33}P isotopes

Molecular Biology: DNA and RNA isolation; Southern, Western and Northern analysis; construction and screening of cDNA and genomic libraries; differential display and sequencing

Transformation: Over expression and RNAi vectors construction; *Agrobacterium* transformation, gene gun and electroporation; trait development and analysis of transgenic plants

Bioinformatics: Public database know how: Gene Bank, SWISS-PROT; Database searches like BLAST, FASTA; DNA/protein analysis software's like DNASTAR, gene ontology, ClustalW, Promoter-scan and ORF finder

Computer: Adobe Photoshop, Windows, Microsoft Office (Excel, Access, Word, Power Point, Exchange), Windows Explorer, and Visual Cloning

Instruments: Gene gun, GelDoc, SEM, Microtome, Sequencer and PhosphorImager

EDUCATION

Ph.D. (Biotechnology) : National Chemical Laboratory, India, 1997

Master of Science (Life Science) : Life Science, Pondicherry University, India, 1991

Bachelor of Science (Botany) : Botany Department, University of Madras, India, 1989

Diana Lynn (Cichewicz) McKinney, Ph.D.

Research Scientist

615 Maury St., OC-T3W, Richmond, VA 23224

Ph. (804) 274-5470 Fax: (804) 274-3489 Diana.L.McKinney@pmusa.com

Employment	Oct. 2004-present	Research Scientist – Sensory Research Philip Morris U.S.A.
	Jan. 2004-Oct. 2004	Postdoctoral Research Fellow – Sensory Research Philip Morris U.S.A. Postgraduate Research Program
	2000-2003	Postdoctoral Fellow Department of Pharmacology & Toxicology Virginia Commonwealth University

Education

Ph.D., Virginia Commonwealth University, Pharmacology/Toxicology

B.S. *cum laude*, University of Richmond, Biology Major/French Minor

Job Responsibilities/Skills

I am currently responsible for the design and implementation of pharmacological studies and assays regarding the health consequences of nicotine and smoking, in a company-wide effort to create reduced harm products. I am also responsible for creation of manuscripts and publication of data in scientific journals, and presentation of these data at international scientific meetings. I serve as a clinical research study coordinator at off-site locations, participating in all facets of the study process from proposal design to contract and budget negotiations to building equipment to monitoring medical staff during human trials to data evaluation and interpretation.

Skills: drug preparation and dilutions, small animal handling and injections, surgeries and brain dissections, behavioral testing (acute and chronic pain models), protein preparation and assays, Western immunoblotting, receptor binding, autoradiography, use of cryostat, spectrophotometer, Brandel harvester, BIOPAC system. Computer skills include, but are not limited to Microsoft Office (Word, Excel, PowerPoint), SigmaPlot, Cricket Graph, JMP, internet literature search via PubMed or Medline, Adobe Photoshop, ChemDraw, LabVIEW.

Professional Affiliations and Committees (selected)

- 2004-present Society for Research on Nicotine and Tobacco
- 2004-present VCU/MCV Alumni Association Board of Trustees
- 2002-present Central Virginia Chapter, Society for Neuroscience
- 2002-present College on Problems of Drug Dependence

Relevant Publications/Abstracts

Cichewicz, D.L., Cox, M.L., Welch, S.P., Selley, D.E. and Sim-Selley, L.J. (2004) Mu and delta opioid-stimulated [³⁵S]GTPγS binding in brain and spinal cord of polyarthritic rats. *Eur. J. Pharmacol.* **504: 33-38.**

Cannabinoid and Opioid Receptor Function in Arthritic and Non-Arthritic Rat Brain. D.L. Cichewicz, S.P. Welch and L.J. Sim-Selley. Virginia Academy of Sciences, May 2003.

ABBREVIATED RESUME

Michael J. Oldham, Ph.D.
Associate Principal Scientist
Exposure Group
Health Science Research

EDUCATION

Doctor of Philosophy, Environmental Toxicology, September 2001. Department of Community and Environmental Medicine, University of California, Irvine.

Masters of Science in Administration, June 1980. University of California, Irvine.

Bachelor of Science, Biological Sciences, December 1977. University of California, Irvine. Honors is Research; paper accepted for J. undergraduate Rsh.

RECENT ACADEMIC EXPERIENCE:

Assistant Researcher, Department of Community and Environmental Medicine, University of California, Irvine, July 2002 to February 2007. Major research interest is inhalation toxicology with an emphasis in particulate dosimetry (human and animal) and tobacco smoke particulate. Funding has included new investigator award, and awards from Health Effects Institute, American Cancer Society, and the U.S. Environmental Protection Agency.

Safety Training:

University of California, Irvine - Laboratory safety (basic and advanced), chemical hygiene plan, bloodborne pathogen exposure control plan, and radiation safety class.

Radioisotope Use:

Radiolabeled aerosols (^{139}Ce , ^{99}Tc , ^{54}Mn , ^{51}Cr , ^{85}Sr , ^{21}Sc) in microcurie amounts for determination of deposition in hollow models of human tracheobronchial airways.

Radiolabeled aerosol (^{51}Cr) also used in microcurie amounts to determine the effect on particle clearance of various exposures of selected air pollutants in rats.

PUBLICATIONS (resulting from above work):

Rasmussen, R.E., Mannix, R.M., Oldham, M.J., Phalen, R.F. Effects of nitrogen dioxide on respiratory tract clearance in the ferret, *J. Toxicol. Environ. Health*, 41:109-120, 1994.

Oldham, M.J. Mannix, R.M. and Phalen, R.F. Deposition of monodisperse particles in hollow models representing adult and child-sized tracheobronchial airways. *Health Phys.*, 72(6):827-834, 1997.

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BACKGROUND:

Extensive experience in research, development and teaching in mechanical engineering particularly in the areas of thermal-fluid sciences, transport phenomena (gas, liquid and particulate matter), combustion systems, computational fluid dynamics, laser-material interactions, micro-nanoscale fluid flow and heat transfer, aerosol formation and transport.

EDUCATION:

Ph.D. in Mechanical Engineering, University of California at Berkeley (1982).

BS in Mechanical Engineering, Sharif University of Technology (1974).

LAB EXPERIENCE

I was involved in the development, use and teaching of labs for Thermodynamics, Heat Transfer and Fluid Mechanics. I have added new experimental setups to the labs, modified some of the existing apparatuses and prepared instruction manuals for experiments. The test equipment included Instrumentation and DAQ, Turbojet Engine, Refrigeration systems, Air conditioning Equipment, Steam Power Plant, Water Tunnel, Fan Coil Testing Facility, Water Chiller Testing Facility, Compressor Testing Setup, Microchannel setup for fluid flow and heat transfer measurements, and heat exchangers. I used various lab equipment for aerosol characterization including Particle Image Velocimetry (PIV), CPC, ELPI, and MOUDI. Worked in lab environment involved in laser applications (LIA safety training).

I have no experience in radiation lab, neither I had any training on the subject, but interested in learning about radio-labeling of particles for our research purpose in aerosol exposure and deposition.

FELLOW of American Society of Mechanical Engineers.

Curriculum Vitae

Rutger Simon van der Hoeven

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CURRENT POSITION:

- Senior Research Scientist at Philip Morris USA

PREVIOUS POSITIONS:

- Staff Scientist at Philip Morris International, Switzerland
- Senior Research Scientist at BASF Plant Science LLC.
- Research Scientist at BASF Plant Science from September 2001-April 2004.
- Postdoctoral Associate in the Departments of Plant Biology and Plant Breeding, Cornell University (Ithaca NY, USA) from June 1999-August 2001

EDUCATION:

Ph.D. Plant Cell and Molecular Biology May 1999
Cornell University, Dept. of Plant Breeding.
M.D. Plant Breeding. Cum laude. July 1996
Wageningen University, The Netherlands.

RELEVANT RESEARCH EXPERIENCE FOR RADIOISOTOPE USE:

Genomics:

- Construction of >20 cDNA libraries using P32-labeled nucleotides (dNTPs).

Molecular biology:

- Co-developed novel differential display technique (cDNA-AFLP: Plant Journal 1996) which includes the use of P33-labeled dNTPs
- Screening of numerous cDNA & BAC libraries involving the use of P32-labeled dNTPs.
- Numerous Southern and Northern blotting experiments, AFLPs, and RFLPs involving the use of P32-labeled dNTPs.

RELEVANT RADIOISOTOPE COURSES:

1993-1995: Qualified to use Radioisotopes after taking required course for use of radioisotopes at Wageningen University (Netherlands).

1995-2001: Qualified to use Radioisotopes after taking Radiation Safety course provided by the department of Environmental Health & Safety (EH&S) at Cornell University (Ithaca, NY).

REFERENCES:

1) Dr. Steven D. Tanksley, Cornell University, USA

Function: Professor in the Departments of Plant Breeding and Plant Biology.

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2) Dr. John C. Steffens, Syngenta, RTP, NC

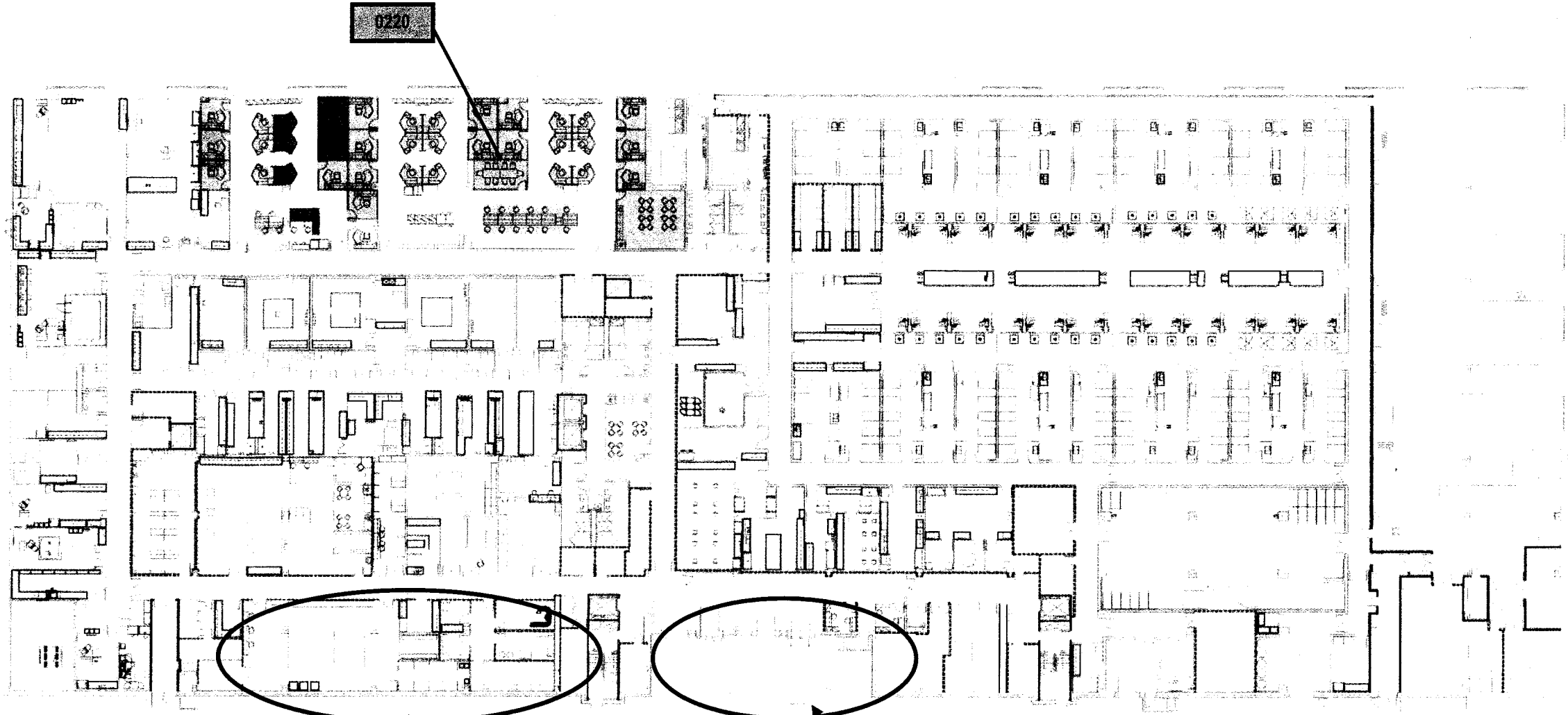
Function: Head of Trait Research.

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Address: Syngenta Biotechnology Inc., 3054 Cornwallis Road, Research Triangle Park, NC 27709, USA

Philip Morris USA NRC License Application

**ATTACHMENT B
FACILITY FLOOR PLANS**

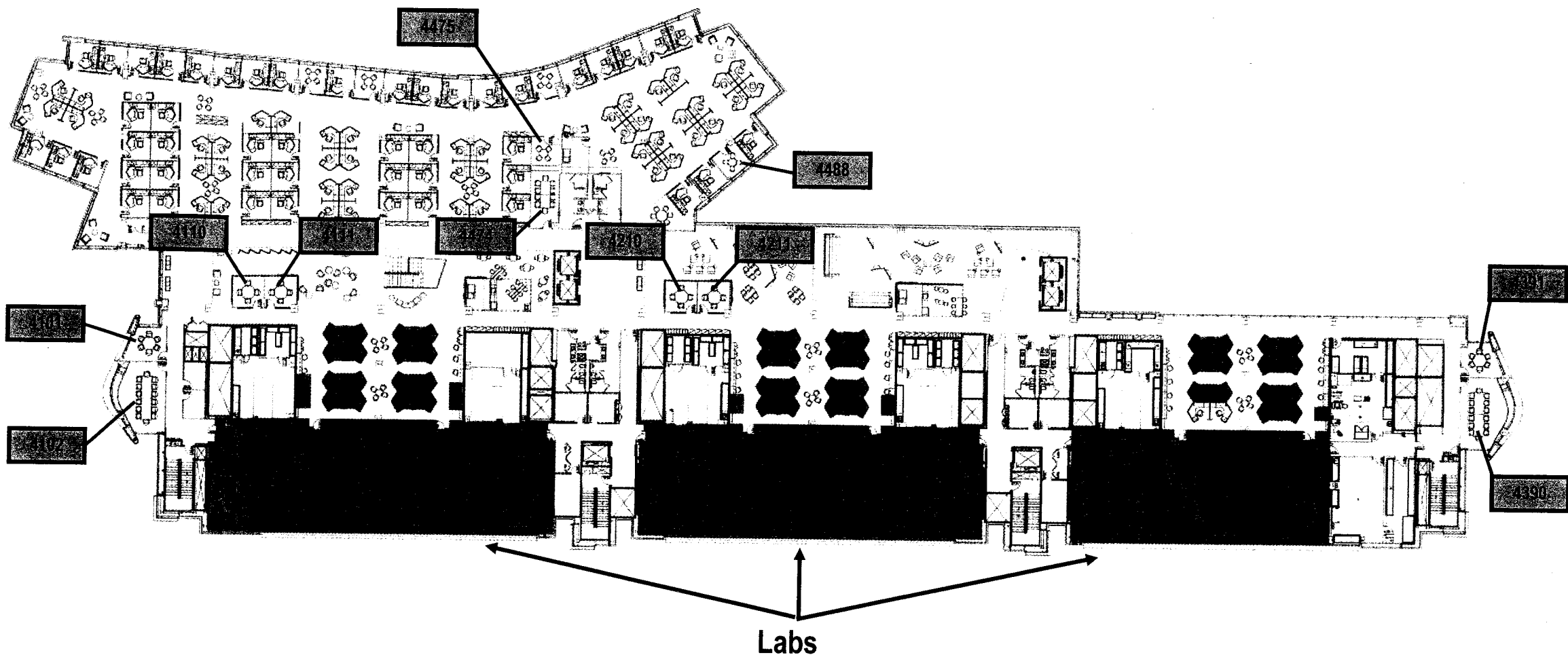


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Chemical Storage

Shipping, Receiving





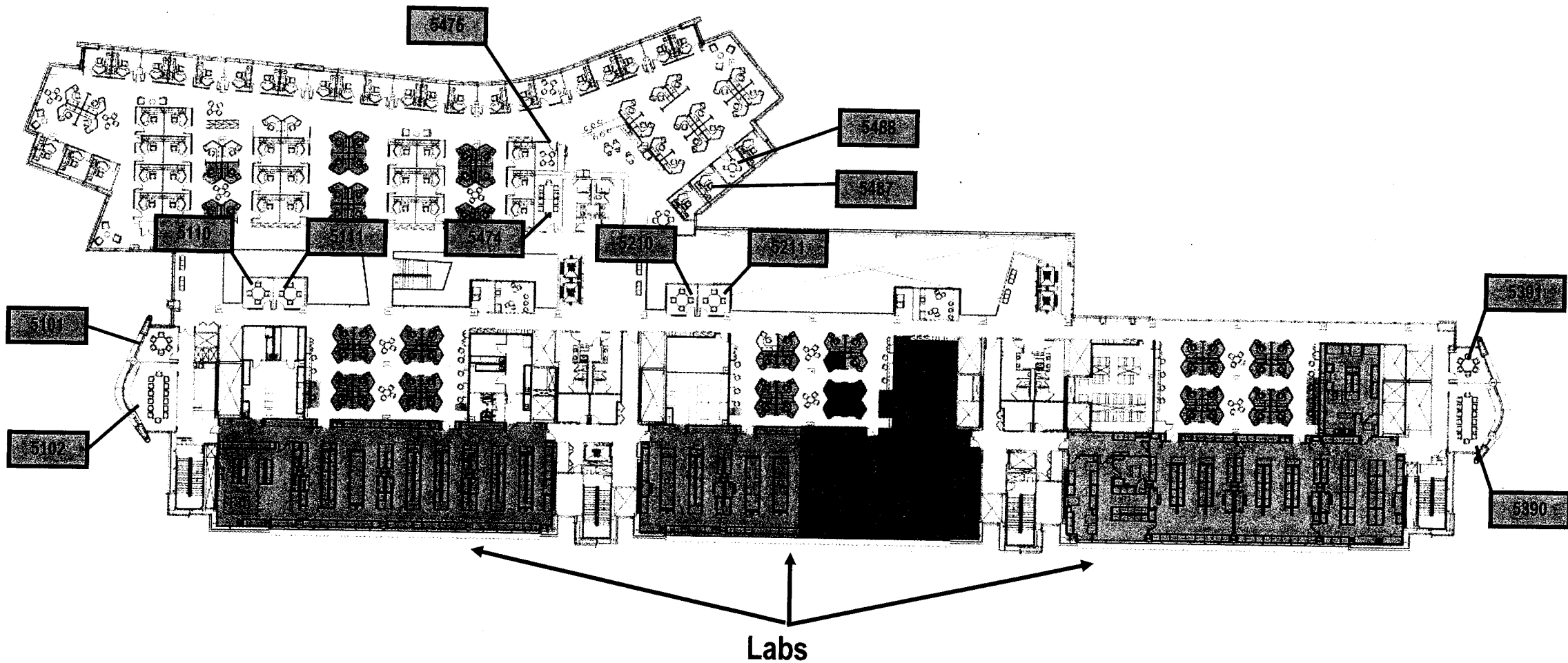
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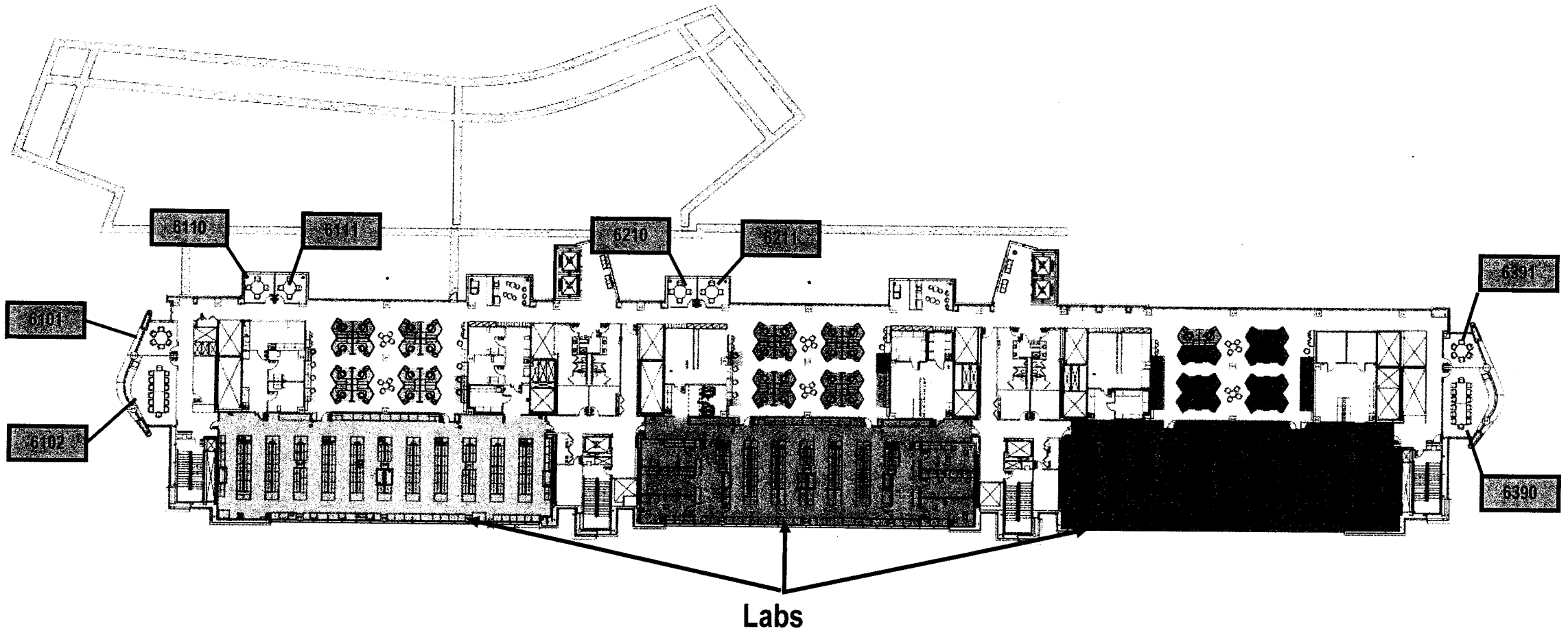
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**Philip Morris USA
Center For Research And Technology
Richmond, Virginia**

Radiation Safety Manual

December 2006

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Standard Operating Procedures

SOP – 001	Survey Meter Quality Control
SOP – 002a	Radioactive Waste Decay-In-Storage
SOP – 002b	Sanitary Sewer Disposal Of Aqueous Liquid Waste
SOP – 002c	Radioactive Waste For Transfer
SOP – 003	Radiation Surveys
SOP – 004	Spill Response
SOP – 005	Material Receipt and Accountability
SOP – 006	Preparation of Radioactive Packages for Shipment
SOP – 007	Estimation Of Internal Dose From Bioassay Data

Radiation Safety Manual

1. Organization for Control of Radiation

- 1.1 This Radiation Safety Manual describes the organization of the Radiation Safety Program and the levels of responsibilities at the Philip Morris USA Center For Research and Technology (CRT), specifies the regulations, policies, and practices which must be followed when using sources of radiation, and describes the radiation services that the Philip Morris USA provides to assist the users with their safety program.
- 1.2 Use of radioactive materials is regulated and licensed by the Nuclear Regulatory Commission (NRC). The Philip Morris USA license references several sections of Title 10 Code of Federal Regulation (10 CFR) for the control of ionizing radiation and reference the information submitted during the license application process.
- 1.3 The radiation safety program described in this manual is designed to provide Philip Morris USA workers, visitors, members of the public, property, and the environment safety from unacceptable exposures to radioactive materials resulting from the utilization of licensed material as biomarkers in biomedical research and development studies. The program is under the direction of the Radiation Safety Officer (RSO).
- 1.4 Radioactive materials may only be used by or under the supervision of qualified and trained individuals identified on the Radioactive Materials License. These consist of the RSO and named Authorized Users (AUs). Other individuals that work in areas posted for radioactive materials must be authorized to do so by the RSO or an AU.

2. ALARA Policy Statement

In practice, radiation doses in the workplace must be maintained As Low As Reasonably Achievable (ALARA). ALARA is a professional philosophy applied to radiation safety that dictates that all doses received must have a commensurate benefit. ALARA is also a regulatory requirement, since all licensees must have an ALARA program. The NRC regulations and the radiation safety program implemented by Philip Morris USA require managing programs and procedures to minimize personal exposure to radiation as well as releases of radioactive materials to air and water (sewer).

A quarterly ALARA goal has been established based on an annual dose of 10% of the regulatory total effective dose equivalent limits; actual worker doses are not expected to reach these values.

ALARA Program Goal	mrem/quarter
Total Effective Dose Equivalent	125
Extremity Dose Equivalent (shallow dose equivalent)	1,250

It is the responsibility of all employees of Philip Morris USA and its contractors to operate within the ALARA guidelines established herein. This is attainable by following the safety procedures developed for radiation protection, including monitoring of the workplace to control the spread of radiological contamination. Practical measures to incorporate the ALARA philosophy into routine work practices are included in this manual to assist radiation workers. Adherence to these measures will prevent unnecessary contamination, exposures, and releases.

3. Radiation Safety Program Structure and Responsibilities

3.1 The **RSO** is responsible for the following:

- Review and approve designation of use areas and all protocols for use of radioactive material.
- Distribute and receive personnel monitoring devices (dosimeters), timely review of results, maintenance of dosimetry records, and issuing reports annually and upon request.
- Provide for the training of all radioactive material users and initial and annual refresher training to ancillary personnel and maintain records of this training to include topics covered, the amount of time spent, the date(s), instructor(s) and roster of trainees.
- Supervise and coordinate radioactive waste disposal activities, including the maintenance of decay-in-storage and sanitary sewer disposal records.
- Maintain records of radioactive materials inventory, receipt and transfer of licensed material, radiation surveys, radiation safety program audits, waste disposal, instrument calibration, instrument use, spill response, and personnel dosimetry.
- Provide supervision and assistance for the management of emergency, accident, or spill situations.
- Conduct monthly health physics surveys of restricted areas as described in SOP-003.
- Ensure that the terms and conditions of the radioactive materials license are met and that the license is amended for changes in the use of radioactive material, responsible individuals, or commitments provided to NRC in the licensing process.
- Ensure that licensed materials are properly secured against unauthorized removal at all times when not in use.

- Investigate any personnel dose which exceeds the ALARA goal established in Section 2. Implement any corrective action deemed necessary as a result of the investigation.
 - Stop all work with licensed materials based on safety considerations.
 - Ensure that the radiation safety program is reviewed at intervals not exceeding 12 months.
- 3.2 The **Radiation Safety Committee (RSC)** has primary responsibility for oversight of the Philip Morris USA CRT radiation safety program. The Committee membership includes the RSO, representatives from the community of material users, and senior management. The RSC is charged with the following:
- Review and approve the procedures for the radiation safety program. Ensure that it:
 - Promotes conformance with the ALARA philosophy for all Philip Morris USA employees, contractors, and the public; and
 - Assures compliance with all applicable regulations and license conditions.
 - Review and approve all authorized uses of licensed materials.
 - Approve revisions to the Radiation Safety Manual. These may be due to changes required by changing NRC regulations or changes in internal management.
 - Assure the continued quality of the radiation safety program.
 - Adjudicate any issues, as appropriate, that arise between Authorized Users and the radiation safety program.

The RSC will meet at least twice per year. A quorum of the Committee consists of:

- Chair of the Committee
 - RSO
 - Representative of CRT senior management
 - Representative of the community of radioactive materials users
- 3.3 An **Authorized User (AU)** is an individual permitted to use radioactive materials without supervision and may supervise work with those materials performed by approved radioactive materials users. AUs must be named on the NRC radioactive materials license. AUs have primary responsibility for the safe practice of individuals working under their supervision. AUs are obligated to:

- Properly train and supervise all individuals working under the AU authorization to ensure a safe working environment and compliance with all Philip Morris USA policies.
- Maintain adequate inventory and knowledge of the various forms and quantities of radioactive materials present in their laboratories.
- Maintain immediate control of radioactive materials to prevent the unauthorized removal or tampering, and assure that workers occupying the area maintain security.
- Assure that all users (e.g., persons who have been trained to utilize radioactive materials and approved by the RSO) under their authorization attend the required radiation safety training programs.
- Report immediately any spills, emergencies, or accidents to the RSO, as appropriate.
- Notify the RSO in writing of any personnel changes, changes in the location where radioactive materials may be used or stored, or adjustments to the possession limits of radionuclides under their authorization.
- Avoid any unnecessary radiation exposure either to themselves or to other workers by adhering to the ALARA policy.
- Procure and dispose of radioactive materials according to the procedures established in this Radiation Safety Manual.
- Be cognizant of the regulations and requirements pertaining to the use of radioactive materials, and disseminate this information to all workers approved to work with radioactive materials under their supervision.

3.4 **Radioactive material users** are responsible for the following:

- Individuals must receive authorization from the RSO prior to begin work with radioactive materials:
 - Participate in radiation safety training as required.
 - Wear the prescribed personnel radiation dosimeters when required.
 - Survey hands, shoes, and body for radioactive contamination before leaving restricted areas after working with radioactive material.
 - Use all appropriate measures such as using protective clothing such as lab coats whenever contamination is possible, wearing vinyl/latex gloves when working with radioactive material, and using designated protective barriers and other shields whenever possible.

- Do not smoke, eat, drink, apply cosmetics, or store/use personal effects in restricted areas. Refrigerators shall not be used jointly for food or beverages and radioactive materials.
- Maintain good personal hygiene. Keep fingernails short to avoid cutting latex/vinyl gloves. Do not work with radioactive materials if there is a break in the skin below the wrist, or use double gloves.
- Wash hands and arms thoroughly following work with radioactive materials.
- Immediately report accidental inhalation, ingestion, or injury involving radioactive materials to the RSO, and carry out the recommended corrective action.
- In addition to using an appropriate survey meter when handling radioactive materials to monitor for radiation levels and contamination, a check of the immediate areas, e.g., floor, benches, etc., must be performed following work with radioactive materials (see Section 4.5.1). Record the results of this monitoring in the radiation monitoring log. Uncontrolled contamination must be cleaned immediately. Check the response of the survey meter using a dedicated check source for proper operation at the beginning of each day radioactive material is used. The RSO will provide assistance and/or advice for decontamination procedures.

3.5 Authorization To Use Radioactive Materials

Approval for the use of radioactive materials is given by the RSC for a period of two years. Approvals may be obtained by submitting a brief application describing the requested material and quantity to be used, the locations of use, the individuals who will handle the material, the training and experience of the applicant, and a brief description of the experimental procedures. The Authorized User submitting the application must have adequate training and experience commensurate with the proposed uses of licensed materials.

Radioactive materials authorizations expire two years from the date of issuance, at which time they must be renewed for uninterrupted use. The RSO will provide a copy of the authorization form to each AU approximately one month prior to the date of expiration with instructions on how to renew the authorization.

Amendments to current authorizations may be obtained to increase possession limits, add or delete authorized laboratories, add new radioisotopes, etc. Amendments may be obtained by submitting a memo to the RSO stating the desired change(s) and the reasons for the change. The amended uses may not begin until written approval is received from the RSO.

An authorization will be terminated if the AU leaves the employment of Philip Morris USA or chooses to no longer work with radioactive material. Upon a change to "inactive" status, the AU will no longer be required to maintain inventory records of licensed materials and attend radiation safety refresher training.

To request inactive status, the AU shall send a memo to the RSO requesting that radiation safety conduct a decommissioning contamination survey of the affected laboratories. The memo should also state that all radioactive materials have been properly disposed of or transferred to another AU and that all dosimeter badges have been returned to the RSO.

4. General Policies and Procedures for Radioactive Materials Use

4.1 Designation of restricted areas due to the presence of radioactive materials (Posted Rooms)

The RSO's office phone number and an off-duty phone number will be posted along with the other postings as required in 10 CFR Part 19 (including this written program, which will be available in the RSO's office).

- 4.1.1 Radioactive Materials are to be used only in rooms or areas as authorized by the RSO.
- 4.1.2 Areas where radioactive materials are used or stored will be posted with the signs as required in 4.2.
- 4.1.3 The RSO or designee will conduct an inspection survey for areas in which radioactive material use has been discontinued and no longer requires designation as a posted area. Only the RSO has the authority to remove a radioactive materials warning posting or label from a posted area.

4.2 Postings

- 4.2.1 A "CAUTION RADIOACTIVE MATERIALS" sign must be conspicuously posted on the doors to the restricted areas or in the areas where radioactive materials are being used or stored.
- 4.2.2 All equipment contaminated with radioactive material shall be marked with tape, signs, decals, or by other conspicuous means.
- 4.2.3 The RSO will post areas with a "CAUTION RADIATION AREA" posting in the vicinity of sources exhibiting external exposure rates exceeding 5 milliroentgen per hour (mR/h) at a distance of 30 cm from the source. [Note: It is not likely that radioactive material use rooms will require posting as a radiation area.]
- 4.2.4 As required in 10 CFR 19.11, a copy of the regulations (10 CFR parts 19 and 20), the license, and this radiation safety manual must be "posted." Employees will understand that these documents are available for review in the RSO's office.
- 4.2.5 NRC Form 3 "Notice To Employees" will be posted in several conspicuous locations within the CRT.

4.3 Shielding of Sources

Licensed materials not in use shall be shielded in such a manner that the radiation levels are less than 2 mR/h in potentially occupied areas.

4.4 Protection of Work Surfaces from Contamination

All radioactive materials work surfaces (bench tops, storage areas and areas adjacent to permanent set-ups and sinks, etc.) will be covered with stainless steel, plastic trays, or other impervious materials. For many purposes a plastic-backed absorbent paper (or laboratory diaper) will be satisfactory.

4.5 Periodic Surveys of Radioactive Material Use Areas

4.5.1 **Daily** - Areas (e.g., bench tops) in which radioactive materials are being used will be monitored for contamination following work with radioactive materials. This monitoring will be conducted by the material user. The daily check is required to be performed only on the days that radioactive materials are used. A log will be kept showing the dates of the monitoring and who performed the monitoring. These daily checks will consist of direct monitoring using portable radiation detection instruments (pancake GM detector or equivalent, thin window thin crystal NaI detector or equivalent, as appropriate). When working with H-3, monitoring must be done via collection and analysis of wipe samples.

4.5.2 **Monthly** – Monthly surveys (i.e., health physics surveys) will be conducted by the RSO or designee in each area posted with a “Caution Radioactive Materials” label. This survey will include, as necessary: direct monitoring using portable radiation detection instruments for contamination, collecting smear samples for removable contamination (in most cases, 10 samples per laboratory will be sufficient), and checking compliance with standard radiation safety practices. If no work with licensed material has been conducted during the calendar month, a survey form indicating ‘no nuclides used’ will be created, signed, and maintained in the radiation safety records. See SOP-003 for survey procedure.

4.5.3 Copies of the monthly surveys will be maintained in the laboratories and/or in the radiation safety files kept by the RSO.

4.6 Radiation Detectors

4.6.1 Portable survey meters (Ludlum model 3 or equivalent), pancake GM detectors (Ludlum model 44-9 or equivalent), and NaI detectors (Ludlum models 44-2 and 44-3 or equivalent) will be available for personnel and area monitoring. All persons approved for work with licensed materials will have access to an appropriate detector. At a minimum, each AU will possess at least one survey meter for use in his/her posted area(s).

4.6.2 Each survey meter or radiation detector will have a dedicated check source. The standard check source will be 1 μCi ^{137}Cs . Check sources may be mounted on the sides of the survey meters or kept in a secure location by the RSO or meter custodian.

- 4.6.3 Survey meters will be calibrated at intervals not exceeding 12 months. Survey meters that exceed the 12 month interval will be taken out of service so that they are not available for use.
- 4.6.4 Many survey meters have both count rate (cpm) and exposure rate (mR/h) scales. The count rate scale is the appropriate scale to use when surveying for contamination.
- 4.6.5 Use the following guidelines when using a radiation survey instrument:
 - Check the battery, instrument background, and response to a check source prior to use.
 - Use the meter on the lowest scale possible. Select higher scales if the reading goes off-scale.
 - Hold the detector approximately 1 cm (or less) above the surfaces being monitored. Survey slowly; move the detector at a rate of no more than 5 cm per second.
 - Always survey with the audible switch in the 'on' position. If the meter has a speed setting (fast/slow), survey with the switch set to 'f.'

5. Radioactive Contamination and Spill Procedures

5.1 Radioactive Contamination of Areas

- 5.1.1 In general, no radioactive contamination will be tolerated. Exceptions to this include stainless steel trays, absorbent paper covered surfaces, or other equipment which is used frequently for radioactive material work and which will be clearly marked with standard radiation caution tape. Any contamination that is not confined to controlled surfaces shall be cleaned immediately.
- 5.1.2 Removable surface contamination action guidelines for restricted and unrestricted areas are as follows:
 - Restricted Areas 1,000 dpm/100 cm²
 - Unrestricted Areas 20 dpm/100 cm²
- 5.1.3 The amount of removable radioactive material per 100 cm² of surface area will be determined by wiping the surface with a dry filter or soft absorbent paper, applying moderate pressure and assessing the amount of radioactive material on the wipe area with an appropriate instrument of known efficiency (e.g. liquid scintillation counter).
- 5.1.4 Fixed contamination on surfaces is not expected to be a problem; however, acceptable limits are one factor of 10 greater than those set for removable contamination in the restricted areas.

5.2 Decontamination of Areas Contaminated with Radioactivity

Preparations for decontamination should begin promptly. Determine the extent and hazard presented by the contamination. The RSO will perform or assist in this evaluation, if necessary.

5.3 Decontamination of Personnel Contaminated with Radioactivity

5.3.1 Notify other personnel in the area and the supervisor immediately after a contamination accident.

5.3.2 Wash any body areas potentially in contact with licensed material thoroughly for 2 or 3 minutes, repeatedly "soaping" and rinsing. Soaps are preferred to synthetic detergents. Avoid prolonged use of any one decontamination procedure. Avoid the use of organic solvents as they may make the skin more permeable to radioactive contaminants.

5.3.3 If this procedure is not immediately and completely effective, decontaminating agents as "Versene" or "Radiacwash" may be used under the direction of the RSO and/or medical personnel.

5.4 Major Spills (greater than 10 μ Ci total or more than 1 m² contaminated area), See SOP-004 Section 5.0.

5.5 Minor Spills (less than 10 μ Ci total and less than 1 m² area), See SOP-004 Section 6.0.

6. Dosimetry

Radiation doses to users of radioactive material under this license are not expected to exceed 10% of the allowable limits in 10 CFR Part 20 from the sum of external and internal sources. However, the following dosimetry program will be implemented:

6.1 External Radiation Monitoring

6.1.1 The RSO will determine the personnel who work with licensed material who will be provided with whole body dosimeters. Dosimeters will be procured from a commercial vendor demonstrating successful participation in the National Voluntary Laboratory Accreditation Program (NVLAP) for personnel dosimetry.

6.1.2 Individuals who work with P-32 and/or other high energy beta-emitting radionuclides will be provided with extremity, or ring dosimeters, to be worn on a finger with the dosimeter facing the inside of the hand.

6.1.3 Dosimeters for personnel monitoring will be exchanged monthly. The RSO is responsible for distributing new dosimeters, storing control dosimeters, and collecting and sending used dosimeters to the vendor.

6.1.4 Dosimeters should be stored in a portion of the facility where no licensed materials are present; they should not be taken home. Under no circumstances

should an individual wear a dosimeter belonging to another person. Lost dosimeters should be reported to the RSO immediately such that a replacement can be obtained.

6.2 Internal Radiation Monitoring - Bioassay

- 6.2.1 Routine bioassay (urine) samples are not required. However, the RSO may require that bioassay samples be collected on an as needed basis following an unusual incident or spill involving radioactive materials.
- 6.2.2 Sample containers will be provided to workers by the RSO, who may procure them from a licensed radioanalytical laboratory. The RSO will be responsible for distributing the sample containers and shipping them to the laboratory for analysis of one or more radionuclides, as appropriate.
- 6.2.3 The RSO will estimate committed effective dose equivalent and thyroid dose equivalent (should radioactive iodine intake be involved) from the bioassay data.
- 6.2.4 Should activity limits increase, bioassay monitoring will be required following iodinations involving more than 1 mCi I-125 (between 12 hours and 3 days after the procedure) or work involving greater than 100 mCi of H-3 (within 24 hours).

6.3 Prenatal Radiation Dose Policy

- 6.3.1 A 0.5 rem dose limit to an embryo/fetus of a declared pregnant female worker has been established in 10 CFR 20.1208.
- 6.3.2 When an employee elects implementation of the 10 CFR 20.1208 fetal dose limit, she must declare her actual, suspected, or planned pregnancy in writing.
- 6.3.3 Control of the fetal dose will be carried out with full cooperation of the employee and without economic penalty or loss of job opportunity. Work assignment changes, consistent with company personnel policy, may be initiated if deemed necessary by the RSO.
- 6.3.4 When the occupational radiation dose of a declared pregnant employee exceeds 50 mrem in one month or 250 mrem since conception, the employee may request (1) maternity leave; (2) other paid leave; (3) leave without pay; (4) reassignment within her work unit; or (5) transfer. The supervisor and RSO shall elect to (1) change the employee eight-hour work assignment or (2) select one of the available leave options until the employee becomes eligible for and requests maternity leave.
- 6.3.5 In conjunction with the fetal dose limit, the ALARA philosophy will be applied to maintain any dose to as low as practicable levels.

7. Disposal of Radioactive Materials

7.1 Radioactive waste consists of any waste that is contaminated with or contains licensed radioactive material. All radioactive waste generated will be disposed of by decay-in-storage (DIS) as described in SOP-002a, discharge to the sanitary sewer as described in SOP-002b, or by transfer to a licensed radioactive waste broker as described in SOP-002c. Generators of radioactive waste are responsible for maintaining a record indicating estimated activity placed in each waste container.

7.2 **Dry waste** consists of paper, gloves, plastic containers, and other forms of contaminated laboratory waste. It does not include liquids, biohazardous material, sharps, sealed sources, hazardous wastes, explosives, or pyrophoric materials. Dry radioactive waste will be placed in labeled radioactive waste stepcans or plastic or cardboard drums lined with plastic bags. Once full, bags will be sealed and transferred to waste containers in the radioactive waste storage area for DIS or storage pending transfer to a licensed radioactive waste broker.

Solid dry waste must be segregated based on radioactive half life according to the following:

- $T_{1/2} \leq 15$ days (P-32)
- $T_{1/2} > 15$ days and ≤ 120 days (P-33, S-35, Cr-51, I-125)
- $T_{1/2} > 120$ days (H-3 and C-14)

7.3 Generation of **soluble liquid waste** is anticipated. Radioactive liquid wastes shall be stored in polyethylene containers known as "carboys" or other suitable labeled containers meeting the following criteria:

- Containers are plastic
- Containers have properly fitting lids
- Containers are stored in appropriate secondary containment
- Containers are used with the understanding that they will not be returned for reuse

Liquid wastes will either be disposed into the sanitary sewer or, when carboys are not more than approximately $\frac{3}{4}$ full, transferred to the waste storage area for transfer to a licensed radioactive waste broker. In labs where liquids are discharged to the sanitary sewer, a monthly record containing a line item entry for each disposal event will be maintained for each radionuclide by the AU and will be forwarded to the RSO at the completion of each month (see SOP-002b). To facilitate accurate record keeping, multiple radionuclides should not be placed in the same liquid waste container.

7.4 **Liquid scintillation vials** can be transferred to the waste storage room in cardboard trays or be placed directly into 30 or 55 gallon drums meeting the following criteria:

- Containers are rigid (capable of containing liquid)
- Containers are double lined with plastic liners

Liquid scintillation vial waste shall not be commingled with other waste streams. Vials must be tightly capped prior to placement in the waste container. Where possible, biodegradable scintillation fluid should be used for liquid scintillation counting. Vials containing H-3 and C-14 may be placed in the same storage drum. All other radionuclides used at CRT may be placed in the same storage drum.

7.5 All wastes held under the DIS program shall be stored in the radioactive waste storage facility located in the posted radioactive waste storage room on the Lower Level. Given the likely quantities of gamma-emitting radioactivity placed in storage and the shielding provided by the structure of the waste storage room, it is extremely unlikely that the surface exposure rate on the outside wall of the storage room would put the facility at risk of exceeding the general public dose limit of 2 mrem in any one hour.

8. Procedures for Procurement, Receipt, and Inventory

8.1 Procurement Procedures

- 8.1.1 Purchase requisition/order (PO) shall be filled out by AUs and approved by the RSO.
- 8.1.2 The RSO shall ensure that the requested material, quantities, and form are authorized by the license and that the possession limits are not exceeded prior to the order being placed with a vendor.
- 8.1.3 The RSO shall ensure that receiving personnel are notified of the requisition.

8.2 Receipt of Radioactive Materials

- 8.2.1 Unexpected deliveries of licensed material shall be refused.
- 8.2.2 Upon arrival, receiving personnel will immediately contact the RSO or designee. The package will be delivered to the EHS laboratory on the Lower Level. If the RSO or designee is not present to accept the package, it will be placed in a locked and labeled cabinet, refrigerator, or freezer. The RSO or his/her designee will survey and open the package as per SOP-005.
- 8.2.3 The individual opening the package will complete a Radioactive Materials Package Receipt Form and begin a Utilization/Disposal Form for the container of licensed material (source vial, etc.). If not delivered to the AU's laboratory, the licensed material will be placed in storage in a labeled and lockable refrigerator, freezer, or cabinet, as appropriate.

- 8.3 AUs will perform semi-annual physical inventories of all radioisotopes in their possession. Isotope present in source vials, samples, and other items will be documented and forwarded to the RSO. Following the steps in SOP-005, the RSO will use the AU inventories to establish compliance with the facility-wide activity limits established in the NRC license.

9. Physical Security of the Radioactive Material Use Areas

- 9.1 Only authorized persons will have access to the posted laboratories at the CRT via the card keys provided to them.
- 9.2 Philip Morris USA employees and contractors shall question any unrecognized persons attempting to take possession of licensed materials.
- 9.3 Source vials will be kept in a lockable refrigerator, freezer, or cabinet in the laboratory posted for work with radioactive materials. The AUs will have keys and may make them available to designated users, as appropriate. Security of all keys will be the personal responsibility of the individuals to whom they are issued. Instead of a lockable refrigerator, an AU may elect to keep isotope vials in lock boxes as long as the lock boxes are tethered securely.
- 9.4 Visitors will not be allowed unescorted in posted areas.

10. Qualifications of RSO, Authorized Users, and Radiation Safety Training

10.1 Qualifications and Training of the Radiation Safety Officer

Minimum 40-hour radiation safety officer training class or 6 months experience working with radioactive materials as an AU or equivalent.

10.2 Qualifications and Training for Authorized Users

AUs are the only persons in addition to the RSO who may order licensed materials and who may supervise work with licensed materials. They must be named on the license.

- 10.2.1 AUs will have a minimum of 3 months experience working with radioactive material under the supervision of an AU or RSO. In the absence of suitable experience, AUs will sit for an AU training class offered by an appropriate vendor offering radiation safety training services.

- 10.2.2 Each AU will have received initial radiation safety training. The training can be any combination of review of written materials, viewing videotapes or classroom instruction. The training covers some combination of the following topics:

- Atomic Structure and Radioactivity
- Biological Effects (NRC Reg Guide 8.29 and 8.13)
- Review of the Radiation Safety Program
- Inventory and Security of Radioactive Materials
- Radioactive Waste
- Review of Rules, Regulations, License, and Procedures
- Use of Dosimeters and Bioassays
- Using Survey Meters
- Performing Contamination Surveys

10.3 Training for Other Workers (Laboratory Technicians)

Other laboratory employees intending to work with licensed material will receive training commensurate with the intended work with radioisotopes. Personnel will be provided information related to potential radioactive hazards present in their work areas and specific training covering the procedures involving radioactive materials which they are expected to implement. Initial radiation safety training will be provided consisting of topics selected from those listed in Section 10.2.2.

10.4 Other personnel

Other personnel such as janitorial staff, administrative staff, and office personnel who could come in contact with packages of licensed material or periodically enter posted areas will be provided with radiation awareness training. Topics may include storage and use of radioactive material, the hazards associated with exposure to radioactive material in the area, means to reduce exposure, recognition of warning signs and labels, dosimetry, and the responsibility to report violations.

10.5 Annual Refresher Training. The RSO will provide or arrange for annual refresher radiation safety training. The focus of the training will be a review of selected elements of the radiation safety program.

10.6 The RSO will maintain training records for all categories of employees who receive radiation safety training.

11. Audit Program

Philip Morris USA will maintain the radiation safety program as described in this Radiation Safety Manual. As a part of the safety program, an audit of the content and implementation of the radiation safety program will be performed at least annually to ensure:

- a) compliance with NRC and DOT regulations and the terms and conditions of the license,
- b) occupational doses and doses to members of the public are ALARA, and

- c) records of audits and other reviews of program content are maintained for 3 years.

Audits will be conducted annually according to the outline of Appendix L, NUREG – 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999.

12. Emergency Phone Numbers

Philip Morris USA Security:

1.0 Scope

Quality control measurements will be taken and documented whenever radiation detection instruments (typically consisting of ratemeters coupled to pancake GM detectors or NaI detectors) are utilized. The schedule for meter calibration and maintenance is also provided herein.

2.0 Related Documents

Not-applicable

3.0 Responsibilities

It is the responsibility of all users of licensed material to perform quality control measurements prior to the first use of a radiation detection instrument and record the quality control data on the attached Radiation Detector Quality Control Sheet. The RSO is responsible for arranging for annual survey meter calibration. It is the responsibility of the RSO and Authorized User to ensure that there is an operable survey meter available whenever licensed material is being used.

4.0 Procedure

4.1 Battery Test

Turn the meter power switch to the battery test position and observe the needle response. If it does not deflect to the battery test indicator region on the dial, check that batteries are in the meter, clean contacts (if needed), or replace with fresh alkaline D cells. If new batteries also fail the battery test, report the failure to the RSO, tag the meter "inoperable" and obtain another meter for use.

4.2 Audio and Background Test

Turn the audio switch to the "on" position. Check for audio response. In an area free of licensed material, observe the instrument background count rate.

4.3 Check Source Test

Place the meter directly over an appropriate check source and compare the meter response to the "known" value; the measured count rate should be within ± 20 percent of the known value. If the check source reading falls outside the control limit, notify the RSO of the failure, tag the meter "inoperable" and obtain a new meter for use.

4.4 Calibration Date Check

Check the calibration date of the meter and be sure that it is current to within one year. If out of calibration, report to the RSO.

4.5 Calibration and Maintenance

The RSO is responsible for procuring maintenance and calibration services. Meters will be calibrated no less than annually at a licensed calibration facility. Calibration certificates will be maintained by the RSO.

1.0 Scope

This procedure describes the solid waste decay-in-storage program, in accordance with 10 CFR 20 and guidance provided in NUREG-1556, Volume 7, enabling solid waste disposal as ordinary trash.

2.0 Related Documents

10 CFR 20 Subpart K
NUREG-1556, Vol. 7, Appendix T
SOP-001 Survey Meter Quality Control

3.0 Responsibilities

It is the responsibility of the person(s) performing waste disposal to perform these functions in accordance with this SOP. It is the responsibility of the RSO to train personnel designated to perform these duties.

4.0 Materials and Equipment

Survey Meter
Pancake GM and NaI detectors
Protective Clothing (Lab coats, gloves)
Labeled radioactive waste containers
Plastic bags

5.0 General Guidelines

5.1 All radioactivity labels must be defaced or removed from containers and packages prior to disposal in ordinary (non-radioactive) waste.

5.2 Non-radioactive waste should not be mixed with radioactive waste being held for decay-in-storage.

5.3 Metal stepcans, 55 gallon drums, or cardboard boxes will be used to decay dry radioactive waste. Each container will be lined with a plastic liner. Polyethylene "carboy" containers will be used to decay aqueous liquid wastes. Liquid waste containers will be placed on a secondary tray while in storage.

5.4 Plastic bags will be used for packaging dry/solid radioactive waste. These bags should be sealed at the top and placed in a labeled container. If there is danger that the bag may be torn or damaged by its contents, multiple bags will be used.

5.5 The outer surface of each container of radioactive wastes will be labeled with "Caution, Radioactive Materials" tape.

6.0 Procedure

Note: A lab coat, dosimeter, and gloves must be worn at all times when handling and/or monitoring radioactive waste.

6.1 Fill out the attached Waste Decay-In-Storage Survey Report Form for each waste container. A form will be started upon the initial placement of contaminated material into a radioactive waste container.

6.2 Place any potentially contaminated waste material in a plastic bag. Typical dry waste stream components consist of paper towels, latex gloves, disposable laboratory diapers and/or absorbent paper.

6.3 Seal each bag of waste with tape. Use a calendar to determine the date at which the waste will have remained in storage for a minimum of 10 half-lives; the date should be determined from the last date which waste was placed in the waste container. Make a copy and furnish the original to the RSO. Attach the second copy to the waste container. Be sure this form is securely attached to its respective container.

6.4 Allow the waste to decay through a minimum of 10 half-lives.

6.5 Monitor the waste for radioactivity as follows:

- Perform quality control measurements with calibrated pancake GM and NaI detectors.
- Survey the contents in the container in a low background area with the pancake GM detector.
- Monitor all surfaces of the container.
- Discard the contents as ordinary trash only if the survey of the contents indicates no residual radioactivity, i.e., surface readings are indistinguishable from background.
- If the surveys indicate residual radioactivity, return the waste to storage.
- Monitor the dose rates along the surface of the waste with the NaI detector. If dose rates are found which exceed background, return the waste to storage.

6.6 Check to be sure there are no radioactive labels present on any of the decayed material. Remove or obliterate any found.

6.7 Fill in the appropriate data on the Waste Decay-In-Storage Survey Report Form. Forward the form to the RSO, who will retain the records of trash disposal for not less than 3 years.

Waste Decay-In-Storage Survey Report Form

Nuclide _____ Half life _____ Disposal Date _____

Waste Last Placed In Container: _____

Earliest Possible Disposal Date (10 Half Lives from above date): _____

Scan results following decay ($\mu\text{R/h}$): low _____ high _____

Background range ($\mu\text{R/h}$): low _____ high _____

Detector model and serial number: _____ Calibration Date: _____

Waste IS _____ IS NOT _____ acceptable for disposal as regular trash

Disposal by: _____

Comments:

1.0 Scope

This procedure describes the methodology for disposal of radioactive material via the sanitary sewer system, in accordance with guidance provided in NUREG-1556, Volume 7, enabling disposal of soluble, biodegradable material via the public sanitary sewer system.

2.0 Related Documents

NUREG-1556, Vol. 7, Appendix T
SOP-001 Survey Meter Quality Control

3.0 Responsibilities

It is the responsibility of the person(s) performing waste disposal to perform these functions in accordance with this SOP. It is the responsibility of the RSO to train anyone designated to perform these duties.

4.0 Materials and Equipment

Survey Meter
Pancake GM and NaI detectors
Protective Clothing (Lab coats, gloves)
Plastic liquid waste containers

5.0 General Guidelines

5.1 Aqueous radioactive waste will be collected in plastic containers, such as 5 gallon plastic carboys. Each container will be labeled with 'CAUTION RADIOACTIVE MATERIALS' tape and the radionuclide placed within.

5.2 Containers will be maintained in posted rooms.

5.3 Containers will be maintained on a tray or absorbent paper to contain any spillage.

5.4 Waste will be poured into designated radioactive waste disposal sinks by the RSO, AU, or AU designee. No waste will be disposed of via the sanitary sewer without the permission of the RSO.

5.5 Compliance with the discharge limits published in 10 CFR 20 Appendix B will be documented by the RSO or his/her designee based on the total activity released from all designated disposal sinks and the monthly volume of water utilized.

6.0 Procedure

Note: A lab coat, dosimeter, and gloves must be worn at all times when handling and/or monitoring radioactive waste.

6.1 A copy of the attached Sanitary Sewer Disposal Form shall be generated for each container used to collect liquid radioactive waste for sewer disposal and for each radionuclide contained in the waste. Therefore, if H-3, S-35, and C-14 in aqueous liquid wastes are stored in the same container, for example, then three Sanitary Sewer Disposal Forms are needed to document the disposal activity. The forms will be started upon the initial placement of liquid waste into an empty container.

- 6.2 Liquid waste will be discharged to the sanitary sewer system via the designated sinks in the posted laboratories where licensed materials are used.
- 6.3 Prior to disposal, if the Sanitary Sewer Disposal Form does not contain an estimate of the quantity of radioactivity in the container, a sample of the liquid waste contents will be collected and analyzed via liquid scintillation counting.
- 6.4 Slowly pour the liquid waste into the designated sink. Following disposal, flush water down the sink for approximately three minutes.
- 6.5 Scan the sink and adjacent area with a Pancake GM or thin window thin crystal NaI detector, as appropriate; decontaminate any areas or surfaces found to be contaminated.
- 6.6 Fill in the appropriate data on the Sanitary Sewer Disposal Form. A form should be used for each radionuclide disposed in the sink.
- 6.7 At the conclusion of each month, each AU must forward all Sanitary Sewer Disposal Forms to the RSO, who will retain the records for not less than 3 years.
- 6.8 The RSO will track facility-wide waste disposed via the sanitary sewer using the Activity and Concentration – Sanitary Sewer Disposal Form. NOTE: One form is filled out for each radionuclide disposed in the sewer.

Sanitary Sewer Disposal Form

AU _____

Sink Location _____

Nuclide _____

Month/Year _____

Collection Date	Container Contents Activity (μCi)	Date	Initials
TOTAL ACTIVITY DISPOSED (μCi):			

Sink scanned following disposal: Yes ____ No ____

Readings Acceptable: Yes ____ No ____

Contamination described (as appropriate):

Detector model and serial number: _____ Calibration Date: _____

FORWARD COPY OF THIS FORM TO RSO AT THE COMPLETION OF EACH MONTH

Activity and Concentration - Sanitary Sewer Disposal For Calendar Year _____

Radionuclide: H-3 C-14 P-32 P-33 S-35 Cr-51 I-125

Average Monthly Volume of Water (mL):

Month	Activity By Department (μCi)				Concentration (μCi/mL)
	New Tech	Sensory	EHS	Other	
January					
February					
March					
April					
May					
June					
July					
August					
September					
October					
November					
December					
TOTAL (Ci)					

Limits:	Annual Activity (Ci)	Monthly Concentration (μCi/mL) ⁺
H-3	5	0.01
C-14	1	0.0003
S-35	*	0.001
Co-57	*	0.0006
Cr-51	*	0.005
I-125	*	0.00005

+ If more than one radionuclide is discharged, the unity rule must be applied.
 * The sum of these nuclides may not exceed 1 Ci annually.

1.0 Scope

This procedure describes the method of tracking the activity placed in radioactive waste containers that will be transferred to a licensed radioactive waste broker for disposal.

2.0 Related Documents

10 CFR 20

NUREG-1556 Volume 7

3.0 Responsibilities

It is the responsibility of the person(s) generating radioactive waste to implement this SOP. It is the responsibility of the RSO to train anyone designated to perform these duties.

4.0 Materials and Equipment

Survey Meter

Pancake GM and NaI detectors

Protective Clothing (Lab coats, gloves)

Labeled radioactive waste containers

Plastic bags

5.0 General Guidelines

5.1 All radioactive waste containers must be labeled with 'CAUTION RADIOACTIVE MATERIALS' tape or labels.

5.2 Non-radioactive waste should not be mixed with radioactive waste being held for transfer.

5.3 Metal stepcans, drums, or cardboard boxes will be used to store solid radioactive waste and plastic containers will be used to store liquid radioactive waste in the laboratories. Each solid waste container will be lined with a plastic bag. No solid waste will be placed in an unlined container. Contents may be transferred into 55 gallon drums in the radioactive waste room.

5.4 Plastic bags will be used for packaging dry/solid radioactive waste. These bags should be sealed at the top and properly labeled. If there is danger that the bag may be torn or damaged by its contents, multiple bags will be used.

6.0 Procedure

Note: A lab coat, dosimeter, and gloves must be worn at all times when handling and/or monitoring radioactive waste. All waste held for transfer will be maintained in posted laboratories or the radioactive waste storage facility located on the Lower Level near the Shipping and Receiving dock.

6.1 Whenever solid waste is placed in a container, the waste generator must make an entry on the Solid Waste Disposal Form. Liquid waste held for transfer should be documented on a Liquid Waste Disposal Form (Transfer). A form should be taped to the top of each waste container. A form will be started upon the initial placement of contaminated material into a radioactive waste container for storage.

6.2 Waste should be segregated in containers by half-life. Solid dry waste must be segregated based on radioactive half life according to the following:

- $T_{1/2} \leq 15$ days (P-32)
- $T_{1/2} > 15$ days and ≤ 120 days (P-33, S-35, Cr-51, I-125)
- $T_{1/2} > 120$ days (H-3 and C-14)

To avoid confusion, use a separate form for each nuclide if more than one nuclide is placed into the same container.

6.3 Place any potentially contaminated waste material in a plastic bag. Typical waste stream components consist of paper towels, latex gloves, disposable laboratory diapers and/or absorbent paper.

6.4 When a container is approximately $\frac{3}{4}$ full; contact the RSO or designated representative for pickup.

6.5 When waste is removed from a laboratory, the RSO or designated representative will collect the appropriate disposal forms such that activity placed in the radioactive waste storage facility can be quantified.

Solid Waste Disposal Form

AU _____ Container Location _____

Nuclide _____

Date	Activity (μCi)	Initials
TOTAL ACTIVITY DISPOSED (μCi):		

FORWARD A COPY OF THIS FORM TO THE RSO WHEN A CONTAINER IS PICKED UP FOR TRANSFER TO RADIOACTIVE WASTE STORAGE

Liquid Waste Disposal Form (Transfer)

AU _____

Nuclide _____

Month/Year _____

Collection Date	Container Contents Activity (μCi)	Date	Initials
TOTAL ACTIVITY TRANSFERRED (μCi):			

FORWARD A COPY OF THIS FORM TO THE RSO WHEN A CONTAINER
IS PICKED UP FOR TRANSFER TO RADIOACTIVE WASTE STORAGE

1.0 Scope

This protocol describes radiation survey requirements. A Survey Report Form to be completed at the time of each survey is attached to this SOP.

2.0 Related Documents

SOP-001 Survey Meter Quality Control
NRC Regulatory Guide 8.23
NUREG-1556, Vol. 7, Appendix Q

3.0 Responsibilities

It is the responsibility of the AU to assure compliance with daily monitoring requirements. It is the responsibility of the RSO to monitor compliance with those requirements, perform monthly surveys of areas posted for licensed materials, and maintain records of monthly surveys. The AUs and RSO may train personnel to perform the surveys.

4.0 Materials and Equipment

Survey Meter
Pancake GM Detector
Thin window, thin crystal NaI detector
Protective Clothing (Lab coats, gloves)

5.0 General Guidelines

Daily monitoring will be performed by users following completion of work with licensed material. Monthly surveys are required in each laboratory or other area where licensed materials are used or stored. Monthly surveys are done by the RSO or designee in each posted room.

6.0 Procedures

Note: A lab coat and dosimeter will be worn when performing radiation safety surveys. Gloves will be worn when collecting swipe samples.

6.1 Daily Monitoring

- Following work with licensed materials, the user will monitor himself/herself and the work area for contamination with an appropriate meter. GM pancake detectors will be used following work with most beta-emitting materials on the license. A thin window thin crystal NaI detector will be used following work with I-125 and Cr-51.
- Following work with tritium, swipe samples will be collected and analyzed via liquid scintillation counting (metering is not effective and therefore unnecessary). The user should not leave the room until the results of the sample analyses have confirmed the absence of contamination.
- Daily monitoring will be documented on a Daily Radiation Contamination Monitoring Log Sheet.

6.2 Monthly Surveys

- Confirm that a “Caution, Radioactive Materials” posting is present on or near the doors to the restricted area.
- Perform SOP-001 using the pancake GM and thin window thin crystal NaI detectors, as appropriate.
- Scan the floor, work surfaces (e.g., lab benches, desks, hoods, tables, etc.) and all other accessible surfaces with the appropriate detector. Identify any contaminated surfaces with CAUTION RADIOACTIVE MATERIALS tape and notify AU or other personnel. Identify areas on the Survey Report Form.
- Confirm that freezers, refrigerators, waste containers and pieces of equipment are labeled with ‘CAUTION RADIOACTIVE MATERIALS’ tape or stickers, as appropriate.
- Confirm that any sink used for disposal is labeled ‘RADIOACTIVE WASTE DISPOSAL SINK,’ or equivalent.
- Confirm that all licensed materials are appropriately secure.
- Collect 10 swipe samples (label samples 1 – 10) and identify sample locations on pre-drawn sketch of the area being surveyed. Sample locations should be selected by the surveyor based on the results of the meter scanning and on the likelihood of finding contamination. Areas to consider include floor surfaces (especially near radioactive waste containers), work benches or tables, refrigerators, freezers or cabinets used to store source vials and labeled samples, labeled equipment (e.g., centrifuges, incubators, etc.), hood surfaces, door handles, etc. Samples will be collected with an appropriate pre-numbered paper filter by swiping approximately 100 cm² while applying moderate pressure. Place each sample in a sample vial. Note the filter numbers on the Monthly Survey Report Form.
- Perform dose rate monitoring with the 1” x 1” NaI detector if count rates greater than twice the average background were observed when scanning surfaces with the pancake GM or thin window thin crystal NaI detector. Note any dose rate which exceeds 2.5 mrem per hour on the Monthly Survey Report Form.
- Prepare samples and count in a liquid scintillation counter.
- Upon receipt of swipe sample data, add data to survey report form.
- If any smear sample result exceeds 1,000 dpm/100 cm², decontaminate the area, rescan and resample.
- Monthly Survey Report Forms will be maintained by the RSO.

MONTHLY SURVEY REPORT FORM

Room or Laboratory: _____ Survey Date: _____
 Surveyor: _____

Survey Meter Serial #: _____ Survey Meter Serial #: _____
 Pancake GM Serial # _____ NaI Serial # _____
 Calibration Date: _____ Calibration Date: _____

QC Measurements acceptable: yes no Initials: _____

Wipe Sample Results (dpm/100 cm ²)		
Nuclide		
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

Other Compliance Items:

Posting: Caution, Radioactive Material yes no
 Waste Container Labels yes no
 Disposal Sink Label yes no NA
 Disposal Sink Records Maintained yes no NA
 Appropriate Meter Available yes no NA
 Labels (refrigerator/freezer/cabinet): yes no
 Security/storage: yes no

Maximum dose rate (mrem/h): _____

Remarks: (include items corrected by inspector)	Decon Wipe Sample Results (dpm/100 cm ²)	
	Sample#	

1.0 Scope

This procedure documents the method of responding to spills of licensed material and is consistent with guidance provided in NUREG-1556, Volume 7. Due to the nature of the work with licensed material, it is possible that spills could fall into either the “minor spill” or “major spill” category.

2.0 Related Documents

NUREG-1556, Vol. 7, Appendix P

3.0 Responsibilities

It is the responsibility of Authorized Users and other trained workers to notify the RSO in the event of a radioactive materials spill. It is the RSO’s responsibility to ensure that the spill response procedures contained herein are implemented properly, to document each spill event, and maintain records of each event in an “Incidents File.”

4.0 Materials and Equipment

Survey Meters
Pancake GM Detector
NaI Detector
Lab coats
Disposable gloves
Disposable shoe covers
Roll of absorbent paper with plastic backing
Masking tape
Plastic trash bags with twist ties
“Radioactive Material” labels and labeling tape
Marking pen, pencil
Box of smear sample filters
Clipboard with a copy of the Radioactive Spill Report Form

5.0 Major Spill Response Procedure (greater than 10 μ Ci total or more than 1 m² area affected)

5.1 Notify personnel in the area that a spill has occurred. Persons not involved should vacate area.

5.2 Cover contaminated area with absorbent paper to minimize spread of contamination.

5.3 Secure area to prevent entry to area. Post a sign indicating a spill of radioactive material has occurred.

5.4 Notify RSO; notify Security.

5.5 Survey all personnel who may have been contaminated with a pancake GM detector.

5.6 Decontaminate any affected areas of skin so as not to increase penetration of the contaminant into the body, i.e., avoid abrasive scrubbing. Use lukewarm water and mild detergent and frequent rinsing.

5.7 Clean spill; proceed from outermost edges of the contaminated area inward. Decontaminate any affected surfaces.

5.8 Place all contaminated items in a radioactive waste container.

5.9 Make reasonable effort to reduce removable surface contamination levels to less than 20 dpm/100 cm² (personal clothing, unrestricted areas) and 1,000 dpm/100 cm² (restricted areas, protective clothing used in restricted areas, and skin).

5.10 Arrange for bioassay sample submission, as appropriate.

6.0 Minor Spill Response Procedure (less than 10 μ Ci total or less than 1 m² area affected)

6.1 Notify personnel in the area that a spill has occurred.

6.2 Cover contaminated area with absorbent paper to minimize spread of contamination.

6.3 Clean spill; proceed from outermost edges of the contaminated area inward.

6.4 Fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Place all contaminated items in the bag.

6.5 Survey the area with a pancake GM detector. Also check hands, clothing, and shoes for contamination.

6.6 Notify the RSO.

6.7 Allow no one to return to work in the area unless approved by the RSO.

7.0 Follow-Up For RSO

7.1 Determine cause of spill.

7.2 Evaluate need for corrective actions, such as additional training or change in procedure. Periodically assess effectiveness of any corrective actions implemented.

7.3 Submit bioassay samples to laboratory, as appropriate.

7.4 Evaluate bioassay sample results and estimate committed effective dose equivalents if necessary.

Radioactive Spill Report

Incident Location _____ Date _____ Time _____

Personnel Present:

Item or Location	Contamination Results*

*Use additional sheet to indicate others contaminated, additional monitoring, or care instituted. Delineate magnitude and extent of contamination (provide summary):

Decontaminate and perform follow-up survey (provide summary and attach survey data as appropriate):

Estimated activity involved (μCi):

Provide description of incident:

Corrective actions instituted:

Correction actions follow-up:

Name (RSO): _____

Date: _____

1.0 Scope

This procedure documents the method of ordering and accounting for licensed material and is consistent with guidance provided in NUREG-1556, Volume 7.

2.0 Related Documents

NUREG-1556, Vol. 7, Appendix N

3.0 Responsibilities

It is the responsibility of the RSO to place or approve orders of licensed material and ensure that the license limits are not exceeded. It is the responsibility of the RSO (or his/her designee) to survey packages of licensed material and maintain records of those surveys.

4.0 Materials and Equipment

Survey Meter
Pancake GM Detector
NaI Detector
Protective Clothing (Lab coats, gloves)

5.0 Ordering

5.1 The RSO shall approve or place all orders for radioactive material and will ensure that the quantities ordered are authorized by the license and do not exceed possession limits.

6.0 Receiving

6.1 During normal business hours, packages containing licensed materials will be delivered to the Shipping and Receiving dock on the Lower Level. Persons working there will be trained to notify the RSO or his/her designee upon receipt of a package containing radioactive materials.

6.2 The RSO shall inform receiving personnel of anticipated deliveries. Unanticipated deliveries of licensed materials shall be refused and returned to the carrier.

6.3 Personnel will not be present to accept delivery of radioactive packages during off-duty hours.

6.4 Upon receipt of package, inspect for any signs of shipping damage. Report any obvious damage to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package to remain for monitoring by the RSO.

7.0 Opening

7.1 All packages containing licensed material will be opened in the EHS laboratory within 3 hours after receipt if received during normal working hours or within 3 hours of the start of the next working day if received after normal working hours.

7.2 Wear gloves.

7.3 Check packing slip for contents and confirm that shipment does not exceed license possession limits. Visually inspect package for damage and evidence of leaking. If package is damaged, stop

the procedure and notify the RSO or other knowledgeable person. **NOTE-The package receipt survey described below is necessary for labeled (White I or Yellow II) Type A packages or damaged packages containing licensed radioactive material.**

7.4 Measure the dose rate from the package at 1 meter and at the package surface (required for Type B packages and those that are damaged, but not for others). If higher than expected, notify the RSO. The expected dose rate in mrem/hr at one meter should be close to the “transportation index” value as noted on the package label. The expected maximum dose rates are listed below:

RADIATION LEVEL LIMITS

(49 CFR 172.403 & 173.441)

Label Category	Transportation Index (TI)	Surface Radiation Limits
WHITE I	N/A	≤ 0.5 mrem/hr
YELLOW II	≤ 1.0	≤ 50 mrem/hr
YELLOW III	≤ 10	≤ 200 mrem/hr

The final delivery carrier and the NRC must be immediately notified by telephone if external radiation levels exceed the limits specified in 10 CFR 71.47.

7.5 Collect a smear sample over approximately 300 cm² of the exterior of the package (50 cm² over each of six sides). Count the smear sample with the pancake GM detector or sample counter. Notify the RSO if the sample exceeds 220 dpm/cm² (or 6,600 dpm total), as per 49 CFR 173.443. Should this occur, the final delivery carrier and the NRC must be immediately notified by telephone.

7.6 Record the results of the radiation and contamination survey measurements on the attached Radioactive Materials Receipt Survey form.

7.7 Remove the packing slip.

7.8 Open the outer package.

7.9 Open the inner package and verify contents.

7.10 Check integrity of the inner source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of packing material. Notify RSO and the appropriate AU if contents are different than ordered or if source container appears to be damaged or leaking.

7.11 Check the user request to ensure that the material received is the material that was ordered.

7.12 Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate or remove radiation labels prior to discarding in the regular trash.

7.13 Maintain Radioactive Materials Receipt Survey forms.

8.0 Licensed Material Utilization

8.1 Following completion of the Radioactive Materials Receipt Survey form, place the material in the locked refrigerator, freezer, or cabinet designated for radioisotope storage or transfer the material to the appropriate AU.

8.2 The RSO or AU will create an Isotope Utilization Form for each source vial received. The appropriate Isotope Utilization Form will be kept in the laboratory where the licensed materials are stored and/or used.

8.3 Each time material is withdrawn from a source vial, the material user will make an entry on the Isotope Utilization Form, indicating appropriate dispositions.

8.4 When all radioactive materials tracked by the Isotope Utilization Form have been used or discarded, the completed form will be maintained by the AU for use in preparing monthly inventory of materials.

9.0 Semi-annual Inventory

9.1 A semi-annual inventory of radioisotopes will be conducted by the RSO. Activity in source vials, samples, and in stored radioactive waste will be identified on the attached Semi-Annual Radioisotope Inventory Form.

9.2 A separate Semi-Annual Radioisotope Inventory Form will be created for each isotope present at the facility.

10.0 Records

10.1 Package receipt records will be maintained in the EHS laboratory or in the radiation safety files maintained by the RSO.

10.2 Isotope Utilization Forms will be maintained by the AU while the vial is being used and by the RSO once the vial has been discarded.

10.3 Semi-Annual Inventory records will be maintained by the RSO.

Radioactive Materials Receipt Form

Date: _____ Person performing survey: _____

General Information

Vendor: _____ Amount and type of activity received: _____

Shipper: _____ Chemical description: _____

Package order # or purchase order #: _____

Surface Radioactivity (Swipe Sample, 300 cm²)

Smear Sample Result: _____ (< 6,600 dpm) _____ (dpm)

Dose Equivalent Rate:

Detector model and serial number: _____ Calibration Date: _____

Maximum surface reading: _____ mrem/hr Transportation Index: _____ (mrem/hr@1m)

Leak related follow up information:

Vendor Contact: Yes _____ No _____

Vendor phone number: _____

Name of vendor representative: _____

Vendors Comments:

Isotope Utilization Form

General Information

Nuclide: _____ Initial Activity: _____ Vial Number: _____

Date placed in inventory: _____ Authorized User: _____

Material Usage

Date	User	Activity withdrawn (mCi)	Activity Remaining in Vial (mCi)	Comments

Date Used Vial Placed in Radioactive Waste: _____

AU signature: _____

Radioisotope Semi-Annual Inventory Form

Date: _____ Person performing inventory: _____
Nuclide: _____

Source	Activity (mCi)	Locations
Waste For Transfer		
Waste For Decay-In-Storage		
Waste For Sanitary Sewer Disposal		
Sum Of AU Inventories		
Other sources		
TOTAL		

Facility license limit (mCi): _____

1.0 Scope

The purpose of this SOP is to outline the proper shipping procedures for radioactive packages. At the present time, the only packages containing radioactive materials offered for shipment by Philip Morris USA personnel consist of radioactive waste transferred to a radioactive waste broker. Should the need to prepare other types of licensed materials for shipment arise, this procedure will be modified accordingly. This procedure will be amended as appropriate to keep current with USDOT and NRC regulations.

2.0 Related Documents

49 CFR 173.403, 173.410, 173.421 thru 173.425, and 173.443
10 CFR 71
SOP-001 Survey Meter Quality Control

3.0 Responsibilities

It is the responsibility of the RSO to ensure that any outgoing package containing radioactive material is prepared compliant with all pertinent regulations. This includes the activity in the package, performing and documenting the appropriate survey measurements, obtaining licenses of entities taking custody of the package, maintaining records of shipments, and amending this SOP to keep current with changes to Federal transportation regulations.

4.0 Equipment

Survey Meters
Pancake GM Detector
NaI Detector

5.0 Background

It is anticipated that the only shipments will consist of low level radioactive waste (primarily tritium and C-14).

6.0 Procedure

6.1 Determine that the total quantity of licensed material in the package is less than the appropriate excepted quantity limit. NOTE: The appropriate values for tritium and C-14 in solid form are 1,080 mCi and 54.1 mCi, respectively.

6.2 Determine that the package meets the general design requirements in 49 CFR 173.410 (strong, tight container, won't leak, etc.).

6.3 Measure the surface radiation levels with a NaI detector (following QC measurements as per SOP-001). Determine that the radiation levels along the package surface do not exceed 0.5 mrem/hr.

6.4 Collect a smear sample over approximately 300 cm² of the external surface of the outer packaging. Count the sample with the pancake GM detector and determine that non-fixed contamination does not exceed 6,600 dpm (or 660 cpm, assuming 10 percent efficiency).

6.5 If not already present, affix a label to the outside of the inner packaging which says "Radioactive."

6.6 Include the name of the consignee and mark the outside of the package with the proper UN Identification number, UN 2910, in characters at least 6 mm in height surrounded by a square on point box whose width is at least 2 mm.

6.7 Seal package and address for shipment.

6.8 Fill out the attached Radioactive Shipment Survey Report form and furnish it to the RSO.

Note: Do not label the outside package "radioactive."

Radioactive Shipment Survey Report Form

Date: _____

Shipment to:

Name _____

Address _____

Phone number _____ Fax number _____

Recipient's License (to be filled out by RSO)

Has a copy of the recipient's license been received? Yes ___ No ___

Is the license current? Yes ___ No ___

License State/NRC _____ License # _____

Package Contents

Radionuclide: _____

Quantity: _____

Chemical Form: _____

Wipe Sample

cpm = _____

dpm/cm² = _____

Confirm less than 22 dpm/cm²: Yes ___ No ___

Package Exterior Dose Equivalent Rate

Detector model and serial number: _____

Calibration Date: _____

Dose equivalent rate maximum (mrem/hr): _____

Individual Performing Survey: _____

1.0 Scope

This procedure documents the method of estimating the committed effective dose equivalent and thyroid dose equivalent from urinalysis data. It is based on the guidance in NUREG/CR-4884, *Interpretation of Bioassay Measurements*. Implementation of this procedure will only be necessary following incidents where internal uptake of radioisotopes is suspected. Any bioassay samples collected under this procedure will be analyzed at a radioanalytical laboratory specifically licensed by the NRC or an Agreement State.

2.0 Related Documents

NUREG/CR-4884 Interpretation of Bioassay Methods
10 CFR 20 Appendix B
NRC Regulatory Guide 8.20 Applications of Bioassay for I-125 and I-131
HPS N13.14-1994 Internal Dosimetry Programs for Tritium Exposure-
Minimum Requirements

3.0 Responsibilities

It is the responsibility of the RSO to estimate the committed effective dose equivalent and thyroid dose equivalent to workers from urinalysis data. The RSO may elect to hire consultants for assistance.

4.0 Background

Urinalysis samples will be collected to measure radioisotope intake. Section 5.0 identifies the type and frequencies of sample collection. The methodology for quantifying internal dose from tritium and I-125 are included below. Similar methodologies will be utilized to quantify internal dose from other licensed radioisotopes, as appropriate.

Producing accurate dose equivalent estimates following an intake is challenging due to the rapid urinary excretion exhibited by iodine and hydrogen. Additional uncertainty is introduced by basing dose on a single void of urine rather than a 24-hour sample, although the total activity excreted may be adjusted based on an expected 1.4 L/d excretion rate as provided for reference man in ICRP 23.

The basic methodology involves utilizing the following equation:

$$Intake_{inh} = \frac{A}{IRF}$$

where: A = Activity in urine
IRF = Intake Retention Fraction expressed as fraction in 24-h urine

The quantity estimated for the intake allows for an estimate of the CEDE via comparison to the stochastic Annual Limit on Intake (ALI) for inhalation, as follows:

$$CEDE = \frac{Intake_{inh}}{SALI_{inh}} \times 5rem$$

Similarly, the dose equivalent to the thyroid from radioactive iodine is estimated by using the non-stochastic ALI and the 50 rem organ dose limit, as follows:

$$CDE_{thyroid} = \frac{Intake_{inh}}{NALI_{inh}} \times 50rem$$

5.0 Types and Frequency

Routine: Based on HPS N13.14, a 100 μ Ci intake in a two-week period would require a routine bioassay. Therefore, persons who work with 1 mCi or more tritium in a two-week period will be asked to submit a bioassay (urine) sample. Following guidance in Regulatory Guide 8.20, routine bioassay sampling will also be established for any worker handling 10 mCi or more unsealed I-125 bound to a nonvolatile compound or 1 mCi or more unsealed, volatile I-125.

Emergency – as soon as possible after any incident that causes the RSO to suspect an intake of any licensed material.

Post-operational – within two weeks of the last possible exposure to I-125 or H-3 when a worker is terminating activities with potential exposure.

Diagnostic – Follow-up weekly samples should be submitted following any measurement indicating a thyroid burden exceeding 0.12 μ Ci I-125.

6.0 Method

The stochastic ALI values for inhalation of H-3 and I-125 are 80,000 μCi and 200 μCi , respectively. The nonstochastic ALI for I-125 is 60 μCi , with the thyroid being the tissue at risk.

The RSO will need to designate the specific “day post intake” related to each urine sample. This designation should follow consultation with each worker and be based on the specific sequence of events leading up to the suspected intake. The appropriate intake retention factor (IRF) value will be selected from the table below.

Tritium Intake Retention Fraction (IRF) for 24-hour urine

Days Post Intake						
1	2	3	4	5	6	7
0.0385	0.0376	0.0351	0.0327	0.0305	0.0285	0.0266

Iodine Intake Retention Fraction (IRF) for 24-hour urine

Days Post Intake						
1	2	3	4	5	6	7
0.31	0.064	0.017	0.005	0.001	0.0005	0.0003

The CEDE may be estimated as follows:

$$H_E \text{ (rem)} = C \left(\frac{\mu\text{Ci}}{\text{L}} \right) \times 1.4 \left(\frac{\text{L}}{\text{d}} \right) \times \frac{1}{\text{IRF}_{\text{inh}}} \times \frac{1}{\text{SALI}_{\text{inh}}} \times 5 \text{ rem}$$

where C = radionuclide concentration in urine sample.

For I-125, the committed dose equivalent to the thyroid may be estimated as follows:

$$H_{\text{thy}} \text{ (rem)} = C \left(\frac{\mu\text{Ci}}{\text{L}} \right) \times 1.4 \left(\frac{\text{L}}{\text{d}} \right) \times \frac{1}{\text{IRF}_{\text{inh}}} \times \frac{1}{\text{NALI}_{\text{inh}}} \times 50 \text{ rem}$$

7.0 Example

A worker submits a 0.1 L sample on Wednesday. We assume that an intake occurred on Monday and the days post intake is therefore established as 3. The sample contains 25 dpm I-125. The CEDE is:

$$H_E \text{ (rem)} = \frac{25 \text{ dpm}}{0.1 \text{ L}} \times 1.4 \left(\frac{\text{L}}{\text{d}}\right) \times \left(\frac{\mu\text{Ci}}{2.22 \times 10^6 \text{ dpm}}\right) \frac{1}{0.017 \text{ d}^{-1}} \times \frac{1}{200 \mu\text{Ci}} \times 5 \text{ rem}$$
$$= 2.4 \times 10^{-4} \text{ rem} = 0.24 \text{ mrem}$$

The committed dose equivalent to the thyroid is:

$$H_{\text{thy}} \text{ (rem)} = \frac{25 \text{ dpm}}{0.1 \text{ L}} \times 1.4 \left(\frac{\text{L}}{\text{d}}\right) \times \left(\frac{\mu\text{Ci}}{2.22 \times 10^6 \text{ dpm}}\right) \frac{1}{0.0162 \text{ d}^{-1}} \times \frac{1}{50 \mu\text{Ci}} \times 50 \text{ rem}$$
$$= 9.7 \times 10^{-3} \text{ rem} = 9.7 \text{ mrem}$$

This is to acknowledge the receipt of your letter/application dated

4/4/2007, and to inform you that the initial processing which includes an administrative review has been performed.

NEW LICENSE APPLICATION (03037449)
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 140364.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

BETWEEN: : (FOR LFYS USE)
 : INFORMATION FROM LFS
 : -----
 :
 License Fee Management Branch, ARM : Program Code: 03620
 and : Status Code: 3
 Regional Licensing Sections : Fee Category: _____
 : Exp. Date: 0
 : Fee Comments: _____
 : Decom Fin Assur Req'd: _
 :

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: PHILIP MORRIS USA, INC.
 Received Date: 20070410
 Docket No: 3037449
 Control No.: 140364
 License No.: 45-00385-07
 Action Type: New License

2. FEE ATTACHED

Amount: \$3,400.00
 Check No.: 781541

3. COMMENTS

Signed W. A. Perkins
 Date 4/10/2007

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /_/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____
 Renewal _____
 License _____

3. OTHER _____

Signed _____
 Date _____