NRC FORM 313

U. S. NUCLEAR REGULATORY COMMISSION

N APPROVED BY OMB: NO. 3150-0120

EXPIRES:08/31/2002

(8-1999) 10 CFR 30, 32, 33 34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this mandatory information collection request 7.4 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 Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjst@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FO		THE EIGENION	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, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.				
INSTRUCTIONS: SEE THE APPR SEND TWO COPIES OF THE EN	NSTRUCTIONS: 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 EXE					ARE LOCATED IN:		
DIVISION OF INDUSTRIAL AND MEDICA OFFICE OF NUCLEAR MATERIALS SAFI U.S. NUCLEAR REGULATORY COMMISS WASHINGTON, DC 20555-0001	L NUCLEAR SAFET ETY AND SAFEGUA SION	Υ		SEND APP	S, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, PPLICATIONS TO: FRIALS LICENSING SECTION NUCLEAR REGULATORY COMMISSION, REGION III		
ALL OTHER PERSONS FILE APPLICATION	IS AS FOLLOWS:			801 WA	VARRENVILLE RD.		
IF YOU ARE LOCATED IN:					; il 60532-4351 L Arizona, Arkansas, California, Colorado, Hawaii, Idaho, Kansas,		
CONNECTICUT, DELAWARE, DISTRICT OF MASSACHUSETTS, NEW HAMPSHIRE, NE RHODE ISLAND, OR VERMONT, SEND AP	W JERSEY, NEW Y	E, MARYLAND, ORK, PENNSYLVANIA,		LOUISIAN/	MARKUNA, ANTANASA, ALTONIA, OSEMMEXICO, NORTH DAKOTA, MA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, DMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, IGTON, OR WYOMING, SEND APPLICATIONS TO:		
LICENSING ASSISTANT SECTION NUCLEAR MATERIALS SAFETY BRANC U.S. NUCLEAR REGULATORY COMMIS 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415	SION, REGION 1			U.S. NU 611 RY	LEAR MATERIALS LICENSING SECTION NUCLEAR REGULATORY COMMISSION, REGION IV NYAN PLAZA DRIVE, SUITE 400 NGTON, TX 76011-8064		
ALABAMA, FLORIDA, GEORGIA, KENTUC RICO, SOUTH CAROLINA, TENNESSEE, V SEND APPLICATIONS TO:	'IRGINIA, VIRGIN IS	IORTH CAROLINA, PUER LANDS, OR WEST VIRGII	TO NIA,				
SAM NUNN ATLANTA FEDERAL CENT U. S. NUCLEAR REGULATORY COMMI 61 FORSYTH STREET, S.W., SUITE 23' ATLANTA, GEORGIA 30303-8931	SSION, REGION II 185						
PERSONS LOCATED IN AGREEMENT STA MATERIAL IN STATES SUBJECT TO U.S.	ATES SEND APPLIC NUCLEAR REGULA	CATIONS TO THE U.S. NU TORY COMMISSION JUR	CLEAR R	NS.	ORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED		
1. THIS IS AN APPLICATION FOR (Chec	k appropriate item)			2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)			
X A. NEW LICENSE				Pinnacle Pharmaceuticals, Inc			
B. AMENDMENT TO LICENSE	NUMBER			1670 Discovery Dr			
c. RENEWAL OF LICENSE NUMBER Suite 211 Charlottesville, VA 22911							
3. ADDRESS(ES) WHERE LICENSED MA	TERIAL WILL BE U	SED OR POSSESSED		<u> </u>	NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION		
1670 Discovery Dr				Richard R Poelling			
Suite 211	4			TELEPHONE NUMBER			
Charlottesville, VA, 2291	1			(434) 951-9490			
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 >	(11" PAPER. THE !	TYPE AND SCOPE OF INF	ORMATIC	ON TO BE P	PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.		
RADIOACTIVE MATERIAL. a. Element and mass number; b. che which will be possessed at any on	mical and/or physica			1	JRPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.		
INDIVIDUAL(S) RESPONSIBLE FOR I TRAINING EXPERIENCE.	RADIATION SAFETY	PROGRAM AND THEIR		8. TRAINING FOR INDIVIOUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.			
9. FACILITIES AND EQUIPMENT.				10. RADIATION SAFETY PROGRAM.			
11. WASTE MANAGEMENT.				12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 3 M. AMOUNT ENCLOSED \$ \$2,500			
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 OFJUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO							
ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION: CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE DATE DATE 12 12 12 12 12 12 12 12 12 12 12 12 12 1							
Sidney M. Hecht, Preside				AZ	20 m Hack \$ 17/03		
FOR NRC USE ONLY							
TYPE OF FEE FEE LOG	FEE CATEGORY	AMOUNT RECEIVED \$	CHECK	NUMBER	COMMENTS		
APPROVED BY			DATE				

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Item 5.0 Radioactive Material

10 CFR 30.14, 10 CFR 30.15, 10 CFR 30.18, 10 CFR 30.19, 10 CFR 30.21, 10 CFR 30.32(g), 10 CFR 30.32(I), 10 CFR 30.33, 10 CFR 31.5, 10 CFR 31.8, 10 CFR 31.11, 10 CFR 32.210.

5.A Element and Mass Number	5.B. Chemical and/or physical form	5.C Maximum amount which will be possessed at any one time.
Phosphorus -32 (P-32)	Any	75 curies
Phosphorus -33 (P-33)	Any	40 curies
Sulphur-35 (S-35)	Any	100 curies
Hydrogen-3 (H-3)	Any Non-Volatile Form	0.095 curies
Carbon-14 (C-14)	Any Non- Volatile Form	0.090 curies

Financial Assurance not required for specified possession limits

Item 6.0 Purpose(s) For Which Licensed Material Will Be Used 10 CFR 30.4, 10 CFR 30.33(a)(1), 10 CFR 51.21, 10 CFR 51.22.

Radioisotope	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
H-3	Bound/Non-Volatile	0.095 Curies	Labeling of compounds
P-32	Any	75 Curies	Labeling of compounds; In vitro studies; Gel Shift Assays
P-33	Any	40 Curies	In vitro studies; Labeling of compounds; Gel Shift Assay
C-14	Bound/Non-Volatile	0.090 Curies	Labeling of compounds; In vitro studies
S-35	Any	100 Curies	Labeling of compounds; In vitro studies, Sequencing

Item 7.0 Individuals Responsible For Radiation Safety Program and Their Training and Experience 10 CFR 30.33(a)(3).

7.1 Radiation Safety Officer (RSO)

Name:

Richard R Poelling.

Education:

University of Missouri, B.S. 1998

Employment:

Present Position

May 2001 - Present Research Specialist II - Pinnacle Pharmaceuticals, Inc

Past 2 Positions

1998 - 2001

Research Scientist - Monsanto Co.

1993 - 1998

Research Assistant - University of MO Dept. of Biochemistry

Training with Radioactive Materials

48 hours Nuclear Engineering 303 (Univ of MO) "Principles of Radiation Safety"

40 hours CSI-Radiation Safety Academy "Radiation Safety Officer" training

3 years Maintained User status at Monsanto (8 hr class w/ yearly refresher classes)

3 years Radiation Worker Univ. of MO - Columbia

Experience with Radioactive materials

Worked with P-32, P-33, S-35, and C-14, (microcurie to curie amounts)

Managed Radioactive Materials at Univ of Mo.

7 years working with radioactive materials in a research environment

7.2 Authorized User

10 CFR 20.1101 (b), 10 CFR 30.33(a)(3).

The authorized user will be the primary supervisor of radioactive material use. This individual will be responsible for the safe use of the materials in their possession at all times.

Name:

Larisa Dedkova, Ph.D.

Education: Novosibirsk State University, Russia

Employment History:

2000-2003 University of Virginia, Research associate, Research Scientist 2003- present Pinnacle Pharmaceuticals, Scientist, Senior Scientist, Senior Scientist II.

Training with Radioactive Materials:

7 hour course on the principles and practices of radiation protection conducted by UVA EHSO; From August, 2000 Restricted User of radioactive material under Authorization # 91-90 (issued to Prof. Sidney Hecht).

Experience with Radioactive materials:

C-14 <33 mCi

H-3 <700 mCi

P-32 <30 mCi

S-35 <20 mCi.

Item 8.0 Training for Individuals Working in or Frequenting Restricted Areas (Occupationally Exposed Individuals and Ancillary Personnel)

10 CFR 19.11, 10 CFR 19.12, 10 CFR 19.13, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.7, 10 CFR 30.9, 10 CFR 30.10, 10 CFR 30.33(a)(3), 10 CFR 30.34(e).

Radiation Safety Program

8.1 Frequency of Training

- · Before assuming work with any or in the vicinity of radioactive materials
- · Whenever the duties, regulations or terms of the license change significantly
- Annually (Refresher Training)

8.2 Individuals Requiring Training

The following are the groups of individuals which have been identified as needing some form of training in regards to proper management of radioactive materials.

- Authorized Users
- · Radiation Workers
- Ancillary Personnel (Maintenance, Housekeeping)

8.3 Concepts and Outline of Training For Authorized and Radiation Workers

Training will consist of a manual and followup test after the initial lecture. This training will test the users ability to safely use and handle radioisotopes in our environment. Training will also be given every year as a refresher to maintain status as a user of radioactive materials.

- General overview of radiation and physical concepts.
- Fundamentals of the Radiation Safety Program
 - Types of Isotopes in Use
 - · Risk's associated with those isotopes
 - Internal vs External Dose
 - Biological Effects of Radiation
- Limiting Exposure
 - Time, Distance, Shielding
 - ALARA
 - Contamination Control
- Regulatory Requirements (Responsibilities of the User)
 - RSO and their Responsibilities

- Procedures for obtaining material
- Inventory Requirements
- · Control and Security of Radioactive Material
- Disposal Requirements
- · Importance of Record Keeping
- Surveys
- · Labeling Requirements for material

All the relevant material that is discussed in training will also be provided by means of a procedural handbook. In this manual will be located the necessary forms and flow diagrams for the following procedures.

- Ordering
- Receiving
- Storage
- Inventory
- Use
- Disposal
- Emergencies

This material will be presented by the RSO followed by a successful passing of a skills based test. The RSO will also perform visual inspections of the procedures while work is in progress.

8.4 Concepts and Outline of Training For Ancillary Personnel

This classification is used for personnel who frequent areas designated as radioactive material usage areas. These individuals include housekeeping and general maintenance staff. Training for these individuals will consist of the following.

- Identification of Radioactive Areas (Signage Designations)
- Identification of Waste Streams (Yellow Bags)
- Contact Information of RSO in case of emergency

8.5 Flexibility Statement

We reserve the right to modify our training program as long as it does not degrade the value of the training or relax regulatory requirements.

Item 9.0 Facilities and Equipment

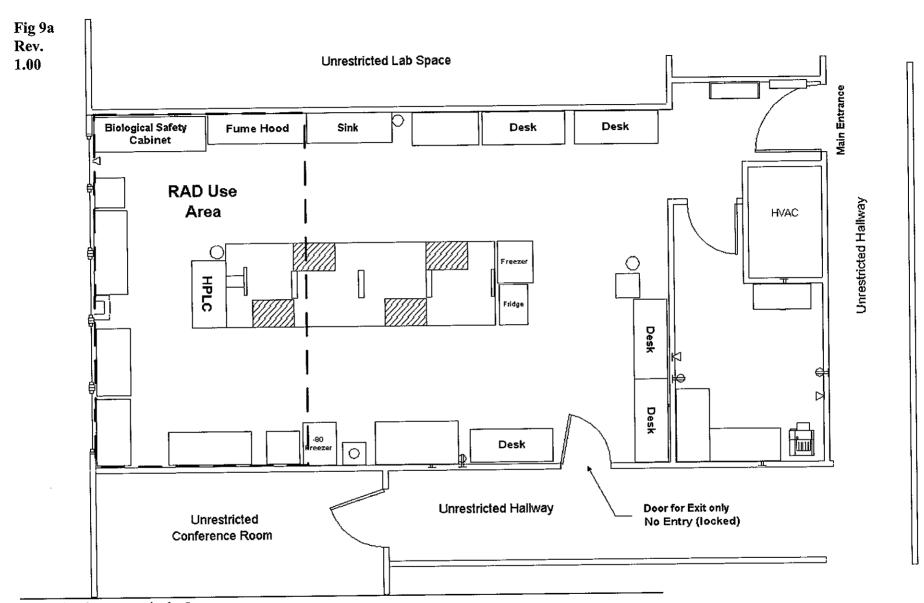
10 CFR 20.1101(b), 10 CFR 20.1406, 10 CFR 30.33(a)(2), 10 CFR 30.35 (g).

Radioactive material use will be confined to an individual lab. This lab will remain locked when personnel are not present. Experiments will be carried out on laboratory benches which are made of a hard epoxy resin that will not absorb spilled material. Double layer laboratory paper (absorbent top/plastic backing) will be used for ALL radiological work to contain possible spills.

Separate benches and equipment will be designated for use with radioactive material to minimize possible cross contamination. This bench will also utilize Lucite shielding to minimize exposure. No food or drink will be allowed in the restricted area at any time.

All material will be kept in the immediate area designated as the RAD use area. Package inspections, inventory and waste will all be handled in this area to minimize contamination. Waste containers will be properly sealed and shielded depending on the isotope in question.

A detailed layout of the facility is located on the next page as Fig 9a



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Item 10.0 Radiation Safety Program

10.1 Radiation Monitoring Instruments

10 CFR 20.1501, 10 CFR 20.2103(a), 10 CFR 30.33(a)(2)

We will use the following instruments to survey for radioactive contamination:

- Ludlum Model 3 (#48-1605) with GM Pancake Probe Model 44-9 (#47-1539)
- Liquid Scintillation Counter to be determined

We 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.

10.2 Material Receipt and Accountability

10 CFR 30.34(e), 10 CFR 30.35(g), 10 CFR 30.41, 10 CFR 30.51, 10 CFR 20.1501(a), 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906, 10 CFR 20.2001, 10 CFR 20.2201, 10 CFR 31.11.

All radioactive materials are to be shipped to the RSO for initial receipt and inspection. Upon arrival, the package will be checked for damage and leaks with the appropriate survey technique (GM and LSC). When the package has been cleared, the Authorized User will be notified of the arrival of the material and it will then be added to the inventory for immediate use. It is the responsibility of the authorized user to maintain current inventories of all isotopes under their control. Copies of the forms which will be used to track radioactive materials are located at the end of the application under the "Attachments" section.

Security of Material

The Authorized User is responsible for the security of all radioactive material within their inventory. All material must be locked when not in use or when not under the direct control of the authorized user or radiation worker. This may be accomplished by maintaining locked doors in unoccupied labs and lockable freezers for storage of inventory.

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

10.3 Occupational Dose

10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.1703, 10 CFR 20.2105, 10 CFR 20.2206, 10 CFR 20 Appendix B.

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

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10.4 Safe Use of Radionuclides and Emergency Procedures

10 CFR 30.34(e), 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1902-1905, 10 CFR 20.2201-2203, 10 CFR 30.32(I), 10 CFR 30.50, 10 CFR 30.72, 10 CFR 21.21, 10 CFR 19.11(a)(3).

Phosphorus-32 Handling Precautions

Physical Data

Maximum Beta Energy: 1.71 MeV (100%)

Maximum Range of Beta in Air: about 6 meters (20 feet)
Maximum Range of Beta in Water: about 8 mm (0.3 inches)

Physical Half-Life: 14.29 days

Dosimetry

The bone is the critical organ for intake of transportable compounds of ³²P. Phosphorus metabolism is complex; 30% is rapidly eliminated from the body, 40% possesses a 19-day biological half-life, and the remaining 30% is reduced by radioactive decay. The lung and lower large intestine are the critical organs for inhalation and ingestion, respectively, of non-transportable ³²P compounds.

The high-energy beta emissions can present a substantial skin dose hazard. Multi 100-millicurie (3.7 GBq) quantities of ³²P can produce significant secondary radiation presenting an external exposure hazard.

The dose rate at the mouth of an open vial containing 1 mCi of ³²P in 1 ml of liquid is roughly 26 rem/hour. Since this dose rate will not be attenuated significantly by air, shielding materials should be placed between the source and personnel to absorb most of the radiation. The best shield for a ³²P source is a material like Lucite 1.3 cm (0.5 inch) thick or other plastic, which will absorb the beta particles while generating little secondary radiation. For mCi amounts of ³²P, thin, high density shielding such as lead 3 to 6 mm thick should be added to the exterior of the Lucite shield to absorb the higher intensity secondary radiation.

A high local dose can be received if the radioactive material is touched and allowed to remain on the skin or gloves. Both the hands and the face can receive a considerable dose of radiation near an open container of ³²P, particularly if the radioactivity is in a concentrated form. Therefore, never work over an open container of ³²P.

Precautions

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- 1. Designate area for handling ³²P and clearly label all containers.
- 2. Store ³²P behind Lucite and/or lead shielding.
- 3. Wear extremity and whole body dosimeters while handling mCi quantities.
- 4. Handle millicurie quantities of ³²P behind 1.3 cm thick Lucite shielding. Where necessary, increase shielding by attaching 3 to 6 mm thick lead sheets to the outside of the Lucite to reduce secondary radiation.
- 5. Do not work over open containers.
- 6. Practice routine operations to improve dexterity and speed before using ³²P.
- 7. Avoid skin exposure by using tools to indirectly handle unshielded sources and potentially contaminated vessels.
- 8. Prohibit smoking, eating, drinking and mouth pipetting in rooms were ³²P is handled.
- 9. Use transfer pipets, spill trays and absorbent coverings to confine contamination.
- 10. Handle potentially volatile chemical forms in ventilated enclosures (fume hoods).
- 11. Use lab coat and disposable gloves for secondary protection, double gloves are preferred.
- 12. Regularly monitor and promptly decontaminate gloves and surfaces to maintain contamination and exposure control.
- 13. Use end window or pancake Geiger-Mueller detector or liquid scintillation counter to detect ³²P.
- 14. Isolate waste in clearly labeled shielded container.
- 15. On completing an operation, secure all ³²P, remove protective clothing, monitor and decontaminate self and surfaces, wash hands and monitor hands again

Phosphorus-33 Handling Precautions

Physical Data

Maximum Beta Energy: 0.249 MeV (100%) Maximum Range of Beta in Air: 46 cm (18 in.)

Physical Half-Life: 25.4 Days

Dosimetry

Millicurie (37 MBq) quantities of ³³P do not present a significant external exposure hazard because the low-energy betas emitted barely penetrate gloves and the outer dead layer of skin. The bone is the critical organ for intake of transportable compounds of P. Phosphorus metabolism is complex; 30% is rapidly eliminated from the body, 40% possesses a 19-day biological half-life, and the remaining 30% is reduced by radioactive decay. The lung and lower large intestine are the critical organs for inhalation and ingestion, respectively, of non-transportable P compounds.

Precautions

- 1. Designate area for handling ³³P and clearly label all containers.
- 2. Prohibit smoking, eating, drinking and mouth pipetting in rooms were ³³P is handled.
- 3. Use transfer pipets, spill trays and absorbent coverings to confine contamination.
- 4. Handle potentially volatile chemical forms in ventilated enclosures (fume hoods).
- 5. Use lab coat and disposable gloves for secondary protection.
- 6. Regularly monitor and promptly decontaminate gloves and surfaces to maintain contamination and exposure control.
- 7. Use end window or pancake Geiger-Mueller detector or liquid scintillation counter to detect ³³P.
- 8. Isolate waste in clearly labeled shielded container.
- 9. On completing an operation, secure all ³³P, remove protective clothing, monitor and decontaminate self and surfaces, wash hands and monitor hands again

Tritium Handling Precautions

Physical Data

Maximum Beta Energy: 0.019 MeV (100%)

Maximum Range of Beta in Air: about 4.7 mm (0.19 inches)

Physical Half-life: 12.3 years

Dosimetry

Millicurie quantities of tritium do not present an external exposure hazard because the low energy betas emitted cannot penetrate the outer dead layer of skin. The critical organ for tritium uptake is the whole body water. Three to four hours after intake, tritiated water is uniformly distributed in all body water. On average, tritiated water is eliminated with a ten-day biological half-life. Elimination rates may be increased by increasing water intake.

Precautions

- 1. Designate area for handling ³H and clearly label all containers.
- 2. Prohibit smoking, eating, and drinking in the room where ³H is handled.
- 3. Confine contamination by using transfer pipets, spill trays, and absorbent coverings.
- 4. Handle potentially volatile compounds in ventilated enclosures.
- 5. Wear lab coat and disposable gloves at all times while working with radioactive material. Select gloves appropriate for chemicals handled.
- 8. Maintain control by prompt decontamination of gloves and surfaces.
- 9. Submit periodic urine samples for bioassay to determine uptake by personnel.
- 10. Isolate, label, and dispose of wastes according to approved guidelines.
- 11. On completing an operation, secure all ³H, remove protective clothing, monitor and decontaminate self and surfaces and wash hands.

Many tritium compounds readily penetrate gloves and skin. Handle these compounds remotely, wear two pairs of gloves and change the outer layer every twenty minutes. Tritiated DNA precursors are considered more toxic than tritiated water. However, they are generally less volatile and do not normally present a significantly greater hazard

Sulfur-35 Handling Precautions

Physical Data

Maximum Beta Energy: 0.167 MeV Maximum Range of Beta in Air: 24 cm.

Physical Half-life: 87.4 Days

Dosimetry

³⁵S can be hard to detect with a GM detector. To properly determine contamination, it is necessary to use a wipe test and a Liquid Scintillation Counter. Millicurie (37 MBq) quantities of ³⁵S do not present a significant external exposure hazard since the low-energy emissions barely penetrate the outer dead layer of skin. The metabolism and retention of sulfur compounds in the body vary considerably for different chemical forms. Sulfur uptakes are assumed to be uniformly distributed throughout all organs and tissues in the body. For uptakes of inorganic sulfur, 15% is assumed to be retained with a 20 day biological half-life and 5% retained with a 2,000 day biological half-life. The remaining 80% is assumed to be rapidly excreted.

Precautions

- 1. Designate area for handling ³⁵S and clearly label all containers.
- 2. Prohibit smoking, eating, and drinking in the room where 35S is handled.
- 3. Confine contamination by using transfer pipets, spill trays, and absorbent coverings.
- 4. Handle potentially volatile compounds in ventilated enclosures. Use of activated charcoal is recommended to control possible radioactive volatiles.
- 5. If enhanced containment is necessary, handle volatile compounds in closed systems vented through suitable traps.
- 6. Wear lab coat and disposable gloves at all times while working with radioactive material. Select gloves appropriate for chemicals handled. Double gloves may be necessary depending on the radiolabeled compound.
- 7. Maintain control by prompt decontamination of gloves and surfaces.

8.	Isolate, label, and dispose of wastes according to approved guidelines.	Do not mix with shorter
	lived isotopes.	

- 9. On completing an operation, secure all ³⁵S, remove protective clothing, monitor and decontaminate self and surfaces and wash hands.
- 10. Use swipe tests with a LSC to determine any possible contamination.

Carbon-14 Handling Precautions

Physical Data

Maximum Beta Energy: 0.156 MeV (100%) Maximum Range of Beta in Air: 22 cm (8.6 in.)

Physical Half-Life: 5730 years

Dosimetry

Millicurie (37 MBq) quantities of ¹⁴C do not present a significant external exposure hazard because the low-energy betas emitted barely penetrate the outer dead layer of skin. ¹⁴C-labeled compound uptake may be assumed to be uniformly distributed throughout all organs and tissues in the body. Most ¹⁴C-labeled compounds are rapidly metabolized and the radionuclide is exhaled as ¹⁴CO₂. Some compounds and their metabolites are eliminated via the urine. Biological half lives vary from a few minutes to 40 days.

- 1. Designate area for handling ¹⁴C and clearly label all containers.
- 2. Prohibit eating, drinking, smoking and mouth pipetting in room where ¹⁴C is handled.
- 3. Use transfer pipets, spill trays and absorbent coverings to confine contamination.
- 4. Handle potentially volatile compounds in ventilated enclosures.
- 5. If enhanced containment is necessary, handle volatile compounds in closed systems vented through suitable traps.
- 6. Wear disposable lab coats, wrist guards and gloves for secondary protection.
- 7. Select gloves appropriate for chemicals handled.
- 8. Maintain contamination and exposure control by regularly monitoring and promptly decontaminating gloves and surfaces.
- 9. Use pancake or end-window Geiger-Mueller detectors or liquid scintillation counter to detect ¹⁴C.
- 10. Submit periodic urine and breath samples (as appropriate) for bioassay to determine uptake by personnel.

10.5 Surveys

10 CFR 30.53, 10 CFR 20.1501, 10 CFR 20.2103.

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. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions.

Item 11.0 Waste Management

10 CFR 20.1904, 10 CFR 20.2001, 10 CFR 20.2002, 10 CFR 20.2003, 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2108,10 CFR 30.51, 10 CFR 61.52.

We will use the model waste procedures 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.

Pinnacle Pharmaceuticals, Inc NRC License Application February 28, 2003 Page 20

Attachments

Pinnacle Standard Forms

P-01	Request for Radioactive Material
P-02	Record of Receipt for Radioactive Material
P-03	Inventory of Radioactive Material
P-04	Waste/ Disposal Record of Radioactive Material

REQUEST FOR RADIOACTIVE MATERIALS (To be submitted to the RSO)

Name:			<u>.</u>			
Date:						
Account:						
Purchase Order #:						
Isotope Requested (Circle one)	³² P	³³ P	³⁵ S	³H	¹⁴ C	
Current Inventory of Isotope:						
Manufacturer: (Address, Phone a.	nd Fax)				
Quantity Catalog #	Desc	<u>criptior</u>	1			 Price
	٦,					
For RSO Use Only						
Date Ordered:						
Package Checked:						

Form P-01 Rev 1.00

RECORD OF RECEIPT FOR RADIOACTIVE MATERIAL

For:	
Date:	
Time:	
PO#:	
Isotope (Circle one) 32P 33P 35S 3H 14C	
Package Condition	
Manufacturer: Catalog#: Lot#: Activity: Date of Activity:	
Removable Contamination (Report in DPM) (Attach	printout)
Survey Results (@ 1 cm)	
Signed RSO:	

Form P-02 Rev 1.00

INVENTORY RECORD

Date:		Activity Information				
Authorized User: Manufacturer: Catalog #:		Lot #: Activity: Activity Date:				
Date	Activity Removed	Remaining Activity	Initials			
.						

WASTE / DISPOSAL RECORD

Room #: (sotope:	211		Start Date: Form: Liquid / Solid			
DATE	ACTIVITY	y Added	User	VOLUME (APPROX.)		
<u></u>						
			Continue	d on next pages		
RSO Use C		II-16 I ifo o	£I angast Isatona			
Activit	isposed: y @ Disposal:	Date of 10 1	f Longest Isotope Half-Lives			
Signed						

DATE	ACTIVITY ADDED	User	VOLUME (APPROX.)

DATE	ACTIVITY ADDED	User	VOLUME (APPROX.)

DATE	ACTIVITY ADDED	User	VOLUME (APPROX.)
		10111	
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