QPS QUEST PHARMACEUTICAL SERVICES

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Three Innovation Way, Suite 240
Newark, Delaware 19711
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Steven Courtemanche
Division of Nuclear Materials Safety
U.S. Nuclear regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

April 25, 2005

Subject: NRC License Amendment (License No. 07-30584-01) 03035435

Dear Mr. Courtemanche,

I am writing to you to amend our NRC license to reflect the addition of new labs to be used by QPS for work involving radioactive materials, and the addition of a new radioactive waste storage shed. This amendment also includes an updated QPS' Radiation Safety Program. To this end, I have included: NRC Form 313 and attachments to address items 5-11 on Form 313, and which also includes floor plans for the new labs.

Thank you very much for your attention to our request and please feel free to contact me at any time, if you should require any further information or if you have any questions.

Sincerely,

Eric Solon, Ph.D.
Radiation Safety Officer
Quest Pharmaceutical Services, L.L.C.
Pencader Corporate Center, Suite 7
Newark, DE 19702
Tel: (302) 369-5300 Ext. 203
FAX: (302) 369-3753
Email: eric.g.solon@questpharm.com

NRC FORM 313 (4-2004) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2005

Estimated burden per response to comply with this mandatory collection request: 7 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 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to Infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. *If a means used to impose an information* collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

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

IF YOU ARE LOCATED IN:

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

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

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

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

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

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - [ ] A. NEW LICENSE
   - [X] B. AMENDMENT TO LICENSE NUMBER 07-30584-01
   - [ ] C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*
   Quest Pharmaceutical Services, L.L.C.
   3 Innovation Way, Suite 240
   Newark, DE 19711

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED
   3 Innovation Way, Suite 240 & 225+211
   1 Innovation Way, Suite 200, Newark, DE 19711
   110 Executive Dr., Suite 7,
   Newark, DE 19702

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
   Eric Solon

   TELEPHONE NUMBER
   302-369-5203

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

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

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

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

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

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

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

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

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Eric Solon, Ph.D., Radiation Safety Officer	Eric Solon	Apr. 25, 2005

FOR NRC USE ONLY

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

Quest Pharmaceutical Services, L.L.C.
Amendment to Byproduct Materials License (License No. 07-30584-01)
(April 29, 2005)

Introduction

Quest Pharmaceutical Services (QPS) is a full-service GLP (Good Laboratory Practice) and GCP (Good Clinical Practice) compliance analytical laboratory providing analytical support to the pharmaceutical industry. Its target market is major, generic, and biotech pharmaceutical companies. Quest Pharmaceutical Services provides assay development and validation, quantitative analysis of drug levels in biological matrices (preclinical and clinical), metabolite identification, bioavailability/bioequivalence, and pharmacokinetic support.

In order to develop sensitive and specific methods for determining drug concentrations in biological fluids Quest Pharmaceutical Services requires the use of byproduct radioactive materials regulated by the Nuclear Regulatory Commission (NRC). We at Quest Pharmaceutical Services understand the responsibilities that accompany the use of radioactive material and will work to keep any radiation doses or releases of radioactive material to the environment as low as reasonably achievable.

5. Radioactive Material

Element and Mass Number	Chemical and/or Physical Form	Maximum Amount that will be possessed at any one
Hydrogen 3	Bio-chemical compounds as unsealed sources	75 millicuries
Carbon 14	Bio-chemical compounds as unsealed sources	50 millicuries
Phosphorus 32	Bio-chemical compounds as unsealed sources	5 millicuries
Phosphorus 33	Bio-chemical compounds as unsealed sources	5 millicuries
Sulfur 35	Bio-chemical compounds as unsealed sources	5 millicuries
Calcium 45	Bio-chemical compounds as unsealed sources	4 millicuries
Chromium 51	Bio-chemical compounds as unsealed sources	5 millicuries
Yttrium 90	Bio-chemical compounds as unsealed sources	10 millicuries
Technetium 99m	Bio-chemical compounds as unsealed sources	10 millicuries
Iodine 125	Bio-chemical compounds as unsealed sources	15 millicuries
Rhenium 188	Bio-chemical compounds as unsealed sources	5 millicuries

6. Purposes for which licensed material will be used (also includes by whom and the location of use)

Radionuclide(s) Max. Possession Activity (mCi)	Principal Investigator	Procedure(s) Performed	Location of Laboratory at QPS
^{3}H (75), ^{14}C (50), ^{125}I (15), ^{35}S (5), ^{32}P (5), ^{33}P(5), ^{45}Ca (4), ^{90}Y(10), ^{99m}Tn(10), ^{188}Rh(5), ^{51}Cr(5) (reflects total possession limits for QPS)	Alfred Lordi	In vitro & in vivo ADME Studies, Whole Body- & Micro-Autoradiography, Radiodetection with HPLC	Pencader Site, 110 Executive Drive, Suite 7 Newark, DE 19702
	Helen Shen	In vitro & in vivo ADME Studies, Radiodetection with LC/MS/MS and HPLC	Pencader Site, 110 Executive drive Newark, DE 19702 AND 1 Innovation Way, Suite 200 Newark, DE 19711
	Larry Duan	ELISA, immunoassays, and Cell Based Assays, molecular biology assays	Delaware Technology Park, 3 Innovation Way, Suite 225 Newark, DE 19711
	Yuan-Shek Chen	Radiodetection with LC/MS/MS, HPLC	Delaware Technology Park, 3 Innovation Way, Suite 240 Newark, DE 19711
	Kumar Ramu	Radiodetection with LC/MS/MS, HPLC	Delaware Technology Park, 3 Innovation Way, Suite 240 Newark, DE 19711

ADME = Absorption, Distribution, Metabolism and Excretion

7. Individuals responsible for Radiation Safety Program and their training and experience

Principal Investigator Training and Experience

Principal Investigator	Radio-nuclide(s) Used in the Past	Max. Activity* (mCi)	Procedure(s) Performed**	Where ***	Hours of Training Course Attendance	Years of RAM Experience
Alfred Lordi	^{3}H, ^{14}C, ^{125}I	5, 18, 1	ADME Studies, Whole Body- & Micro-Autoradiography	Schering-Plough Research Institute, NJ	2-3 / yr	1993-2002
	^{111}In, ^{32}P, ^{33}P	5, 5, 3,		QPS, Newark, DE	>12 (including shipping regulations for RAM)	2002-present
Helen Shen	^{3}H, ^{14}C	1, 1	Synthesis, Biosynthesis & Metabolism	Univ Of CA, San Francisco	1	1975-1979
	^{3}H, ^{14}C	1, 1	In vivo Pharmacokinetics In Vitro assays	DuPont	8	1983-1988
	^{3}H, ^{14}C	1, 1	In vivo Pharmacokinetics In Vitro assays	DuPont Pharmaceuticals	8	1994-2001
	^{32}P, ^{125}I	5, 5	ADME Studies	QPS, Newark, DE	2	2002-present
Larry Duan	^{125}I	0.100	Protein labeling	Hoffman LaRoche	8	1995
	^{33}P, ^{3}H, ^{14}C	1, 1, 2	ELISA/cell based assays	QPS, Newark, DE	4	2002-present
Yuan-Shek Chen	^{14}C, ^{3}H, ^{125}I, ^{32}P,	0.100, 0.100, 1, 1	LC-Radiodetection	QPS, Newark, DE under supervision of Kumar Ramu and Eric Solon	8	1998, 1998 2001, 2002-present
Kumar Ramu	^{3}H, ^{14}C	5, 5	PK / Metabolism	University of Mississippi	3	1994 – 1998
	^{3}H, ^{14}C, ^{125}I, ^{35}S, ^{32}P	5, 5, 500, 500, 500	PK / Metabolism & Molecular Biology	University of Texas	8	1994
	^{3}H, ^{14}C	5, 5	PK / Metabolism	CoCensys, Inc.	4	1995 – 1999
	^{3}H, ^{14}C, ^{125}I,	5, 5, 4	Bioanalysis by LC/MS/MS	QPS, Newark, DE	2	1999-present

* Refers to the maximum amount used at any one time for a given procedure.

** General Procedure/experiment name.

*** Refers to the institution licensed to conduct such procedures.

ADME = Absorption, Distribution, Metabolism and Excretion

Radiation Safety Officer
Training and Experience

Eric Solon, Ph.D.
Director of Autoradiography Laboratories

Education:

1996 Ph.D., Entomology, Rutgers University, New Brunswick, NJ

1990 M.S., Biology, Fairleigh Dickinson University, Madison, NJ

1983 B.S., Biology, Delaware Valley College, Doylestown, PA.

Dr. Solon is responsible for implementing the radiation protection program for the QPS sites located in the Delaware Technology Park Facility (1 and 3 Innovation Way, Newark, DE, 19711) and Pencader Industrial Park (110 Executive Drive, Suite 7, Newark, DE, 19702). Dr. Solon has the independent authority to stop any operations the he considers unsafe and he will directly supervise the use of licensed material at all QPS facilities. He will ensure that the security of, and that access to licensed material is maintained, and will respond to events or accidents involving licensed material to prevent the spread of contamination.

During his 9 years of experience with storage, handling and disposal of the radioactive isotopes Dr. Solon was trained in weighing (solids and liquids), making dosing formulations, animal (rat and mouse) dosing, as well as, in collection and processing of blood, urine, feces, frozen and fresh whole body and tissue samples for pharmacokinetic and metabolism studies. These samples were then subjected to bioanalytical methods of analysis for quantitation of drugs and metabolites. He has also served as the Radiation Safety Representative for DuPont Pharmaceuticals Preclinical Drug Metabolism Department.

Experience with Radiation

Isotope	Activity Used	Where Experience was Gained	Duration of Experience	Type of Use
$^{14}C/^{3}H$ ^{125}I ^{90}Y	≤75 mCi ≤25 mCi ≤50 µCi	DuPont Pharmaceuticals	3 years	Pk/Metabolism
$^{14}C/^{3}H$ ^{125}I	≤50 mCi ≤25 mCi	Schering-Plough Research Institute	3 years	Pk/Metabolism
$^{14}C/^{3}H$	≤5 mCi	Rutgers University	2 years	Molecular Biology

Additional Training:

2 Day: Radiation Safety Training for RSOs, Englehardt & Associates, Inc., Las Vegas, NV, March 2005

1 Hour: Radioactive Material User Refresher, DuPont Pharmaceuticals, July 2001

8 Hour: Radiation Protection Seminar, DuPont Pharmaceuticals, March 2000

1 Hour: Radioactive Material User Refresher, DuPont Pharmaceuticals, Sept 2000

1 Hour: Radioactive User Orientation, DuPont Pharmaceuticals, Sept 1999

1 Hour: Radiation Safety Training, Schering-Plough, October 1998

1 Hour: Radiation Safety Training, Schering-Plough, October 1997

3 Hour: Radiation Safety Training, Schering-Plough, October 1996

8 Hour: Radioisotope Safety Training, Ciba-Geigy Pharmaceuticals, August 1996

4 Hour: Radiation Safety Training, Rutgers University, October 1994

8. Training for Individuals working in or frequenting restricted areas

Dr. Eric Solon has extensive experience and will provide additional training to QPS personnel at Quest Pharmaceutical Services on a continuos basis.

See Attachment I - QPS Radiation Protection Program for description of Training Program.

9. Facilities and Equipment

The authorized locations for the use of radioactive materials by Quest Pharmaceutical Services will be at:

Delaware Technology Park -
1 Innovation Way, Suite 200, Newark, DE 19711
3 Innovation Way, Suites 211, 225 & 240, Newark, DE 19711

Pencader Corporate Center –
110 Executive Drive, Suite 7, Newark, DE 19702.

These facilities consist of office space and laboratories in industrial office parks. The surrounding land use consists of mixed office space, biotechnology laboratories and warehouses.

The floor plans of Quest Pharmaceutical Services laboratory spaces for all sites are presented in Attachment II and indicate the possible areas where radioactivity will be used and/or stored. The areas shown will be used to support the work of users who will receive and use the licensed material. The RSO will maintain a list of those specific labs that are commissioned for radioactive material use and will assure there decommissioning, when necessary.

The areas in which radioactive materials are to be used are standard biomedical research laboratories. The bench tops are made of non-porous materials and will be covered with plastic-backed absorbent paper or non-porous trays when radioactive materials are used. Secondary containers will be used whenever possible. The

floors, which are of concrete slab construction, are covered with a non-porous standard vinyl floor covering. Refrigerator/freezers are available to store labeled materials, which require such storage. Sinks are available near the radioisotope use areas.

Personnel safety equipment includes standard laboratory supplies such as gloves, lab coats, mechanical pipette devices, radioactive waste containers, radioactive material warning signs/tapes, and polycarbonate beta shields for work with high energy beta emitters.

"We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to draft NUREG-1556, Vol. 7, 'Program Specific Guidance About Academia, Research & Development, and Other Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary."

Survey meters will be calibrated by a service provider(s) authorized by NRC or Agreement State license to perform such calibrations.

Liquid scintillation counters (LSC from Packard, Beckmam or Wallac or equivalent, with automatic sample changer and DPM reporting) will be available for counting of wipe tests and urine bioassays (if necessary). If an LSC is not available then licensed services will be obtained for the needed analyses until one is available.

Designated labeled step cans and/or containers provided by an NRC-approved radioactive waste handler will be used as receptacles for dry radioactive waste and high density polyethylene carboys or equivalent as provided by an NRC-approved radioactive waste handler will be used for liquid waste. Decontamination agents and disposable cleaning cloths will be available for management of minor and major spills.

A fenced-in, locked, shed (approximately 10' x 10'), which will be used to temporarily hold radioactive and hazardous waste that is to be picked up for disposal by approved services, will be located at the back of the Pencader site. Waste stored in the shed will be properly contained according to QPS SOPs.

10. Radiation Safety Program

A written Radiation Safety Program can be found in Attachment I.

The Program addresses organization for radiation control, duties and responsibilities, personnel radiation dosimetry, survey meters and monitoring equipment, spill procedures, waste disposal, record keeping, shipping / receiving and other key issues of radiation safety.

"We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to draft NUREG-1556, Vol. 7, 'Program-Specific Guidance About Academia, Research & Development, and Other Licenses of Limited Scope,' dated December 1999."

The RSO or designate will perform a yearly audit of each Principal Investigator's and User's records and each Principal Investigator is required to perform monthly Self-Audits of their respective areas. Audits will review compliance to QPS SOPs on Radioactive Materials use and include such topics as: users' inventory and wipe test records; radiation warning signs and labels; use of personnel protective equipment; use of shielding; use of contamination control techniques; survey meter condition; and proper radioactive waste handling techniques. Documented wipe test surveys of the radioactive material use areas will be conducted weekly whenever more than 1 mCi of material is used within that week. The action level for contamination is ≥ 300 dpm per wipe test sample.

Occupational Dose: "We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive in one year, a radiation dose in excess of 10 percent of the allowable limits in 10 CFR Part 20."

In the event of a skin contamination incident, the dose equivalent to skin tissue from external contamination will be assessed at a depth of 7 mg/cm^2. The software used will be Varskin MOD2 and SADDE MOD2 or appropriate updates to this software: Computer Codes for Assessing Skin Dose from Skin Contamination (NUREG/CR-5873) averaged over a 1 cm^2 area.

11. Waste Management

Complete procedures for radioactive waste disposal are discussed in the Radiation Protection Program, Section 9.0. A summary of the plans for radioactive waste disposal follows:

Short-Lived RAM Waste

Only short-lived waste (physical half life of less than or equal to 120 days) may be disposed of by Decay In Storage (DIS).

Short-lived waste will be segregated from long-lived waste (half-life greater than 120 days) at the source.

Liquid and solid wastes will be stored separately.

When the container is full, it will be sealed and identified with a label affixed or attached to it.

The identification label will include the date when the container was sealed, the longest-lived radioisotope in the container, the date at which ten half-lives of the longest-lived radioisotope will transpire, and the initials of the individual who sealed the container. The container will then be transferred to the DIS area. The contents of the container should be allowed to decay for at least 10 half-lives of the longest-lived radioisotope in the container.

Prior to disposal as ordinary trash, each container should be monitored as follows:

- Check the radiation detection survey meter for proper operation
- Survey the contents of each container in a low background area.
- Remove any shielding from around the container.
- Monitor all surfaces of the container.
- Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity, i.e., surface readings are indistinguishable from background.
- If the survey indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.

If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material. gloves, et.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste.

Long-Lived RAM Waste

Long-lived waste (half-life greater than 120 days) will be segregated from short-lived waste at the source.

Liquid and solid wastes will be stored separately.

When the container is full, it will be sealed and identified with a label affixed or attached to it.

The identification label will include the date when the container was sealed, the longest-lived radioisotope in the container and the initials of the individual who sealed the container.

Long-lived waste will be contained and removed from the QPS site(s) as per instructions from the radioactive material waste removal service, such as Chem-Nuclear Systems, L.L.C., Barnwell, DuraTek, and/or SC; PermaFix.

ATTACHMENT I

Quest Pharmaceutical Services

Radiation Safety Program

Quest
Pharmaceutical Services, L.L.C. (QPS)

Radiation Protection Program

Prepared In Support of the Use of Radioactive Materials in Biotechnology Research and Development

April 2005

Table of Contents

Quest
Pharmaceutical Services, L.L.C.
Radiation Protection Program

1. Organization for Control of Radiation

1.1 Use of radioactive materials is regulated and licensed by the Nuclear Regulatory Commission (NRC). The license references sections of Title 10 Code of Federal Regulation (10 CFR) for the control of ionizing radiation and references the information submitted during the license application process.

1.2 The Radiation Protection Program is designed to provide safety for personnel, property, the environment and the public for use of radioactive materials used in biomedical research by a small laboratory. The program is under the direction of the Radiation Safety Officer (RSO).

1.3 Radioactive materials may only be used by or under the supervision of qualified and trained individuals identified on the Radioactive Materials License. Workers that use radioactive material under supervision must be authorized to do so by the Radiation Safety Officer.

1.4 QPS utilizes Standard Operating Procedures (SOP) to assure uniform compliance to the conduct of procedures and key procedures outlined in this Radiation Safety program will be updated in QPS SOPs.

2. RSO Duties and Responsibilities

The RSO is responsible for the following:

2.1 Review and approve designation of use areas and all protocols for use of radioactive material.

2.2 Distribute and receive personnel monitoring devices (dosimeters), timely review of results, maintenance of dosimetry records, and issuing reports.

2.3 Provide for the training of all radioactive material users, which includes initial and annual refresher training to ancillary personnel. Maintain records of this training to include topics covered, the amount of time spent, the date(s), instructor(s) and student(s) names.

2.4 Supervise and coordinate radioactive waste disposal, including the maintenance of waste in storage (including decay-in-storage) and disposal records.

2.5 Maintain records of radioactive materials inventory, receipt and transfer of licensed material, radiation surveys and audits, waste disposal instrument calibration reports, and personnel dosimetry reports.

2.6 Provide supervision and assistance for the management of emergency, accident, spill, or exposure situations.

2.7 Conduct yearly health Physics surveys of all laboratories or areas where radioactive materials are being used or stored.

2.8 Ensure that monthly health physics surveys are performed for laboratories or areas where radioactive materials are used or stored.

2.9 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.

2.10 Ensure that licensed materials are properly secured against unauthorized removal at all times when not in use.

2.11 Ensure that the radiation safety program is reviewed at intervals not exceeding 12 months.

3. Responsibilities and Requirements of Users

3.1 Individuals must complete the following requirements before entering into work with radioactive material or working in a radiation area:

3.1.1 Prospective user's must submit a ' QPS Background & Experience In Radiation Safety' form and Principal Investigators must submit an Approval Use form prior to performing any procedures that include radioactive materials.

3.1.2 Receive authorization from the RSO, which includes attendance at New User's Orientation Training and yearly Refresher training.

3.1.3 Administrative processing and receipt of a personnel monitoring device (if required for the work to be performed or the work area).

3.2 Individual User Responsibilities. Each individual who has contact with radioactive materials must adhere to the following procedures:

3.2.1 Keep exposures to ionizing radiation to levels as low as reasonably achievable (ALARA). The ALARA goals are 10% of the regulatory limits. However, actual doses are expected to be less than 10% of these values.

Table 3.1 Maximum doses under the ALARA program.

	mrem/y
Total Effective Dose Equivalent	500
The sum of the deep dose equivalent and the committed dose equivalent to any organ or tissue other than the lens of the eye	5000
Eye dose equivalent	1500

Skin and any extremity	5000

3.2.2 Participate in radiation safety training as requested by the RSO.

3.2.3 Wear the prescribed personnel radiation dosimeters such as whole body badges and extremity (ring) badges when required for the radioactive materials used.

3.2.4 Survey hands, shoes, and body for radioactive contamination before leaving the laboratory area when working with radioactive material.

3.2.5 Use all appropriate protective measures such as:

- Wear protective clothing such as lab coats whenever contamination is possible. Wear vinyl/latex gloves when working with radioactive material and respiratory protection when necessary.
- Use protective barriers and other shields whenever possible.
- Use mechanical devices whenever their aid will assist in reducing doses.
- Use pipette-filling devices. Never pipette radioactive solutions by mouth.
- Perform work with volatile radioactive material in an approved hood or glove box.

3.2.6 Do not smoke, eat, drink, apply cosmetics, or store/use personal effects in radionuclide use/storage laboratories. Refrigerators shall not be used jointly for foods and radioactive materials.

3.2.7 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 before handling any object to limit intake through the mouth, nose, or eyes.

3.2.8 Immediately report accidental inhalation, ingestion, or injury involving radioactive materials to the supervisor and the RSO, and carry out their recommended corrective action.

3.2.9 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., hoods, benches, etc., must be performed following the use on the day that radioactive materials were used. Record the results of this monitoring in the logbook. Uncontrolled contamination must be cleaned immediately. Check the response of the survey meter using the dedicated check source for proper operation at the beginning of each day radioactive material is

used. The RSO will provide assistance and/or advise for decontamination procedures.

4. General Policies and Procedures for Radioactive Materials Use

4.1 Designation of Radioactive Materials Use Areas and Laboratories (Posted Laboratories).

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).

4.1.1 Radioactive Materials are to be used only in rooms or areas as authorized by the RSO.

4.1.2 The RSO will be responsible for the designation of Posted Laboratories/Areas and areas to be Commissioned for radioactive material use will be inspected by the RSO prior to any radioactive work being performed in that area. Documented approval of commissioned areas will be maintained by the RSO.

4.1.3 Laboratories or areas where radioactive materials are used or stored will be posted with the signs as required in 4.2.

4.1.4 The RSO will conduct an inspection survey for areas in which radioactive material use has been discontinued and no longer requires designation as a posted area.

4.2 Signs and Labels for Laboratories, Areas and Equipment.

4.2.1 A "CAUTION RADIOACTIVE MATERIALS" sign must be conspicuously posted on the doors to laboratory areas where radioactive materials are being used or stored.

4.2.2 All equipment contaminated with radioactive material shall be marked with signs, decals, or by other conspicuous means. Labeling shall not be required for contaminated equipment such as beakers, flasks, and test tubes when in the presence of the user.

4.3 Shielding of Sources

Radioactive sources or stock solutions when not in use in the laboratory shall be shielded in such a manner that the radiation levels at contact are less than 2 milliroentgen per hour (mR/h).

4.4 Protection of Work Surfaces from Contamination

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

4.5 Periodic Surveys of Radioactive Material Use Areas

4.5.1 The RSO, user, or designee will, at a minimum, perform monthly wipe test surveys of the radioactive material (RAM) use areas and self-audits regardless of RAM use. Wipe tests and self-audits will be documented on the Radiation Safety Survey/Wipe Test and Self-Audit Record (see forms at end of this document). The self-audit will include checking compliance (by the users) of standard radiation safety practices. Self-audits will include reviews of: Dosimetry badges, radiation levels, users' inventory and survey records, RAM posting and labeling, evaluation of users' radiation safety procedures through observation and discussion, use of personnel protective equipment, use of shielding, use of absorbent paper or other contamination control techniques, and proper radioactive waste handling techniques, calibration of survey meter(s), wipe test records.

An informal survey (by wipe test and/or survey meter) will be performed every day that radioactivity is used in an area. If contamination ($\geq$300 dpm) is found then a wipe test will be performed and documented and appropriate measures will be taken to clean up the areas of contamination.

User's must perform a documented survey whenever 1 mCi or more of any isotope is used within a weeks time.

The immediate areas (e.g., hoods, bench tops) in which radioactive materials are being used will be monitored for contamination at least once daily following the use of the radioactive materials by the users in that laboratory. The daily check is required to be performed only on the days that radioactive materials are used. A logbook will be kept in each area showing the dates of the monitoring and who performed the monitoring. These daily checks will consist of direct monitoring using portable radiation detection instruments appropriate for the radionuclides being used. If only materials with ^{3}H are being used, only wipe tests for contamination monitoring are required (monthly survey frequency).

4.5.2 Surveys will be done at a frequency appropriate to the types and quantities of radioactive materials used in each lab or area in which unsealed forms of radioactive materials are used. If the activity used is greater than or equal to the smallest annual limit on intake (ALI) (either for ingestion or inhalation) as identified in 10 CFR part 20, Appendix B, then documented surveys should be performed at least daily in accordance with 10 CFR 20.2103. This survey will include, as necessary: direct monitoring using portable radiation detection instruments for contamination, measuring exposure rates, performing wipe tests for removable contamination and checking compliance with standard radiation safety practices.

4.5.3 Copies of the monthly surveys will be kept on file by the RSO and/or in the Radiation Safety Logbook in the respective areas where RAM is used.

4.5.4 An inventory of the total radioactivity (test material, samples and waste) will be summarized monthly for each Principal Investigator / User and their respective lab(s). Inventories will be submitted to the RSO who will keep them on file to monitor possession limits.

4.6 Laboratory Radiation Detectors

4.6.1 Each laboratory or area shall have available for use a portable survey meter to be used for personnel and area monitoring appropriate for the radionuclide in use.

4.6.2 Each survey meter or radiation detector will have a dedicated check source. The standard check source will be 1 uCi ^{137}Cs for beta/gamma GM detectors and will be mounted on the sides of the survey meters.

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 A Scintillation counter is also available for use by all RAM Users and will be used to analyze wipe test samples.

5. Radioactive Contamination and Spill Procedures

5.1 Radioactive Contamination of Areas

5.1.1 In general, no radioactive contamination can be tolerated. Exceptions to this includes certain hood surfaces, dry boxes, 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 the standard radiation caution tape stickers. Any contamination that is not confined to controlled surfaces shall be cleaned immediately.

5.1.2 Surface contamination action guidelines for unrestricted areas will be as follows:

- Removable (beta-gamma) 300 dpm/100 cm^2
- Fixed (beta-gamma) 5,000 dpm/100 cm^2

5.1.3 Amounts of removable radioactive material per 100 cm^2 of surface area will be determined by wiping the surface with a cotton swab, dry filter or soft absorbent paper that may or may not be pre-moistened with methanol or another suitable solvent. The amount of radioactive material on the wipe area will be assessed using an appropriate radiodetection instrument of known efficiency (e.g. liquid scintillation counter).

5.1.4 Amounts of fixed contamination will be determined from direct monitoring using an appropriate survey meter over the surface of the item in question. Background- and efficiency-corrected measurements that consider the area and geometry of the metered location of contamination will be determined. For most situations, approximations of areas that assume point source geometry will be sufficient.

5.2 Decontamination of Areas Contaminated with Radioactivity

Preparations for decontamination should begin promptly. The extent and hazard presented by the contamination will be determined by the User and/or the RSO. The individual responsible for the contamination will be expected to do most of the clean-up under the supervision of the RSO.

5.3 Decontamination of Personnel Contaminated with Radioactivity

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

5.3.2 Survey arms, hands, legs, and feet with an appropriate survey meter. If there is an indication of radioactive contamination on the skin, record the survey meter response and the approximate size of the contaminated area.

Wash the contaminated area for 2 or 3 minutes with soap and water, repeatedly soaping and rinsing. Consideration should be given to the chemistry of the contaminant and an attempt made to find a suitable agent for dissolving it. Cleansing agents may be used, but 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 Survey the contaminated body area after washing the area and record the results. If this procedure is not immediately and completely effective, notify the RSO. Such decontaminating agents as "Versene" or "Radiacwash" etc., may be used under the direction of the RSO and medical personnel.

5.3.4 The individual and/or supervisor is required to complete and submit an 'Incident report' for all spills and/or actual or potential incidents involving contamination.

5.4 Major Spills (greater than 10 uCi total or more than 1 m^2 contaminated area)

5.4.1 CLEAR THE ROOM: Notify all persons not involved in the spill to vacate the room, but to not leave the area until they have been surveyed for contamination.

5.4.2 PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel to prevent the spread.

5.4.3 CLOSE THE ROOM: Turn off hoods and ventilation systems. Leave the room and lock the door(s) to prevent entry.

5.4.4 CALL FOR HELP: Notify the RSO immediately.

5.4.5 SURVEY PERSONNEL AND DECONTAMINATE IF NECESSARY: Contaminated clothing should be removed and stored for further

evaluation by the RSO. If the spill is on the skin, flush thoroughly and then wash with mild soap and warm water.

5.4.6 PLAN FURTHER ACTION: The RSO will supervise the decontamination effort and provide guidance for the decontamination methods and the potential need for follow-up bioassay.

5.4.7 The individual and/or supervisor is required to complete and submit an 'Incident report' for all spills and/or actual or potential incidents involving contamination.

5.5 Minor Spills (less than 10 uCi total and less than 1 m^2 area)

5.5.1 NOTIFY: Notify persons in the area that a spill has occurred and call the RSO.

5.5.2 PROTECT PERSONNEL: Perform any personnel decontamination before proceeding with spill clean up.

5.5.3 CONTROL: Restrict the contaminated area. Do not allow anyone or anything to leave the contaminated area without being monitored for radioactivity before starting clean up work.

5.5.4 SURVEY: Use a low-range, thin window GM survey meter for beta/gamma emitters, wipes and liquid scintillation counting for ^{3}H and ^{14}C, or < 1 uCi ^{125}I. Check the area around the spill, hands, and clothing for contamination. Mark off the contaminated area with "RAD" tape.

5.5.5 CLEAN UP: Gather decontamination supplies. Wear protective clothing (lab coat and disposable gloves at a minimum). Wear assigned dosimetry. Clean up the spill using dry paper towels first. Use decontamination agents after dry techniques have been used. Work from the outside edge of the spill in towards the center. Use only 1 "pass" of the paper towel then place in radioactive waste.

5.5.6 SURVEY AGAIN: Use appropriate survey meter for direct measurements and take wipes and analyze for "removable" contamination.

5.5.7 REPORT: Report the results of the decontamination effort to the RSO. The individual and/or supervisor is required to complete and submit an 'Incident report' for all spills and/or actual or potential incidents involving contamination.

6. Radiation Dosimetry for Personnel

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 either external or internal sources. However, to demonstrate compliance with the requirement the following program will be implemented:

6.1 External Radiation Monitoring

6.1.1 External monitoring will not be required for 3H, 14C, 35S, and 33P.

6.1.2 Users of more than 0.5 mCi of gamma/x-ray or high-energy beta emitting radioisotopes will have whole body doses measured with film, OSL's or other equivalent technology as provide by a commercial vendor (with successful participation in the National Voluntary Laboratory Accreditation Program for personnel dosimetry). The quantities apply to both the quantity handled at any one time or the integrated amount of activity introduced in 1 month.

6.1.3 Dosimeters for personnel monitoring will be at a minimum of a quarterly exchange frequency.

6.1.4 Doses to the extremities will be evaluated with ring badges for users of high-energy beta/gamma emitters who perform procedures involving handling more than 1 mCi in 1 month.

6.2 Internal Radiation Monitoring - Bioassay.

6.2.2 Emergency bioassays will be performed in case of a spill involving more than 1 mCi of licensed material or for other possible intake in excess of 10% of the allowable limits.

7. Area Survey Procedures

7.1 Routine Survey After Radioactive Material Use

7.1.1 Survey the work area with a GM detector survey meter with a "pancake" probe.

1. Check battery condition, replace if necessary.
2. Check meter response using "check source".
3. Take a background reading in a normal background area of room.
4. Perform the surveys required. Use good technique (probe close to surface, <1 cm, audio "on", moving detector <5 cm per s).

7.2 Or perform a series of wipe test (area of 100 cm2) to assess surface contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect less than 500 dpm per 100 cm2.

7.3 Results will be recorded in the Radiation Safety logbook for the respective area of use (see lab survey form at the end of this document).

7.4 Scheduled Surveys

7.4.1 All laboratory areas authorized for use of radioactive material will be surveyed monthly by the responsible Principal Investigator or User. Each lab or area where unsealed forms of radioactive materials are used will perform surveys at a frequency appropriate to the types and quantities of radioactive materials in use.

7.4.2 A weekly survey is required whenever > 1 mCi of RAM is used at one time in an area and the survey will consist of:

A series of wipe tests (area of 100 cm^2) to assess surface contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect less than 300 dpm per 100 cm^2 for the isotopes used.

7.4.3 Daily surveys will be conducted at the end of the day whenever RAM is used within a lab/area. A survey meter may be used for higher energy emmitters however, a wipe test, that utilizes a scintillation counter, will be performed whenever ^{3}H, ^{14}C or small amounts of ^{125}I are used.

7.4.4 All surveys will be performed in accordance with the following requirements.

- All surveys will be documented in the Radiation Safety Logbook for each lab/area.
- A measurement of radiation levels in restricted and unrestricted areas with a survey meter sufficiently sensitive to detect 0.1 mR/h and surface contamination levels at or less than 5,000 dpm/100 cm^2 (for 32P).
- The action limits for external radiation levels for Radiation Surveys of Unrestricted Areas will be as follows: Any radiation levels above normal background will be investigated to insure compliance with the dose limits to the public of 2 mrem in any 1 hour and less than 100 mrem in 1 year.
- A series of wipe tests (area of 100 cm^2) to assess surface contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect less than 300 dpm per 100 cm^2 for the isotopes used.
- The action limit for contamination is 300 dpm and areas over this limit must be cleaned up immediately and a second wipe test performed to assure that the clean-up was successful.

8. Disposal of Radioactive Materials in the Laboratory

8.1 Radioactive waste generated in the licensee laboratories must be disposed of according to special procedures.

8.2 All radioactive waste must have a RAM Waste Tag securely attached to it.

8.3 All radioactive waste must be presented for pick up from the laboratory in a condition suitable to be handled manually. It is the user's responsibility to ensure this. The user must also be able to

provide accurate descriptions of the waste including radionuclide and the activity of each radionuclide.

8.4 Plans for proper handling of pathogenic waste, mixed chemical and radioactive waste or other unusual waste must be made prior to the generation of the waste in consultation with the RSO.

8.5 All waste containers must be conspicuously marked "Caution Radioactive Material" and located away from other non-radioactive waste containers. No liquid waste is permitted in the solid radioactive waste and no solids (such as eppendorf tips) can be placed into the liquid waste.

8.6 Radioactive waste handling in the laboratory.

8.6.1 Dry/Solid Radioactive Waste

- All dry/solid radioactive waste must be placed in the step cans (or equivalent) provided. Additional waste containers can be requested as needed. They must be kept fitted with a disposable 0.004" (4 mil) polyethylene liner.
- Broken glassware must not be placed directly in the dry/solid radioactive waste container but into a "sharps" container that is labeled with "Caution Radioactive Material" warnings.
- Sharps, pipettes, sharp plastic and glass are to be placed into cardboard boxes or equivalent designed for this waste. Needles must be placed, un-capped, into marked and labeled sharps boxes.

8.6.2 Liquid radioactive waste

- Liquid waste must be aqueous based and contain no other hazardous wastes. Liquid scintillation vials or counting fluid is handled as a designated "mixed" waste and is therefore segregated from other liquid waste (see below).

- The quantity of radioactive material that is released into the sewer in one month divided by the average monthly volume of water released into the sewer does not exceed the concentrations listed in Table 3 of Appendix B to 20.1001-20.2401. The sum of the fractions for each radionuclide required does not exceed unity. The total quantity of radioactive material that is released into the sanitary sewerage system in a year does not exceed 5 Ci of ^{3}H, 1 Ci of ^{14}C and 1 Ci of all other radioactive materials combined.

- Radioactive material that meets the above criteria may be discarded into the sanitary sewer, using designated laboratory sinks. Any sink that is used for disposal of radioactive waste must be indicated with "Caution Radioactive Materials" label, and must be included in monthly swipe tests. Sinks will be flushed for a minimum of 10 minutes. Sink walls and surfaces will be checked with a

Geiger counter to assure that any unknown splashes or spills occurred.

- A disposal log will be maintained for each sink. The radionuclide, activity (μCi or mCi), initials and date are recorded in the log book. Consult the log before discarding waste to assure the limit in not exceeded. It is expected that waste levels will be under the maximum levels calculated above. When the log form is completed, remove from the lab and take it to the RSO.
- Original source vials containing high activities in low volumes should be handled separately from low activity, concentration liquid waste. Consult the RSO for guidance. Lead shielding that may be supplied by a manufacturer for shielding source vials will not be collected unless it is still needed to shield the source vial for disposal. Remove or obliterate the radioactive markings, survey for contamination, and dispose of the shielding as lead (not in the regular trash).

8.6.3 Liquid scintillation vials (LSV)

- All LSV should be tightly capped and returned to original shipping trays or another appropriate container. The total activity for each radionuclide in the tray must be marked on the outside of the tray and the tray labeled "Caution Radioactive Material".
- LSV must be segregated by radionuclide. This provides the greatest flexibility for disposal.

8.7 Preparing radioactive wastes for disposal

8.7.1 The user will complete a RAM Waste Tag that will identify the following information regarding the contents of each radioactive waste container: User's Name, Date, Activity (uCi or mCi), isotope, waste type (solid, liquid).

8.7.2 Only clear or translucent 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.

9. Final Disposal of Radioactive Materials

9.1 Procedure for Disposal by Decay-in-Storage

Only short-lived waste (physical half life of less than or equal to 120 days) may be disposed of by DIS.

Short-lived waste should be segregated from long-lived waste (half-life greater than 120 days) at the source.

Liquid and solid wastes must be contained separately.

When the container is full, it should be sealed. The sealed container should be identified with a RAM Waste label affixed or attached to it.

The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, the date when ten half-lives of the longest-lived radioisotope will have transpired (for DIS waste only), and the initials of the individual who sealed the container. The contents of the container should be allowed to decay for at least 10 half-lives of the longest-lived radioisotope in the container.

Prior to disposal of DIS waste as 'ordinary trash', each container should be monitored as follows:

- Check the radiation detection survey meter for proper operation
- Survey the contents of each container in a low background area.
- Remove any shielding from around the container.
- Monitor all surfaces of the container.
- Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity, i.e., surface readings are indistinguishable from background.
- If the survey indicates residual radioactivity, the waste container will be returned the to DIS area and the RSO will be contacted for further instructions.

If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material. gloves, et.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste. This will be documented in the Radiation Safety Logbook for the DIS area.

9.2 Procedure for Long-Lived Isotope Disposal.

Long-lived waste (half-life greater than 120 days) will be segregated from short-lived waste at the source.

Liquid, solid and biological (animal carcasses, tissues, bodily fluids, feces) wastes must be contained and identified on the RAM Waste tag separately.

When the container is full, it should be sealed. The sealed container should be identified with a RAM Waste label affixed or attached to it.

The identification label should include the date when the container was sealed, identification of the longest-lived radioisotope in the container, the form of waste, the estimated total amount of radioactivity, and the initials of the individual who sealed the container.

Biological waste such as animal carcasses, tissues, feces and bodily fluid may be stored refrigerated/frozen in an approved RAM area before being picked-up for final disposal by an authorized radioactive waste disposal service.

All long-lived waste will be picked-up as necessary and disposed of by an authorized radioactive waste disposal service as arranged by the RSO or designee.

10. Procedures for Procurement, Receipt, and Inventory

10.1 Procurement Procedures

10.1.1 The user will notify the RSO regarding all purchases and/or transfers of radioactive substances into or out of QPS and the RSO will be responsible for checking to see that possession limits will not be exceeded. This may be accomplished via email or written notification.

10.1.2 The RSO will insure that the requested material, quantities and form are authorized by the Permit Holder and that the possession limits are not exceeded prior to the order being placed with a vendor.

10.1.3 Transfers of radioactive material between QPS Principal Investigators/Users can be made and it is the responsibility of the Investigators to promptly update the transfer on their electronic Radioactive Material Accounting records (limited access Excell Spreadsheets on protected database folders), so that the RSO is aware of possession limits.

10.2 Receipt of Radioactive Materials Packages - Instructions to Shipping and Receiving Personnel:

10.2.1 Upon arrival, receiving personnel will immediately contact the RSO. The RSO or designee will monitor and wipe test packages as required by 10 CFR 20.

10.2.2 During off-duty hours security or other designated, trained personnel may accept delivery of radioactive packages in accordance with the procedure outlined:

- Any package containing radioactive material that arrives during off duty hours shall be signed for by designated trained personnel on duty an taken immediately to the designated receiving area and placed in a secure RAM storage area.
- If the package appears to be damaged, immediately contact the RSO. Ask the carrier to remain at the facility until it can be determined that neither the carrier nor the vehicle is contaminated.

10.3 Procedure for Opening Packages Containing Radioactive Material

10.3.1 All shipments must follow US DOT regulations. "Excepted" shipments of certain isotopes (depending on the type, quantity). "This package conforms to the condition and limitation specified in 49 CFR 173.421 for expected radioactive material, limited quantity N.O.S. UN 2910:. For packages received under the specific license, authorized individuals (Study Director and RSO) shall implement procedures for opening each packages, as follows:

- Use an appropriate shielding and wear gloves to prevent hand contamination.
- Visually inspect the package for any sign of damage (e.g. crushed or puncture). If damage is noted, stop and notify the RSO.
- Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents, so shipment does not exceed possession limits.
- Monitor the external surfaces of a labeled package with appropriate survey meter (refer to 7.1 on meter usage). According to specifications in the following table.

Package	Contents	Survey Type	Survey Time
Labeled White I, Yellow II, Yellow III	Not Gas or Special Form Less than Type A Quantity	Contamination	As soon as practicable but not less than 3 hours after receipt of package
Not Labeled	Licensed Material	None	None
Damaged	Licensed Material	Contamination Radiation Level	As soon as practicable but not less than 3 hours after receipt of package

- Open the outer package (following supplier's directions if provided) an remove packing slip. Open inner package to verify contents (compare requisition, packing slip and label on the bottle or other container). Check integrity of the final source container (e.g. inspection for breakage of seals or vials, or loss of liquid, discoloration of packaging material, high-count rate on smear). Again check that the shipment does not exceed license possession limits. Notify the RSO of any problems or discrepancies.
- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash.
- Maintain records of receipt, package survey, and wipe test results.
- Notify the final carrier and by telephone or facsimile the NRC Regional Office when removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(I) or external radiation levels exceed the limits of 10 CFR 71.47.

10.4 Inventory Procedures

10.4.1 The RSO or designee will complete the top section of a 'RAM receipt, Inventory Tracking and Disposal' form, and release the package and form to the user.

10.4.2 The using laboratory will receive radioisotopes from the RSO, along with the form and as the radioactive material is used, lab personnel will complete the lower portions of the inventory record, indicating appropriate dispositions.

10.4.3 When all radioisotope materials have been used, the form will be completed, and immediately returned to the RSO.

11. Other Procedures

11.1 Physical Security of the Radioactive Material Use Areas

11.1.1 Access to areas posted for RAM use will have locked doors or another suitable means to prevent entry by unauthorized personnel. The main entrance, or access, will be attended when doors are not closed and locked.

11.1.2 Visitors will be escorted while in posted areas and personnel have the right to challenge unfamiliar persons as to their identity and reasons for being in posted areas or laboratories.

11.2 Special Procedures for Use of More Than 1 mCi of 32P

11.2.1 Consult the RSO before performing any unfamiliar procedures.

11.2.2 New procedures must be planned and practiced ("dry run") without radioactive material.

11.2.3 During use, handle and store millicurie quantities behind ½ inch (1.3 cm) thick plastic shielding.

11.2.4 Reduce doses to skin by using tongs and handling tools, regular monitoring, and prompt removal of contaminated clothing.

11.2.5 Add secondary protection: Use disposable lab coats and double or triple disposable gloves.

11.2.6 When working with more than 10 mCi of ^{32}P the wearing of safety glasses (or face shield) is required (standard safety glasses reduces the radiation by about ½).

11.2.7 Extremity dosimeters (ring dosimeters are standard) are required for use of more than 1 mCi of ^{32}P.

11.2.8 In addition to survey meter monitoring the area for contamination during and after use, a wipe test survey must be performed at the end of the day and documented in the Radiation Safety Logbook for that lab/area.

12. Radiation Safety Training and Qualifications of Users

12.1 Radiation Awareness Training

All personnel will be given radiation awareness training (New User Orientation and/or a complete 8hr seminar) prior to assuming duties or frequenting areas where licensed material are used or stored. This training will include instructions on concerning the licensed use of radioactive material, personnel authorized to handle and use licensed material, use and storage locations, warning signs, warning labels, disposal of licensed material, and emergency procedures. The training will be presented by the Radiation Safety Officer, Designee or a Principal Investigator.

This training will be updated if there is a significant change in duties, regulations, the radiation safety program or its implementation or the terms of the license.

12.2 Qualifications of Principal Investigators

Principal Investigators are the primary users of radioactive material and are named on the license and can supervise others in the use of radioactive material. In addition to radiation safety training, Principal Investigators will have a minimum of 3 months experience working with radioactive material (open bench top biotechnology research) and must be approved as Principal Investigators by the Radiation Safety Officer.

12.3 Radiation Safety Training for Principal Investigators and Users

12.3.1 Each Principal Investigator and Authorized User must have received a minimum of 8 hours of training in Radiation Safety during the first year of service. The training can be any combination of review of written materials, 1-on-1 training, video tapes or classroom instruction. The following topics must have been addressed:

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

12.3.2 Training at another facility can be used to meet this requirement if a review of this Radiation Protection Program is provided. In addition, the RSO or his/her designate will review the user's laboratory technique and procedures and offer critique and instruction as necessary in a "1-on-1 session". All training will be documented in the Employee's QPS Training Record.

12.3.3 The radiation safety training will be presented by the Radiation Safety Officer (or designee), a qualified instructor, such as a Certified Health

Physicist, academic institution, or professional radiation safety consulting organization.

12.3.4 Annual re-fresher training. The RSO will provide a minimum of 1 hour of refresher radiation safety training on the above listed topics. The training can be any combination of reading, 1-on-1 training, video tapes or classroom instruction. Lectures and written materials, which are read and completed by radiation workers, may also be used to complete the annual refresher training.

12.4 Qualifications and Training of the Radiation Protection Officer

The RSO will have a minimum of 6 months experience working with radioactive materials as a principal investigator, receive specific training from incumbent RSO or training class for Radiation Protection Officers.

Review regulations for the Control of Radiation and the Radiation Protection Program.

ATTACHMENT II

Floor Plans for Quest Pharmaceutical Services at:

Delaware Technology Park
1 Innovation Way, Suite 200
Newark, DE 19711

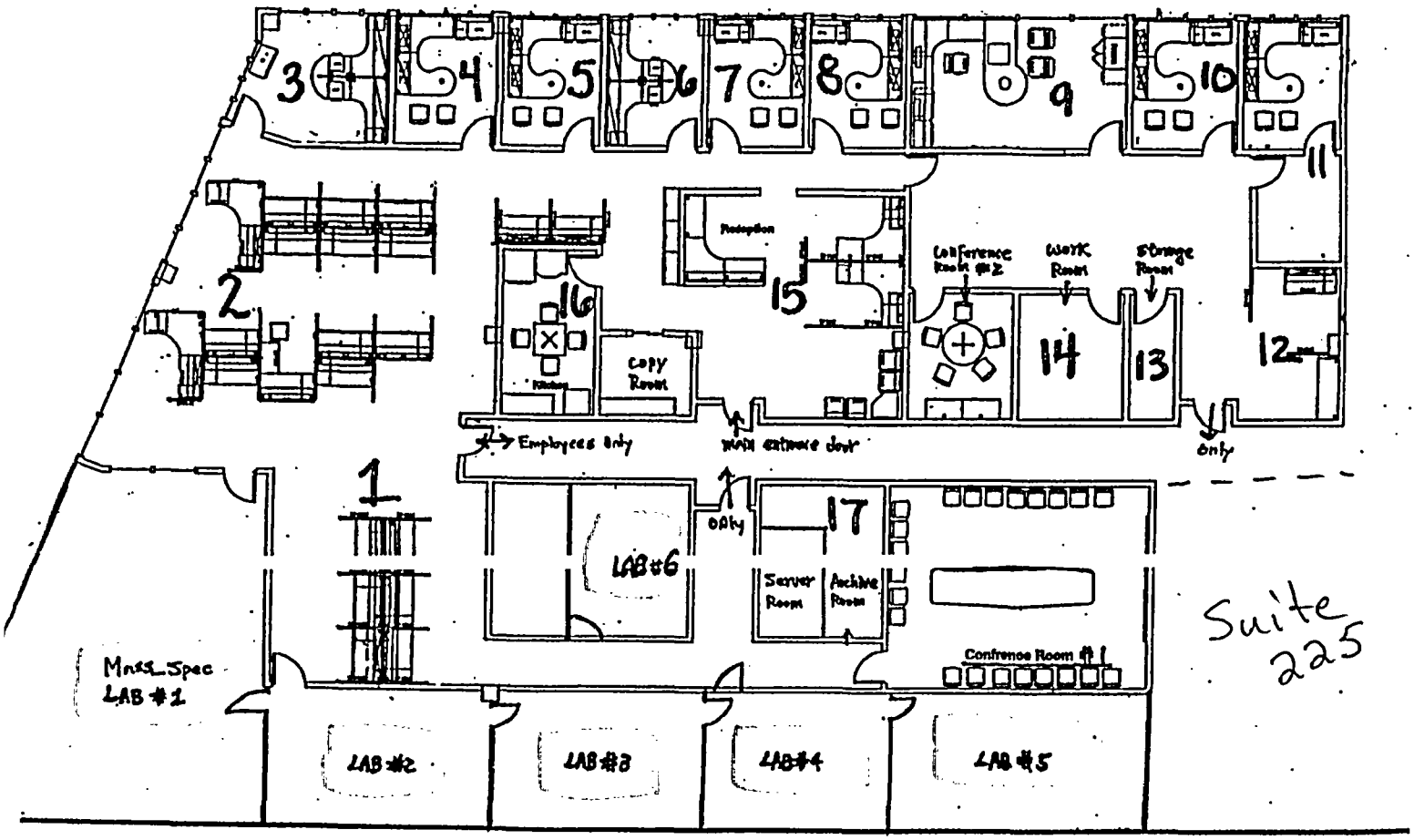
Delaware Technology Park
3 Innovation Way, Suites 211, 225 & 240
Newark, DE 19711

Pencader Corporate Center
110 Executive Drive, Suite 7
Newark, DE 19702

DTP Suite 240
3 Innovation Way
Newark, DE

Pg 1

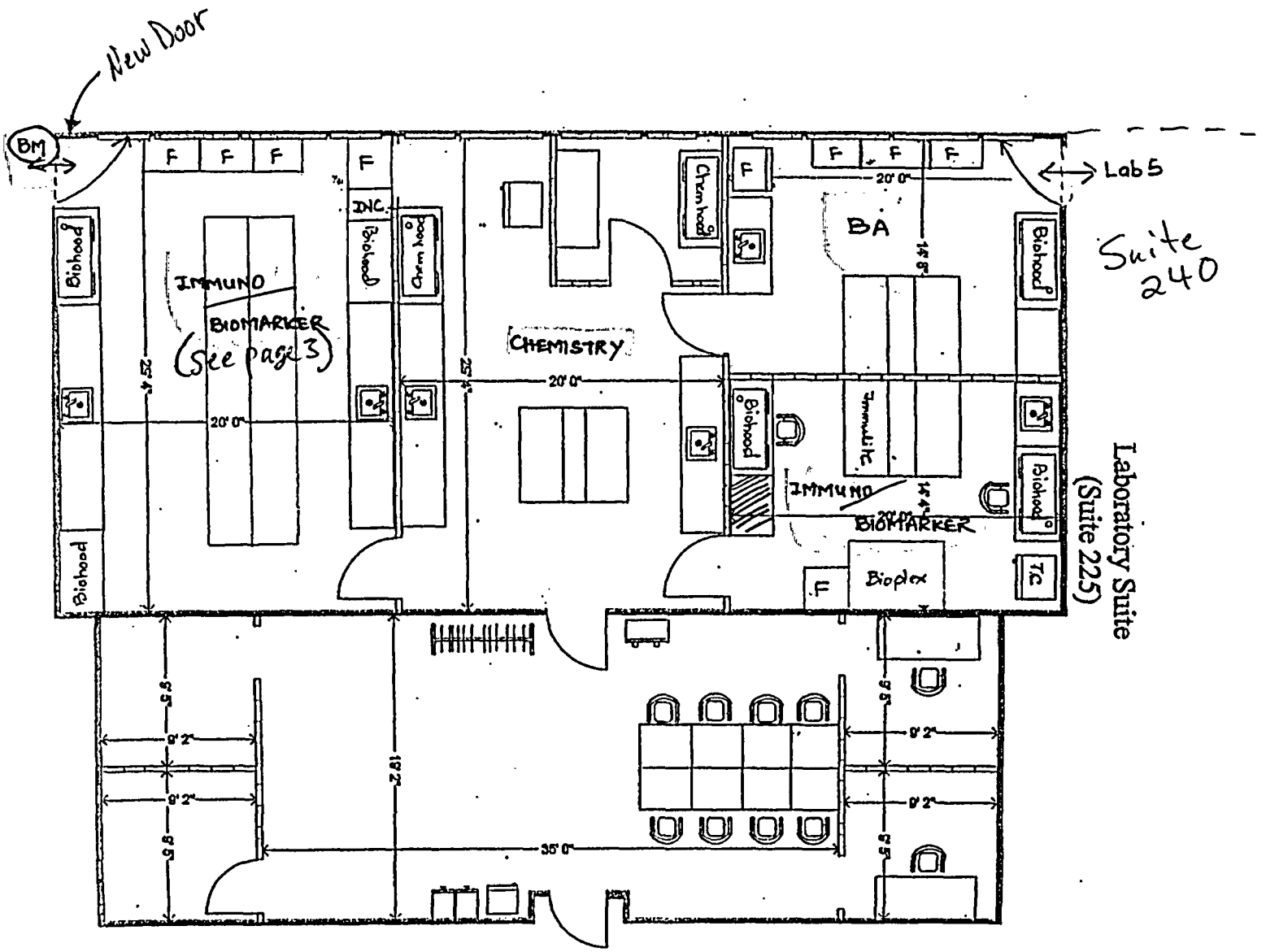
QUEST PHARMACEUTICAL SERVICES, L.L.C.
Delaware Technology Park
3 Innovation Way, Suite 240
Newark, DE 19711
Square Footage: 12,800



Suite 225

DTP Suite 225
3 Innovation Way
Newark, DE

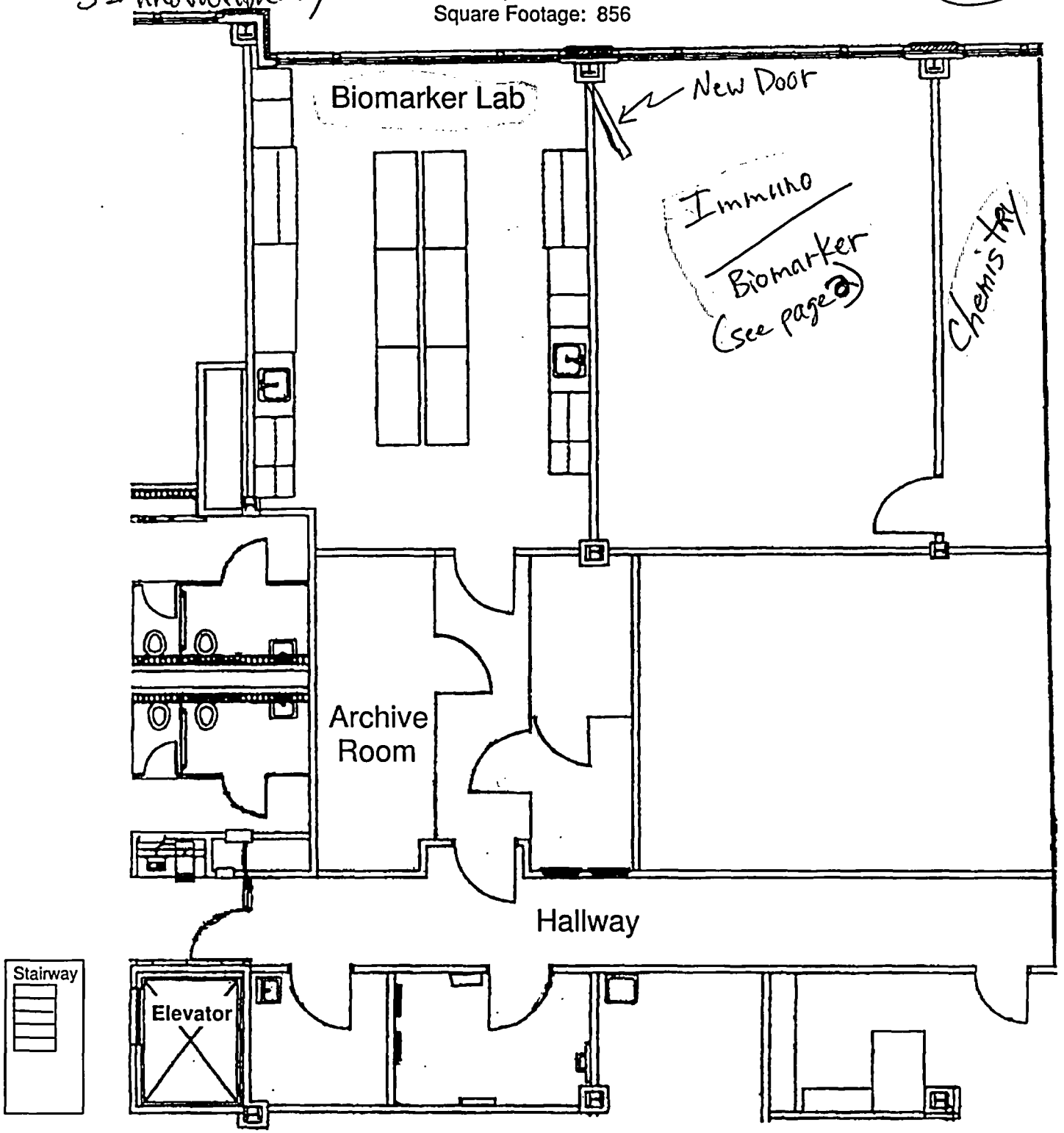
Pg 2 of 3



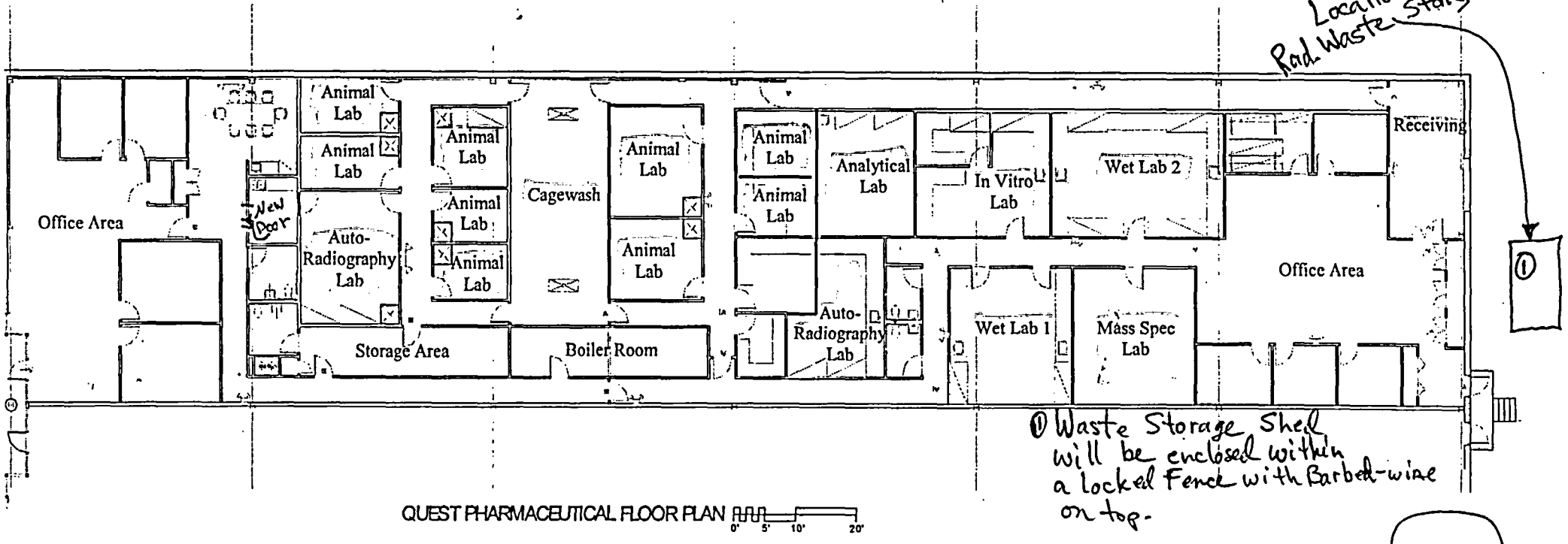
DTP Suite ~~225~~ 211
Cont.
3 Innovation Way

Quest Pharmaceutical Services, LLC
Delaware Technology Park
3 Innovation Way
Newark, DE 19711
Square Footage: 856

Pg #3



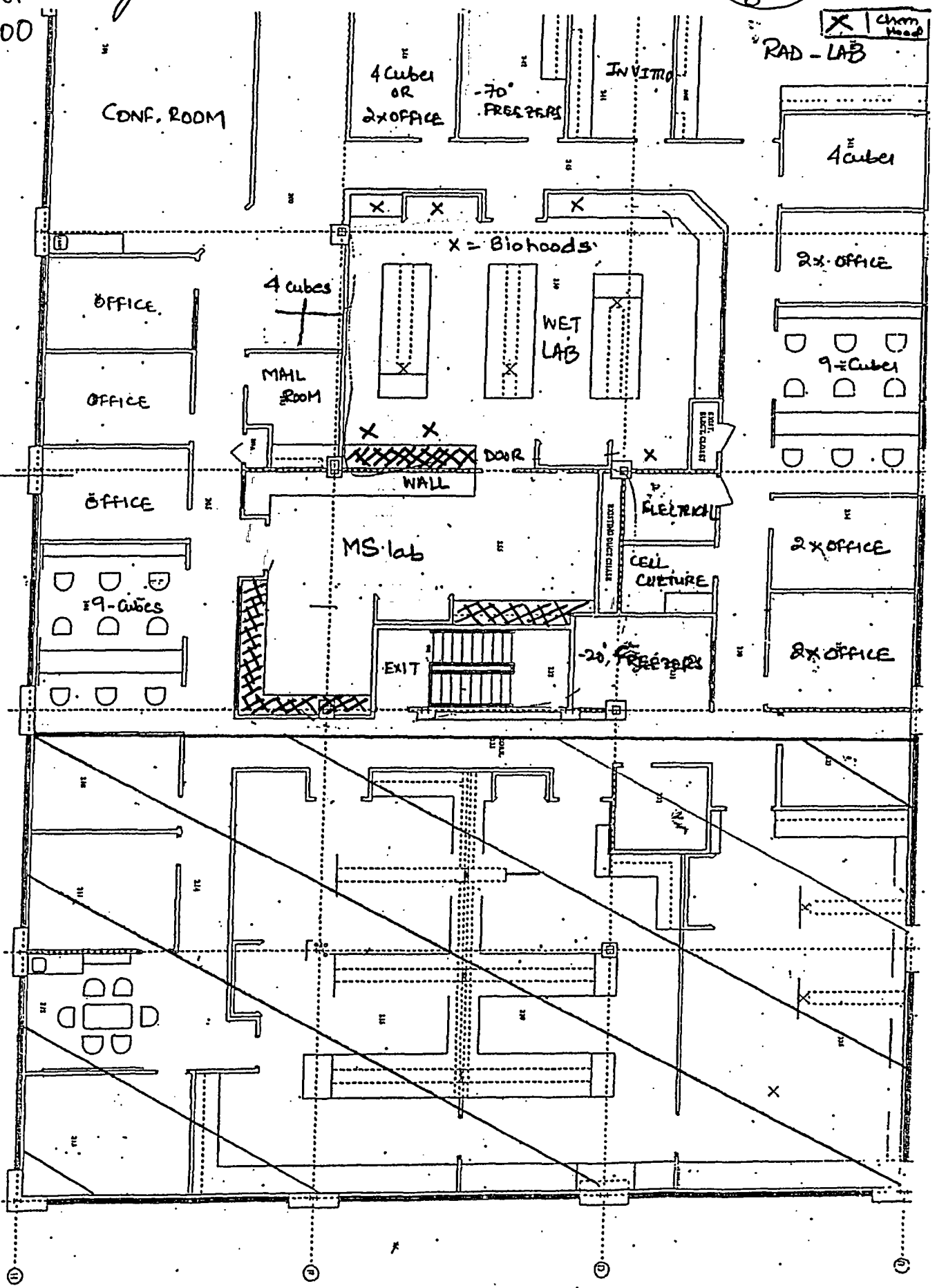
QPS, Pencader Corporate Center, 110 Executive Drive, Suite 7



QUEST PHARMACEUTICAL FLOOR PLAN 0' 5' 10' 20'

5 of 5

1 Innovation Way
Suite 200
DTP



NAPRO BIOPHERAPEUTICS
11,290 SQ. FT.

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

4/25/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 07-30594-01

[X] 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

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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** 136946.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(8-96)

Sincerely,
Licensing Assistance Team Leader

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 03620
Status Code: 0
Fee Category: 3M
Exp. Date: 20101031
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
   Applicant/Licensee: QUEST PHARMACEUTICAL SERVICES, LLC
   Received Date: 20050426
   Docket No: 3035435
   Control No.: 136946
   License No.: 07-30584-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: /
   Check No.: /

3. COMMENTS

Signed Rebecca Jurad
Date 5/13/2005

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 _____