

NRC FORM 313 (10-2005) 10 CFR 30.32, 33, 34, 35, 36, 39, and 40		U.S. NUCLEAR REGULATORY COMMISSION		APPROVED BY OMB: NO. 3150-0120 Estimated burden per response to comply with this mandatory collection request, 4 1/2 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0061, or by internet e-mail to infocollections@nrc.gov , and to the Desk Officer, Office of Information and Regulatory Affairs, NE0B-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.		EXPIRES: 10/31/2008	
APPLICATION FOR MATERIAL LICENSE							
INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.							
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001 ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415				IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 115LE, 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 411 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TX 76011-4005 (06-31263-01) BIORELIX, INC. J.R. KENNETH F. BLOUNT 5 SCIENCE PARK AT YALE NEW HAVEN, CT 06511-3572 IZABELA PUSKARZ (203) 785-9282			
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) <input checked="" type="checkbox"/> A NEW LICENSE <input type="checkbox"/> B AMENDMENT TO LICENSE NUMBER <input type="checkbox"/> C RENEWAL OF LICENSE NUMBER				2 NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code) J.R. KENNETH F. BLOUNT 5 SCIENCE PARK AT YALE NEW HAVEN, CT 06511-3572			
3 ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED BIORELIX, INC. 5 SCIENCE PARK AT YALE NEW HAVEN, CT 06511-3572				4 NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION IZABELA PUSKARZ TELEPHONE NUMBER (203) 785-9282			
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 3M AMOUNT ENCLOSURE : 3,400			
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 Ronald W. Lennox - CEO				SIGNATURE Ronald W. Lennox		DATE 7-3-07	
FOR NRC USE ONLY							
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS		
APPROVED BY				DATE			

APPENDIX C

Item No.	Suggested Response	Yes	Description Attached
5.	<p>RADIOACTIVE MATERIAL</p> <p>Unsealed and/or Sealed Sources</p> <ul style="list-style-type: none"> • For unsealed materials: <ul style="list-style-type: none"> – Provide element name with mass number, chemical and/or physical form, and maximum requested possession limit. – For potentially volatile materials (e.g., I-125, I-131, H-3), specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form. • For sealed materials: <ul style="list-style-type: none"> – Identify each Radionuclide (element name and mass number) that will be used in each source. – Provide the manufacturer's (distributor's) name and model number for each sealed source and device requested. – Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State. – Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State. • Provide an Emergency Plan (if required). <p>Financial Assurance and Recordkeeping for Decommissioning</p> <p>No response is needed from most applicants. If F/A or a DFP is required, submit the required documents as described in Regulatory Guide 3.66.</p>	<ul style="list-style-type: none"> • • <p>N/A</p>	<p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p>[]</p>
6.	<p>PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED</p> <p>List the specific use or purpose of each radioisotope.</p>	<ul style="list-style-type: none"> • 	<p><input checked="" type="checkbox"/></p>

Item No.	Suggested Response	Yes	Description Attached
7.	<p>INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE</p> <p>RSO</p> <p>Provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.</p> <p>AUs</p> <p>Provide the name of each proposed AU, with the types and quantities of licensed material to be used. Also provide information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials.</p>	<p>•</p> <p>•</p>	<p>✗</p> <p>✗</p>
8.	<p>TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (Occupationally Exposed Individuals and Ancillary Personnel)</p> <p>Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.</p>	<p>•</p>	<p>✗</p>

APPENDIX C

Item No.	Suggested Response	Yes	Description Attached
9.	<p>FACILITIES AND EQUIPMENT</p> <p>Describe the facilities and equipment to be made available at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage, preparation and measurement of radioactive materials. Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted.</p>	•	✗
10.	<p>RADIATION SAFETY PROGRAM</p> <p>Audit Program</p> <p>The applicant is not required to, and should not, submit its audit program to the NRC for review during the licensing phase.</p>	N/A	N/A

Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Radiation Monitoring Instruments</p> <p>Describe the instrumentation that will be used to perform required surveys and state that: "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."</p> <p style="text-align: center;">OR</p> <p>Describe the instrumentation that will be used to perform required surveys and state that: "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. Additionally, we will implement the model survey meter calibration program 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."</p> <p>Material Receipt and Accountability</p> <p>Develop and maintain procedures for ensuring material accountability,</p> <p style="text-align: center;">AND</p> <p>State that: "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."</p>	<p>•</p> <p>•</p>	<p><input checked="" type="checkbox"/></p> <p>[]</p> <p><input checked="" type="checkbox"/></p>

APPENDIX C

Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Occupational Dose</p> <p>State that: "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% of the allowable limits in 10 CFR Part 20," or "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."</p> <p>Public Dose</p> <p>No response is required from the applicant in a license application.</p> <p>Safe Use of Radionuclides and Emergency Procedures</p> <p>Develop and maintain procedures for safe use and emergencies. State that such procedures have been developed.</p> <p>If an emergency response plan is needed, submit it as a separate part of the application.</p>	<p>•</p> <p>N/A</p> <p>•</p> <p>[]</p>	<p><input checked="" type="checkbox"/></p> <p>N/A</p> <p><input checked="" type="checkbox"/></p> <p>[]</p>

Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Survey</p> <p>State that: "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."</p>	<p>•</p> <p>[]</p>	<p>✕</p>

APPENDIX C

Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p style="text-align: center;">OR</p> <p>State that: "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. As an alternative, we will implement the model leak test program published in Appendix R to NUREG - 1556, Vol. 7, "Consolidated Guidance about Materials Licenses: 'Program-Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope,' dated December 1999."</p> <p>Transportation</p> <p>No response is needed from applicants during the licensing phase.</p>	<p>[]</p> <p>N/A</p>	<p></p> <p>N/A</p>

Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Minimization of Contamination</p> <p>The applicant does not need to provide a response to this item under the following condition. NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: "Radioactive Material - Unsealed and/or Sealed Sources," "Facilities and Equipment," "Radiation Safety Program - Safe use of Radioisotopes and Emergency Procedures," "Radiation Safety Program - Surveys," and "Radiation Safety Program - Waste Management."</p>	N/A	N/A
11.	<p>WASTE MANAGEMENT</p> <p>State that: "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."</p> <p style="text-align: center;">OR</p> <p>"We will use the (<i>specify either (1) Decay-In-Storage, (2) Disposal of Liquids Into Sanitary Sewerage</i>) model waste procedures that are published in Appendix T to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999."</p>	<p>•</p> <p><input checked="" type="checkbox"/></p> <p>[]</p>	<p><input checked="" type="checkbox"/></p>

ITEM 5: RADIOACTIVE MATERIAL

- Sealed materials
Identification of the Radionuclide: P-32
Distributor: GE Healthcare (former Amersham)
This sealed source is registered as an approved sealed source by NRC.
Total possession limit including licensed material storage and waste:
25 MBq (millicuries)

ITEM 6: PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

Radioisotope	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
P-32	any	25 millicuries	internal labeling of the DNA and RNA molecules; in vitro studies

ITEM 7: INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

RSO: Izabela Puskarz

B.S. Biology, Central Connecticut State University, 1999

M.Sc. Molecular Biology, Quinnipiac University, 2002

Research Assistant (200-2003) and Research Associate (2003-2007) at Yale University, Dr. Ronald R Breaker Laboratory. Radiation Safety

Training provided by OEHS at Yale University, 2000 (and annual refreshment training). Dr. R. Breaker laboratory is licensed to use P-32, P-33, S-35, and H-3. Hands-on experience with P-32, P-33.

Committed to a RSO training in August 2007

AU: Kenneth F. Blount

B.S. Biochemistry, University of Arkansas, 1994

Ph.D. Chemistry and Biochemistry, University of Colorado, 2001

Radiation Training provided by both universities.

Associate Research Scientist (2005-2007) at Yale University. Radiation Safety Training provided by OEHS at Yale University, 2005 (and annual refreshment training). Hands-on experience with P-32, P-33.

ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (OCCUPATIONALLY EXPOSED INDIVIDUALS AND ACCILLARY PERSONNEL)

- Radiation Safety Training will be provided to ALL new employees in the beginning of their employment
- Refreshment course will be provided annually
- The training will be in a form of a lecture with a visual presentation or self study
- All trainees will be provided hand-out and Company Radiation Safety Manual
- The training will be conducted by assigned RSO
- The training will be followed by short test
- All participants will sign a form confirming their participation in the training
- All the trainees will be supervised by RSO or AU during their first hands-on experiment.

Topics covered by radiation Safety Training:

1. Radioactivity - terms (half-life, decay, etc.), law of radioactive decay, units of radioactivity, types of radiation
2. Radiation Safety Principles (ALARA program, internal vs external exposure, use of time, distance and shielding exposure, personal dosimeter and personal monitoring, contamination control)
3. Policies and Procedures (instrumentations, laboratory monitoring - surveys, purchasing, record keeping, secure storage, waste management, emergency procedures, caution signs, smoking and food consumption regulations, isotope handling techniques, report unsafe use to RSO) will be discussed in a great details

Ancillary Personnel Safety Training:

RSO will inform housekeeping staff about radiation hazards and the appropriate precautions. RSO will overview all posted signs in the laboratory and clarify which areas they can access and which waste is safe to remove from the laboratory.

ITEM 9: FACILITIES AND EQUIPMENT

We are planning to use two rooms for work with radioactivity (see Drawing # 1 – Radiation Room #1 and Radiation Room #2). Both rooms are isolated from the rest of the lab by doors.

- Radiation Room #1 will be designated as a receipt, secure storage place for all isotopes and working area
- There are two sinks – one for a disposal of radioactive waste to the sanitary sewage system and second with the eye wash system for non-radioactive usage
- The room has smooth and non-porous surface bench top areas for sealed sources use only. Bench tops will be covered with absorbent covers to catch and retain spilled liquids
- All radioactive waste will be stored in Radiation Room #1. Central liquid radioactive waste will be collected in a 1 gallon jug placed in a high-density plastic box. Tips, tubes and sharps (personal waste) will be collected in a containers placed in a high-density plastic box. All central dry radioactive waste will be placed in a plastic radiation safety bags inserted in a in a high-density plastic box. All central waste will be appropriately labeled and will be supplied with the log sheets for personnel to record the waste disposal
- All personnel will be supply with a lab coat, personal shield, goggles, appropriate gloves, dosimeter badge and Geiger counter
- Scintillation counter and gel dryers will be located in Radiation Room #1
- Radiation Room #2 will be designated as a dark room and if needed as long term secure waste storage
- It will be equipped with film developer and necessary accessories, Geiger counter and personal shield
- This room is also equipped with a non-radioactive usage sink

ITEM 10: RADIATION SAFETY PROGRAM

RADIATION MONITORING INSTRUMENTS

All packages containing isotopes, any contamination surveys will be surveyed using G-M Pancake Detectors (Ludlum Measurements) and Tri-Carb 2800TR Low Activity Liquid Scintillation Analyzer (PerkinElmer). Calibrations of the instruments will be performed by the instrument manufacturer and all the results will be recorded.

We will use instruments that meet the radiation monitoring instrument specification published by Appendix M to NUREG – 1556, vol.7, 'Program-Specific Guidance About Academic, Research and Development, and Other Laboratory Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary.

MATERIAL RECEIPT AND ACCOUNTABILITY

RSO will place all orders for radioactive material and will ensure that the requested material, quantities, manufacturer, and model are authorized by license and that possession limits are not exceeded. RSO will keep all the relevant records of licensed material. Receiving and disposal of the radioactive material as well as the record keeping will be responsibility of RSO, RSO Assistant or AU. Surveys of the received material will be performed as soon as practicable but no later than 3 hours after receipt of package.

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.

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% of the allowable limits in 10 CFR Part 20 or 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 Material Licenses: Program Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope' dated December 1999.

SAFE USE OF RADIONUCLIDES AND EMERGENCY PROCEDURES

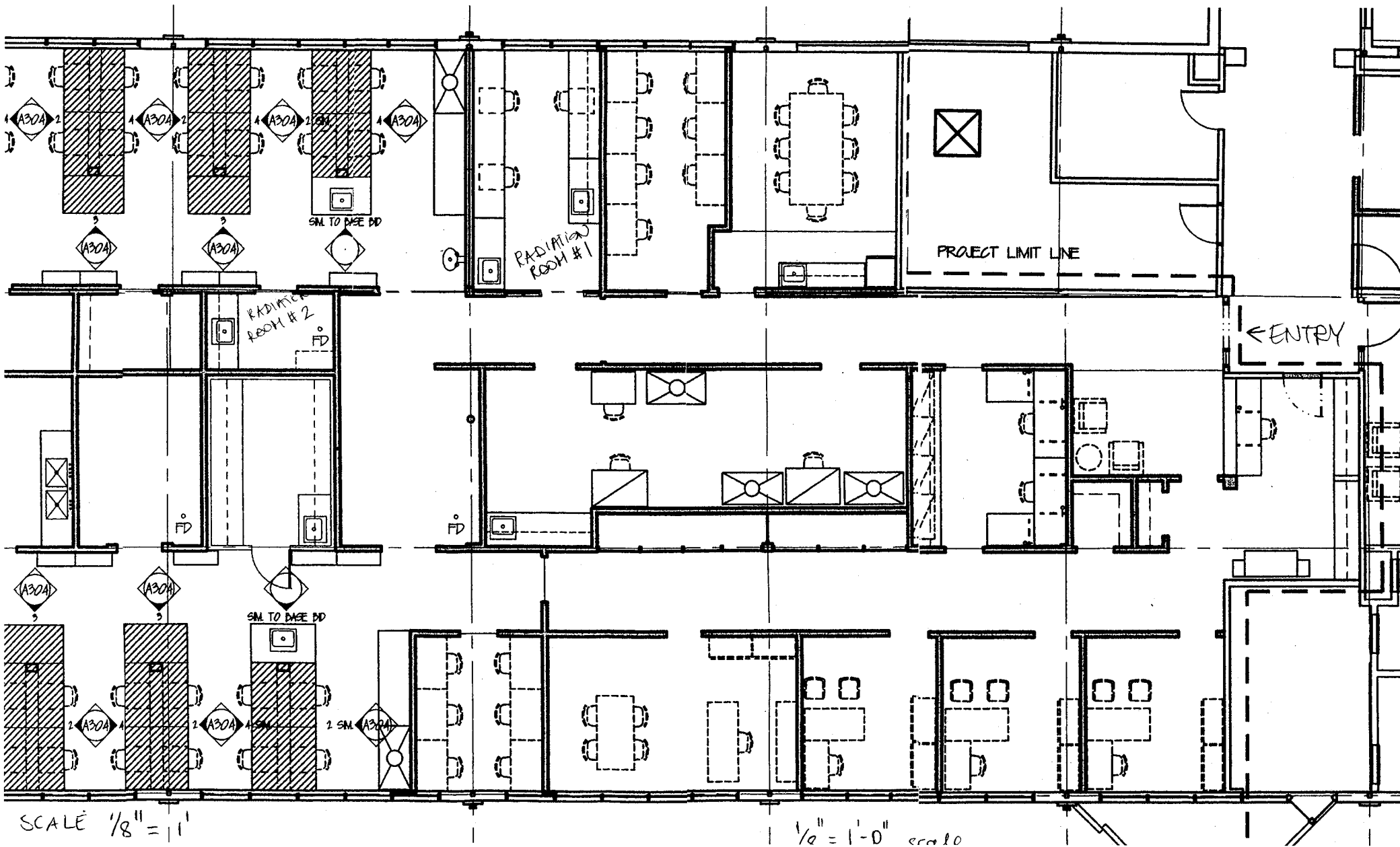
Procedures for safe use, including security of material, and emergencies will be developed before receipt of licensed material.

SURVEYS

We will survey our facility and maintain contamination level 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 test is not required because sources will contain byproduct material with the half-life of less than 30 days. All the material will be surveyed by wipe test upon arrival to the facility. Secure storage will be frequently checked with the G-M Pancake Detector.

ITEM 11: WASTE MANAGEMENT

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



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

7/3/2007, and to inform you that the initial processing which includes an administrative review has been performed.

☒ NEW LICENSE APPLICATION (0303758)
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

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

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

Your action has been assigned **Mail Control Number** 140774.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

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

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: BIORELIX, INC.
 Received Date: 20070706
 Docket No: 3037508
 Control No.: 140774
 License No.: 06-31263-01
 Action Type: New Licensee

2. FEE ATTACHED

Amount: \$3,400.00
 Check No.: 323

3. COMMENTS

Signed M. A. Perkins
 Date 7/9/2007

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

1. Fee Category and Amount: _____

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

Amendment _____
 Renewal _____
 License _____

3. OTHER _____

Signed _____
 Date _____