COVANCE

Covance Inc.
8211 Scicor Drive
Indianapolis, IN
46214

1 November 2010

Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL. 60532-4352

Re: NRC Form 313 - License Application for Amendment - License No. 13-26058-01

To Whom It May Concern:

Enclosed are the original and one copy of **NRC FORM 313, Application for Materials License; license amendment** for use of radioactive materials at Covance Laboratories Inc. in Indianapolis, Indiana. Please note the items contained in this license amendment shall be added to the existing license 13-26058-01 which is under timely renewal (renewal application submitted 16-July-2010, Control # 573176) and no other conditions or terms of this license will change. This application contains security-related information and should be withheld from public disclosure under 10 CFR 2.390.

Your diligent review and approval of this license application for amendment is kindly appreciated. Please contact Ms. Cheryl Grove directly at (317) 271-1200, Ext. 7258 should you need any additional information regarding this license application for amendment.

Sincerely,

Cheryl Grove 1 NOV 2010

Cheryl Grove
Radiation Safety Officer
Supervisor Immunology
Covance Laboratories, Inc.
Indianapolis, IN

Enclosure

COVANCE

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8211 Scicor Drive
Indianapolis, IN
46214

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NOTE TO THE REVIEWER:

We request that Radioactive Materials License 13-26058-01 granted to Covance Laboratories, Inc. be updated to include the changes described below. These changes are detailed in the documentation that follows.

1. Request the addition of Carbon-14 with a possession limit of 10 millicuries for analyzing biological samples in support of drug development activities.

2. Request the addition of two authorized users within the Bioanalytical Chemistry department.

3. Request the addition of laboratories within the Bioanalytical Chemistry department to specifically work with Carbon-14.

4. Addition to the currently authorized chemical/physical forms for ^{3}H: Biological samples and/or reference standards containing quantities or concentrations in excess of those specified in 10 CFR 30.14 or 10 CFR 30.18.

NRC FORM 313 (3-2009) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects.resource@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:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
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, 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, MISSISSIPPI, 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
612 E. LAMAR BOULEVARD, SUITE 400
ARLINGTON, TX 76011-4125

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 13-26058-01
- [ ] C. RENEWAL OF LICENSE NUMBER

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

Covance Laboratories
8211 SciCor Drive
Indianapolis, IN 46214

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Covance Laboratories
8211 SciCor Drive
Indianapolis, IN 46214

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Cheryl Grove, M.T.

TELEPHONE NUMBER

(317) 271-1200

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. maiximum 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 3P 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 CONTANED 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
Marietta M. Henry, M.D.	Marietta M. Henry, MD	04-Nov-2010

FOR NRC USE ONLY

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

REQUEST FOR LICENSE AMENDMENT
NRC LICENSE NO. 13-26058-01

Background Information

Covance periodically receives biological samples from outside clients who are developing new drugs. Such samples are occasionally contaminated with radioactive tracers (e.g. ^{14}C or ^{3}H) that were utilized in the drug development process. In most cases, the concentrations and/or amounts of radioactive material in these samples are less than those specified in 10 CFR 30.14 or 10 CFR 30.18. However, it is possible that samples might contain ^{14}C or ^{3}H in excess of those concentrations or amounts. As such, Covance wishes to amend their current license as follows:

Item 5: Radioactive Material

a. Additional Radionuclide: ^{14}C
b. Chemical/Physical Forms: Biological samples and/or reference standards containing quantities or concentrations in excess of those specified in 10 CFR 30.14 or 10 CFR 30.18.
c. Maximum Possession Limit: 10 mCi

Addition to the currently authorized chemical/physical forms for ^{3}H: Biological samples and/or reference standards containing quantities or concentrations in excess of those specified in 10 CFR 30.14 or 10 CFR 30.18.

Item 6: Purpose for Which Licensed Material Will Be Used

For both ^{3}H and ^{14}C: Analysis of biological samples containing ^{3}H and/or ^{14}C in excess of exempt quantities or concentrations as specified in 10 CFR 30.14 or 10 CFR 30.18.

Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience.

The following individuals will be performing or supervising the analysis of non-exempt biological samples and should be added as "Authorized Users" under this license:

a. Shon Logue
b. Donnely Tyler

A description of the training and experience that the aforementioned individuals have had with radioactive materials is described in Exhibit 7.2.

Dr. Harold Yoshimura, Ph.D. is currently listed as an Authorized User on this license. Dr. Yoshimura has retired and his name should be deleted from the license.

Item 8: Training for Individuals Working In or Frequenting Restricted Areas

The training program specified in Covance's NRC license renewal application, dated July 16, 2010 will be implemented for individuals handling these non-exempt biological samples.

Item 9: Facilities and Equipment

The use, receipt, and storage of non-exempt biological samples will be in areas that are physically separate from those areas currently authorized on the license. The areas where these biological samples will be used, received, and stored include the "Extraction Lab", "Sample Management Lab and Receiving Dock", and "Freezer and Refrigerator Storage." Drawings of these areas are included in Exhibits 9.1, 9.2, and 9.3. Access to these areas is restricted to Covance personnel only. While the specific locations (e.g. benches, hoods, refrigerators, etc.) of the use and/or storage of these non-exempt biological samples are indicated on the attached drawings, Covance reserves the right to relocate the specific use and/or storage areas within these rooms as necessary. Equipment and supplies typically available and utilized to minimize both personal and area contamination will be as described in Item 9 of Covance's NRC license renewal application, dated July 6, 2010.

Item 10: Radiation Safety Program

Radiation Monitoring Instruments: A liquid scintillation counter (LSC) will be utilized to count wipe tests for removable contamination. The method for determining the counting efficiency of the LSC will be a described in Item 10 of Covance's NRC license renewal application, dated July 16, 2010.

Material Receipt and Accountability: As indicated above, non-exempt biological samples will be received in the Sample Management Lab and Receiving Dock." Once the non-exempt samples have been received and are determined to be in good condition, they will be transferred to the Extraction Lab and opened by Authorized Users or individuals who have been specifically trained to handle radioactive material and working under the supervision of an Authorized User. The package check-in procedure is described in Item 10 of Covance's NRC license renewal application, dated July 16, 2010.

Personnel Monitoring and Occupational Dose: Due to the small quantities of ^{14}C or ^{3}H associated with non-exempt biological samples, personnel monitoring is not required.

Safe Use of Radionuclides and Emergency Procedures: The procedures described in Item 10 of Covance's NRC license renewal application, dated July 16, 2010 will be utilized for non-exempt biological samples.

Surveys: The survey procedures for removable contamination described in Item 10 of Covance's NRC license renewal application, dated July 16, 2010 shall be utilized for the areas where non-exempt biological samples are used or stored.

Item 11: Waste Management

Radioactive waste associated with non-exempt biological samples will be handled as described in Item 11 of Covance's NRC license renewal application, dated July 16, 2010.

Exhibit 7.2 – Radiation History and Experience

Name: Shon Logue

Timeframe of use and isotopes handled: 2003-2007, ^{14}C & ^{3}H
1998-2007, ^{125}I

Brief description of work activity: Use of gamma counter and LSC counter for R&D, validation and analysis work. Prepared radioactive standards and quality controls. Prepared radioactive dosing solutions dosed and bled rats and beagles. Analyzed radioactive tissues from equine, swine, and monkeys. Performed wipe tests of designated areas. Disposal of radioactive solutions. Previous work at ABC Laboratories as a radiation safety officer for the bioanalytical department.

Brief description of radiation training: Participated in a 1 week (40hr) safety training course at ABC Laboratories which included an 8 hour radiation safety course. Attended annual radiation safety refresher courses at ABC Laboratories and MDS Pharma Services.

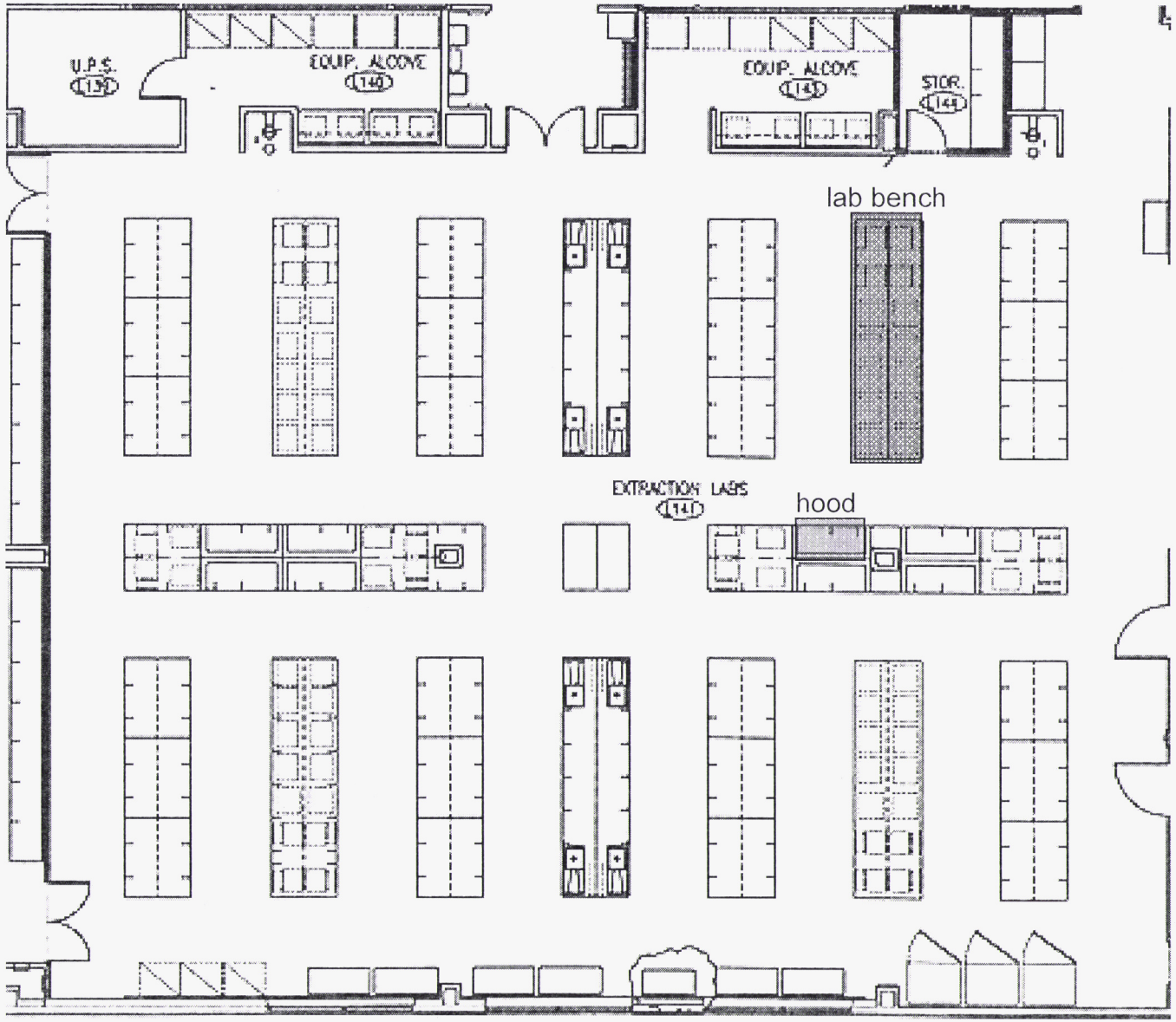
Name: Donnelly Tyler

Timeframe of use and isotopes handled: 2006-2007, ^{14}C

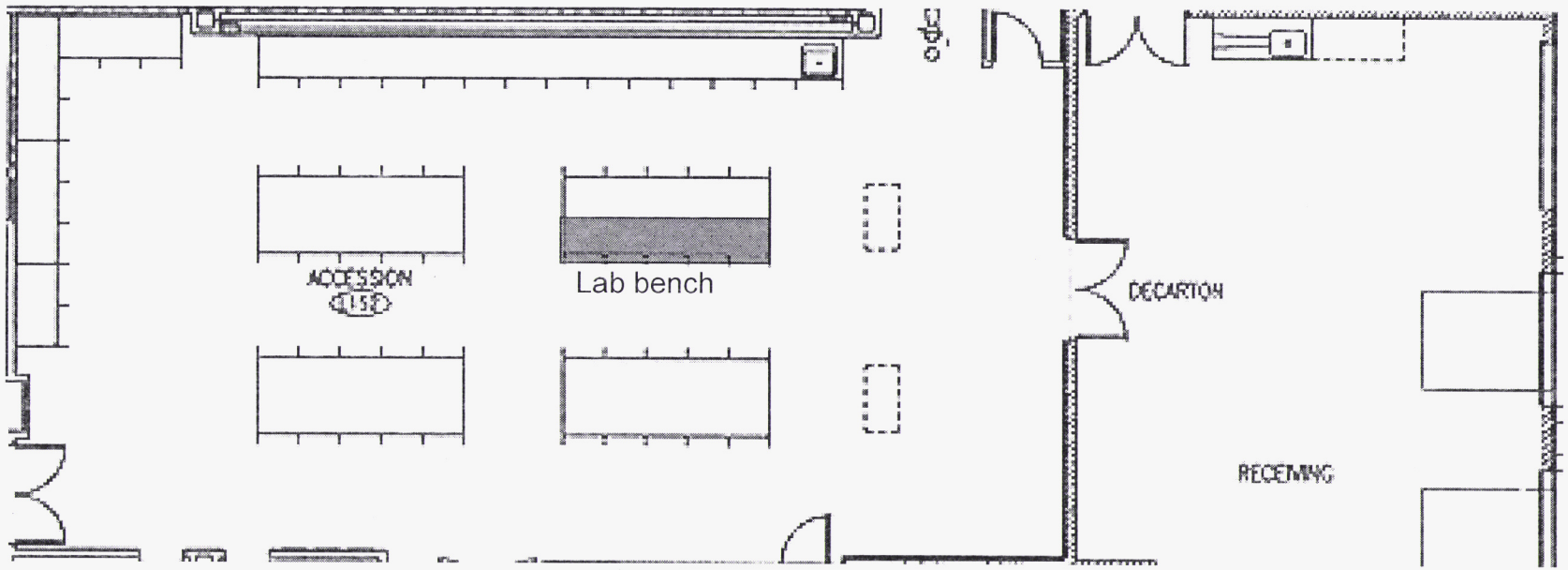
Brief description of work activity: Analyzed soil samples using combustion and liquid scintillation counting. Performed solid phase extractions on soil from radiolabeled crops and analyzed the extracted samples using a LSC. Tended to radiolabeled crops in greenhouse. Performed wipe tests of countertops, glassware and several other surfaces.

Brief description of radiation training: Attended Dow AgroSciences in-house radiation safety training on an annual basis.

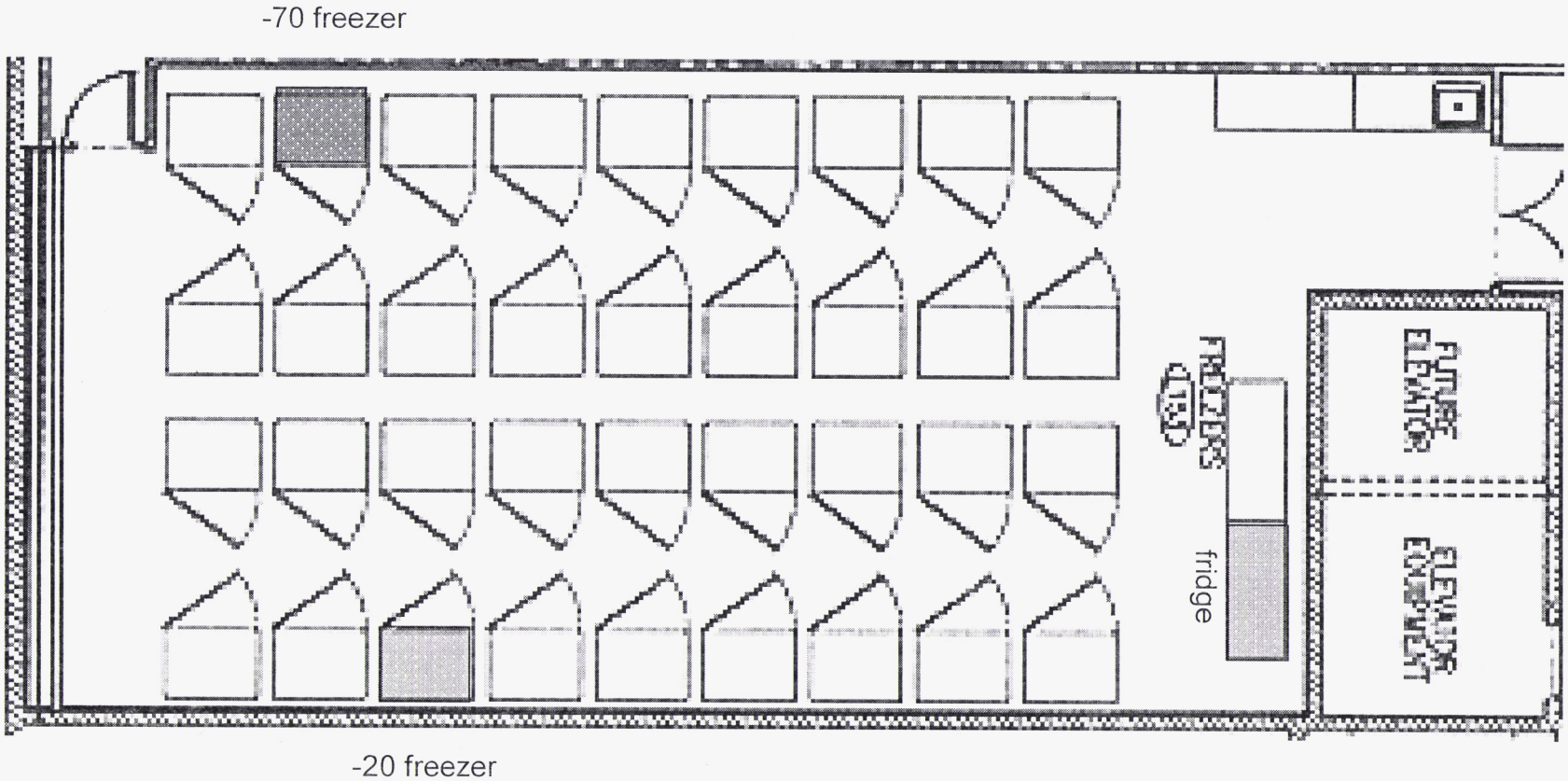
Extraction Lab – Exhibit 9.1



Sample Management Lab and Receiving Dock Exhibit 9.2



Freezer and Refrigerator Storage
Exhibit 9.3



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Services Inc.

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