


<b>NRC FORM 313</b> (10-2005) 10 CFR 30.32, 33, 34, 35, 36, 39, and 40	<b>U.S. NUCLEAR REGULATORY COMMISSION</b>	<b>APPROVED BY OMB: NO. 3150-0120</b> Estimated burden per response to comply with this mandatory collection request: 4.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to <a href="mailto:infocollections@nrc.gov">infocollections@nrc.gov</a> , and to the Desk Officer, Office of Information and Regulatory Affairs, NE08-10202, (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.
<b>APPLICATION FOR MATERIAL LICENSE</b>		
<b>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.</b>		
<b>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</b>  DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001  <b>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</b>  <b>IF YOU ARE LOCATED IN:</b>  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		<b>IF YOU ARE LOCATED IN:</b>  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
<b>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.</b>		
1. THIS IS AN APPLICATION FOR (Check appropriate item) <input type="checkbox"/> A NEW LICENSE <input type="checkbox"/> B AMENDMENT TO LICENSE NUMBER _____ <input checked="" type="checkbox"/> C RENEWAL OF LICENSE NUMBER <u>24-13365-01</u>		2. NAME AND MAILING ADDRESS OF APPLICANT (include ZIP code) Analytical Bio-Chemistry Laboratories, Inc. 7200 E. ABC Lane Columbia MO 65202
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED Analytical Bio-Chemistry Laboratories, Inc. 7200 E. ABC Lane Columbia MO 65202		4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Sheila C. Hecht  TELEPHONE NUMBER (573) 443-9070
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 <u>3L</u> AMOUNT ENCLOSURE \$ <u>8,400.00</u>
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 82 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 G. Scott Ward Sr. VP Chief Administrative Officer		SIGNATURE  DATE 02/21/2007
<b>FOR NRC USE ONLY</b>		
TYPE OF FEE	FEE LOG	FEE CATEGORY
AMOUNT RECEIVED		CHECK NUMBER
APPROVED BY		DATE
COMMENTS		

RECEIVED FEB 27 2007

**ITEM 5.**

## RADIOACTIVE MATERIAL

- |    |  |   |
|----|--|---|
| a) | Element:   | Any byproduct material with a physical half life equal to or less than 120 days with atomic numbers 1 through 83 inclusive  |
|    | Chemical and/or physical form:   | Any (excluding sealed sources and volatile forms of iodine-131 and iodine-129)  |
|    | Maximum amount that the licensee may possess at any one time under this license: | Not to exceed 5 Curies per nuclide and 100 Curies total except as listed below:<br>phosphorus-33    10 curies<br>sulfur-35        10 curies<br>iodine-125       10 curies |
| b) | Element:   | Carbon-14   |
|    | Chemical and/or physical form:   | Any   |
|    | Maximum amount that the licensee may possess at any one time under this license: | 20 curies   |
| c) | Element:   | Nickel-63   |
|    | Chemical and/or physical form:   | Foil Sources<br>Varian Number:<br>03-908377-00<br>Varian Aerograph<br>Number: 02-001972-00  |
|    | Maximum amount that the licensee may possess at any one time under this license: | No single foil to exceed 8 millicuries, 80 millicuries total  |

- |    |  |   |
|----|--|---|
| d) | Element:   | Nickel-63   |
|    | Chemical and/or physical form:   | Foil Sources<br>Hewlett-Packard Model<br>Number: 19235  |
|    | Maximum amount that the licensee<br>may possess at any one time under<br>this license: | No single foil to exceed<br>15 millicuries, 200<br>millicuries total                                    |
| e) | Element:   | Carbon-14   |
|    | Chemical and/or physical form:   | Solid and/or liquid waste<br>from laboratory studies  |
|    | Maximum amount that the licensee<br>may possess at any one time under<br>this license: | Less than 20 curies   |
| f) | Element:   | Cesium-137  |
|    | Chemical and/or physical form:   | Sealed sources (registered<br>pursuant to Section 32.210 of<br>10 CFR part 32 or an<br>Agreement State) |
|    | Maximum amount that the licensee<br>may possess at any one time under<br>this license: | No single source to exceed<br>30 microcuries  |
| g) | Element:   | Hydrogen-3  |
|    | Chemical and/or physical form:   | Any   |
|    | Maximum amount that the licensee<br>may possess at any one time under<br>this license: | 1.0 curie   |
| h) | Element:   | Europium-154  |
|    | Chemical and/or physical form:   | Liquid or solid   |
|    | Maximum amount that the licensee   |   |

	may possess at any one time under this license:	2 microcuries
i)	Element:	Cesium-137
	Chemical and/or physical form:	Liquid or solid
	Maximum amount that the licensee may possess at any one time under this license:	300 microcuries
j)	Element:	Barium-133
	Chemical and/or physical form:	Liquid or solid
	Maximum amount that the licensee may possess at any one time under this license:	750 microcuries
k)	Element:	Manganese-54
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	200 millicuries
l)	Element:	Lutetium-177
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	500 millicuries
m)	Element:	Technetium-99
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	30 millicuries
n)	Element:	Molybdenum-99
	Chemical and/or physical form:	Any

	Maximum amount that the licensee may possess at any one time under this license:	30 curies
o)	Element:	Technetium-99m
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	30 curies
p)	Element:	Cobalt-60
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	1 microcurie
q)	Element:	Gadolinium-153
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	1 microcurie
r)	Element:	Terbium-160
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	60 microcuries
s)	Element:	Thulium-170
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	15 microcuries
t)	Element:	Holmium-166m

Chemical and/or physical form:	Any
Maximum amount that the licensee may possess at any one time under this license:	150 microcuries

**ITEM 6.**

**PURPOSES FOR WHICH LICENSED MATERIAL WILL BE USED**

a., b. and g.

**A. Animal Studies**

1. Ecotoxicology
  - a. Static and Flow-Through Acute and Chronic Aquatic and Terrestrial Toxicity Tests
  - b. Bioaccumulation Studies
  - c. Soil Biodegradation Studies
  - d. Mesocosm/Microcosm Studies
2. Mammalian Studies – Includes Residue, Metabolism, Toxicity, FDA Animal Health, and Dermal Application
3. Avian Studies – Includes Residue, Metabolism, FDA Animal Health, and Toxicity.
4. Non-Target Insects, Specifically honeybees

**B. Metabolism/Environmental Fate/Biodegradation Studies**

1. Plant and Animal Metabolism Studies – Includes In-Vitro and Analyses
2. Field E-Fate Studies – Includes dissipation, irrigation, and leaching studies.
3. Laboratory E-Fate Studies - includes metabolism, photolysis, soil leaching, adsorption/Desorption,

hydrolysis, Mobility, Volatility, Solubility, vapor pressure, octanol/water partition coefficient, etc.

4. Laboratory Biodegradation Studies – includes activated sludge and aerobic and anaerobic biodegradation studies
- C. Metabolite Characterization – Metabolite characterization work could be performed on all studies mentioned above. This would involve the analysis of samples incorporated with  $^{14}\text{C}$ ,  $^3\text{H}$  or  $^{35}\text{S}$ .
- D. Methods Development – Occasionally microcurie to low millicurie amounts of material are utilized to develop analytical methods which will ultimately be used for residue analysis.
- E. Custom Radiolabeled Organic Synthesis – Analytical Bio-Chemistry Laboratories offers their clients the option of having test material synthesized on site for use in their studies being conducted here. Low-to middle-millicurie quantities of “raw” material may be used during the synthesis process. Upon completion of the study, the remaining compound is considered the property of the client and is delivered to them or disposed of as per their request.
- F. For possession, use, and processing incident to synthesis of radiochemicals.
- G. For storage prior to distribution of synthesized radiochemicals.
- H. For packaging and distribution of synthesized radiochemicals to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or Agreement State.

c. and d.

Nickel-63 electron capture detector cells will be used (in sealed-source form) in gas chromatographs for sample analysis and for cleaning.

e.

Possession incident to storage of waste.

f.

Cesium-137 sealed sources are utilized for the calibration of the various liquid scintillation counters operated at ABC Laboratories, Inc.

h. through j.

These sources are utilized for the calibration of various liquid scintillation counters operated at ABC Laboratories, Inc.

k. through m.

1. For possession, use, and processing incident to synthesis of radiochemicals
2. For packaging and distribution of synthesized radiochemicals to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or Agreement State.

n. and o.

For research and development as defined in 10 CFR 30.4

p. through t.

For research and development as defined in 10 CFR 30.4 including studies in animals.

## **ITEM 7.**

### **INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE**

All ABC Laboratories personnel who will be working in areas designated for radioisotope studies are required to read and accept the radiation safety program prior to beginning work at the lab. Their performance in handling radioactive materials is monitored by the following listed people. All personnel who will be handling radioisotopes are required to attend in-house radiation safety seminars, and attend periodic refresher courses.

#### **Executive Management**

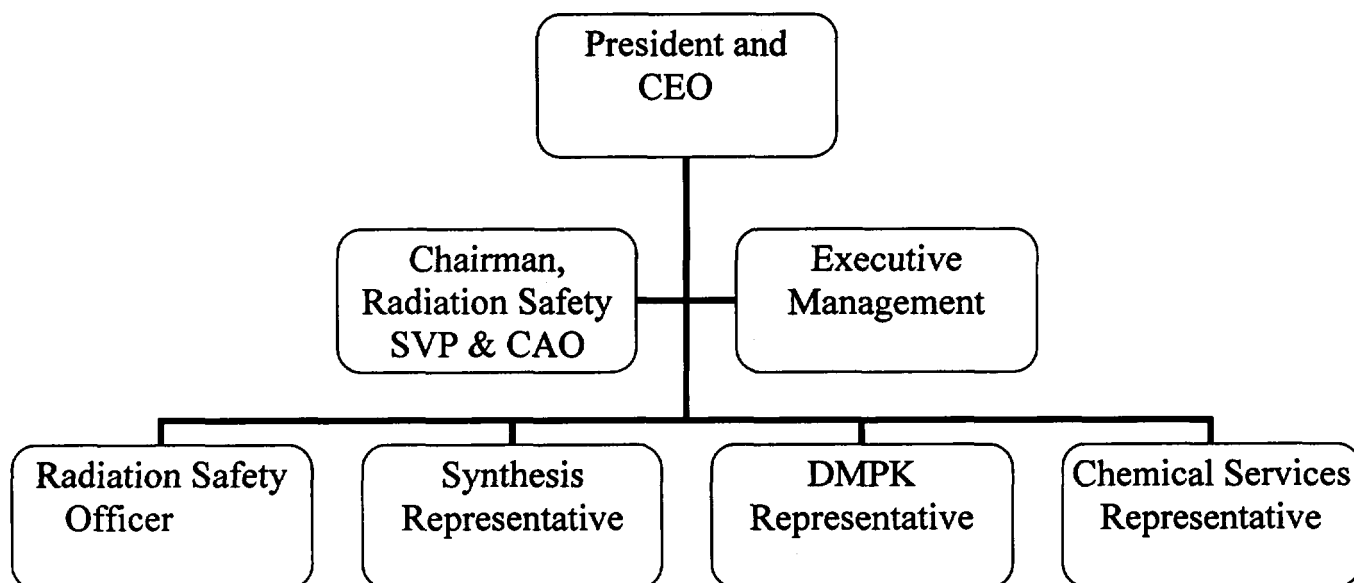
The Chief Executive Officer (CEO) is responsible for the use of radioactive materials under this license. Oversight of all safety and regulatory compliance programs, including radiation safety and compliance, has been delegated to the Senior Vice President & Chief Administrative Officer who also sits as the Chairman of the Radiation Safety Committee. Another member of the Senior



Management Team will also serve on the Radiation Safety Committee as the Executive Management Representative.

### **Responsibilities of the Executive Management**

- Radiation safety, security and control of radioactive materials, and compliance with NRC and Department of Transportation (DOT) regulations and operating and emergency procedures;
- Completeness and accuracy of radiation safety records and all information provided to the NRC;
- Knowledge about the contents of the license and application;
- Commitment to provide adequate resources (including space, equipment, personnel, time) to the radiation protection program to ensure that public and workers are protected from radiation hazards and meticulous compliance with regulations is maintained;
- Selection and assignment of qualified individuals to serve on the Radiation Safety Committee, and to serve as Radiation Safety Officer.
- Prohibition against discrimination of employees engaged in protected activities;
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in 10 CFR 30.7 and 10 CFR 30.10;
- Obtaining NRC's prior written consent before transferring control of the license; and
- Notifying the appropriate NRC Regional Administrator in writing, immediately following filing of petition for voluntary or involuntary bankruptcy.



**Radiation Safety Officer: Sheila C. Hecht**

### **Training**

Ms. Hecht received approximately 180 hours of training in a radiation specialist training course sponsored by the U. S. Navy at the Naval Undersea Medical Institute in New London, CT. She also received 200 hours of training in the "Medical Officers' Course in Nuclear Medicine and Radioisotope Techniques Course" at the National Naval Medical Center, Bethesda MD. The courses involved training in the detecting isotopes of alpha, beta, gamma, x-ray and neutron emission. Exposure limits, safety operations and various calculations dealing with exposure and activity levels were also covered.

Listed below is a course outline:

- 1) Atomic and Nuclear Structure
  - a) Nuclear Notation
  - b) Nuclear Stability
  - c) Isotopes
- 2) Radioactive Decay
  - a) Decay Schemes
  - b) Half-life
  - c) Chart of the Nuclides
  - d) Curie and Becquerel
- 3) Types of Radiation and Interaction
  - a) X and Gamma
  - b) Alpha and Beta

- c) Neutrons
  - d) Bremsstrahlung
- 4) Radiation Dosimetry
- a) Absorbed Dose: rad, gray
  - b) Exposure Dose: roentgen, C/kg
  - c) Dose Equivalent: rem, sievert
  - d) Quality Factor
- 5) Biological Effects of radiation
- a) Acute and Chronic Effects
  - b) Radiation and protection Guides
  - c) Dose Limits
- 6) External Radiation
- a) Time
  - b) Distance
  - c) Shielding
- 7) Internal Radiation Hazard
- a) Control of Contamination
  - b) Waste Disposal
- 8) Radiation Detection Equipment
- a) Survey Meters
  - b) Radiation Scalers
  - c) Personnel Dosimeters
- 9) Regulatory Control
- a) Licensing Procedures
  - b) Code of Federal regulations
- 10) Compliance
- a) Establishing and Posting radiation Areas
  - b) Surveying and Wipe Testing Work Areas
  - c) Leak testing Sealed Sources
  - d) Counting Statistics of Radioactive Materials

### **Experience**

<b><u>Isotope</u></b>	<b><u>Maximum Amount</u></b>	<b><u>Where Gained</u></b>	<b><u>Duration</u></b>	<b><u>Type of Use</u></b>
$^3\text{H}$	200 mCi	NNMC Bethesda	1 year	Research and Development, Instrument

				Calibration
$^{14}\text{C}$	200 mCi	NNMC Bethesda	1 year	Research and Development, Instrument Calibration
$^{137}\text{Cs}$	600 mCi	NNMC Bethesda	1 year	Any manual Brachytherapy Procedure permitted by 10 CFR 35.400
$^{125}\text{I}$	500 mCi	NNMC Bethesda	1 year	Any manual Brachytherapy Procedure permitted by 10 CFR 35.400
$^{131}\text{I}$	2 Ci	NNMC Bethesda	1 year	Any diagnostic study or therapy procedure permitted by 10 CFR 35.300 for which a written directive is required

Ms. Hecht was the Radiation Safety Officer at Naval Hospital Pensacola, Florida for 2 years. Her duties included monitoring of radioactive material packages received, oversight of the usage of radioactive materials in the Nuclear Medicine Clinic, personnel dosimetry and training of hospital personnel in radiation safety procedures.

## **Responsibilities of the Radiation Safety Officer (RSO)**

Responsible for:

- Proper posting, procedural instructions and cautions are displayed in the appropriate areas.
- Ensure security of radioactive material.
- Monitoring and surveys of all areas in which radioactive material is used.
- Reporting and recommendations for corrective actions to management when a radiation hazard exists or when there is a general trend of increased laboratory background.
- Submitting semi-annual evaluation reports to management on the handling of radioactive materials in relation to achieving the minimum practical hazard to ABC employees.
- Training of procedural techniques used by ABC Laboratories personnel.
- Oversight of ordering, receipt, surveys, and delivery of byproduct material.
- Maintain an inventory of all radioisotopes possessed under the license and ensure that licensed material possessed by the licensee is limited to the types and quantities of byproduct material listed on the license.
- Packaging, labeling, surveys, etc., of all shipments of byproduct material leaving ABC Labs.
- Personnel monitoring program, including determining the need for and evaluating bioassays, monitoring personnel exposure records, and developing corrective actions for those exposures approaching maximum permissible limits.
- Radioactive waste disposal program.
- Inventory and leak tests of sealed sources.
- Decontamination.
- Investigating any incidents and responding to any emergencies.
- Maintaining all required records.

- Review and approve all licensing agreements with the NRC.
- Act as liaison with NRC and other regulatory authorities.

The Radiation Safety Officer will be responsible for training personnel involved in working with radioactive materials. Laboratory personnel will be required to attend periodic in-house seminars on radiation safety conducted by the RSO or a designated consultant. The training text may be changed to reflect new NRC regulations or company policies. Ancillary personnel will be trained in the proper safety precautions when in radioactive use areas. This training will involve identifying radioactive waste receptacles (leave for laboratory personnel), general cleaning of laboratory floors, and avoidance of exposure to radioactive materials. Documentation of such training will be in the form of a signature of the attendees on a list which will be maintained by the RSO with the NRC records.

### **Radiation Safety Technician**

- 1) Schedule and conduct wipe tests as required on:
  - a) ECD cells every 6 months
  - b) Laboratory work areas every three months
- 2) Submit wipe swabs to analytical personnel for analysis by UC.
- 3) Date and record results of wipe surveys by category for future reference.
- 4) Recognize the radiation tolerance levels on wipe tests as specified by the ABC radiation safety guidelines and, if necessary, report the levels to the RSO to implement corrective action.
- 5) Survey all radioactive parcels received by ABC Laboratories and report contamination to the RSO for reporting under 10 CFR 20.1906. Parcels to be shipped from ABC Laboratories will be monitored for activity and documentation of said shipments and surveys will be maintained.
- 6) Deliver all radioactive materials received to the appropriate Material Compliance Office.
- 7) Maintain a file containing documentation of the amount of radioactive materials on site to assure that license limits are not exceeded.
- 8) Maintain calibration procedures and current certification of calibration for survey meters which are to be used in radioactive material surveys.

- 9) Assure that radioactive waste shipments are conducted properly, by supervising all such shipments. This will include notification of shipments to be made, verify proper preparation of waste shipped and prepare the proper documentation for the shipment.
- 10) Maintain a file of NRC licenses for all firms to which ABC sends radioactive material. Review the file to ensure licenses are current when the shipment is made.

### **ABC Laboratories Radiation Safety Committee**

The members of the Radiation Safety Committee will consist of the Chairman of the Radiation safety Committee, Radiation Safety Officer, Executive Management Representative, authorized users from the operating divisions, and/or selected representatives from the divisions.

### **Responsibilities of the Radiation Safety Committee (RSC)**

- 1) Review and approval of program and procedural changes by the RSC.
- 2) Monitor the implementation of program and procedural changes.
- 3) Technical review of study protocols. Approval of handling techniques and application procedures outlined in the protocol, (Any protocol which differs dramatically from those previously used will still be submitted to the NRC for review and approval).
- 4) Periodically perform audits of licensed operations to determine compliance with license, and taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.
- 5) Review of safety procedures used in the laboratory to assure safe practices are being followed.
- 6) Assist in informing personnel of safety practices and promote safety awareness in the laboratory.
- 7) Assisting the RSO in maintenance of accountability records, and minimizing levels of radioactive compounds in storage.
- 8) To observe and report unsafe practices or conditions in the laboratory to the RSO and to assist in correcting the problem by making recommendations to management.
- 9) To recommend new radiation safety procedures or equipment as needed.

- 10) To inform the committee of concerns of laboratory personnel in reference to radiation safety issues.
- 11) Periodically review the radiation safety program to initiate new policies or revise existing ones.
- 12) Determine and assign limits of activity which each division at ABC Laboratories may possess at any one time.

The Radiation Safety Committee will meet approximately every three months to discuss safety issues. Seventy percent of the members must be present to have a quorum. A quorum is required to approve new study protocols, approve new safety policies and procedures (NOTE: approval of new study protocols may be obtained via email without convening a formal meeting of the RSC). The Chairman, RSO, and Executive Management Representative (or his/her designee) must always be present to constitute a quorum.

The Radiation Safety Committee will decide if lab areas are adequate to assure safe use of radioactive materials. The committee will use 10 CFR 20 as a guide in determining which areas are adequate. The following items will be considered when evaluating areas for radiation use:

- 1) Are counter tops impervious to solvents, to avoid adsorption of radioactive materials?
- 2) Will adequate absorbent material be available to allow work areas to be covered?
- 3) Are the floors constructed so that cracks are filled, to avoid trapping of material?
- 4) Is there adequate ventilation in the area?

New areas built for radiation use, which have not previously been approved by the NRC, will be presented to the NRC for approval. Approval of these new areas by the NRC is required before radioactive materials can be used.

The committee will be responsible for contacting and working with radiation consultants when required, to aid in the training of personnel or training of general use of radioactive materials.

The committee will have the authority to require a change in any procedure that is not in compliance with the safety procedures of ABC Laboratories. All instances of this will be reported to the group manager.



## **Authorized User**

Licensed material will be used by personnel who have the training and experienced to handle individual isotopes. The competency of the individuals will be assessed by the Radiation Safety Officer and the Radiation Safety Committee. Authorized users of byproduct material with the isotopes for which they are approved will be documented on a list maintained by the RSO. No persons will be allowed to use material if they are not on the list.

Assessment of personnel for use of radioactive materials will use the following criteria:

1. Training received – The Radiation Safety Committee will review the training each individual has received. Length of training, location of training and content of training will be assessed.
2. Experience – The Radiation Safety Committee will review the amount of experience a person has with specific isotopes and the levels of activity that have been used in the past. The committee will authorize persons for use with individual isotopes.

The Authorized Users List will contain the following information:

1. Name of Individual
2. Isotopes for which they are approved.
3. Levels of activity for which they are approved.

There will be four levels of activity for which personnel will be approved. They will be at the following levels:

1. Microcurie level (Class 4) – The user may only use materials in the microcurie range. This means from zero to 999 microcuries.
2. Millicurie level (Class 3) – The user may only use materials in the millicurie range. This means from zero to 999 millicuries.
3. Curie level (Class 2) – The user may use materials in the curie range up to and including 5 curies.
4. Curie level (Class 1) – The user may use materials in the curie range at higher levels than Level II. This means from zero to the possession limit of the isotope on the license.

## **ITEM 8.**

### **TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (INSTRUCTIONS TO WORKERS)**

New employees at ABC Laboratories who will be working with radioactive isotopes are required to attend a training seminar conducted by the Radiation Safety Officer, Sheila Hecht. The frequency of training for all personnel will be:

- Before assuming duties with, or in the vicinity of, radioactive materials
- Whenever there is a significant change in duties, regulations, or the terms of the license
- Annually (refresher training)

We will maintain records of training to include, duration, place, instructor, subjects covered and names of attendees.

We will follow the model training program that was established in Appendix J, to NUREG-1556 Volume 7.

Any revision or changes to the training program will be review and approved by the Radiation Safety Committee before implementation.

## **ITEM 9**

### **FACILITIES AND EQUIPMENT**

The Radiation Safety Committee will decide if lab areas are adequate to assure safe use of radioactive materials. The committee will use 10 CFR 20 as a guide in determining which areas are adequate. The following items will be considered when evaluating areas for radiation use:

- 1) Are counter tops impervious to solvents, to avoid adsorption of radioactive materials?
- 2) Will adequate absorbent material be available to allow work areas to be covered?
- 3) Are the floors constructed so that cracks are filled, to avoid trapping of material?
- 4) Is there adequate ventilation in the area?

New areas built for radiation use, which have not previously been approved by the NRC, will be presented to the NRC. Approval of these new areas by the NRC is required before radioactive materials can be used.

**Figure 1:**

Figure 1 is the site diagram of ABC's facilities. The locations of all subsequent figures are designated, as are the lagoon/land application system.

**Figure 2:**

Figure 2 is a floor plan of ABC's Building 'B' which now has been converted for use by the Environmental Health & Safety Department. This building has concrete floors and laboratory benches with impervious tops. Laboratory ventilation is provided by a ventilation hood.

**Figure 3:**

Figure 3 is a floor plan of ABC's Building 'D'. All radioactive materials brought into the building are received at the building's material compliance office, room #723. The material compliance specialist checks each parcel for potential leakage, documents the material's receipt, and stores it as per client specifications in the material compliance office. Radioactive standards are weighed either in the balance room (#722) or on a balance in the metabolism programs laboratory (#732). These areas have counter tops of impervious materials. Standard procedures have been established to avoid contamination of counter tops and floors.

Rooms #721, 726, 730, 731, and 732 are laboratory areas in which personnel may utilize radioisotopes during the conduct of their studies. All laboratory areas are equipped with ventilation hoods and laboratory bench counter tops constructed of impervious materials. In areas where radioisotopes are most frequently used, rooms #732, and #737, the floors are covered with linoleum, which may easily be removed and replaced in the event of accidental contamination. Radioisotopes utilized in these areas are almost exclusively carbon-14 and hydrogen-3, although phosphorus-32 may be used in rooms #732 and #737.

Several environmental chambers are located in this building and may be utilized on occasion for the performance of environmental fate and assessment studies utilizing radioisotopes. These chambers are located in rooms #719 and #723.

Rooms #723, 732 and 737 contain instrumentation dedicated to and/or occasionally used during the analysis of radiolabeled compounds. Instrumentation includes gas/liquid and/or high performance liquid chromatographs (rooms 723 and 732), scintillation counters (Room #732), and mass spectrometry instrumentation (#737).

Radioactive samples, typically from metabolism-related studies are maintained in freezer "A". In the event that the freezer becomes full, samples may be relocated into one of the existing freezers at the discretion of the personnel in charge of the sample preparation unit.

Radioactive samples are processed for analysis by the sample preparation unit or designated personnel from the operating groups in room #716. The area is equipped with a large ventilation hood and stainless steel counter tops to facilitate easy decontamination.

**Figure 4:**

Figure 4 is a floor plan of ABC's Building 'E'. Shipments of radioactive material are received at the loading dock by room #824 where the integrity of the package is immediately assessed. Packages are then transferred to the material compliance offices in either the Building 'D' (figure 3) or Building 'J' (figure 7) for further survey procedures, documentation of receipt by the material compliance specialists and storage.

**Figure 5:**

Figure 5 is the floor plan of the Waste Storage Facility. The building is designed as a storage facility for retention of solid low-level radioactive waste. The facility also serves as a storage and shipment point for RCRA and laboratory waste materials generated at ABC Laboratories.

**Figure 6:**

Figure 6 is a floor plan of the interim waste storage area. This building has been decommissioned and is awaiting approval for removal.

**Figure 7:**

Figure 7 is a floor plan of ABC's Building 'J'. Radioactive materials are received in the building's material compliance compound storage room (#919). The material compliance specialist checks each parcel for potential leakage, documents the material's receipt, and stores it as per client specifications in the material compliance office. Radioactive standards are weighed in the balance room (#928) on a balance dedicated for this activity. The balance sits on a polished marble table covered with plastic-backed absorbent material to contain any spilled material.

Rooms 934, 938, and 940 are the laboratory areas utilizing radioisotopes during the conduct of their studies. The laboratories are well equipped with ventilation hoods to maintain adequate air turnover rates. The floors in rooms #938, 939, and

940 are covered with linoleum to facilitate decontamination should the need arise. All laboratory benches are covered with impervious counter tops.

Room #934 is primarily used to conduct studies with radiolabeled and nonradiolabeled compounds. The room is equipped with two standard hoods and one laminar flow biological safety hood. Room #934 is primarily dedicated to the performance environmental toxicology studies.

Room #938 contains one walk-in freezer used for the storage of samples pending analysis and/or return to the client or disposal. The unit is located on the central south side of the room.

Room #939 is the primary instrument room for this building. This area contains gas and liquid chromatographs.

Two environmental chambers are located immediately outside the southeast corner of room #940 (the Environmental Fate and Affects laboratory). These constant temperature rooms are utilized for various types of fate and affects studies utilizing (typically) carbon-14 labeled compounds. The floors and walls are metal and thus are inherently easy to decontaminate should the need arise.

#### **Figure 8:**

Figure 8 is a drawing of one of two greenhouse test areas used at ABC Laboratories. This area contains four greenhouses and is located to the east of Building 'J'. The greenhouses are constructed of metal and fiberglass and are equipped with environmental controls to maintain temperatures within study protocol specified parameters. Studies are usually conducted in epoxy-lined livestock watering tanks of various sizes (typically 3' x 10') to prevent contamination of the greenhouse floors or facility structure.

To the west of the four greenhouses lie an open air site and another open air site covered by a semi-transparent roof to allow exposure to sunlight, but to exclude rainfall. The greenhouses and open air sites are enclosed by an 8-foot high chain-link fence with a 2-ft angled barbed extension on the top to prevent entry to the test site by climbing. The entrance to the area is kept locked during non-business hours and is appropriately designated as a radiolabeled material usage area. The studies in this area are conducted in a manner that prevents exposure to the environment. Shields are used in treatment of the test systems to prevent spray from leaving the confinement area. Application of test compounds are limited to days when the wind speed is less than 5 mph. Filter papers are placed around the test system during application procedure. These filters may then be assayed if over-spray is suspected. If there is no suspicion of over-spray, the filters may not be assayed, but will be retained until the completion of the study.

**Figure 9:**

Figure 12 is a schematic of ABC Laboratories' Lysimeter test area. The approximately 100' by 50' area is enclosed by 7 foot chain-link fencing topped with three rows of barbed wire secured to outwardly angled supports. The facility currently contains three types of research plots: 1) lysimeters, 2) stock tanks, and 3) open air.

- 1) The lysimeters consist of 12" diameter steel tubes closed at the bottom and open at the top. The upper portion of the tube is connected to a runoff collection unit and the bottom to a leachate collection unit. This design does not allow for transfer of radiolabeled test material to the environment.
- 2) The stock tanks are epoxy-lined and, due to distance from surface of the test soil to the top of the container, do not allow for discharge of water even during heavy rain events.
- 3) The small open air plots are designed as follows: Metal flashing and 2" by 12" wooden frames are embedded at least eight inches into the soil. Four to six inch PVC pipe is buried approximately two to three inches into the plot soil and sloped sufficiently to the end of the plot to allow free drainage of runoff water. The PVC pipe is fastened onto the wooden edging around the plot. The pipe is perforated with one-half inch diameter holes one-half inch above the surface to allow drainage of any ponded water. The pipes drain into a 300-gallon subsurface collection tank, which can be pumped out and the water collected for testing on an as scheduled basis.

**Figure 10:**

Figure 12 is the floor plan of the Waste Retention Facility. The building is designed as a storage facility for retention of solid low-level plant and soil radioactive waste. This was also used for storage of radioactive waste with half-lives less than 120 days for decay to background.

**Figure 11:**

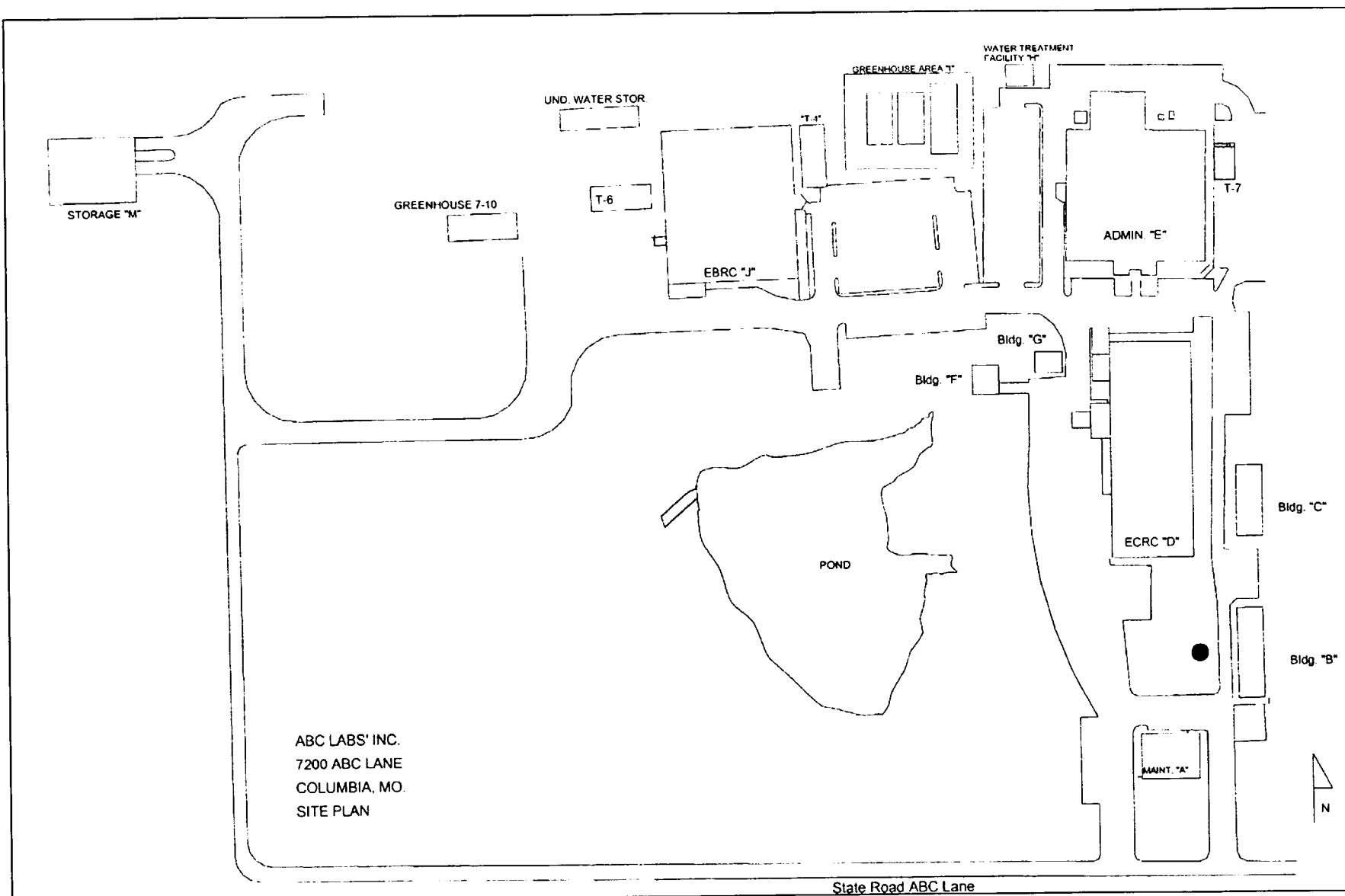
Figure 14 is the sanitary lagoon that was constructed in 1986 on the western part of the site above Grindstone Creek. The lagoon had a design area of 0.31 acre (13,500 ft<sup>2</sup>) and a design operating depth of 3 ft and maximum depth of about 6 ft. The actual size of the lagoon as constructed is somewhat smaller. A small amount of radioactive carbon-14 has been periodically discharged to the sanitary lagoon under the land application provision of ABC Lab's radioactive materials license, as described in condition number 20 of the current NRC license (Amendment

No. 26). This material was very dilute effluent from environmental fate and toxicology activities in building J. No other discharge of radioactive material to the sanitary lagoon system was ever authorized or allowed.

**FIGURES 1-14**

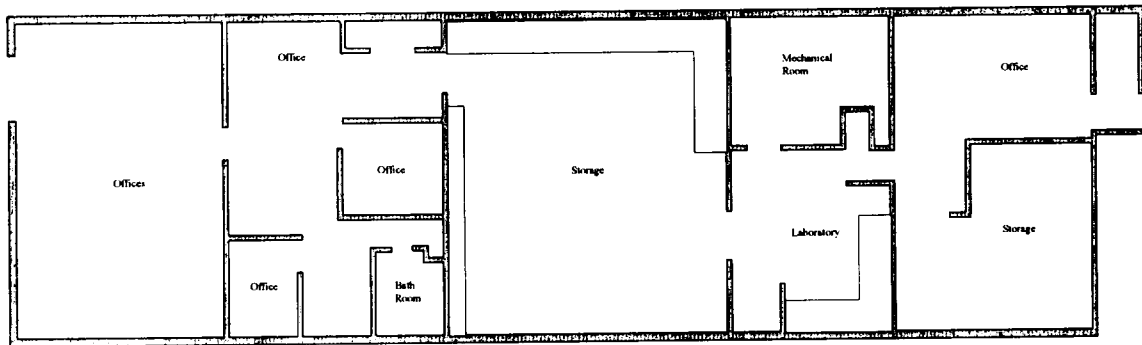


FIGURE 1 - ABC LABORATORIES SITE PLAN

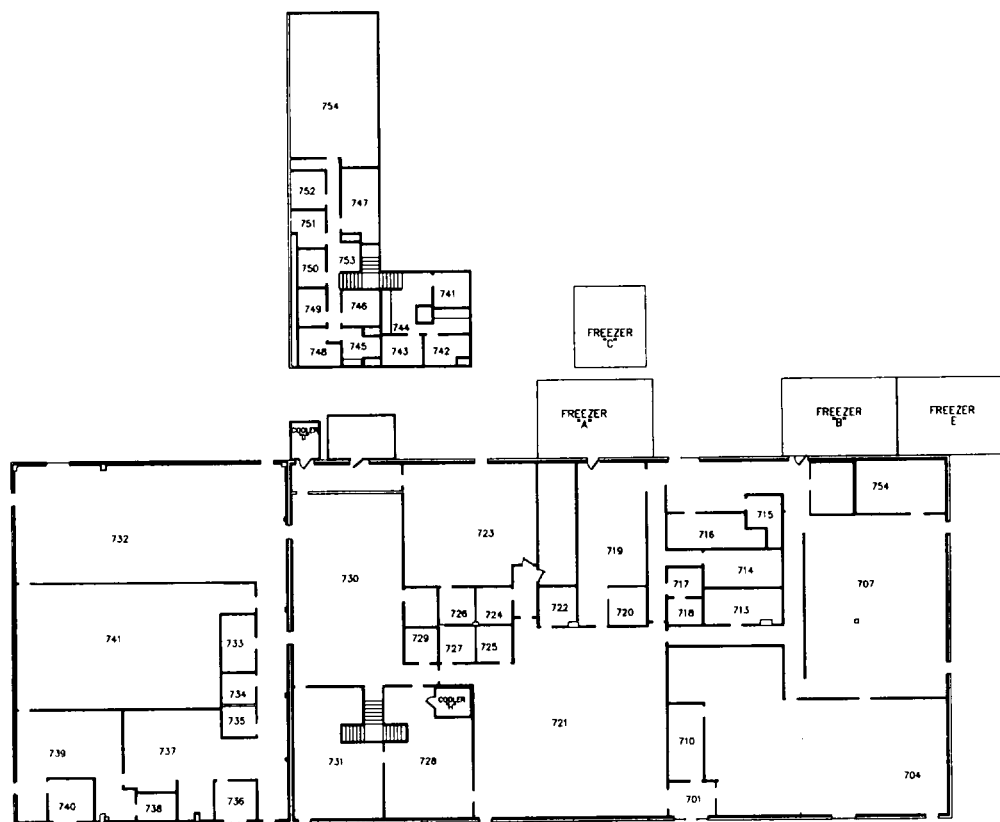


**FIGURE 2**  
**BUILDING B**

East

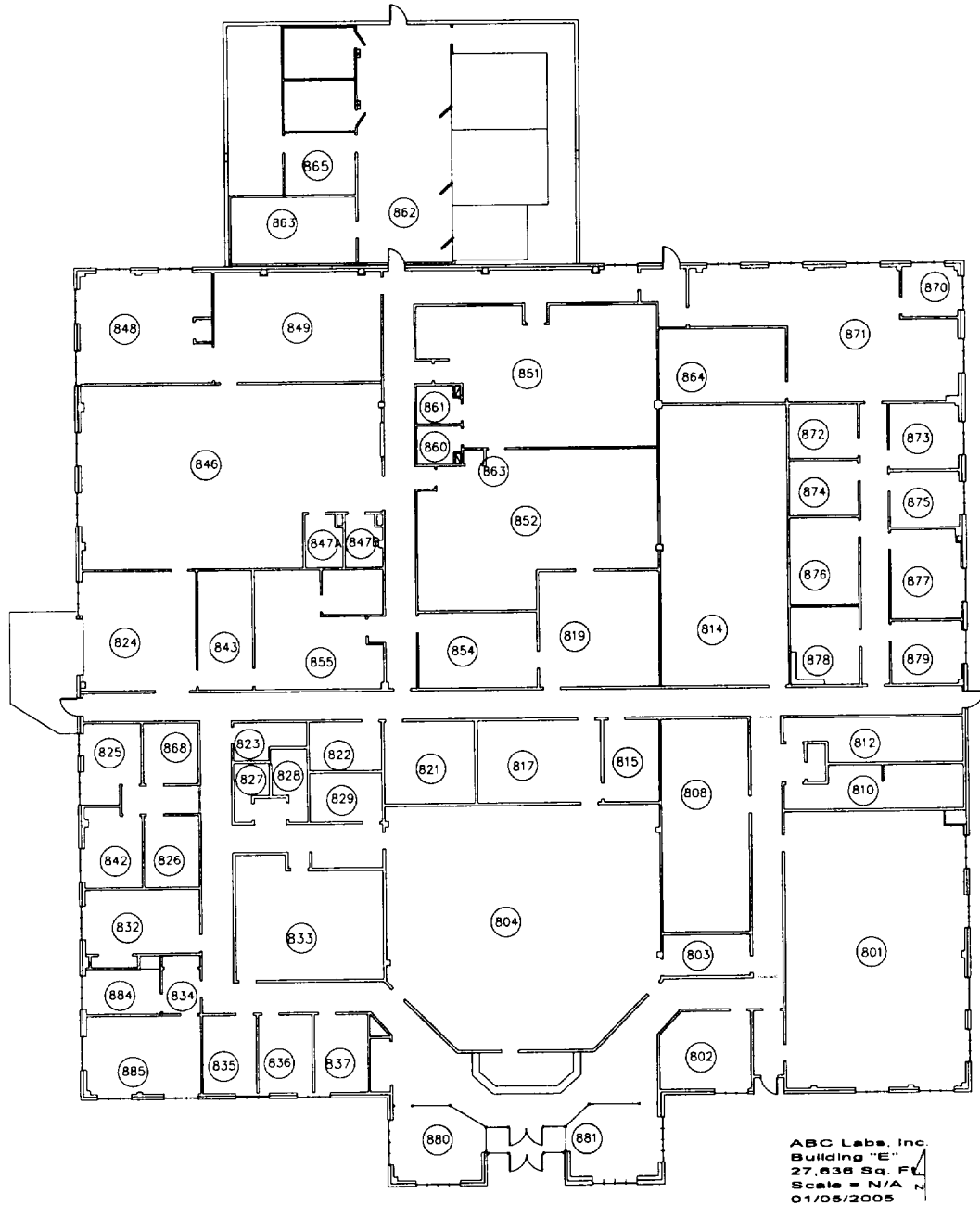


**FIGURE 3**  
**BUILDING D**

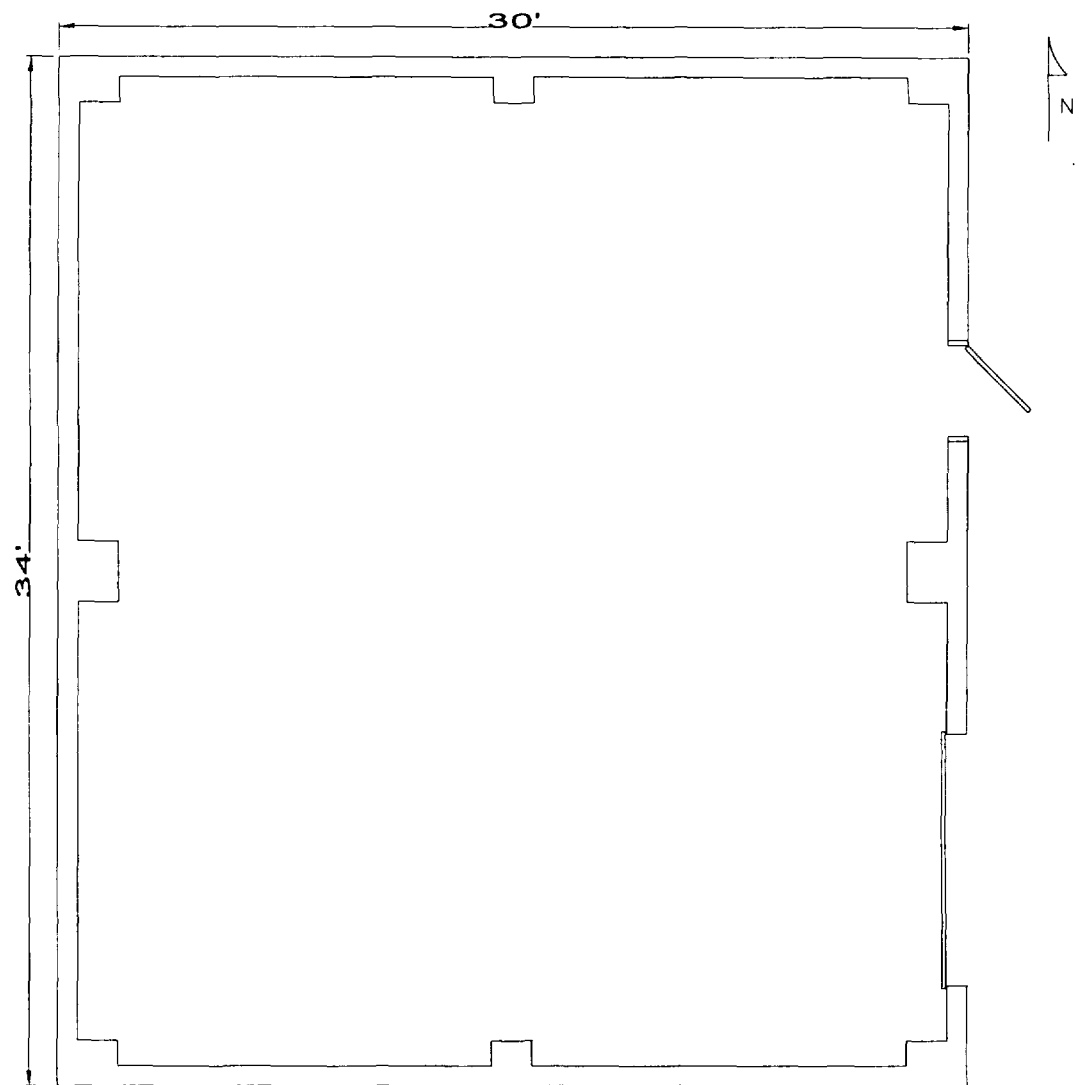


ENVIRONMENTAL CHEMISTRY RESEARCH CENTER  
BLDG. "D"  
26,448 SQ. FT.  
SCALE: N/A  
10/11/04

**FIGURE 4**  
**BUILDING E**



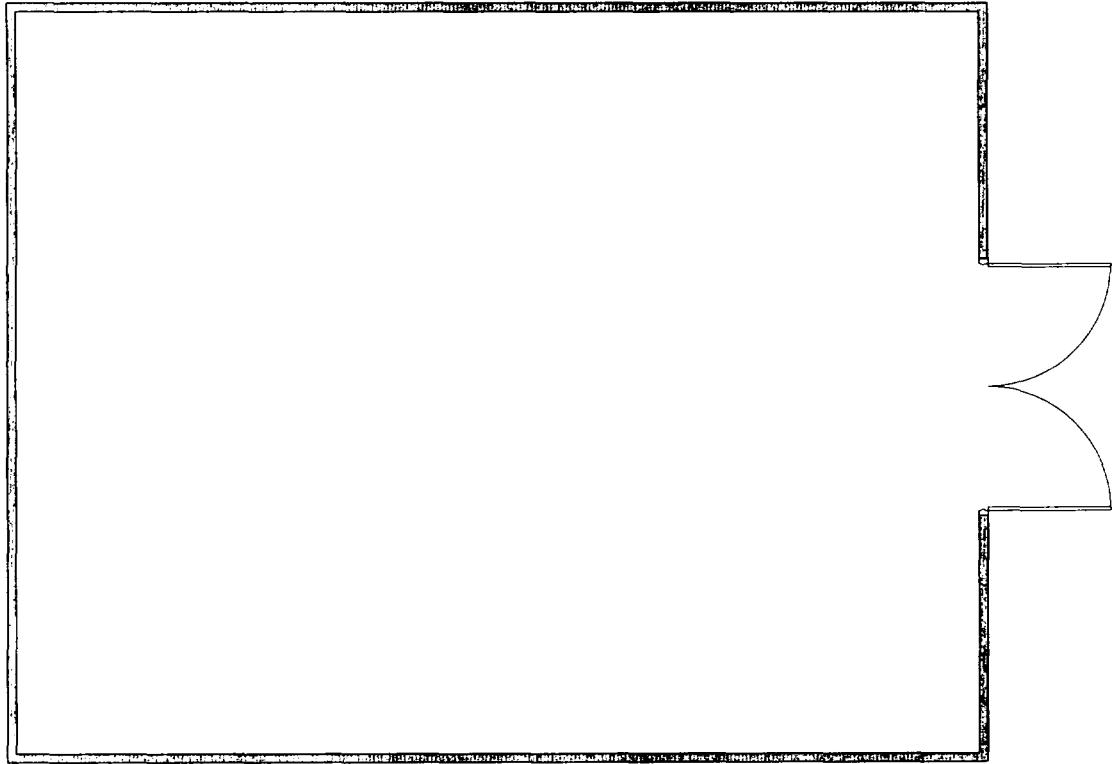
**FIGURE 5**  
**WASTE STORAGE FACILITY**



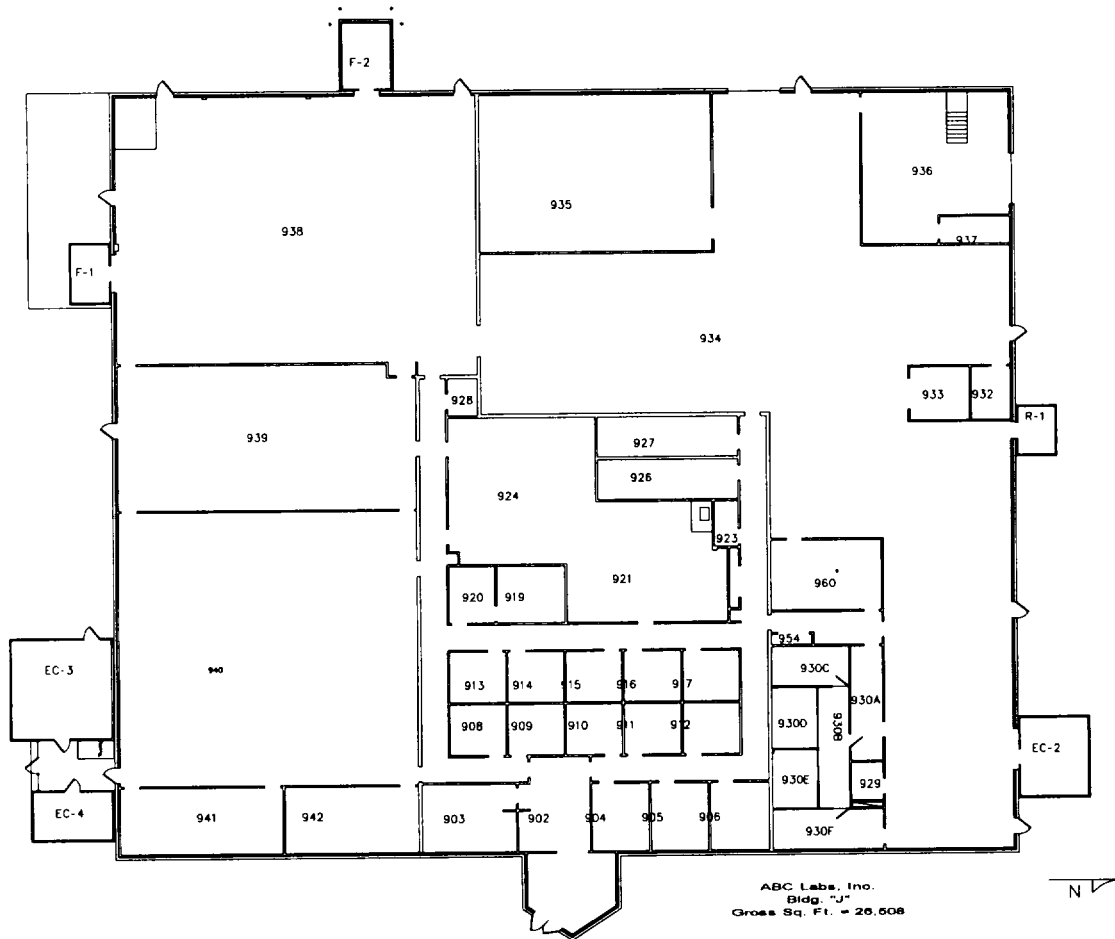
**ABC Labs, Inc.**  
**Bldg. "F"**  
**Gross Sq. Ft. = 1,020**

**FIGURE 6**  
**INTERIM WASTE STORAGE FACILITY**

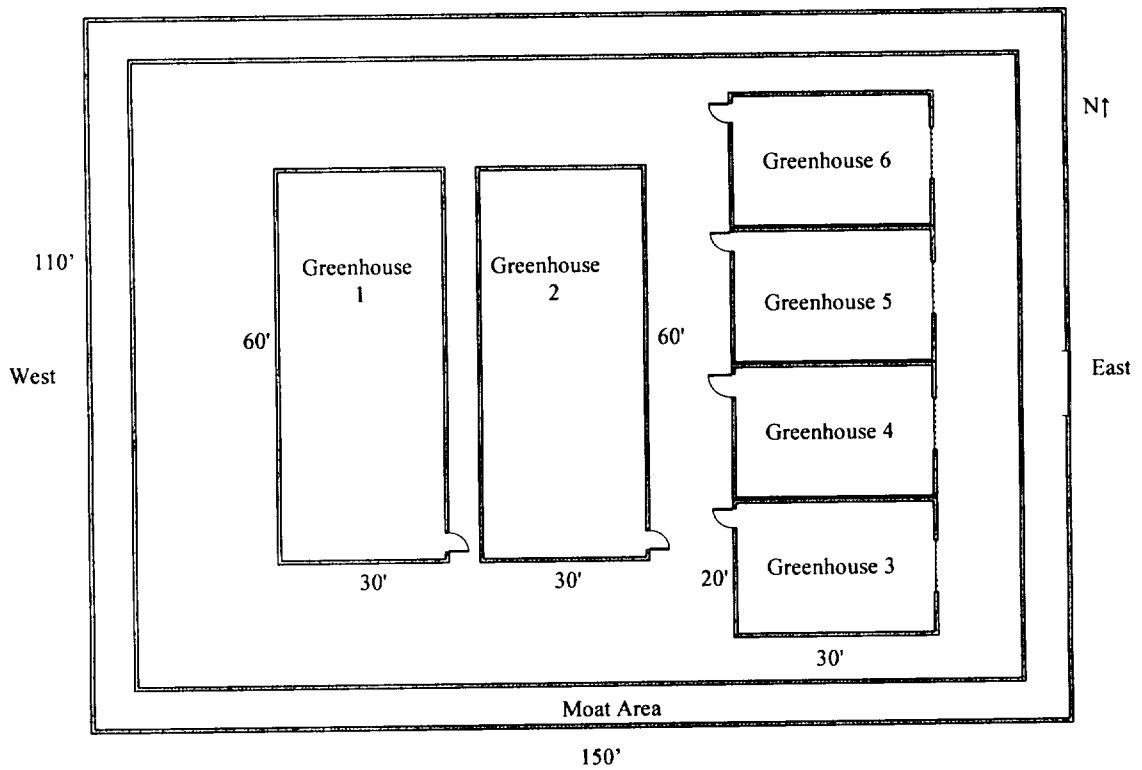
North



**FIGURE 7**  
**BUILDING J**

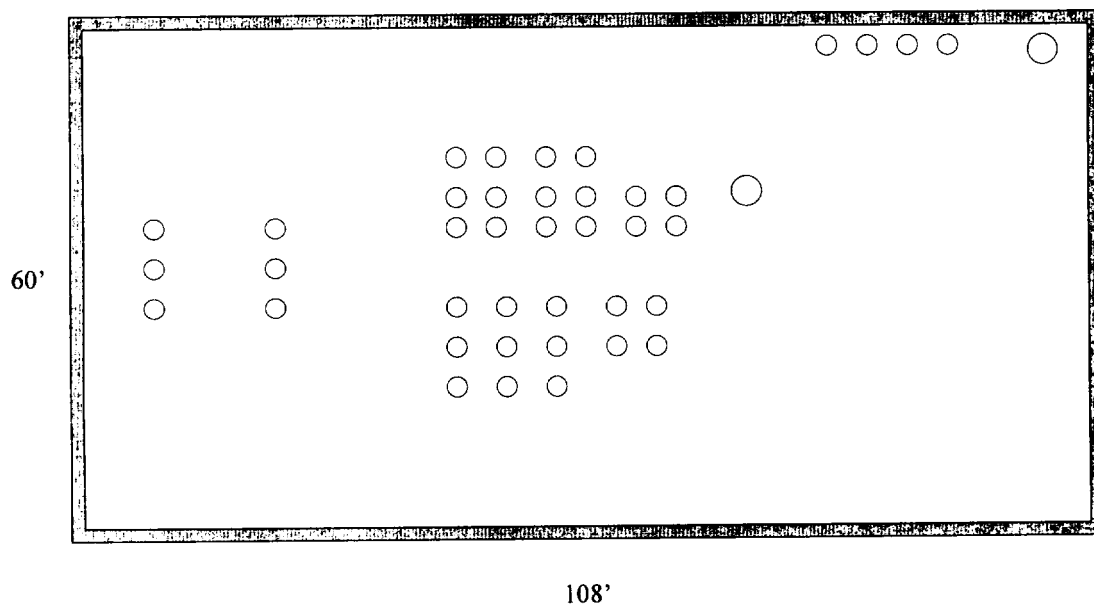


**FIGURE 8**  
**GREENHOUSE FACILITIES**  
**(East Side of Environmental Biology Research Center)**

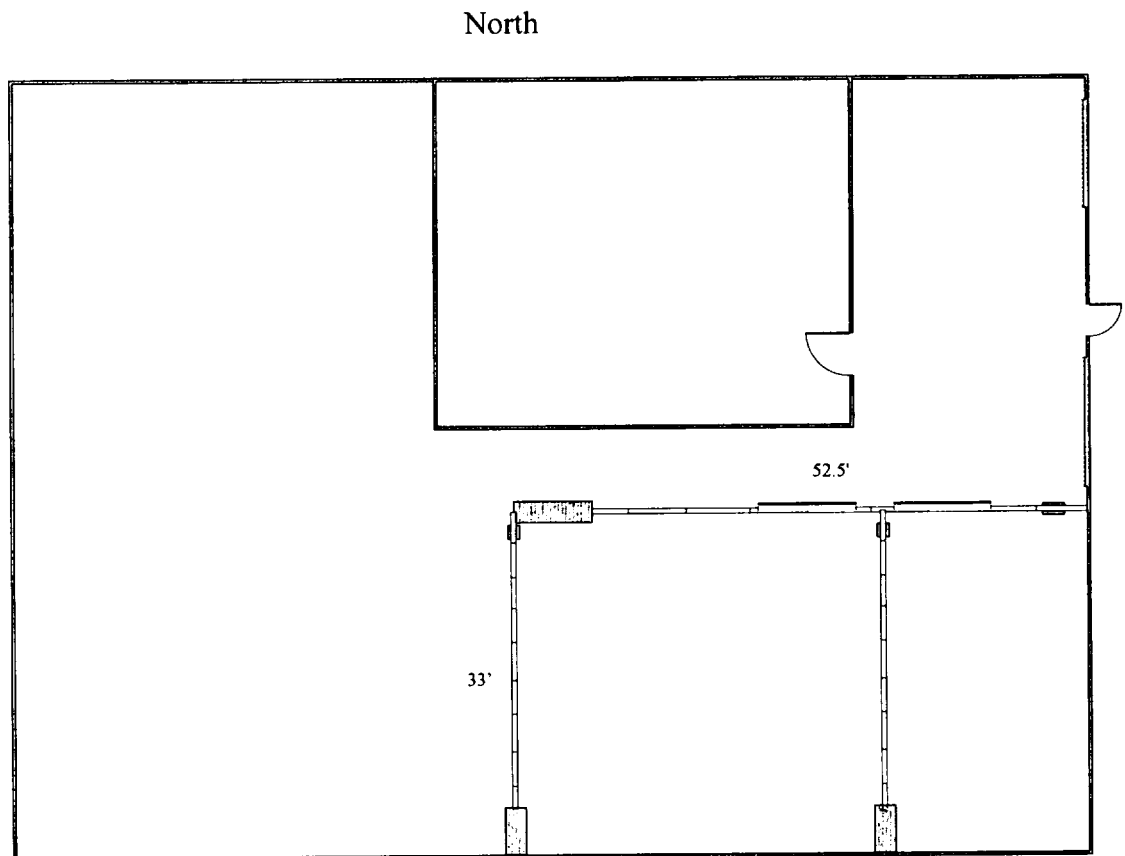


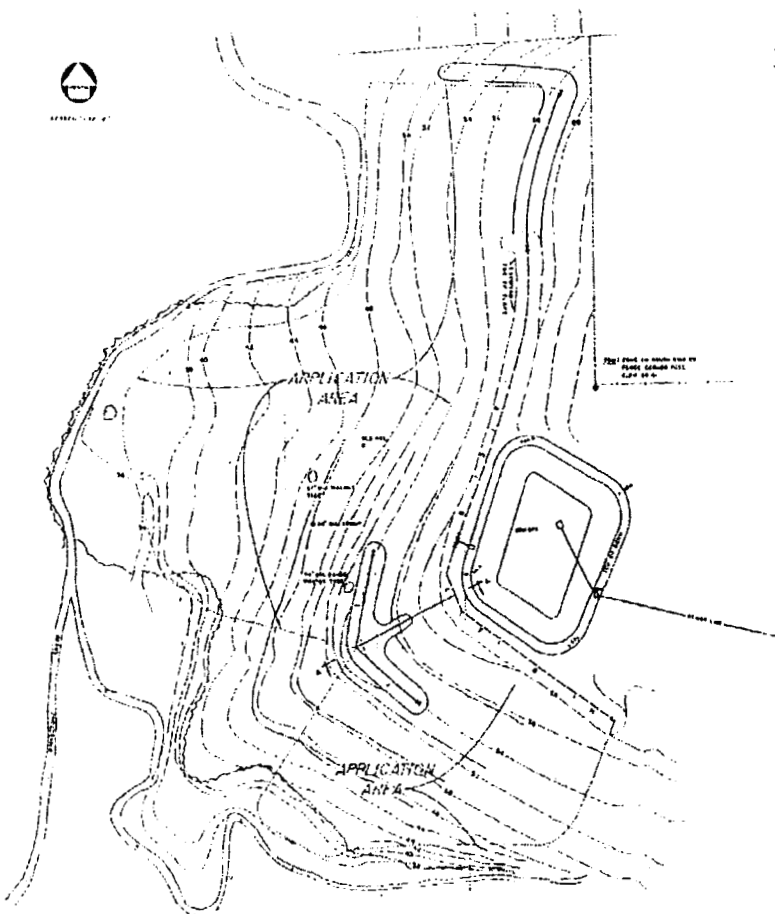


**FIGURE 9**  
**LYSIMETER TEST AREA**



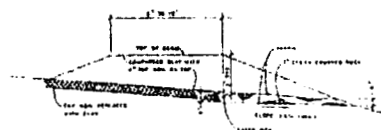
**FIGURE 10**  
**WASTE RETENTION FACILITY**



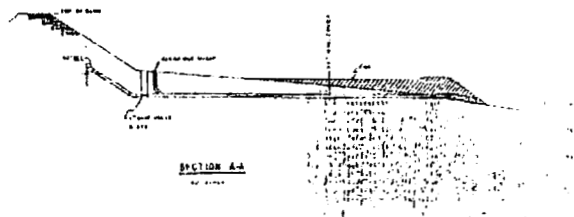


LAGOON AND DRAINFIELD

**FIGURE 11**

[illegible]

TYPICAL EXTENDED BEAM  
SECTION



PROJECT		ABC LABORATORY	
SUBJECT		REVISED LAND APPLICATION SYSTEM	
DATE		MARSHALL	
BY		BUD BERRY	

## ITEM 10.

### RADIATION SAFETY PROGRAM

#### Audit Program

We will follow the model audit program that was established in Appendix L, to NUREG-1556 Volume 7.

The RSC will periodically perform audits to determine compliance with the license, and will take appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.

#### Instruments

### RADIATION SAFETY INSTRUMENTS USED AT ABC LABORATORIES

#### List of Radiation Safety Instruments

Type of Instrument	Manufacturer	Model	Number of Instruments	Radiation Detected	Sensitivity Range
Surveying	Ludlum	44-9 Probe 3-Counter	21	Beta/gamma	0-200 mR/hr
Surveying	Ludlum	43-68 Probe 16-Counter	1	Beta/gamma	0-500,000 cpm
Surveying	Beckman	LS-6500	2	Beta	1-1,000,000 cpm
Scintillation Counter	Beckman	LS-60001C	3	Beta	1-1,000,000 cpm
Scintillation Counter	Beckman	LS-6000SC	3	Beta	1-1,000,000 cpm
Scintillation Counter	Beckman	3801	1	Beta	1-1,000,000 cpm

#### Calibration:

The surveying instruments are calibrated yearly by Ludlum Measurements, Inc, 501 Oak Street, Sweetwater, TX 79556. Calibration certificates are issued by

Ludlum Measurements, Inc. and maintained at ABC Laboratories as proof of compliance with the pertinent NRC regulations concerning survey instruments.

The scintillation counters are calibrated monthly by ABC Laboratories' personnel using NBS-certified sources of the appropriate isotope.

Air monitoring for radioactivity will be conducted at least annually using a calibrated portable air particle sampler. Samples will be taken in each laboratory actively using radioactivity. Sampling time per sample will be for a minimum of 4 hours. Documented activities found through LSC analysis (corrected for reagent blank background levels) will be in  $\mu\text{Ci}/\text{M}^3$  averaged for the time of sampling. Activities found will be compared to the exposure levels for the isotopes of interest in Part 20, Appendix B, Table 1.

### **Material Receipt and Accountability**

We will follow the model programs published in Appendix P of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."

The Radiation Safety Committee will review any procedural changes submitted to ensure compliance with changes in NRC and DOT regulations.

### **Occupational Dose**

Dosimetry will be provided by an organization holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology.

No personnel monitoring will be required when using carbon-14 or hydrogen-3 in low millicurie amounts.

Urine specimens will be taken from personnel dosing or spraying subplots for field type studies or from metabolism and/or FDA animal health studies where single dose activities per animal are greater than 10 mCi. Bioassays for tritium will be conducted following the guidelines in Regulatory Guide 8.32. This guide will also be used to determine action levels and subsequent calculation of exposure to personnel.

Urine samples assayed for carbon-14 will be evaluated based on section 20.1203 of the Code of Federal Regulations. If the activity in the sample is above the minimum quantifiable limit, a calculation using Appendix B, table 1, column 1 will be performed to assure that over exposure has not occurred.

### **Safe Use of Radionuclides and Emergency Procedures**

We will follow the model programs published in Appendix R of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."

The Radiation Safety Committee will continue to review any safety or procedural changes submitted to ensure compliance with changes in NRC and DOT regulations.

### **Surveys**

We will survey our facility and maintain contamination levels and perform bioassays of occupationally exposed workers in accordance with the survey frequencies and contamination levels published in Appendix S of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."

We will implement the model leak test program published in Appendix T of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."

The Radiation safety Committee will continue to review any safety or procedural changes submitted to ensure compliance with NRC regulations.

## **ITEM 11.**

### **WASTE MANAGEMENT**

#### **Waste Disposal**

We will follow the model programs published in Appendix T of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."

*Analytical Bio-Chemistry Laboratories, Inc.*

*7200 E. ABC Lane, Columbia, MO 65202*



Nuclear Regulatory Commission  
Region 3  
801 Warrenton Rd  
Lisle, IL 60532-4351

FedEx | Ship Manager | Label 7929 3794 9604

Page

From: Origin ID: COUA (573)443-9033  
Dawn Spurlock  
ABC LABORATORIES  
7200 E. ABC LANE

COLUMBIA, MO 65202



CL 88 12 18 7/21/23

SHIP TO: (573)443-9070

BILL SENDER

Kevin Null  
Nuclear Regulatory Commission  
801 Warrenville Road  
Region 3  
Lisle, IL 60532

Ship Date: 22FEB07  
ActWgt: 1 LB  
System#: 3018271/NET2600  
Account#: S \*\*\*\*\*

Delivery Address Bar Code



Ref # Sheila H-700  
Invoice #  
PO #  
Dept #

\*\* 2DAY \*\*

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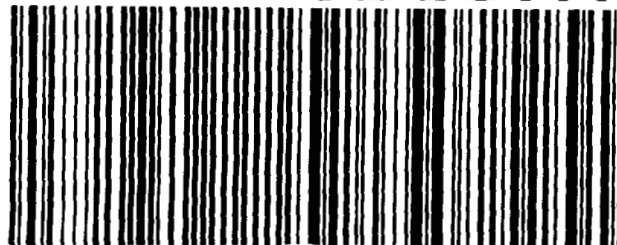
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