

ABT American Bio- Technologies, Inc.

November 15, 1990

John D. Kinneman
Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

Dear Mr. Kinneman,

This is in response to your letter received 10/25/90 regarding Routine Inspection No. 030-30334/90-001 by Betsy Ullrich on 9/13/90 of American Bio-Technologies, Inc. License No. 20-28133-01. During this inspection three violations were identified and discussed with members of American Bio-Technologies staff.

The violations were:

1. Failure to record surveys of incoming radioactive packages.
2. Failure to record surveys of radioactive waste storage areas.
3. Missing survey records 10/89 through 5/90.

To remedy the first two violations, I have included sample copies of forms which have been prepared to record surveys of incoming radioactive packages and of waste storage areas. I have also enclosed a list of duties that the individual(s) responsible for these surveys must follow and the frequency at which these surveys must be made.

In the past year, American Bio-Technologies redirected its emphasis from a service oriented company to a manufacturing company. As a result of this restructuring, the company experienced a turnover of personnel which led directly to a misunderstanding of assigned duties during this brief period. The list of duties enclosed with this letter is now included with the radiation safety records as instruction for maintaining survey documents so this lapse in information transfer will not repeat in the future.

The last violation is more difficult to address. The individual responsible for record keeping during 10/89 through 5/90 is no longer with the company. This individual was released by the company under adverse conditions and we are presently engaged in legal proceedings to recover records that this individual removed from the company. He has admitted, in court, to discarding information and records generated at the company during this time period. We are unable, at this time, to produce these record or track their existence. In June 1990, I became responsible for the survey duties and my records were in order at the time of the inspection. I have included a diagram of the survey areas as an example of the present monitoring procedure.

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All violations have been corrected and full compliance was achieved with the first receipt of an isotope shipment 10/4/90 (see enclosure). Weekly waste storage and research areas surveys began 10/1/90 (see enclosure) and are conducted at the end of each week.

I believe you will find this in order. If you have any questions, please do not hesitate to contact me.

Sincerely,

Elizabeth C. Romanik

Elizabeth A. Romanik, Ph.D.

Assistant Radiation Safety Officer

American Bio-Technologies, Inc.
September 17, 1990

Duties Assigned to Assistant Radiation Safety Officer

1. Biweekly wipe tests of research areas using radioactivity
 1. Main Lab isotopes used ^{35}S and ^3H
 2. Molecular Lab isotopes used ^{35}S and ^{32}P
 3. Sequencing Lab isotopes used ^{35}SUse LKB Scintillation counter Program 1 window 5 - 655
2. Weekly survey of waste storage area (loading dock area)
Survey three random areas 1 m from external surface of storage containers with Geiger counter.
3. Weekly survey of research lab engaged in radioactive work.
Survey required only if radioactivity used during that week.
4. Receipt of radioactive materials from the manufacturer.
Upon delivery of radioactive materials:
 1. Notify the individual ordering isotope
 2. Measure radioactivity a distance 1 m from external package.
 3. Open package, survey packing material and inspect for damage to container.
 4. Wipe test the external surface (i.e. plastic container or plastic bag etc.)
 5. Wipe test the internal surface (i.e. bottle or vial containing the isotope)
 6. Count both wipe tests using Program 1, window 5 - 655
 7. Store isotope per manufacturer's instructions.
5. Miscellaneous
All records are to be kept on approved forms and in a 3-ring binder.
Indicate on all records who entered the information.

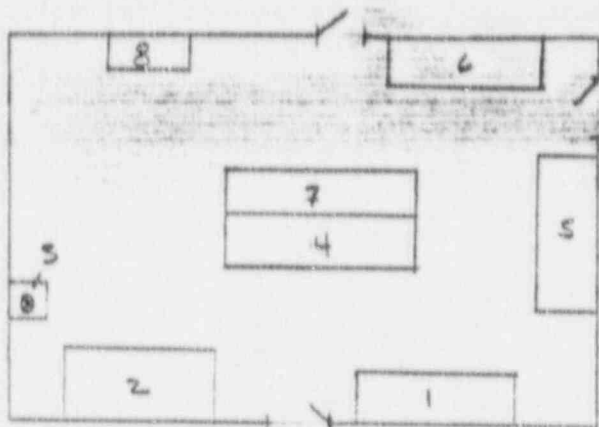
Date: _____ RSO _____

Survey
Instrument _____

Main Lab _____

Isotope used during survey period Y N

- 1 _____
- 2 _____
- 3 _____
- 4 _____
- 5 _____
- 6 _____
- 7 _____
- 8 _____

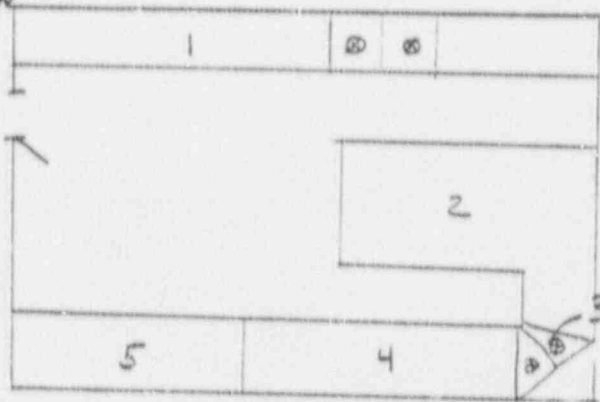


Molecular Lab _____

Isotope used during survey period Y N

Isotope: _____

- 1 _____
- 2 _____
- 3 _____
- 4 _____
- 5 _____

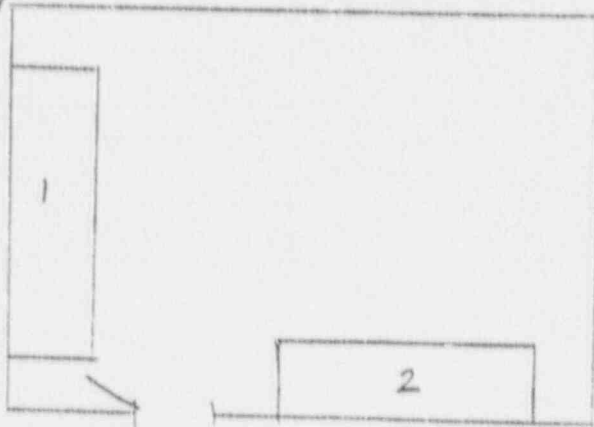


Sequencing Lab _____

Isotope used during survey period Y N

Isotope: _____

- 1 _____
- 2 _____



Sink in Equip
Room

Radioactive Waste Storage Area Survey

- I. Weekly monitor of waste storage area (Loading dock area)
Use Ludlum monitor instrument Model 44-9 Probe 040649

Week of: _____

Monitor 3 random areas 1 meter from the storage containers

1. _____ mRem/hr

2. _____ mRem/hr

3. _____ mRem/hr

- II. Weekly monitor of research lab engaged in radioactive work.

Week of : _____

Isotope used _____Y _____N

Isotope: _____

1. Survey of waste containers _____ mRem/hr

2. Survey of work area _____ mRem/hr

3. Survey of storage areas _____ mRem/hr

Radioactive Package Receiving

Date received: _____

Isotope: _____

Amount: _____

Ordered by: _____

Received by: _____

Radioactivity measured 1 meter from external surface of
package: _____ mRem/hr Listing on package from
supplier: _____ mRem/hr

Outer surface wipe test: _____cpm

Final surface wipe test: _____cpm

Scintillation counter window used: _____

Machine background: _____

Storage conditions: _____ Location: _____

Radioactive Package Receiving

Date received: 10/1/90

Isotope: ^{35}S cl ATP

Amount: 1 mCi

Ordered by: TB Romoik

Received by: B Romoik

Radioactivity measured 1 meter from external surface of
package: < 0.1 mRem/hr Listing on package from
supplier: none mRem/hr

Outer surface wipe test: 36 cpm

Final surface wipe test: 31 cpm

Scintillation counter window used: 5-655

Machine background: 46 cpm

Storage conditions: -20°C Location: freezer Frige #2

Radioactive Waste Storage Area Survey

I. Weekly monitor of waste storage area (Loading dock area)
Use Ludlum monitor instrument Model 44-9 Probe 040649

Week of: 10/1-5/90

Monitor 3 random areas 1 meter from the storage containers

1. < 0.1 mRem/hr

2. < 0.1 mRem/hr

3. < 0.1 mRem/hr

II. Weekly monitor of research lab engaged in radioactive work.

Week of: 10/1-5/90

Isotope used Y N

Isotope: ³⁵S ATP

1. Survey of waste containers < 0.1 mRem/hr

2. Survey of work area < 0.1 mRem/hr

3. Survey of storage areas < 0.5 mRem/hr