GENE-TRAK SYSTEMS

GENE-TRAK SALMONELLA ASSAY

CUSTOMER TRAINING PROGRAM

RADIOISOTOPE HANDLING PROCEDURES

OCTOBER 22, 1986 EELGENET

I. Introduction

GENE-TRAK Systems customers receive on-site instruction in radioisotope handling procedures as part of their training in use of the GENE-TRAK assay. Training is conducted by GENE-TRAK Systems Technical Services personnel, all of whom have received formal training in the safe use and handling use of radioactive compounds.

The standard training session is two days in duration. Customers are first briefed on general principles of radioisotope use, including safety procedures, necessary instrumentation, waste disposal and recordkeeping. The customer is provided with a Health Physics Materials Manual, which discusses general principles of radioisotope handling. The GENE-TRAK assay is then demonstrated in total by the GENE-TRAK Systems representative, with the customer's personnel observing. On the second day of the training session, the assay is performed by the customer's personnel under the guidance of the GENE-TRAK Systems representative.

II. Radiation Protection Program

The radiation protection program established in the customer's Nuclear Regulatory Commission (NRC) or appropriate state Radioactive Materials License application is discussed, with attention to the following specifics.

A. Radiation Safety Officer (RSO)

The RSO is responsible for the following:

1. Maintaining the Radioactive Material License(s) in a compliance status.

2. Providing traning of personnel to insure that safe procedures in the laboratory are practiced.

3. Providing consultation to management and radiation workers on all matters relating to radiation safety.

4. Be available to respond to any radiation emergency.

5. Reviewing all proposed procedures to insure that staff personnel will not become unnecessarily exposed to radiation. In addition, the RSO will insure that maximum permissible concentrations in air and water are within acceptable limits as outlined in state regulations.

6. Insuring that the following documents are properly posted in the laboratory.

   a. Radioactive Material License and all supporting documents.
   b. NRC Form 3 or equivalent state form.
   c. Emergency procedures.

7. Advising radiation workers of any unusual procedures which they must employ in order to reduce unnecessary exposure. Also, advising workers of the location of radioactive material, and their responsibilities with regard to the safe use of radioactive materials.
8. Preparing any requests for license amendments.

9. Conducting a monthly physical inventory of all radioactive material to insure that possession limits are not exceeded.

10. Conducting a weekly radiation survey of all areas where radioactive materials are used or stored.

B. General Rules for the Safe Use of Radioactive Material

1. Laboratory coats and other protective clothing will be worn at all times in areas where radioactive materials are used.

2. Disposable gloves will be worn at all times while handling radioactive materials.

3. There will be no eating, drinking, smoking, or application of cosmetics in any area where radioactive material is stored or used.

4. There will be no storage of food, drink, or personal effects with radioactive materials.

5. Radioactive waste will be disposed of only in specially designated receptacles.

6. No pipetting by mouth will be permitted.

7. Radioactive solutions will be confined in covered containers, plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

8. Radioactive material will always be transported and maintained in shielded containers.

9. The laboratory will be locked when personnel are not

present.

10. Clothing and gloves will be checked for contamination using a survey meter before leaving the laboratory.

11. Hands will be washed before leaving the laboratory.

12. Emergency notification home telephone numbers will be posted in the laboratory.

C. Emergency Procedures

1. Radioactive Spills

a. All persons in the area will be notified when a spill has occurred.

b. The spill will be covered with absorbent paper to prevent its spread.

c. Disposable gloves and tongs will be used to clean up the spill. The absorbent paper and pad will be carefully folded, inserted into a plastic bag and disposed of in the radioactive waste container. All other contaminated materials such as disposable gloves will also be inserted into the plastic bag.

d. A contamination survey will be conducted using a low range, thin-end window G-M survey meter. The area around the spill, hands and clothing will be checked for contamination.

e. If the spill is on the skin, the area will be flushed thoroughly and washed with mild soap and lukewarm water.

f. The incident will be reported to the Radiation Safety Officer.

D. Personal Dosimetry

The program for personal dosimetry (beta-gamma film badges) established in the Radioactive Materials License is reviewed, including:

1. Placement of the film badge in the most appropriate position on the body.

2. Storage away from radioactive sources when not in use.

3. Interpretation of results.

III. Ordering and Receipt of Radioactive Materials

Procedures for ordering, receiving and inspecting shipments of radioactive materials are established and discussed:

A. Procedures for Ordering Radioactive Materials

1. Prior to placing an order, the inventory will be reviewed to insure possession limits will not be exceeded. The RSO will review these inventories and related procedures on a monthly basis.

2. During normal duty hours carriers will be instructed to deliver radioactive material packages directly to the receiving department.

3. Incoming shipments will be examined visually. If the shipment appears damaged or wet, the RSO will be notified immediately.

4. The RSO will provide their office and home telephone numbers to any authorized user, and the numbers will be available in the laboratory.

B. Receipt of Radioactive Shipments

1. Gloves will be worn to prevent hand contamination.

2. Packages will be visually inspected for any sign of damage, i.e. wetness, crushed, etc. If damage is noted, the procedure will be stopped and the RSO notified.

3. The external surface of the outer package will be surveyed with a survey meter and the results recorded.

4. The outer package will be opened in a restricted area and the packing slip removed. The inner package will be opened and the contents verified by comparing requisition, packing slip, and label on source container. The final source container will be checked for breakage of seals or vials, loss of liquid, discoloration of packaging materials, etc.

5. A wipe test will be performed on the outer surface of the source container and the results recorded.

6. Packing materials will be scanned with a survey meter and disposed as common trash as long as there is no detectable radioactive contamination; otherwise, contaminated packing materials will be disposed in a container reserved for solid radioactive waste.

7. The source container will be stored in an appropriately labelled refrigerator in the radioisotope laboratory.

8. The above procedures will be documented for each radioactive materials shipment using an appropriate form.

IV. Instrumentation

Instrumentation used in conjunction with the GENE-TRAK assay and for health physics survey purposes are discussed and demonstrated:

A. General Instrumentation

1. Results of the GENE-TRAK assay are determined by use of a GENE-TRAK Beta Detector or liquid scintillation counter.

   a. Instruction is given regarding the use and maintenance of the instrument.

   b. Calculations relating to efficiency of counting and the conversion of cpm to dpm are discussed.

B. Health Physics Instrumentation

1. Customers are trained in the use and maintenance of a survey meter fitted with a thin-end window Geiger-Muller (GM) tube. Topics covered are:

   a. Applications
   b. Use and maintenance
   c. Calibration - the instrument will be calibrated annually be a licensed company.
   d. Units measured (e.g. cpm, mRem/hr) and a discussion of efficiency of counting and conversion factors.

V. Health Physics Surveys

A program of contamination surveys, surpervised by the RSO, is established, and procedures discussed:

1. Surveys will be conducted weekly.

2. Surveys are accomplished by use of a survey meter and/or

through the use of wipe tests.

3. Surveys will be taken in all areas of likely radioactive contamination, including bench tops, floors, equipment, refrigerator doors, sink used for disposal of liquid radioactive waste, etc.

4. Permissible levels of radioactive contamination are established at 500 dpm per 100 cm^2. Contamination in excess of this level will be reported to the RSO and appropriate measures for decontamination enacted.

5. The above procedures will be documented using an appropriate form.

VI. Handling of Radioisotope Used in GENE-TRAK Test Kit

The following principles concerning use of ^{32}P-labelled material are demonstrated during performance of the GENE-TRAK assay. (See GENE-TRAK Salmonella Assay Instruction Manual).

1. Handling concentrated isotope behind Lucite (one-half inch) shielding.

2. Proper pipeting of radiolabelled aqueous compounds.

3. Proper disposal of contaminated materials, e.g. pipet tips, tubes, etc.

4. Proper disposal of liquid radioactive waste in marked containers.

5. Principles of shielding, dilution, and distance from the source of radioactive materials are demonstrated with the use of a survey meter.

VII. Waste Disposal

The program for radioactive waste disposal established in the Radioactive Materials License is discussed and procedures demonstrated:

A. Solid Waste

1. Solid radioactive waste will be collected in double-lined, covered, marked containers.

2. Solid waste will be stored in sealed, marked boxes in a secure area for decay.

3. After a period of approximately 20 weeks, stored material will be checked with a survey meter.

4. If no detectable radioactivity is measured, all radioactive materials warning labels will be removed or obliterated and the waste will be disposed of as common trash.

B. Liquid Waste

1. During performance of the GENE-TRAK assay, liquid radioactive waste will be collected in marked, capped glass or plastic containers.

2. Liquid waste will be discharged into the sewerage system via a designated sink drain in accordance with 10 CFR Part 20.303 and appropriate state and local regulations.

3. A record will be kept of waste discharged into the sewerage system using an appropriate form.

VIII. Recordkeeping

The following recordkeeping procedures are discussed and example

SAL RECORD FOR ISOTOPES RELEASED INTO THE SEWERAGE SYSTEM

ISOTOPE	VOLUME	MICROCURIES	INITIALS

ATA HAS BEEN ENTERED ON LINE 40, CONTACT THE RADIATION SAFETY OFFICE
OTHER DISPOSAL RECORD.

P-32 INVENTORY LOG

Date	uCi Received	uCi Drain Disposed	uCi Added to Solid Waste	Decay from Prev. Week	Current Quantity

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forms provided:

1. Radioactive shipment receipt and inspection (example Form 1).

2. Disposal of liquid radioactive waste into the sewerage system (example Form 2).

3. On-site radioisotope inventory (example Form 3). Example calculations are shown for keeping track of radioisotope in inventory and solid waste, correcting for decay on a periodic basis.

4. Contamination surveys (example Form 4).

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RADIOACTIVE SHIPMENT RECEIVING/INSPECTION REPORT

1. Isotope: _____ Total No. of mCi. _____

Date Rec'd _____ Time Rec'd _____ P.O. No. _____

2. Visual Inspection of Vendor's Shipping Carton. If the shipping carton is damaged, notify the RSO immediately.

___ Intact ___ Punctured ___ Wet ___ Crushed ___ Other (note) _____

3. Vendor's Stated Radiation on Shipping Carton Label (s) _____ (Total in Curies).

4. Closed Shipping Carton Radiation Scan.
   A. Meter Identification: _____
   B. Background Count (BKG): _____ (mRem/hr)
   C. Activity at 1 meter: _____ (mRem/hr)
   D. Activity carton surface: _____ (mRem/hr)

NOTE: If C exceeds 10 mRem/hr or D exceeds 200 mRem/hr, notify the Radiation Safety Officer or Deputy immediately.

5. Open carton (s). Total number of vials: _____

6. Do the P.O., Packing slip & Vials agree as to:

   A. Radioisotope _____ yes _____ no, difference _____
   B. Quantity _____ yes _____ no, difference _____
   C. Chemical Form _____ yes _____ no, difference _____

7. Wipe Results From:

   A. Outer Shipping Carton $\left(\frac{\text{cpm} - \text{BKG}}{\text{DPM Factor}}\right) =$ _____ DPM

   B. Source Container $\left(\frac{\text{cpm} - \text{BKG}}{\text{DPM Factor}}\right) =$ _____ DPM

8. Survey results from packaging materials and empty shipping carton (s) _____ mRem/hr.

   If contamination is dectected, its source must be located and the RSO notified.

9. A. Disposition of packaging materials _____.
   B. Disposition of source container (s) _____.

10. If NRC/carrier notification is required, log time _____, Date: _____ Person (s) notified: _____.

Received/Inspected By: _____

Date: _____

IG# _____ - _____

Form HP-006-03

DATE	BACKGROUND (dpm)	LOCATION NO.*	NET dpm/100 cm^2**

*Location No. — Location

1
2
3
4
5
6
7
8
9
10

** - Net dpm/100 cm^2 = (Total cpm/100 cm^2 - Background) x 2.5

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Date and Place of Birth: May 18, 1955 Detroit, Michigan

Citizenship: U.S.A.

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31 New York Avenue
Framingham, Massachusetts 01701
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Home Address: 35 Hemlock Drive
Holden, Massachusetts 01520
(617) 829-7324

Education:

a. Henry Ford High School, Detroit, Michigan

b. The University of Michigan, B.S. (with distinction), 1977, Microbiology

c. The University of Michigan, M.S., 1979, Microbiology

d. The University of Michigan, Ph.D., 1982, Microbiology

Teaching and Professional Appointments:

1978-1980	Graduate Student Teaching Assistant, Department of Microbiology and Immunology, The University of Michigan Medical School, Ann Arbor, Michigan
1980-1982	Graduate Student Research Assistant, laboratory of Dr. David I. Friedman, Department of Microbiology and Immunology, The University of Michigan Medical School, Ann Arbor, Michigan
1982-1984	Postdoctoral Research Associate, laboratory of Dr. Royston C. Clowes, Programs in Biology, The University of Texas at Dallas, Richardson, Texas
1984-1986	Staff Scientist, Integrated Genetics, Inc., Framingham, Massachusetts
1986-	Technical Service Manager, GENE-TRAK Systems, Framingham, Massachusetts

Honors and Awards:

1977-1978	Horace H. Rackham School of Graduate Studies Fellowship, The University of Michigan

Memberships in Professional Organizations:

American Society for Microbiology
Association of Official Analytical Chemists
Institute of Food Technologists
International Association of Milk, Food and Environmental Sanitarians

Articles:

Mozola, M.A., D.I. Friedman, C.L. Crawford, D.L. Wulff, H. Shimatake and M. Rosenberg. 1979. Mutations reducing the activity of c17, a promoter of phage lambda formed by a tandem duplication. Proc. Natl. Acad. Sci. USA 76: 112-1125.

Miller, H.I., M.A. Mozola and D.I. Friedman. 1980. Int-h: an int mutations of phage lambda that enhances site-specific recombination. Cell 20:721-729.

Mozola, M.A., R.B. Wilson, E.M. Jordan, R.K. Draper and R.C. Clowes. 1984. Cloning and expression of a gene segment encoding the enzymatic moiety of Pseudomonas aeruginosa exotoxin A. J. Bacteriol. 159:683-687.

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Flowers, R.S., M.A. Mozola, M.S. Curiale, D.A. Gabis and J.H. Silliker. 1987. Comparative study of a DNA hybridization method and the conventional culture procedure for detection of Salmonella in foods. J. Food Sci. 52: 781-785.

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playing a temperature-sensitive growth defect in HimA strains. Abstracts of the Cold Spring Harbor Bacteriophage Meeting, p. 73.

Mozola, M.A. and D.I. Friedman. 1981. A phi80 function inhibitory for phage growth in HimA mutants of E. coli. Abstracts of the Cold Spring Harbor Bacteriophage Meeting, p. 71.

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Flowers, R.S., M.J. Andrle, M.A. Mozola, M.S. Curiale, D.A. Gabis and J.H. Silliker. 1986. Collaborative study: A DNA hybridization assay for the detection of Salmonella in foods. Abstracts of the 100th Annual Meeting of the Association of Official Analytical Chemists, p.31.

Curiale, M.S., R.S. Flowers, M.A. Mozola and A.E. Smith. 1986. A commerical DNA probe-based diagnostic for the detection of Salmonella in food samples. In: DNA Probes. Applications in Genetic and Infectious Disease and Cancer (L.S. Lerman, ed.), Cold Spring Harbor Laboratory, Cold Spring Harbor, N.Y., pp. 143-148.

Mozola, M.A. 1987. Rapid detection of Salmonella in foods using DNA probes. In: Special Report. Rapid Microbiological Methods (D.L. Downing and Y.D. Hang, eds.), New York State Agricultural Experiment Station, Geneva, N.Y., vol. 60, pp. 20-23.

Deibel, R.H., R.J. Siakel, C. Kowalewski and M.A. Mozola. 1987. Rapid detection of Salmonella in foods using the GENE-TRAK assay in conjunction with a modified enrichment procedure. 74th Annual Meeting of the International Association of Milk, Food and Environmental Sanitarians.

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RADIOISOTOPE EXPERIENCE AND TRAINING

Experience:

	Isotopes	Maximum Amount	Date	Place	Use
1.	^{3}H, ^{14}C, ^{32}P, ^{35}S	1mCi	1977-1982	U of Michigan Ann Arbor, MI	Labelled compounds for *in vitro* biochemical analyses
2.	^{32}P, ^{125}I	1mCi	1982-1984	U of Texas Richardson, TX	"
3.	^{32}P	1mCi	1984-Present	GENE-TRAK Systems Framingham, MA;	"

Training:

1. Orientation course in radiation safety, University of Michigan, Ann Arbor, MI, 1977.

2. Orientation course in radiation safety, University of Texas, Richardson, TX, 1982.

3. Annual refresher course in radiation safety GENE-TRAK Systems, Framingham, MA, 1984-1987.

EXPANDED RESUME ON RADIOACTIVE SUBSTANCES EXPERIENCE

In my university Physics and Chemistry courses, we did go into the basics of radioactive substances. These basics included the principles and practices of radiation protection from the different types of rays, exposure limits and effect, half lives, etc. This amounted to about 10 hours of classroom experience. We did not actually handle radioactive material in the Physics or Chem. labs associated with these courses.

During my 15 months (Feb 1971 to June 1972) at the Enzyme Institute, TB Research Lab, I worked mostly with Carbon-14 and some tritium.

We would introduce a radioactive labelled substrate into the enzyme system we were looking at and take a sample from that system at specific time intervals. Then we would take the time samples and put them on thin layer chromotography plates. After running the TLC plates through our solvent system we would put portions of the TLC into scintilatior vials and place the vials into a Beckman Tri Carb Scintilation Spectrometer. I have worked over 40 total hours with this type of radioactive material.

GENE-TRAK SYSTEMS

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It is our understanding that the calibration methods of the University of Wisconsin have been evaluated by the NRC, Region III and have been found to be acceptable. Therefore, it is our opinion that the methods of calibration do not have to be submitted.

Signed: Karenlee Voltz-Dow

Karenlee Voltz-Dow
Manager, Regulatory Affairs

Date: 10/1/87