Dairilab Service, Inc.
2415 Western Ave.
Manitowoc, Wisconsin 54220
414-682-7998

Northland Food Laboratory
2973 Allied Street
Green Bay, Wisconsin 54307
414-336-7465

Quality Control Service for Industry and Municipality

30-17753

September 2, 1987

Analytical Testing
Food
Milk
Meat
Dairy Products
Water
Wastewater

- Microbiological
- Component (Milk)
- Chemical
- Sanitation
- Research

Reference: Docket No. 83816

To New License Reviewer,

In regard to your request for the methods and procedure used to calibrate the Ludlum Survey Meter by the calibration service stated, I have contacted Dr. Steven Goetch of the University of Wisconsin-Madison. He is in charge of the calibration services department. He has informed me that all of their procedures for calibration are on file at the Region III Glen Ellyn, Illinois office and can be found under license number 48-00361-18. He stated that in the past, the information kept on file there has provided sufficient information to regulatory questions.

Sincerely,

Debra M Cherney

Debra Cherney
Microbiologist

DC/lkp

Certified
Laboratory
since 1949

GENE-TRAK SYSTEMS

31 New York Avenue
Framingham, Massachusetts 01701
617-872-3113

ORIGINAL

July 22, 1987

TO WHOM IT MAY CONCERN

This is to certify that Debra Cherney , Northland Food Laboratories, received training in the performance of the GENE-TRAK Assay and its attendent use of Phosphorus-32 labelled material. This training was conducted by GENE-TRAK Systems, Framingham, Massachusetts, on July 20-21, 1987. The instruction included hands-on experience in the performance of the procedure, as well as training in the safe use and handling of phosphorus-32 labelled aqueous material. The topics of isotope handling, disposal, and recordkeeping were covered in the training session.

GENE-TRAK Systems is authorized to provide training in radioisotope handling and safety procedures to students under NRC license number 20-19858-01, amendment 05 (expiration date February 29, 1992) as issued to Integrated Genetics/GENE TRAK Systems.

Sincerely,

Mark A. Mozola, Ph.D.
Technical Service Manager

Date

GENE-TRAK SYSTEMS

GENE-TRAK SALMONELLA ASSAY

CUSTOMER TRAINING PROGRAM

RADIOISOTOPE HANDLING PROCEDURES

OCTOBER 22, 1986

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 will be 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

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).

/1341b

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

'OSAL RECORD FOR ISOTOPES RELEASED INTO THE SEWERAGE SYSTEM

ISOTOPE	VOLUME	MICROCURIES	INITIALS

N DATA HAS BEEN ENTERED ON LINE 40, CONTACT THE RADIATION SAFETY OFFICE
ANOTHER DISPOSAL RECORD.

P-32 INVENTORY LOG

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

/1669b

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

/1697b

Name: Mark A. Mozola

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

Citizenship: U.S.A.

Mailing Address: GENE-TRAK Systems
31 New York Avenue
Framingham, Massachusetts 01701
(617) 872-3113

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

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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.

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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.

revised 7-09-87

/1475b

MARK A. MOZOLA, Ph.D.

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.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

Northland Food Laboratory
ATTN: Debra Cherney
Microbiologist
2973 Allied Street
Green Bay, WI 54307

Dear M- Cherney:

We have reviewed your application dated July 6, 1987, requesting Byproduct Material License and find that we will need additional information as follows:

Authorizing Official

1. Please confirm that Debra Cherney, Microbiologist, is authorized by the administration of Northland Food Laboratory to sign for actions concerning the company's NRC license. The certification should be in letter form addressed to this office and signed by a company official, (e.g., President, Vice President, etc.).

Training

2. In order to approve Ms. Cherny as RSO (or for NRC to approve other named authorized users) she must obtain or document additional training and experience in handling radioactivity. Ms. Cherney must have hands on experience with the types and quantity of material being requested. This training and experience must be obtained before issuance of the license. Further, the RSO and any others who intend to be named on the license (who can train and/or directly supervise the users) will need approximately 40 hours of appropriate training and experience in handling radioactive material. Please provide the following information regarding all training and experience received:

   a. Training topics should include:

      (1) Principles and practices of radiation protection (i.e., time, distance, and shielding, etc.);

      (2) Radioactivity measurements and monitoring techniques;

      (3) Mathematics basic to use and measurement of radioactivity; and

      (4) Biological effects of radiation.

b. Extent and qualification of training:

(1) Length of time spent (hours) covering each topic;

(2) Name and qualification of each instructor;

(3) Method of determining trainee's competency; and

(4) Records of training received.

c. Experience handling radioisotopes. For each isotope, include the following:

(1) Maximum amount used at one time;

(2) Institution/organization where experience was gained;

(3) Duration of experience (hours); and

(4) Type of use.

Your letter dated July 21, 1987, states that on July 20 and 21, 1987, Ms. Cherney received training in performance of the GENE-TRAK assay, as briefly described in your application, at the GENE-TRAK Technical Services Department in Framingham, Massachusetts. This should provide part of the needed training for her to serve as RSO. Please provide a complete description of the course including the information described above.

Please note that you may take credit for any training in the above topics that was obtained during any college education. Please provide a description of the training as outlined in a., b., and c., above, using clock hours for each topic rather than semester hours.

3. Ancillary personnel (clerical, housekeeping, security, etc.) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. Outline your method to assure that these employees receive the necessary instructions. Confirm that this instruction will be given both initially and annually thereafter on a refresher basis.

Authorized Users

4. The term "authorized user" is used by the NRC to designate someone who has submitted a record of his training and experience to the NRC and has been specifically named on the license document to work independently with radioactive material. In this regard, it is noted that in Addendum D to your license application, you state that the RSO will

supervise the training and use of licensed material by authorized users. Please note that the RSO will not be authorized to approve authorized users. She will only be permitted to designate appropriately trained personnel who will be supervised in their work with radioactivity (i.e., technicians).

At the end of Addendum C to your license application, you list five individuals you request to be "certified as operators of the GENE-TRAK System." Please note that the NRC has no designation of "certified operator" in the byproduct material licensing program. If you wish to add the names of these five individuals to the license document as authorized users, please submit for each a description of their training and experience with radioactive material in the format described in Item 2 above.

Laboratory Procedures

5. Please affirm that laboratory procedures will be posted or made readily available to laboratory users.

6. Please modify your laboratory procedures, "General Rules for the Safe Use of Radioactive Material" contained in Section F. of Addendum F to your application, to include the following instructions:

   a. Wear personnel monitoring devices when performing GENE-TRAK assay. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring should be stored in the work place in a designated low-background area; and

   b. Either after each procedure or before leaving the area, monitor your hands and clothing for contamination in a low-background area with a low range survey meter capable of detecting the material(s) used.

Survey Instrument Calibration

7. Please submit the procedure used by your consultant for calibrating the survey instrument described in your application. To ensure its adequacy, please compare the procedure with the model procedure contained in Appendix B of Regulatory Guide 10.8 (August 1985), copy enclosed.

Health Physics Surveys

8. In Section B.1 of Addendum F of your license application you describe your wipe test survey criteria. You specify that a 100 cm^2 area will be wiped and that permissible contamination levels have been established at 500 dpm per cm^2. It appears that a typographical error may have been made and that the permissible level intended was 500 dpm per 100 cm^2. Please clarify.

If you have any questions or require clarification on any of the information stated above, you may contact us at (312) 790-5625.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 83816.

Sincerely,

Loren J. Hueter
Materials Licensing Section

Enclosure: Appendix B
Regulatory Guide 10.8
(August 1985)