NRC FORM 313
(9-88)
10 CFR 30, 32, 33, 34, 35 and 40

APPLICATION FOR MATERIAL LICENSE

RECEIVED
U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-31-91

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.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNEYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

(030-30189)
L09764

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 JURISDICTION.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Food and Drug Administration
3032 Bryan Street
Dallas, TX 75204

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

Same as provided in #2

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Charles McKee 255-5308 FTS

TELEPHONE NUMBER: 214-767-0310

SUBMIT ITEMS 5 THROUGH 11 ON 8½ 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. Reference Addendum A

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED. Reference Addendum B

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE. Reference Addendum C

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. Reference Addendum D

9. FACILITIES AND EQUIPMENT. Reference Addendum E

10. RADIATION SAFETY PROGRAM. Reference Addendum F

11. WASTE MANAGEMENT. Reference Addendum G

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY | AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 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, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial–proprietary–information furnished to the agency in confidence)*
- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
			FEE EXEMPT	

AMOUNT RECEIVED	CHECK NUMBER	DATE
		461423

8711200203 871009
REG4 LIC30
42-09764-02 PDR

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PRIVACY ACT STATEMENT ON THE REVERSE

ADDENDUM A

Radioactive Material

A. Element and Mass Number: Phosphorus-32

B. Chemimcal and/or physical form: Aqueous nucleotides

C. Maximum possession: one (1) millicurie

Application for
Radioactive Material License
Food and Drug Administration

ADDENDUM B

Purpose(s) for which Licensed Material will be used

Licensed material used is incorporated in the GENE-TRAK Systems pre-packaged, pre-labelled, and pre-tagged kit for detection of microorganisms in test specimens. The test is an in-vitro diagnostic assay similar to clinical radioimmunoassays (RIA). The usual amount of isotope handled at one time will be 75 microcuries or less.

Application for
Radioactive Material License
Food and Drug Administration

ADDENDUM C

The Radiation Safety Officer will be:

Charles R. McKee

A copy of Mr. McKee's curriculum vitae is appended.

Authorized users will be:

Thomas J. Arista
David M. Beltran
Charles D. Brown
Mary V. Gipson
Warren L. Landry
Mildred M. Lister
Charles W. Noah
Charles N. Roderick
Sylvia Y. Yetts

Curriculum viates are appended.

Application for
Radioactive Material License
Food and Drug Administration

ADDENDUM D

The individual named in Addendum C may use the radioactive material, and will supervise the training and use of the licensed material by other authorized users.

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III.11.1

ADDENDUM E

Facilities and Equipment

Facilities

Licensed material will be used at:

Food and Drug Administration
Public Health Service
3032 Bryan Street
Dallas, TX 75204

Equipment:

1. Diagnostic tests are completed on a membrane filter and results are determined by use of the GENE-TRAK Beta Detector.

2. The Detector is Model CTC-4, manufactured by Radiation Monitoring Devices, Inc., 44 Hunt Street, Watertown, MA 02172. Performance of the Detector will be routinely checked in accordance with the GENE-TRAK Systems quality control procedures.

3. A Geigercounter, such as a Ludlum Model 2 or 3, or equivalent, will be used to survey incoming packages, and the work area. Calibration of the survey meter will be performed annually by:

   FDA Winchester Engineering and Analytical Center
   109 Holton Street
   Winchester, MA 01890

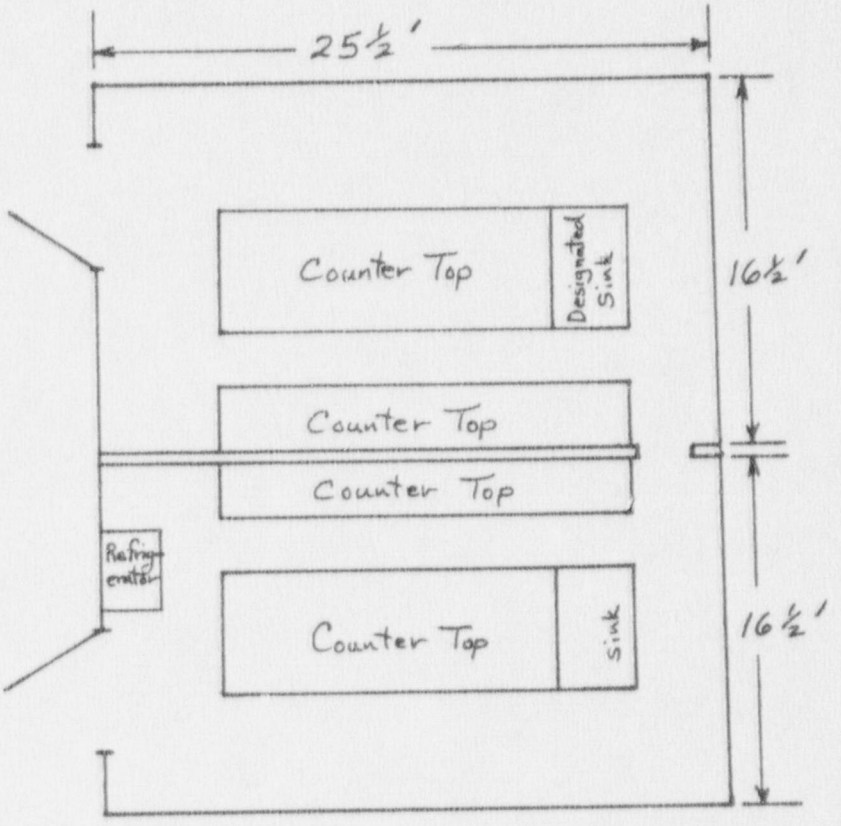
4. Personnel monitoring devices will be worn when performing the GENE-TRAK assay. Monitoring will include the use of beta-gamma film badges supplied and processed monthly by:

   Radiation Detection
   Sunnyvale, CA

5. Shielding, composed of one-half inch thick lucite will be used during handling and storage of the isotope.

Application for
Radioactive Material License
Food and Drug Administration

Diagram of FDA Dallas Microbiology Laboratory,
Facility for P-32 labeled DNA testing.



Application for
Radioactive Material License
Food and Drug Administration

ADDENDUM F

Radiation Safety Program

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A. Radiation Safety Officer (RSO)

The RSO is responsible for the following:

1. Maintaining the NRC license(s) in a compliance status.

2. Providing training 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 emergency.

4. Be available to respond to any radiation emergency.

5. Reviewing all proposed procedures to insure that 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 10 CFR Part 20 and appropriate state regulations.

5. Insuring that the following documents are properly posted in the laboratory:

   a. NRC or state license, respectively.
   b. 10 CFR Parts 19, 20.
   c. NRC Form 3, "Notice to Employees".
   d. 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.

B. Health Physics Surveys

On a weekly basis, the RSO will conduct a radiation safety survey of all areas where radioactive materials are used or stored. However, when no radioactive materials have been used or manipulated since the last radiation safety survey, the results of that most recent survey will be considered current and no new survey will be performed for that week. The surveys will include the following:

1. A survey of the work area by means of wipe tests. Wipe tests will be conducted using 25mm diameter filter paper circles. For each

B. Health Physics Surveys (con't)

test, a 100 cm^2 area will be wiped, and results determined by counting filters in the Model CTC-4 Beta Detector. This instrument has a counting efficiency for ^{32}P on dry filters of 0.4. Results will be recorded as disintegrations per minute (dpm). Permissible contamination levels have been established at 500 dpm per 100 cm^2. Contaminations detected in excess of this level will be immediately reported to the responsible user who will insure that appropriate decontamination is achieved. Follow-up reports will be submitted to the RSO accordingly.

A standard pattern of wipe tests will be performed in all areas of possible contamination, including: benchtops(s), floors, refrigerator door handle, water bath cover, sink used for disposal of aqueous ^{32}P waste, etc.

2. Review radioactive material storage areas to insure that materials are properly shielded, stored in double containers and properly labeled.

C. Authorized Users

The authorized users will be responsible within the department for the daily on-site management of radiation safety. They will report directly to the RSO who has overall responsibility if any of the following occur:

1. Spill of radioactive material.
2. Suspected overexposure of personnel.
3. Malfunctioning radiation detection equipment.
4. Contaminated shipment of radioactive material.
5. Any other conditions that may result in unnecessary radiation exposure.

D. Procedures for Ordering Radioactive Materials

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.

During normal duty hours, carriers will be instructed to deliver radioactive material packages directly to the receiving department. There will be no after hour deliveries.

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

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

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E. Procedures for Safely Opening Packages Containing Radioactive

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 the survey meter and the results recorded. If a surface exposure rate of greater than 10m REM/hour is obtained, the procedure will be stopped and the RSO notified.

4. The outer package will be opened in a restricted area in accordance with the manufacturer's directions (if supplied), and the packing slip removed. The inner package will be opened and the contents verified by comparing requisition, packing slip, and label on bottle. the final source container will be checked for breakage of seals or vials, loss of liquid, discoloration of packing materials, etc. The possession limits will be checked to insure they are not exceeded.

5. A wipe test will be performed on the outer surface of the final source container and results recorded. contamination in excess of 500 dpm per 100 cm^2 will be reported to the RSO.

6. Packing materials will be surveyed with the survey meter and results recorded before disposal.

F. General Rules for the Safe Use of Radioactive Material

1. Laboratory coats and other protective clothing will be worn at all times when radioactive materials are being 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 which radioactive material is used or stored.

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, radionucleotide, date, activity and indication level, if applicable.

F. General Rules for the Safe Use of Radioactive Material (con't)

8. Radioactive materials will always be transferred and maintained in shielded containers.

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

G. Personnel Training Program

The personnel training program will be given to all personnel who work with radioactive materials. The training will be in the form of lectures and the duration of each session will depend on the extent of applicability to the employees involved. The training program will be of sufficient scope to insure that all personnel receive proper instruction in the items specified in 10 CFR Part 19, to include:

1. Areas where radioactive material are used or stored.

2. Potential hazards associated with radioactive material.

3. Radiological safety procedures appropriate to their respective duties.

4. Pertinent NRC regulations and terms of Radioactive Material License.

5. Rules and regulations of the license.

6. Their obligation to report unsafe conditions.

7. Appropriate responses to emergencies or unsafe conditions.

8. Their right to be informed of their radiation exposure.

9. Locations where the license is posted or made available, notices, copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

Personnel will be properly instructed as follows:

1. Before assuming duties with or in the vicinity of radioactive materials:

2. During annual refresher training.

3. Whenever there is a significant change in duties, regulations or the terms of the license.

H. 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 is spread.

c. Disposable gloves and tongs will be used to clean up the spill. The absorbent paper wand 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. The 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. The incident will be reported to the Radiation Safety Officer.

f. Decontamination will be accomplished by scrubbing the spill area with an industrial cleaner using disposable towels until survey on the readings indicate background levels have been achieved.

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

Application for
Radioactive Material License
Food and Drug Administration

ADDENDUM G

Waste Management

Management will insure that the volume of waste is minimized to the lowest practical level.

Short-lived radioactive waste will be stored for decay until indication levels as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels, to insure that radiation levels do not exceed natural background. All radiation labels will be removed or obliterated and the waste will subsequently be disposed of in normal trash.

Liquid radioactive waste may be discharged into sanitary sewerage in accordance with 20.303 of 10 CFR Part 20, through the designated sink.

MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO All Dallas Lab Personnel

DATE: February 12, 1987

FROM M. Virginia Gipson
Acting Laboratory Director

SUBJECT: Data for Dallas Laboratory Profile Book
DUE BY COB 2/20/87

The Dallas Laboratory supervisors would like to prepare a "profile book" for our Laboratory that would compile the analytical experiences and capabilities of the individual analysts as well as give an overview of the total Dallas Laboratory capabilities. Your cooperation is requested by providing the following information in "short answer" format:

Name: Charles R. McKee

Position Title: Microbiologist - GS-11

Years of Dallas Lab Service: 8½ plus 6 yrs. FDA Investigator in Dallas

Education: North Texas State Univ. — BA, Biology Major, Chemistry Minor
Univ. of Texas at Arlington — 13 hours microbiology (4 courses)

Analytical Specialties: Recovery of and identification of the various microorganisms routinely tested for by our lab, with special attention to Clostridium perfringens and Aeromonas hydrophila
C. botulinum spore recovery & toxin detection & typing.
canned foods analysis
water activity (a_w) analysis.

Major Work Experiences:
Salmonella refrigerated enrichment collaborative study
Staph. aureus enhanced recovery media (MPN) collaborative Study
60 day pesticide lab detail — sample prep. through GLC ident. of compounds
Lab Safety Officer
Graphic arts
Christmas Toy Drive coordinator for Dallas FDA, 1982
FDA Schools include:
Bacti. Sanitation, Advanced Course for Food Inspectors: Canning Technology
HACCP, Epidemiological Investigations, a_w analysis, Datatrieve.

Information due to me no later than 2/20/87.

M. Virginia Gipson
Acting Laboratory Director

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

CHARLES R. MCKEE

Has completed

Foodborne Microbial Pathogens:
Listeria Testing, Gene Probes

June 1-5, 1987

Presented at

Cincinnati District Laboratory
Cincinnati, Ohio

Director, Education and
Training Section

Project Officer

(See also reverse side of this sheet)

FORM FDA 2805e (11/86)

MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : All Dallas Lab Personnel

DATE: February 12, 1987

FROM : M. Virginia Gipson
Acting Laboratory Director

SUBJECT: Data for Dallas Laboratory Profile Book
DUE BY COB 2/20/87

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Name: thomas j. arista

Position Title: microbiologist GS-9

Years of Dallas Lab Service: ten (10)

Education: b of a biology
a of a medical laboratory technology

Analytical Specialties: vibrio cholera, campylobacter, listeria, yersinia dna hybridization, water activity. familiar with various clinical laboratory equipment and their operations.

Major Work Experiences: various sanitation inspection; crabmeat plants, pecan plant, canning of green chilies, manufacturing of green chili products, food service establishments, (i.e skychief facility/dfw airport, furr's production facility/ lubbock, tx., baylor medical facility) teaching food service sanitation management @ eastfield college, lecture of abnormal cans in the food service establishment @ texas tech university, cabinet maker, aircraft mechanic 1 & 2 jets.
volunteer to assist in the famine relief in africa. Speaks Spanish

Information due to me no later than 2/20/87.

M. Virginia Gipson
Acting Laboratory Director

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MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO All Dallas Lab Personnel

DATE: February 12, 1987

FROM M. Virginia Gipson
Acting Laboratory Director

SUBJECT Data for Dallas Laboratory Profile Book
DUE BY COB 2/20/87

The Dallas Laboratory supervisors would like to prepare a "profile book" for our Laboratory that would compile the analytical experiences and capabilities of the individual analysts as well as give an overview of the total Dallas Laboratory capabilities. Your cooperation is requested by providing the following information in "short answer" format:

Name: David M. Beltran

Position Title: Microbiologist - GS-5

Years of Dallas Lab Service: 12

Education:
North Texas State University

Analytical Specialties:

General Microbiology —

Major Work Experiences:

Micro - lab Forever
Began with FDA as stay in school (at age 16.

Information due to me no later than 2/20/87.

M. Virginia Gipson
Acting Laboratory Director

Charles Brown

MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : All Dallas Lab Personnel

DATE: February 12, 1987

FROM : M. Virginia Gipson
Acting Laboratory Director

SUBJECT: Data for Dallas Laboratory Profile Book
DUE BY COB 2/20/87

The Dallas Laboratory supervisors would like to prepare a "profile book" for our Laboratory that would compile the analytical experiences and capabilities of the individual analysts as well as give an overview of the total Dallas Laboratory capabilities. Your cooperation is requested by providing the following information in "short answer" format:

Name: Charles Brown

Position Title: Sample Custodian WG-6

Years of Dallas Lab Service: 2 1/2 years

Education: Associate Degree in Business
Chemistry Course by Dr. Irn Cobb

Analytical Specialties:
NDL, S.E.I., Protein, Fiber, Fat, Fatty Acid, Refine & Bleach Oil, I.V., Flash Point, Wet Break,

Major Work Experiences:
3 years Chemical Quality Control Lab Tech
1 week Chemistry Lab Training in Atlanta, GA.

Came to work with DAL-DO as part-time assisted micro lab in extensive oyster survey.

Information due to me no later than 2/20/87.

M. Virginia Gipson

M. Virginia Gipson
Acting Laboratory Director

Ginger

MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : All Dallas Lab Personnel

DATE: February 12, 1987

FROM : M. Virginia Gipson
Acting Laboratory Director

SUBJECT: Data for Dallas Laboratory Profile Book
DUE BY COB 2/20/87

The Dallas Laboratory supervisors would like to prepare a "profile book" for our Laboratory that would compile the analytical experiences and capabilities of the individual analysts as well as give an overview of the total Dallas Laboratory capabilities. Your cooperation is requested by providing the following information in "short answer" format:

Name: Mary Virginia Gipson (Ginger)

Position Title: Supervisory Microbiologist

Years of Dallas Lab Service: 26

Education: B.A. Bacteriology Texas Tech Univ.

Analytical Specialties: [illegible] Food Microbiology
[illegible] work

Major Work Experiences: FDA Dallas Microbiologist
Microbiologist
[illegible] Supervisory
[illegible]
[illegible] communication [illegible]
Coordination and
State liaison work
Detail FSB - Detail Lab. Dir. Buf. DO
Taught micro course in Trinidad WI - 1985

Information due to me no later than 2/20/87.

M. Virginia Gipson
M. Virginia Gipson
Acting Laboratory Director

MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVIC
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO All Dallas Lab Personnel

DATE: February 12, 1987

FROM M. Virginia Gipson
Acting Laboratory Director

SUBJECT Data for Dallas Laboratory Profile Book
DUE BY COB 2/20/87

The Dallas Laboratory supervisors would like to prepare a "profile book" for our Laboratory that would compile the analytical experiences and capabilities of the individual analysts as well as give an overview of the total Dallas Laboratory capabilities. Your cooperation is requested by providing the following information in "short answer" format:

Name: WARREN L. LANDRY

Position Title: MICROBIOLOGIST - GS-12

Years of Dallas Lab Service: 19 3/4 years

Education: BS in MICROBIOLOGY - 48 hours
Minor in Chemistry
24 FDA training courses - various subjects
6 Computer training courses

Analytical Specialties:

Canned Food Specialist	Vibrio parahaemolyticus research
GLC Specialist	Headspace Gas research
Computer Specialist	Anaerobic identification research
Method Developement	Designing Analytical Worksheets
Organizational ability	Artistic talents

Major Work Experiences:
Acting Supervisory Microbiologist
Compliance Officer
Administrative Officer
Laboratory Safety Officer
Microbiological Purchasing Agent
Training Instructor - AOAC & ASM
MCMI Pilot study
Mobile Laboratory
Microbiological Information System
Inspectional experience

Information due to me no later than 2/20/87.

M. Virginia Gipson
Acting Laboratory Director

MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : All Dallas Lab Personnel

DATE: February 12, 1987

FROM : M. Virginia Gipson
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SUBJECT: Data for Dallas Laboratory Profile Book
DUE BY COB 2/20/87

The Dallas Laboratory supervisors would like to prepare a "profile book" for our Laboratory that would compile the analytical experiences and capabilities of the individual analysts as well as give an overview of the total Dallas Laboratory capabilities. Your cooperation is requested by providing the following information in "short answer" format:

Name: Mildred M. Lister

Position Title: Microbiologist

Years of Dallas Lab Service: 19½ GS-11

Education: BS in Biol + Chem. ~~Higbee~~ Wiley
12 hr. micro U.T. Arlington

Analytical Specialties:
Yersinia enterocolitica
EEC
~~Campylobacter~~ Can sean Teardrop
Staph enterotoxins

Major Work Experiences:
Salmonella
Bacillus cereus
Canned foods
E. Coli + EEC
Yersinia enterocolitica
Staph enterotoxins
DNA hybridization
Listeria

Started in Cal Lo as technician - converted to microbiologist 1973

Assist. Regional Bennet Dir of Micro in presentation of Staph ent. courses

Information due to me no later than 2/20/87.

EEO Counselor

M. Virginia Gipson
Acting Laboratory Director

MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : All Dallas Lab Personnel

DATE: February 12, 1987

FROM : M. Virginia Gipson
Acting Laboratory Director

SUBJECT: Data for Dallas Laboratory Profile Book
DUE BY COB 2/20/87

The Dallas Laboratory supervisors would like to prepare a "profile book" for our Laboratory that would compile the analytical experiences and capabilities of the individual analysts as well as give an overview of the total Dallas Laboratory capabilities. Your cooperation is requested by providing the following information in "short answer" format:

Name: WES NOAH

Position Title: MICROBIOLOGIST - GS-11

Years of Dallas Lab Service: 13

Education:
B.S IN BIOLOGY, UTA
MINOR - SOCIOLOGY

Analytical Specialties:
DEVELOPMENT OF ID. METHODOLOGY OF BACILLUS Cereus
ID OF LISTERIA MONOCYTOGENES
ID. OF STAPH ENTEROTOXIN
ID. OF ENTEROTOXIGENIC E.coli UTILIZING DNA COLONY HYBRIDIZATION

Major Work Experiences:
ART WORK
ENROLLEE OF NORTHWESTERN SCHOOL OF TAXIDERMY
ACTING EXPERIENCE
FILM AND VIDEO PRODUCTIONS / PRODUCER/WRITER, /DIRECTION / EDITING
/SET DESIGN AND STAGE SCENERY CONSTRUCTION /
STILL PHOTOGRAPHY WORK

Information due to me no later than 2/20/87.

M. Virginia Gipson
Acting Laboratory Director

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MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : All Dallas Lab Personnel

DATE: February 12, 1987

FROM : M. Virginia Gipson
Acting Laboratory Director

SUBJECT: Data for Dallas Laboratory Profile Book
DUE BY COB 2/20/87

The Dallas Laboratory supervisors would like to prepare a "profile book" for our Laboratory that would compile the analytical experiences and capabilities of the individual analysts as well as give an overview of the total Dallas Laboratory capabilities. Your cooperation is requested by providing the following information in "short answer" format:

Name: Charles V. Kederick

Position Title: Microbiologist GS 12-9

Years of Dallas Lab Service: 22

Education: B S in Microbiology – Texas Technological University

Analytical Specialties: GRAM NEGATIVE NON FERMENTERS, CANNED FOODS ANALYSIS, CAMPYLOBACTER JEJUNI, V. hario Cholera, Vibrio PARAHAEMOLYTICUS AND RELATED VIBRIO SPECIES. ISOLATION AND IDENTIFICATION OF YEAST AND MOLD.

Major Work Experiences:
20 YEARS EXPERIENCE IN FOOD MICROBIOLOGY AT FDA. 20 YEARS EXPERIENCE IN INSPECTIONAL WORK INCLUDING FOOD, DRUGS COSMETICS AND NON CLINICAL LABORATORIES.
3 OR FOUR DETAILS OF 30 OR 60 DAYS AS COMPLIANCE OFFICER
SEVEN YEARS EXPERIENCE IN MILK, WATER + FOOD MICRO BIOLOGY AT CITY OF DALLAS HEALTH DEPARTMENT.
EXPERIENCE IN CONGOCCI, CULTURE AND SMEAR EXAMINER ACID FAST BACILLI (MYCOBACTERIA RELATED ORG. WORK WITH RINGWORM CLINICAL SPECIMENS AND SOME WORK WITH PARASITOLOGY

Information due to me no later than 2/20/87.

M. Virginia Gipson
Acting Laboratory Director

MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Memorandum to Accompany
Application for Material License

DATE: 9/25/87

FROM : Charles R. McKee
Radiation Safety Officer, HFR-6160

SUBJECT: Request for Change of Application to an Amendment of an Existing License

In reference to the telephone conversation on 9/24/87 between Jack Whitten, NRC Materials Licensing Section, and Charles R. McKee, Radiation Safety Officer, HFR-6160, this confirms our request to void the present application for a new license and resubmit the application as an amendment to our existing license. As we discussed, we would like to add the phosphorus-32 radioactive material to our existing license, Number 42-09764-02.

Our existing license lapsed and was then submitted for renewal on March 31, 1987, as acknowledged by a letter from Charles L. Cain dated May 27, 1987. We have not yet received the renewed license showing the new expiration date.

Charles R. McKee

Charles R. McKee
RSO, Microbiologist

CRM/hm

46/473
~~46/478~~

MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Memorandum to Accompany
Application for Material License

DATE: 9/23/87

FROM : Charles R. McKee
Radiation Safety Officer, HFR-6160

SUBJECT: Application for Material License, L09764 (030-30189)

In reference to the telephone conversation on 9/22/87 between Jack Whitten, NRC Materials Licensing Section, and Charles R. McKee, Radiation Safety Officer, HFR-6160, four additional items were identified as needing to be further specified. The following is an explanation of the items we discussed and expresses the applicant's commitment regarding them:

Item 1 - The application is signed by the certifying official, Darryl E. Brown, Laboratory Director.

Item 2 - A copy of the course outline for the radiation safety training received by RSO Charles R. McKee is attached.

Item 3 - Addendum G has been changed to include a more specific explanation of waste management.

Item 4 - Addendum E has an additional paragraph (paragraph 6) further explaining the storage location of the radioactive material.

Charles R. McKee

Charles R. McKee
RSO, Microbiologist

Attachments

CRM/hm