

## MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

301772

Licensee		3. License Number	34-26752-01
1. Chiron Diagnostics Corporation		4. Expiration Date	December 31, 2001
2. 132 Artino Street Oberlin, OH 44074		5. Docket or Reference No.	030-34229
6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License	
A. Iodine-125	A. Bound/non-volatile	A. 5 millicuries	
B. Technetium-99m	B. Any	B. 10 millicuries	

## 9. Authorized Use:

A. through B. For use in the development/design of instruments for medical diagnostic equipment.

## CONDITIONS

1. Licensed material shall be used only at the licensee's facilities located at 132 Artino Street, Oberlin, Ohio.
2. Licensed material shall be used by, or under the supervision of, Linda Harrison or Terry Ketchum.
3. The Radiation Safety Officer for this license is Linda Harrison.
4. Licensed material shall not be used in or on human beings.
5. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
6. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
  - A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

190048

COPY

2ml  
230  
50

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number  
34-26752-01

Docket or Reference Number  
030-34229

- B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
7. The licensee may not possess and use materials authorized in Items 6, 7, and 8 until:
1. The licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and
  2. The U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Materials Licensing Branch, 801 Warrenville Road, Lisle, IL 60532-4351 has been notified that activities authorized by the license will be initiated.
8. Within 30 days of the date of a decision not to complete the facility, acquire equipment, or possess and use authorized material, the licensee must notify the Commission in writing, of the decision.
9. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated August 13, 1996; and
  - B. Letters dated August 13, 1996, September 13, 1996, October 7, 1996; and
  - C. Facsimile dated November 11, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date December 6, 1996

By Loren J. Hoster  
Nuclear Materials Licensing Branch, Region III

R8

```

: Program Code: -----
: Status Code: 3-----
: Fee Category: -----
: Exp. Date: 0-----
: Fee Comments: -----
: Decom Fin Assur Req?-----
: .....

```

Log Aug 15 III  
Remitter \_\_\_\_\_  
Check No. 10186378  
Amount \$1500  
Fee Category 3M  
Type of Fee App  
Date Check Rec'd 8/29/96  
Date Completed 9/4/96  
By: SC

SEP 09 1996

1976 AUG 29 PM 4:25

(10-94)  
10 CFR 30, 32, 33  
34, 35, 36, 39 and 40

## APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 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. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-8 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

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.

## APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY  
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS  
U.S. NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555-0001

## 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, PENNSYLVANIA,  
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION  
NUCLEAR MATERIALS SAFETY BRANCH  
U.S. NUCLEAR REGULATORY COMMISSION, REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PA 19406-1415

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

NUCLEAR MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION II  
101 MARIETTA STREET, NW, SUITE 2900  
ATLANTA, GA 30323-0199

## IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION III  
801 WARRENVILLE RD.  
LISLE, IL 60532-4351

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 SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TX 76011-8064

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.

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

- ☒ A. NEW LICENSE  
☐ B. AMENDMENT TO LICENSE NUMBER \_\_\_\_\_  
☐ C. RENEWAL OF LICENSE NUMBER \_\_\_\_\_

## 2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

CIBA CORNING DIAGNOSTICS CORP.  
132 ARTINO STREET  
OBERLIN, OHIO 44074

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

CIBA CORNING DIAGNOSTICS CORP.  
132 ARTINO STREET  
OBERLIN, OH 44074

## 4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Terry L. Ketchum

## TELEPHONE NUMBER

(216) 776-6462

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. 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, 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 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.

## CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Lyle Staab, Exe. Dir. Mfg. Operations

## SIGNATURE

Lyle Staab

## DATE

8-13-96

## FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

RECEIVED

AUG 26 1996

REGION III



CIBA-CORNING

\* Ciba Corning Diagnostics Corp.  
132 Artino Street  
Oberlin, Ohio 44074-1293  
Telephone 216-774-1041

August 13, 1996

Materials Licensing Section  
U.S. Nuclear Regulatory Commission  
Region III  
801 Warrenville Road  
Lisle, IL 60532-4351

Dear Ms./Sir:

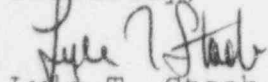
Please find our application (1 original and 1 copy) for a material license in accordance with the requirements of Title 10 of the Code of Federal Regulations (see enclosure 1). Included in the application is a check for the \$1,500 licensing fee.

The training identified in Section 7 of the application is scheduled for September 9-11th. A copy of the course outline is provided as enclosure 2. Upon completion of the course, a copy of the training certificates for Linda Harrison and Terry L. Ketchum will be forwarded to you.

Questions concerning this application request should be directed to Susan J. Engelhardt (Engelhardt & Associates) at 1-(800)-525-3078 or Terry L. Ketchum at (216) 776-6462.

Your cooperation in the matter is greatly appreciated.

Sincerely,

  
Lyle T. Staab  
Executive Director,  
Manufacturing Operations

2 Enclosures

CC: Susan Engelhardt, Engelhardt & Associates

RECEIVED  
AUG 26 1996  
REGION III

pm 8/22/96

AUG 26 1996

5. RADIOACTIVE MATERIALS

- a. Radionuclide: Iodine-125
- b. Physical form: Bound
- c. Maximum Quantity: 5 millicuries
  
- a. Radionuclide: Technetium-99m
- b. Physical form: Any
- c. Maximum Quantity: 10 millicuries

6. PURPOSES FOR WHICH RADIOACTIVE MATERIALS WILL BE USED

Radioactive materials will be used in the development/design of instruments used in medical diagnostic equipment. Basically, the radioactive materials will be used as tracers within the instruments for quality control purposes. The radioactive materials are bound or in a non-volatile form for all uses.

7. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY AND THEIR TRAINING AND EXPERIENCE

The radiation safety officer for this program is Linda Harrison. The alternate radiation safety officer for the program is Terry Ketchum. The training and experience forms for these individuals is attached. In addition, they will be attending a 2.5 day radiation safety seminar sponsored by Engelhardt & Associates, Inc. A copy of their certificates of completion and their exams will be forwarded to the commission.

See attached Curriculum Vitae.

Curriculum Vitum

RADIATION SAFETY OFFICER

Name: Linda Harrison

Job Title: Associate Scientist

Education: Bachelor of Science in Biology, Ohio State University

Training in Radiation Safety:

- A. Radiation Protection
- B. Sources of Radiation Exposure
- C. Radiation Detection Equipment
- D. Radiation Biology
- E. Radiation Safety Procedures
- F. Radiation Emergencies

Institution: Engelhardt & Associates  
2800 Fish Hatchery Road  
Madison, WI 53711

Work Experience with Radiation:

<u>Isotope</u>	<u>Max. Amount Handled (mCi)</u>	<u>Where</u>	<u>Duration</u>	<u>Usage</u>
I-125	0.01	North Central Labs	1 year	radioim- munoassay
I-125	0.20	Providence Hospital	2 years	radioim- munoassay
I-125	0.20	Lorain Community Hospital	5 years	radioim- munoassay

Curriculum Vitum

ALTERNATE RADIATION SAFETY OFFICER

Name: Terry L. Ketchum

Job Title: Safety Engineer (Environmental, Health & Safety)

Education: Bachelor of Science in Chemical Engineering,  
Youngstown State University

Training in Radiation Safety:

- A. Radiation Protection
- B. Sources of Radiation Exposure
- C. Radiation Detection Equipment
- D. Radiation Biology
- E. Radiation Safety Procedures
- F. Radiation Emergencies

Institution: Engelhardt & Associates  
2800 Fish Hatchery Road  
Madison, WI 53711

Work Experience with Radiation: None.



7. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY AND THEIR TRAINING AND EXPERIENCE (Continued)

Other individuals who use radioactivity shall do so under the supervision of one of the above named individuals. The training they receive shall consist of at least the following topics:

- Basics of ionizing radiation
- Basic terminology
- Radiation protection principles, including ALARA
- Declared pregnant worker policy
- Radiation measurements
- Radiation biology
- Surveys for radioactive contamination.
- Emergency response/notification requirements
- Security of radioactive materials
- Methods of radioactive waste minimization and handling
- Other topics as they pertain to the use of radioactivity; performance based reviews of the operational uses of radioactive materials.

8. TRAINING FOR PERSONS WORKING IN OR FREQUENTING AREAS WHERE RADIOACTIVE MATERIALS ARE USED OR STORED

These individuals include the ancillary personnel that are employees of the company as well as contractor employees who would have to work on a temporary basis in restricted areas.

The training for these persons shall include:

- Awareness of where the Form-3 is posted; which also indicates where copies of the license are kept, where documents pertaining to the license and emergency phone numbers, including the RSO and Alternate RSO can be found.
- Locations of use and storage of radioactive materials.
- Specific training on what to do if they suspect there may be a problem in the areas where radioactive materials are used or stored.

9. FACILITIES AND EQUIPMENT

Survey instruments are as follows:

Model:	Ludlum
Type	Portable GM Ratemeter-3
Model #:	Model III
# Available:	2
Radiation Detect:	gamma, beta, x-ray
Sensitivity Range:	0.01-200 mR/Hr
Window Thick.:	1.7 mg/sq cm mica
Use:	Survey

Manufacturer:	Ludlum
Type:	Portable Scintillation Ratemeter-3
Model #:	44-3
#Available:	2
Radiat. Detect.:	Low energy gamma
Window Thick:	25 mg/sq cm Al, 7 mg/sq cm mylar
Sensitivity Range:	10 cpm-500 kcpm

The above survey instruments reflect units that we are in the process of procuring; we may purchase other instruments if they are equivalent to the above.

Gamma Counter: In addition, we will have a gamma counter on site that is made by Packard, Cobra model, that can count several samples at a time. This counter uses a NAI (TI) activated crystal. The counter will be calibrated before use and periodically thereafter. An equivalent counter may be used at the discretion of the licensee.

Facilities: There are two labs located in our building where radioactive materials will be used/stored. In addition, there is a room where radioactive wastes are stored. This is the hazardous waste storage area, which is locked at all times. Please see the diagram of the building, which indicates where these three rooms are located within the facility. In addition, there are individual diagrams detailing each of the three rooms we use.

9. FACILITIES AND EQUIPMENT (Continued)

Counter tops: These are made of an epoxy resin with aggregate (non-porous rock like material) so that absorption of radioactive material will be minimized.

Sinks: There are sinks that can be used by the licensee.

Refrigerator/Freezer: There is a refrigerator/freezer available for storage of radioactive materials. This unit is locked.

Storage Cabinet: Radioactive materials may be stored in a specified locked storage cabinet in the lab, if the need should arise.

Hood: A hood is not necessary for the uses described. The radioactive materials are all bound.

Security: The building itself is a controlled area. Access is only through a receptionist. The rest of the facility requires key-card/interlock-door codes to gain access. The radioactive materials are secured against unauthorized removal by locking the material in a storage cabinet or refrigerator/freezer when not in use. Material that is inside of test equipment is not accessible.

10. RADIATION SAFETY PROGRAM

Training: Training has already been discussed in another section. However, in addition to the initial training annual refresher training shall be provided.

Meter Calibration: Meters will be calibrated annually by a company licensed by the NRC/Agreement State to do so; such as Ludlum, Compliance Management.

Radiation Badges: Badges will be provided if there is a potential for a person to receive 10% of the allowable occupational limit. If badges are needed, they will be provided by R. S. Landauer, or any other NVLAP certified vendor. Because of the low quantities of radioactive material used per experiment, it is not anticipated that badges will be required.

10. RADIATION SAFETY PROGRAM (Continued)

Bioassays: Because the quantities of radioactive materials used is so small, under 100 uCi/protocol and the fact that the iodine is bound, bioassays will not be required. If, however, there is an incident involving radioactive materials, then an iodine bioassay will be performed using the scintillation probe described in equipment and facilities. A standard will be counted to determine detector efficiency and then a neck count will be done to determine if an uptake has occurred. If there is an uptake, then the uptake will be added to any other uptake for the year to assure non-excedence of the ALI. If an uptake of Tc-99m is suspected that would exceed the ALI, then a count of that person will be performed at a local hospital, using a gamma camera and quantification of the uptake determined.

ALARA: All radiation exposures will be kept as low as reasonably achievable. This will be done through employee training and awareness programs. If radiation badges are used, then the licensee will investigate any quarterly report indicating an exposure greater than 125 mrem/quarter, deep dose, whole body.

Declared Pregnant Worker: All workers are informed of their rights as a worker; in accordance with regulatory guide DG8014 or equivalent. A fetal monitor badge may also be supplied if dose greater than 10% of limit is expected. This must be a monthly film badge to be worn in the abdominal area. The fetus will not receive greater than 500 mrem over the term of pregnancy. In addition, this dose must be spread uniformly over the term of the pregnancy, not delivered all at once.

Surveys: Wipe tests shall be performed on the work areas where radioactive materials are used, at least weekly during the time a project is operational using a method sufficiently sensitive to detect 200 dpm/100 sq cm. Wipes will be removed to a low background area for measurement. During operation of a project, a daily meter survey will be done to record the dose rate. At the end of each project, a final survey of the lab shall be done. Records of all surveys will be kept in accordance with commission requirements. All surveys shall be expressed as dpm/100 sq cm.

10. RADIATION SAFETY PROGRAM (Continued)

Decontamination: Decontamination shall be done on any surface where the contamination levels exceed 220 dpm/100 sq cm.

Decontamination of stock bottles shall be done when contamination levels reach 2200 dpm/100 sq cm.

Inventory: A continuous inventory of radioactive materials will be kept via computer. This will include the location and form the radioactive materials are in, including wastes. This is to assure that the license limits are not exceeded.

Procurement of Radioactive Materials: Only the RSO and the Alternate RSO will be authorized to order radioactive materials. These individuals must sign all orders or they will not be ordered. When material is ordered, a record of the order is entered into the inventory program as "ordered material", the date it was ordered and the expected arrival date, this is to assure that the license limits are not exceeded.

Receipt of Radioactive Materials: Packages containing radioactive materials, shall be checked for exposure rates upon arrival and contamination levels within three hours of receipt, as required by 10CFR20. Packages shall be processed in only by the RSO, Alternate RSO, or their designees.

Protective Apparel: Any persons working with radioactive material will wear protective apparel, such as lab coats and gloves to prevent contamination of personnel. All personnel, before leaving the radioactive material use areas, are to remove all protective apparel and monitor their hands with a survey meter. If the presence of contamination is detected, the individual must wash the affected area and resurvey before leaving the area.



10. RADIATION SAFETY PROGRAM (Continued)

Emergency Response: The following are the procedures to be followed in the event of emergencies, by category:

1. **Loss/Theft of Radioactive Material:** Notify the RSO/Alternate RSO immediately. Initiate a search of the material. If, after reasonable attempt has been made to ascertain the location of the material, if not found, then notify the NRC within the required reporting time. (If notification levels are exceeded, then see 10CFR 20.2201.)
2. **Minor Spills:** Decontaminate the area with some decon materials such as Rcdiac, until the levels reach 220 dpm/100 sq cm. If the spill cannot be decontaminated, cover the area with an impervious material, label as contaminated, the level of contamination, date, material, and meter survey results. Affix appropriate radioactive material labels. Allow the radioactive material to decay away. Be sure to notify the RSO/Alternate RSO immediately.
3. **Major Spills:** Isolate the area, remove personnel once you determine that they are not contaminated.
  - Notify the RSO/Alternate RSO immediately.
  - Shut down all affected equipment
  - Vacate the area
  - Await instructions from the RSO/Alternate RSO on how to mitigate the problem
4. **Personnel Contamination:** Notify the RSO/Alternate RSO immediately. Do not let the person leave the area. Determine where the contamination is located and wash the affected area with copious amounts of cool water and soap. Do not debride the skin. Resurvey. If all the contamination cannot be removed, note where the contamination is located and then instruct the person to wash the area often. Resurvey the contaminated areas with a survey meter.
5. **Injured Personnel:** If a person is injured while using radioactive materials, such as a cut or puncture, then wash the area with copious amounts of cool water; encourage bleeding, unless the injury is life-threatening. Notify the RSO/Alternate RSO immediately. If the injury is life-threatening, then call an ambulance immediately. The radioactive contamination is irrelevant at this point.

10. RADIATION SAFETY PROGRAM (Continued)

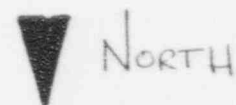
Audits: At a minimum, an annual audit of the program will be conducted and presented to management. More frequent audits and spot checks will be done at the discretion of the RSO/Alternate RSO.

Recordkeeping: Records will be kept of program activities as required by regulatory code.

11. RADIOACTIVE WASTE DISPOSAL

Radioactive wastes will most likely be stored for decay (DIS) for a period of at least 10 half lives. Two types of wastes may be in DIS at any one time, solids and liquids. At this time, the wastes will be surveyed and if found to be at or below background levels, they will be disposed of without regard to radioactivity. Liquid waste may be discharged into the local sanitary wastewater system.

If the licensee so chooses, then the waste may be shipped off site for disposal by a licensed radioactive waste broker.



# SYSTEMS EVALUATIONS LAB

WINDOWS

OVERHEAD CABINETS

OVERHEAD CABINETS

OVERHEAD VENT

SINK

REFRIGERATORS

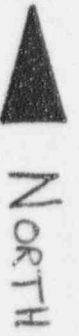
DOOR

DOOR

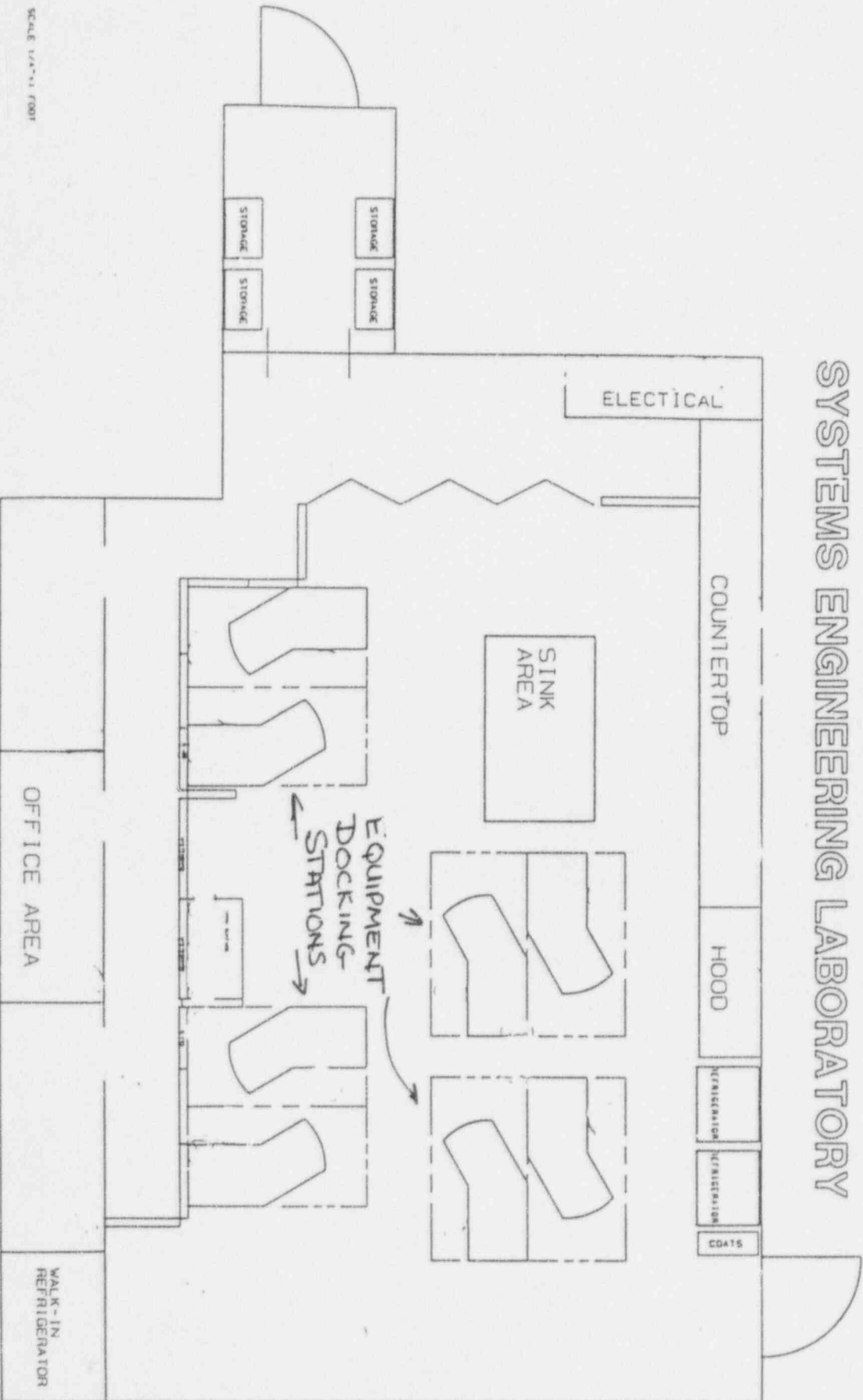
\* DRAWING NOT TO SCALE

(DIMENSIONS 21' X 15' X 9")

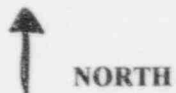
#1



# SYSTEMS ENGINEERING LABORATORY



# HAZARDOUS WASTE STORAGE ROOM



FLAMMABLE  
WASTES

CORROSIVE  
WASTES

POISON  
WASTES

CLASS 9  
WASTES

ENTRANCE

aisle

LAB PACK  
MATERIALS  
AWAITING  
SEGREGATION

EMPTY PAILS

SUPPLIES & STORAGE SPACE



E. Lorain Street

South  
Parking  
Lot

North  
Parking  
Lot

132 Artino Street

(See Figure #2)

(See figure)

#1

DECAY  
IN  
STORAGE

(See figure  
#3)

# ENGELHARDT & ASSOCIATES, INC.

*Presents...*

## **A Radiation Safety Seminar**

**September 9-11, 1996**

**Hilton Riverside in New Orleans**

### **Who Should Attend:**

People in industry, government, hospitals and universities who are responsible for the safe use of radiation sources and radioactivity, or need to understand the principles of radiation safety.

This seminar meets regulatory requirements for RSO training for fixed gauge users.

- Radiation and Radioactive Decay
- Radiation Quantities and Units
- Biological Effects of Radiations
- New 10CFR Part 20
- 10CFR 19, 30, 33, 34 and 35 Requirements
- Radiation Risks
- Radioactive Waste Disposal
- Radiation Measurements
- Personal Dosimetry
- Licensing Requirements
- Records Management
- Preparing for Radiation Safety Inspections
- Emergency Response

ENCLOSURE 2

This course provides comprehensive training for industry, medicine, academic, and biotechnology/R&D personnel. The course uses a "nuts and bolts" approach to radiation safety, so each attendee receives information pertinent to them. All persons attend "core" lectures, and then the class is split into separate groups for gauge, medical and academic/biotechnology users. Each group receives specific instruction as well as hands-on for specific needs and regulatory requirements.

### Evaluation Comments from Past Attendees...

*"Excellent Value- best course I've attended."*

*"Exceed expectations. Material was right on target."*

*"Excellent course! Far above my expectations!! Look forward to coming again."*

*"I was very satisfied with the course. There was not excessive theory in the lectures, which would have probably confused me."*

*"I've had training under 3 other organizations. This one covered the areas better. Others focused on one or two aspects, you covered more aspects. The text is EXCELLENT. It will serve well as a reference."*

### Seminar Coordinator

Sue Engelhardt has over 22 years experience in Health Physics. After receiving her M.S. she worked as a Health Physicist in the uranium fuel cycle, and then as the RSO at the University of Wisconsin for 10 years. At the University Susan had experience with multi-curie quantities of radioactive material. She also taught on a consulting basis several RSO courses in heavy industry settings. As President of Engelhardt & Associates, Inc. she organizes and presents a wide spectrum of training courses, as well as preparing many different types of licenses.

Our seminar speakers have been selected, based on their individual expertise to best address your needs.

### Location

Hilton Riverside in New Orleans

There is no better place to take in the action than the New Orleans Hilton Riverside, right in the middle of it all. Restaurants, shopping, casino gaming and night life are all at your doorstep. Located on the banks of the Mississippi River the Hilton Riverside gives you the best New Orleans has to offer - all within easy walking distance. Three blocks away, the historic French Quarter beckons you to explore, and the fabulous Aquarium of the Americas is just one block away.

*Continental Breakfast begins at 7:30 a.m. with class starting at 8:00 a.m. each day. We will wrap-up by 4:00 p.m. Monday and Tuesday, and by 2 p.m. on Wednesday.*

### Day One

#### How Radiation is Used

- Medical
- Industrial
- Academic

#### Regulatory Agencies

- Who regulates what
- Where regulatory standards come from

#### Basic Terminology and Basic Physics

- Quantities and units of radiation
- Types of radiation; interaction of radiation and matter; how radiation is produced
- Half-life; shielding; half-value layers

#### Radiation Protection

- Dosimetry: Types of dosimeters and how they work
- Time, distance, shielding: inverse square
- Allowable limits of exposure; how conservative are these limits?
- Rules of thumb to protect yourself from radiation
- ALARA

#### Sources of Radiation Exposure

- Natural occurring, medical, work, life-style, nuclear power

### Day Two

#### Radiation Detection Equipment

- Types of equipment and what it can be used for
- Demonstration of equipment uses
- Appropriate methods of use

#### Radiation Biology

- Radiation biology at the cellular level
- Early somatic effects, acute effects, delayed effects
- Radiation Risk

#### Radiation Safety Procedures

- Leak test: description and purpose with hands on experience
- Radiation safety surveys
- Instrument calibrations; why?
- Instrument checks; why?
- Hands on use of meters

#### Radiation Emergencies

- Source leakage, spills, loss of sources, injuries involving radioactive materials
- Licensee perspective

- Emergency room personnel as responders to incidents
- Emergency personnel as responders (ambulance, fire, police)

#### **Radioactive Waste Management/Minimization**

- Status of radioactive waste processing in the U.S.

#### **Transportation**

- Regulatory requirements
- Shippers responsibility

### **Day Three**

#### **License Writing**

- How to prepare an NRC/State license; what will be approved and what will not

#### **NRC/State Inspections**

- How to deal with an NRC/State inspector
- What to do if the inspection appears to be going badly
- What to do if you are called in for an enforcement conference; can you prepare for it; can you plan for it?

#### **Reportable Incidents**

- Determination of reportable incidents
- Reporting requirements

#### **Radiation Licensing and Regulations**

- Revised 10CFR Part 20
- 10CFR 30-34, and 10CFR 35
- Gauges, specific licenses, general licenses, special requirements
- Agreement vs non-agreement states

We will break into three separate groups (i.e. medical, biotech, research, industrial/gauge) twice a day. This will assure that specific questions and problems are addressed. Bring a copy of your license or device registration and operations manual for reference.

#### **Your Registration Fee Includes:**

Continental Breakfasts  
Comprehensive Radiation Safety Manual  
Radiation Training Materials  
Licensing Sessions

#### **Send or Fax To: Engelhardt & Associates**

2800 S. Fish Hatchery Road  
Madison, WI 53711

Phone: (608) 274-4227

(800) 525-3078

Fax: (608) 273-6989

*Please send payment prior to the conference.*

*Feel free to let us know if this is a problem. Thank You!*

*Continuing education credits are available for: Society for Nuclear Medicine, ARRT and the American Board of Industrial Hygiene. Approved by Agreement States for Fixed Gauge users - NRC approval assistance available.*

*If you are unable to attend, please pass this on to someone who may be interested.*

Registration Fee: \$675.00 per person

Number of People Attending \_\_\_\_\_

**REGISTRATION MUST BE RECEIVED BY AUGUST 16, 1996; PLEASE CALL IF THIS IS A PROBLEM**

Name: \_\_\_\_\_

Position: \_\_\_\_\_

Organization: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_

☐ Check enclosed    ☐ Check, Purchase Order To Follow

**Hotel Reservations:** Please contact the Riverside Hilton • (504) 561-0500  
Poydras at the Mississippi River • New Orleans, LA 70140  
**(Space Is Limited, Make Your Reservation Early)**

Single/Double: \$120.00

(Please state that you are attending the Engelhardt & Associates Radiation Safety Seminar in order to receive this discounted room rate.)

DEC 09 1996

Lyle Staab  
Executive Director, Manufacturing  
Operations  
Chiron Diagnostics Corporation  
132 Artino Street  
Oberlin, OH 44074

Dear Mr. Staab:

Enclosed is your NRC Material License Number 34-26752-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:
  - a. You have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and
  - b. You have notified the U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Nuclear Materials Licensing Branch, in writing, that activities authorized by the license will be initiated.
3. Notify NRC, in writing, within 30 days:
  - a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
  - b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

301772



4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
  - a. When you decide to terminate all activities involving materials authorized under the license; or
  - b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.
5. Request and obtain a license amendment before you:
  - a. Change Radiation Safety Officers;
  - b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
  - c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
  - d. Change ownership of your organization.
6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the

L. Staab

-3-

General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By  
Loren J. Hueter  
Nuclear Materials Licensing Branch

License No. 34-26752-01  
Docket No. 030-34229

Enclosures:

1. License No. 34-26752-01
2. 10 CFR Part 20
3. 10 CFR Part 30
4. Form NRC-3
5. NRC Form 313

DOCUMENT NAME: M:\03034229.CL6

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	<input checked="" type="checkbox"/>							
NAME	HUETER:sjd	<i>LJH</i>							
DATE	12/06/96								

OFFICIAL RECORD COPY

## CONVERSATION RECORD

TIME

DATE

10-28-96

☐ VISIT☐ CONFERENCE☒ TELEPHONE☐ INCOMING☒ OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

Terry Retchum

Chiron Diagnostics Corp  
(Ciba Corning)216-  
776-6462

SUBJECT

CN 301772

FAX 216-774-3939

## SUMMARY

1. Confirm that General Laboratory Safety Instruction regarding use of lab coats, gloves, monitoring hands before leaving etc., will be posted in the area of use.
2. Regarding package receipt and opening, provide the following:
  - a. Specify the location where incoming shipments will be delivered (should be a single location).
  - b. Address provisions for receipt of packages after normal working hours.
  - c. If packages will be opened by <sup>persons</sup> other than the RSO or alternate RSO, please describe the training and procedures that will be provided to these individuals. It should include applicable requirements in 10 CFR 20.1906.
3. Regarding radioactive waste:
  - a. Specify the location where 'decay-in-storage' waste will be stored. Also confirm that all radiation labels will be removed or obliterated before disposal.
  - b. Confirm that any liquid waste to the sanitary sewer system will meet criteria in 10 CFR 20.2003. (over)

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Loren J. Hunter

10-28-96

ACTION TAKEN

SIGNATURE

TITLE

DATE

4. Regarding your request to name an alternate RSO on the license, our past experience has demonstrated the need to have a single individual with overall responsibility for a radiation safety program. It is acceptable, however, to request that we name an alternate Radiation Safety officer on a license provided certain conditions are satisfied. The alternate must report to and be responsible to the RSO for any assigned RSO duties. You need to clearly state the duties, responsibilities and limitations placed on the alternate RSO and in what situations he will act for the RSO (i.e. will assume all duties of the RSO, only in the absence of the RSO, for short periods of time not exceeding 30 days, etc.).
5. Please respond in 15 days and reference Control No. 301772
6. Confirm that you will perform and maintain on file a survey/evaluation showing individual (s) are not likely to exceed 10% of annual dose limit if you choose not to provide Personnel monitoring badges.

# CIBA-CORNING

\* Ciba Corning Diagnostics Corp.  
132 Artino Street  
Oberlin, Ohio 44074-1293  
Telephone 216-774-1041

October 7, 1996

Materials Licensing Section  
Attn: Mr. Loren Heuter  
U.S. Nuclear Regulatory Commission  
Region III  
801 Warrenville Road  
Lisle, IL 60532-4351

Re: NRC License Application, Control No. 301772

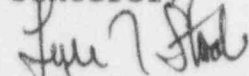
Dear Mr. Heuter:

This correspondence is to inform you the we will be changing our name effective November 1, 1996, from Ciba Corning Diagnostics Corp. to Chiron Diagnostics Corporation. At this location, there will be no changes in management or workers as a result of the name change. The license is to reflect the new name of the company, Chiron Diagnostics Corporation. Please note, until November 1st, the legal name of the company is Ciba Corning Diagnostics Corp.

Questions concerning this correspondence or the license application request should be directed to Susan J. Engelhardt (Engelhardt & Associates) at 1-(800)-525-3078 or Terry L. Ketchum at (216) 776-6462.

Your cooperation in the matter is greatly appreciated.

Sincerely,



Lyle T. Staab  
Executive Director,  
Manufacturing Operations

CC: Susan Engelhardt, Engelhardt & Associates

RECEIVED

OCT 15 1996

REGION III

pm, 10-8-96

OCT 15 1996



CIBA-CORNING

\* Ciba Corning Diagnostics Corp.  
132 Artino Street  
Oberlin, Ohio 44074-1293  
Telephone 216-774-1041

September 13, 1996

Materials Licensing Section  
U.S. Nuclear Regulatory Commission  
Region III  
801 Warrenville Road  
Lisle, IL 60532-4351

RE: Ciba Corning Diagnostics Corp. NRC License Application

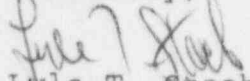
Dear Ms./Sir:

In support of Ciba Corning Diagnostics Corporation's application submittal of August 13, 1996, enclosed please find two training certificates. Radiation safety training (identified in Section 7 of our application) was completed on September 11th for Linda Harrison and Terry L. Ketchum.

Questions concerning this correspondence or the license application request should be directed to Susan J. Engelhardt (Engelhardt & Associates) at 1-(800)-525-3078 or Terry L. Ketchum at (216) 776-6462.

Your cooperation in the matter is greatly appreciated.

Sincerely,



Lyle T. Staab  
Executive Director,  
Manufacturing Operations

2 Enclosures

CC: Susan Engelhardt, Engelhardt & Associates

RECEIVED

SEP 23 1996

REGION III

301772

SEP 23 1996

Pm: 9-19-96

# *Certificate of Completion*

awarded to

*Linda Harrison*

for participation in a radiation safety training course

Given by Engelhardt & Associates, Inc.  
September 9-11, 1996  
New Orleans, LA

*Susan J. Engelhardt*  
Susan J. Engelhardt, M.S.

*Ralph Grunewald*  
Ralph Grunewald, Ph.D.

*Dee Kaiser*  
Dee Ann Kaiser, M.S.

*Judith Grunewald*  
Judith Grunewald, R.N., M.S.

# Certificate of Completion

awarded to

*Terry Ketchum*

for participation in a radiation safety training course

Given by Engelhardt & Associates, Inc.

September 9-11, 1996

New Orleans, LA

*Susan J. Engelhardt*  
Susan J. Engelhardt, M.S.

*Ralph Grunewald*  
Ralph Grunewald, Ph.D.

*Dee Kaiser*  
Dee Ann Kaiser, M.S.

*Judith Grunewald*  
Judith Grunewald, R.N., M.S.