

## MATERIALS LICENSE

Amendment No. 23

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.

OFFICIAL RECORD COPY

## Licensee

1. Chiron Diagnostics Corporation

2. 333 Coney Street

East Walpole, Massachusetts 02032

In accordance with the letter dated  
July 23, 1996,3. License Number 20-12960-02 is amended in  
its entirety to read as follows:

4. Expiration Date October 31, 2004

5. Docket or  
Reference No. 030-090016. Byproduct, Source, and/or  
Special Nuclear Material7. Chemical and/or Physical  
Form8. Maximum Amount that Licensee  
May Possess at Any One Time  
Under This License

A. Hydrogen 3

A. Any

A. 10 millicuries

B. Carbon 14

B. Any

B. 10 millicuries

C. Phosphorus 32

C. Any

C. 40 millicuries

D. Phosphorus 33

D. Any

D. 40 millicuries

E. Sulfur 35

E. Any

E. 20 millicuries

F. Iodine 125

F. Any

F. 9 curies

G. Iodine 129

G. Any

G. 1 microcurie

## 9. Authorized use

A. through E. Research and development as defined in 10 CFR 30.4.

F. Research and development as defined in 10 CFR 30.4; manufacture of radioimmunoassay kits. Packaging and distribution of manufactured radioimmunoassay kits to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or any Agreement State.

G. Calibration source.

## CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 333 Coney Street, East Walpole, Massachusetts.

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MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

20-12960-02

Docket or Reference Number

030-09001

Amendment No. 23

(Continued)

## CONDITIONS

11. A. Licensed material shall be used by, or under the supervision of, James Aswell, Lawrence Cappucci, Michael Dionne, Richard Martinelli, Uri Piran, William A. Sartorelli, Robert Thoms, and John Weare.
- B. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:
- | <u>Authorized Users</u> | <u>Material and Use</u>  |
|-------------------------|--|
| Ronald Cinelli          | Iodine 125 and Iodine 129  |
| Michael Macedo          | Iodine 125 and Iodine 129  |
| Joseph Fertitta         | Iodine 125 bound to nonvolatile compounds  |
| James Driscoll          | Iodine 125 bound to nonvolatile compounds  |
| Bertha Aseltine         | Iodine 125 in unopened prepackaged <u>in vitro</u> kits  |
| Patrick O'Leary         | Iodine 125 in unopened prepackaged <u>in vitro</u> kits  |
| John Monahan            | Hydrogen 3, Carbon 14, Phosphorus 32, Phosphorus 33, Sulfur 35, Iodine 125 in prepackaged <u>in vitro</u> kits, and Iodine 129 |
| Douglas Ludtke          | Hydrogen 3, Carbon 14, Phosphorus 32, Phosphorus 33, Sulfur 35, Iodine 125 in prepackaged <u>in vitro</u> kits, and Iodine 129 |
| David Sharpe            | Hydrogen 3, Carbon 14, Phosphorus 32, Phosphorus 33, Sulfur 35, Iodine 125 in prepackaged <u>in vitro</u> kits, and Iodine 129 |
- C. Prepackaged in vitro kits may be used by, or under the supervision of, individuals who have received the training described in letter dated March 21, 1994.
12. The Radiation Safety Officer for this license is Maureen T. Gillis.
13. Licensed material shall not be used in or on human beings.
14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

20-12960-02

Docket or Reference Number

030-09001

Amendment No. 23

(Continued)

## CONDITIONS

16. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days and Sulfur 35 for decay-in-storage before disposal in ordinary trash, provided:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
  - B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument 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.
  - C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
17. Radioactive waste generated shall be stored in accordance with the statements, representations, and procedures included with the waste storage plan described in the licensee's application dated March 21, 1994.
18. 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 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 March 21, 1994
  - B. Letter dated September 11, 1994
  - C. Letter dated September 22, 1994
  - D. Letter dated July 23, 1996

OCT 25 1996

Date \_\_\_\_\_

For the U.S. Nuclear Regulatory Commission

Original Signed By:

John R. McGrath

By \_\_\_\_\_

Nuclear Materials Safety Branch  
Region I

King of Prussia, Pennsylvania 19406

OCT 25 1996

Maureen T. Gillis  
Radiation Safety Officer  
Chiron Diagnostics Corporation  
333 Coney Street  
East Walpole, Massachusetts 02032-1597

Dear Ms. Gillis:

This refers to your license amendment request. Enclosed with this letter are the amended licenses. Please note that as part of these amendments, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration dates of your licenses have been extended by a period of five years. The new expiration date is stated in Item 4 of each license.

Please review the enclosed documents carefully and be sure that you understand and fully implement all the conditions incorporated into the amended licenses. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By:  
John R. McGrath

John R. McGrath  
Senior Health Physicist  
Division of Nuclear Materials Safety

License Nos. 20-12960-02  
                  20-12960-04G  
Docket Nos. 030-09001  
                  030-10907  
Control Nos. 123491  
                  123492

Enclosures:  
Amendment No. 23  
Amendment No. 07

DOCUMENT NAME: R:\WPS\MLTR\L2012960.02

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

|        |                    |     |         |     |     |     |     |
|--------|--------------------|-----|---------|-----|-----|-----|-----|
| OFFICE | DNMS/RI            | N   | DNMS/RI |     |     |     |     |
| NAME   | McGrath <i>JAM</i> |     |         |     |     |     |     |
| DATE   | 09/24/96           | 09/ | /96     | 09/ | /96 | 09/ | /96 |

OFFICIAL RECORD COPY

CIBA-CORNING

\* Ciba Corning Diagnostics Corp.  
333 Coney Street  
East Walpole, Massachusetts 02032-1597  
Telephone 508-668-5000  
Fax 508-668-4591

July 23, 1996

030-09001

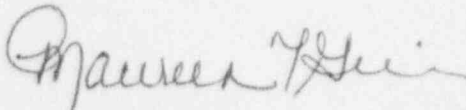
Licensing Assistant Section  
Nuclear Materials Safety Branch  
U. S. Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

To Whom It May Concern,

Please see the attached two amendment applications for NRC license numbers 20-12960-02 and 20-12960-04G. Enclosed is one check for the administrative fees.

Thank you.

Sincerely,



Maureen T. Gillis  
Radiation Safety Officer

OFFICIAL RECORD COPY

ML 10

123491

JUL 25 1996



## 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 (MNBB 7714), 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

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW  
MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, 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

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

RADIOACTIVE MATERIALS SAFETY BRANCH  
U.S. NUCLEAR REGULATORY COMMISSION, REGION V  
1450 MARIA LANE  
WALNUT CREEK, CA 94596-5368

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 20-12960-02  
☐ C. RENEWAL OF LICENSE NUMBER \_\_\_\_\_

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

Ciba Corning Diagnostics Corp.  
333 Coney Street  
East Walpole, MA 02032

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

Same as 2.

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

Maureen T. Gillis

TELEPHONE NUMBER  
508-660-4207

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<br>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)<br>FEE CATEGORY <u>3B</u> AMOUNT ENCLOSED \$ <u>580.00</u> |
| 13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.<br>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.<br>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

William A. Sartorelli, Exec. Dir. Operations

## SIGNATURE

William A. Sartorelli

## DATE

7/22/96

## FOR NRC USE ONLY

|             |         |              |                 |              |             |
|-------------|---------|--------------|-----------------|--------------|-------------|
| TYPE OF FEE | FEE LOG | FEE CATEGORY | AMOUNT RECEIVED | CHECK NUMBER | COMMENTS    |
|             |         |              | \$              |              | 123491      |
| APPROVED BY |         |              |                 | DATE         | JUL 25 1996 |

**Information Needed for Change of Ownership Application**  
**(Re: In 89-25, Rev. 1)**

The applicant should provide the following information concerning changes of ownership or control by the applicant (transferor and/or transferee, as appropriate):

1. The new name of the licensed organization. If there is no change the licensee should state so.

**Chiron Diagnostics Corporation - effective November 1, 1996.**

2. The new licensee contact and telephone number(s) to facilitate communications.

**The license contact will remain the same, i.e. Maureen T. Gillis, Radiation Safety Officer at (508) 660-4207.**

3. Any changes in personnel having control over licensed activities (i.e. officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.

**No changes in personnel having control over licensed activities will occur.**

4. An indication of whether the transferor will remain in non-licensed business without the license.

**Not applicable.**

5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and changes of ownership.

**Chiron Diagnostics Corporation is a wholly owned subsidiary of Chiron Corporation, 4560 Horton Street, Emeryville, CA 94608-2916.**

6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e. changes in operating or emergency procedures).

**No changes in organization, location, facility, equipment, or procedures are planned.**



7. A detailed description of any changes in the use, possession, location or storage of the licensed materials.

**No changes in the use, possession, location, or storage of licensed materials are planned. We will continue up to November 1, 1997 to use our current stock of labels and package inserts for our RIA products sold to specific licenses.**

8. Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without the change of ownership.

**We would like to request a change in our survey and inspection frequency for solidified and dry solid wastes in storage-for-decay. Rather than a biannual survey and quarterly inspection/inventory, we would like to conduct a biannual survey/inspection/inventory for these wastes.**

9. An indication of whether all surveillance items and records (i.e. calibrations, leak tests, surveys, inventories and accountability requirements) will be current at the time of transfer. A description of the status of all surveillance requirements and records should also be provided.

**All surveillance items required by the current license are up to date.**

10. Confirmation that all records concerning the safe and effective decommissioning of the facility, pursuant to 10 CFR 30.35(g), 40.36(f), 70.25(g), and 72.30(d), public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee, if licensed activities will continue at the same location, or to the NRC for license termination.

**All records concerning the public dose, waste disposal by release to sewers, incineration, radioactive materials spills will continue as currently performed (i.e. will be maintained by Chiron Diagnostics Corporation.)**

11. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?

**As the licensed use of radioactive material is still planned, decontamination will not occur. Chiron Diagnostics Corporation agrees to assume responsibility for decontamination at the facility.**

12. A description of decontamination plans, including financial assurance arrangements of the transferee, as specified in 10 CFR 30.35, 40.36 and 70.25. This should include information about how the transferee and transferor propose to divide the transferor's assets, and responsibility for any cleanup at the time of transfer.

**Given that our possession limits are less than the thresholds, decontamination plans are not required by regulation.**

13. Confirmation that the transferee agrees to abide by all commitments and representations previously made to NRC by the transferor. These include, but are not limited to: maintaining decommissioning records required by 20 CFR 30.35(g), implementing decontamination activities and decommissioning of the site, and completing corrective actions for open inspection items and enforcement actions.

**Chiron Diagnostics Corporation agrees to abide by all license conditions.**

With regard to contamination of facilities and equipment, the transferee should confirm in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to before change of control or ownership.

**See item 11.**

With regard to open inspection items, etc. the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions, or the transferee proposes alternative measures for meeting the requirements, or the transferor provided a commitment to close out all such actions with NRC before license transfer.

**There are no open inspection items.**

14. Documentation that the transferor and transferee agree to the change in ownership or control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.

**See item 13.**

15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its programs, to ensure compliance with the license and regulations.

**Chiron Diagnostics Corporation agrees to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license.**

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM  
AND  
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)  
INFORMATION FROM LTS

PROGRAM CODE: 03214  
STATUS CODE: 0  
FEE CATEGORY: 3B  
EXP. DATE: 20041031  
FEE COMMENTS: NOT BROAD  
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION *I*

1. APPLICATION ATTACHED  
APPLICANT/LICENSEE: CIBA CORNING DIAGNOSTICS CORP.  
RECEIVED DATE: 960725  
DOCKET NO: 3009001  
CONTROL NO.: 123491  
LICENSE NO.: 20-12960-02  
ACTION TYPE: AMENDMENT

2. FEE ATTACHED  
AMOUNT: \$ 890.00  
CHECK NO.: 60011668

3. COMMENTS

REF. 123492.

SIGNED  
DATE

*M. A. Perkins*  
7/25/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED ☒)

1. FEE CATEGORY AND AMOUNT: 3B \$ 580

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:  
AMENDMENT  
RENEWAL  
LICENSE

3. OTHER

SIGNED  
DATE

|                  |                                     |
|------------------|-------------------------------------|
| Log              | Aug 9                               |
| Remitter         |                                     |
| Check No.        | 60011668                            |
| Amount           | \$ 890 - \$ 580 - Remainder applied |
| Fee Category     | 3B to Control                       |
| Type of Fee      | AMC                                 |
| Date Check Rec'd | 8/4/96                              |
| Date Completed   |                                     |
| W                | DB                                  |

(A has rec'd  
123492)