

MATERIALS LICENSE

Amendment No. 06

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, 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.

<p>Licensee</p> <p>1. DIANON Systems, Inc.</p> <p>2. 200 Watson Boulevard Stratford, Connecticut 06497</p>		<p>In accordance with application dated January 9, 1992,</p> <p>3. License number 06-23655-01 is amended in its entirety to read as follows:</p>
		<p>4. Expiration date: November 30, 1997</p>
		<p>5. Docket or Reference No 030-29575</p>
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen 3 B. Iodine 125</p>	<p>7. Chemical and/or physical form</p> <p>A. Any B. Prelabelled radioimmunoassay kits, proteins, or organic compounds</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 10 millicuries B. 30 millicuries</p>
<p>9. Authorized use</p> <p>A. and B. For use in <u>in vitro</u> diagnostic testing.</p>		

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at 200 Watson Boulevard, Stratford, Connecticut.
11. A. Licensed material shall be used by, or under the supervision of, Phyllenore D. Howard, Ph.D.
B. The Radiation Safety Officer for this license is Phyllenore D. Howard, Ph.D.
12. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.
13. 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.
 - B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

06-23655-01

Docket or Reference number

030-29575

Amendment No. 06

(Continued)

CONDITIONS

14. 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. Letter dated April 25, 1989
- B. Application dated January 9, 1992

For the U.S. Nuclear Regulatory Commission

Original Signed By:

Kenn G. Brown, Ph.D

By

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

Date NOV 16 1992

NOV 16 1992

License No. 06-23655-01
Docket No. 030-29575
Control No. 115992

DIANON Systems, Inc.
ATTN: Phyllenore D. Howard, Ph.D.
200 Watson Boulevard
Stratford, Connecticut 06497

Dear Dr. Howard:

Please find enclosed the renewal of your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5093, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

DIANON Systems, Inc.

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We wish you success in operating a safe and effective licensed program.


Sincerely,

Original Signed By:
Keith D. Brown, Ph.D.

Keith D. Brown, Ph.D.
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

Enclosures:

1. Amendment No. 06
2. Requirements for Materials Licensees
3. NRC Forms 3 and 313
4. 10 CFR Parts 2, 19, 20, 30 and 170


DRSS:RI
Brown/cmm

11/13/92

FEB 3 1992

Docket No. 030-29575

License No. 06-23655-01

Control No. 115992

Dianon Systems, Incorporated
ATTN: Phyllenore D. Howard, Ph.D.
200 Watson Boulevard
Stratford, Connecticut 06497

Dear Dr. Howard:

SUBJECT: LICENSE RENEWAL APPLICATION

This is to acknowledge receipt of your application for renewal of material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified above.

Sincerely,

Original Signed By:
Sheryl Villar

Sheryl Villar, Chief
Licensing Assistant Section
Division of Radiation Safety
and Safeguards

mat
2/3/92 (5)
2/3/92

OFFICIAL RECORD COPY

ML 10

DIANON SYSTEMS INCORPORATED - 0001.0.0
01/15/92

30-29575

NRC FORM 313
(8-90)
10 CFR 72.33,
34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY DMB NO. 31600120
EXPIRES 6/30/93

APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST 325 HRS FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNB 7-14) U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT (3160 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.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR 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, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
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
NUCLEAR MATERIALS SAFETY SECTION
101 MARITTA STREET, SUITE 2000
ATLANTA, GA 30320

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
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94606

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):

☐ A. NEW LICENSE

☐ B. AMENDMENT TO LICENSE NUMBER _____

☒ C. RENEWAL OF LICENSE NUMBER 06-23655-01

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

DIANON Systems, Inc.
200 Watson Boulevard
Stratford, CT 06497

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

200 Watson Boulevard
Stratford, CT 06497

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Phyllenore D. Howard

TELEPHONE NUMBER

203-381-4023

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 AND 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

3P

AMOUNT

ENCLOSED \$ 500.00

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, 53, 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

Phyllenore D. Howard

Phyllenore D. Howard

Vice President,
Laboratory Operations

1/9/92

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

COMMENTS

Ren

Jan 14 I

3P

AMOUNT RECEIVED

CHECK NUMBER

\$500

7896

APPROVED BY

DATE

Rita Jacques

1/28/92

5. Radioactive Material
 - a. Hydrogen 3
Iodine 125
 - b. Covalently bound to proteins or steroids for use in radioimmunoassays.
 - c. 10 millicuries of tritium and 20 millicuries of I-125 is the maximum which will be possessed at any one time.
6. Isotopes are used for in vitro diagnostic tests.
7. Phyllenore D. Howard, Ph.D.
Laboratory Director
Twenty-five years of experience using radiolabelled proteins and steroids in radioimmunoassays for diagnostic purposes.
Ph.D. from Washington University, St. Louis.
Clinical laboratory experience at the University of Texas Medical School in San Antonio, The Reference Laboratory in Albuquerque, New Mexico (5 years), and six years in the present position.
8. All personnel who use the tracer materials are medical technicians, technologists, or clinical chemists and have received training in the use of radiolabelled products. A complete safety manual is maintained. New employees are given verbal and written instructions. TLD badges are used.
9. Radioactive material and kits are stored in appropriately labeled refrigerators. All testing is done in one location. Detection is by gamma counters (ICN/Micromedics model 10/600 Plus) and Beckman Scintillation Counter. Berthold LB1210B Geiger counter is used to monitor hands at the end of a work shift and to scan for contaminated work areas. This counter is calibrated annually by NDL, Inc.
10. The Radiation Safety Program consists of written instructions and verbal instructions of new personnel. TLD badges are used from Thermoanalytical, Inc./Eberline, Albuquerque, New Mexico. Badges are exchanged quarterly and records are kept on all employees using radioactive material. Latex gloves are used at all times. At the end of a work shift, employees monitor their hands after washing and record this activity. Wipe tests of all work areas are performed regularly. Millicurie amounts of radioactivity are not used by any employee and, thus there does not appear to be a need for bioassay.
11. Solid waste containing I-125 is held in a trailer at the rear of the laboratory for a minimum of 10 half-lives. Before disposal as normal waste, radioactive waste is surveyed to guarantee that its radioactivity cannot be distinguished from background. The material is crushed to consolidate for storage and all radiation labels are removed before final disposal. Records are kept of all containers as they are placed in storage and the date of disposal to a land fill.

Tritium solid waste and scintillation fluid is collected in drums and shipped by NDL, Inc., Peekskill, New York to their facility in New York or to Gainesville, Florida.

Water soluble liquid waste containing I-125 is flushed down the drain but no more than 1 curie is disposed of in one year by this means according to regulation. In fact, significantly less than this is disposed of in this manner.

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03620
STATUS CODE: 2
FEE CATEGORY: 3P
EXP. DATE: 19920229
FEE COMMENTS: -----
DECOM FIN ASSUR REQD: N

02410

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: DIANON SYSTEMS, INC.
RECEIVED DATE: 920113
DOCKET NO: 3029575
CONTROL NO.: 115992
LICENSE NO.: 06-23655-01
ACTION TYPE: RENEWAL

2. FEE ATTACHED

AMOUNT: \$500.00
CHECK NO.: 7896

3. COMMENTS

SIGNED M.A. Perkin
DATE 1/14/92

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1 1)

1. FEE CATEGORY AND AMOUNT: 3P \$500

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT -----
RENEWAL -----
LICENSE -----

3. OTHER -----

SIGNED Rita Jacque
DATE 1/18/92