

MATERIALS LICENSE

Amendment No. 10

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

| | |
|--|--|
| <p>Licensee</p> <p>1. DIANON Systems, Inc.</p> <p>2. 200 Watson Boulevard Stratford, Connecticut 06497</p> | <p>In accordance with the letter dated May 12, 1997,</p> <p>3. License Number 06-23655-01 is amended in its entirety to read as follows:</p> <p>4. Expiration Date November 30, 2002</p> <p>5. Docket or Reference No. 030-29575</p> |
|--|--|

| 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. Hydrogen 3 B. Phosphorus 32 C. Iodine 125 | A. Any B. Any C. Non-volatile compounds | A. 10 millicuries B. 200 millicuries C. 30 millicuries |

9. Authorized use

A. through C. In vitro clinical or laboratory testing; research and development as defined in 10 CFR 30.4.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 200 Watson Boulevard, Stratford, Connecticut.
11. A. Licensed material shall be used by, or under the supervision of the following individuals for the materials and uses indicated:

Authorized Users

Material and Use

Kim McGowan

Iodine 125



Melanie Michaels

Phosphorus 32

Valerie Palmieri

Hydrogen 3; Iodine 125

Ruth Kornreich, Ph.D.

Hydrogen 3; Phosphorus 32; Iodine 125

Mathews Plamkoodan

Iodine 125

B. The Radiation Safety Officer for this license is Ruth Kornreich, Ph.D.

12. Licensed material shall not be used in or on human beings.

9706240059 970609
PDR ADOCK 03029575
C PDR

ML 10

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

06-23655-01

Docket or Reference Number

030-29575

Amendment No. 10

13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
14. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days 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.
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."
16. 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
 - C. Letter dated November 23, 1992
 - D. Letter dated December 18, 1992
 - E. Letter dated January 13, 1993
 - F. Letter dated April 5, 1994
 - G. Letter dated June 27, 1994

JUN -9 1997

Date _____

For the U.S. Nuclear Regulatory Commission

ORIGINAL SIGNED BY:

JOHN D. KINNEMAN

By

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

JUN - 9 1997

Ruth Kornreich, Ph.D.
Director, Molecular Genetics
DIANON Systems, Inc.
200 Watson Boulevard
Stratford, CT 06497

Dear Dr. Kornreich:

This refers to your license amendment request dated May 12, 1997. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. 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 D. KINNEMAN**

John D. Kinneman, Chief
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

License No. 06-23655-01
Docket No. 030-29575
Control No. 124579

Enclosure:
Amendment No. 10

DOCUMENT NAME: R:\WPS\MLTR\LO623655.01

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 | <input checked="" type="checkbox"/> N | DNMS/RI | <input checked="" type="checkbox"/> E | | | |
| NAME | SLodhi | | Kinneman | | | | |
| DATE | 05/22/97 | | 05/22/97 | | 05/ /97 | | 05/ /97 |

OFFICIAL RECORD COPY ML 10

DIANON SYSTEMS

Diagnostic Innovations for Medicine

May 12, 1997

Thomas K. Thompson
Sr. Health Physicist
Region 1
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Request for amendment to license # 06-23655-01

Dear Mr. Thompson:

Pursuant to the General Policy and Procedures for NRC, Title 10 CFR, DIANON Systems, Inc. is requesting the following amendments to our license:

Section 11A. Authorized users:

Add: Ruth Kornreich, Ph.D. - Phosphorus 32, Iodine 125, Hydrogen 3

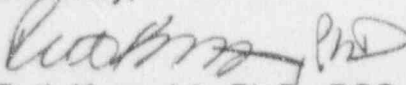
Remove: Steven P. Piccoli, he is no longer with the company.

Jodi F. Pliml, She is no longer with the company.

Section 11B. Radiation Safety Officer:

Remove: Steven P. Piccoli, Ph.D. and replace with Ruth Kornreich, Ph.D.

Sincerely,


Ruth Kornreich, Ph.D., RSO
Director, Molecular Genetics

enclosures

/RM

NRC license amendment may 1997.doc

SUPPLEMENT A

| SUPPLEMENT | | U.S. NUCLEAR REGULATORY COMMISSION | | |
|---|---|--|---|------------------------------|
| TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER | | | | |
| 1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER RUTH KORNREICH, PhD | | 2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED — | | |
| 3. CERTIFICATION | | | | |
| SPECIALTY BOARD A | CATEGORY B | MONTH AND YEAR CERTIFIED C | | |
| American Board of Medical Genetics | Clinical Molecular Genetics | Sept. 1993 | | |
| 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES | | | | |
| FIELD OF TRAINING A | LOCATION AND DATE(S) OF TRAINING B | TYPE AND LENGTH OF TRAINING | | |
| | | CLOCK HOURS IN LECTURE OR LABORATORY | CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE | |
| a. RADIATION PHYSICS AND INSTRUMENTATION | NYU Medical Br. 1981-1989 | ~2/yr | ~5/wk | |
| b. RADIATION PROTECTION | Mt Sinai School of Medicine 1985-1990 | ~2/yr | ~5/wk | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | MetPath Laboratories 1990-1994 | ~2/yr | ~2/wk | |
| d. RADIATION BIOLOGY | Dianon Systems 1995 - present | ~2/yr | ~2/wk | |
| e. RADIOPHARMACEUTICAL CHEMISTRY | Engelhardt & Associates Radiation Safety Training Course Jan 13-15, 1997 Las Vegas NV | 24 hr | — | |
| 5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience) | | | | |
| ISOTOPE | mCi USED AT ONE TIME | LOCATION | CLOCK HOURS | TYPE OF USE |
| 32P | 5-500 µCi | NYU, Mt. Sinai, MetPath, DIANON | 2-5/wk | Research, Diagnostics |
| 35S | 1-10 µCi | Mt. Sinai School of Medicine | ~5/wk | |

Certificate of Completion

awarded to

Ruth Kornreich

for participation in a radiation safety training course

Given by Engelhardt & Associates, Inc.

January 13-15, 1997

Las Vegas, NV

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.

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: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
: Program Code: 03620
: Status Code: 0
: Fee Category: 3P
: Exp. Date: 20021130
: Fee Comments: -----
: Decom Fin Assur Req'd: N
: .....

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License Fee Management Branch, ARM
and
Regional Licensing Sections

A. REGION

| | |
|---------------------|----------------------|
| Applicant/Licensee: | DIANON SYSTEMS, INC. |
| Received Date: | 970519 |
| Docket No: | 3029575 |
| Control No.: | 124579 |
| License No.: | 06-23655-01 |
| Action Type: | Amendment |

Amount: \$ 300.00
Check No.: 137509

Signed Drown, K. J.
Date 5/20/97

1. Fee Category and Amount: 3P \$300

Amendment
Renewal
License

Signed _____
Date 6/3/97

Log *May 17*
Remitter
Check No. *137509*
Amount *\$300*
Fee Category *3P*
Type of Fee *Amo*
Date Check Rec'd *5/28/97*
Date Complied *6/3/97*
By *SC*