

OFFICIAL RECORD COPY

MATERIALS LICENSE

Amendment No. 1

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.

Licensee

1. Princeton Diagnostics Isotopes, Inc.

2. 34 New Hope Road
Princeton, West Virginia 24740

In accordance with letter dated February 24, 1997

3. License Number 47-25322-01MD

is amended in its entirety to read as follows:

4. Expiration Date March 31, 2005 (extended)

5. Docket or
Reference No. 030-337586. 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. Molybdenum 99

A. Any molybdenum 99/
technetium 99m generator
manufactured, labeled,
packaged, and distributed in
accordance with a specific
license issued pursuant to
10 CFR 32.72 or a specific
license issued to the
manufacturer by an
Agreement State pursuant to
equivalent State regulations

A. 50 curies (1.85 TBq)

B. Any byproduct material
authorized under 10 CFR,
35.57(a).B. Any sealed source listed in
10 CFR 35.57(a) that has
been manufactured, labeled,
packaged, and distributed in
accordance with a specific
license issued pursuant to 10
CFR 32.74 or a specific
license issued to the
manufacturer by an
Agreement State pursuant to
equivalent State regulations

B. 50 millicuries total (1.85 GBq)

130091

9706190297 970513
PDR ADOCK 03033758
C PDR0/1
ML20

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- | | | |
|--|--|--|
| 6. Byproduct, source, or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
| C. Xenon 133 | C. Unit dose containers of gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by the FDA or an active (i.e., not withdrawn or terminated, or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA | C. 0.3 curies (11.1 GBq) |
| D. Iodine 131 | D. Capsule form listed in 10 CFR, Parts 35.100, 35.200, and 35.300. | D. 900 millicuries (33.3 GBq) |
| E. Technetium 99m | E. Any form listed in Parts 35.100 and 35.200 | E. 50 curies (1.85 TBq) |
| F. Any byproduct material, except technetium 99m or iodine 131, listed in 10 CFR 35.100. | F. Any form listed in 10 CFR 35.100. | F. 100 millicuries (3.7 GBq) total |
| G. Any byproduct material, except technetium 99m or iodine 131, listed in 10 CFR 35.200. | G. Any form listed in 10 CFR 35.200. | G. 500 millicuries (18.5 GBq) total |
| H. Any byproduct material, except iodine 131, listed in 10 CFR Part 35.300. | H. Any form listed in 10 CFR, 35.300. | H. 100 millicuries (3.7 GBq) total |

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6. Byproduct source, or special
nuclear material7. Chemical and /or physical
form8. Maximum amount that licensee may
possess at any one time under this
licenseI. Any byproduct material listed
in 10 CFR, Parts 35.400 and
35.500I. Any sealed source that has
been manufactured, labeled,
packaged, and distributed in
accordance with a specific
license issued pursuant to
10 CFR 32.74 or a specific
license issued to the manu-
facturer by an Agreement
State pursuant to equivalent
State regulationsI. 500 millicuries (18.5 GBq) total
under 10 CFR 35.400.4.5 curies (166.5 GBq) total, no
single source to exceed 1.5 curies
(174.8 GBq) under 10 CFR 35.500.J. Any byproduct material
identified in 10 CFR,
Part 31.11(a)J. Prepackaged in vitro diag-
nostic test kits

J. 50 millicuries (1.85 GBq) total

K. Uranium (depleted in the
isotope uranium 235)K. Metal enclosed in stainless
steel

K. 220 kilograms

9. Authorized Use:

- A. For production of technetium 99m pertechnetate. Redistribution of unused generators to authorized recipients in accordance with statements, representations and procedures in application dated December 27, 1994.
- B. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to 10 CFR, Part 32.74, the licensee is authorized to redistribute sources to persons licensed in accordance with 10 CFR 35.57, or equivalent Agreement State licenses.
- C. Distribution to authorized recipients.
- D. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients in capsule form only..
- E. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium 99m pertechnetate for processing with reagent kits in preparing radiopharmaceuticals.

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(continued)

F. through H. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

- I. Redistribution of sealed sources as received from the manufacturer in the manufacturer's original packaging and shielding and accompanied by the manufacturer's approved instructions to authorized recipients for use and storage.
- J. Redistribution to general and specific licensees in accordance with statements, representations and procedures in application dated December 27, 1994.
- K. Shielding for molybdenum 99/technetium 99m generators.

Pursuant to 10 CFR, Parts 32.72 and 32.74 of 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 A. through K. of this license to persons licensed in accordance with Sections 35.100, 35.200, 35.300, 35.400, and 35.500 of 10 CFR Part 35, or under equivalent Agreement State licenses.

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities located at 34 New Hope Road, Princeton, WV.
- 11. A. Licensed material shall be used by, or under the supervision of:
 - (1) a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 32.72(b)(2) and 32.72(b)(3) of 10 CFR Part 32, or
 - (2) authorized nuclear pharmacists David McLeland, R.Ph., Sydney Bauer, R.Ph., Cory Clifton, R.Ph., Byron Alfrey, R.Ph., Dan Adams, R.Ph., Gregory E. Green, R.Ph., or Jeffrey A. Clanton, R.Ph.
- B. The Radiation Safety Officer for this License is Jeffrey A. Clanton, R.Ph.
- 12. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed six (6) months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

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CONDITIONS

(continued)

12. D. Sealed sources need not be leak tested if:
- (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- E. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region II, ATTN: Chief, Licensing/Inspection Branch, 61 Forsyth Street, S.W., Suite 23T85, Atlanta, Georgia 30303-3415. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
12. F. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.
13. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.
14. The licensee shall conduct a physical inventory every six months to account for all sources and/or devices received and possessed under this license. Records of inventories shall be maintained for 5 years from the date of each inventory.
15. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."
16. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in December 27, 1994.

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CONDITIONS

(continued)

17. 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 ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate 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.
 - C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
18. Any proposed changes in packaging, labeling, shielding, or instructions for use and storage shall be submitted for review to the Chief, Licensing/Inspection Branch, U.S. Nuclear Regulatory Commission, Region II, 61 Forsyth Street, S.W., Suite 23T85, Atlanta, Georgia 30303-3415. Approval of the changes shall be received by the licensee prior to implementing the changes.
19. In addition to the possession limits in condition 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
20. The licensee shall maintain records of information related to decommissioning at the licensee's facilities located at 34 New Hope Road, Princeton, West Virginia as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.
21. 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 II, ATTN: Chief, Licensing/Inspection Branch, 61 Forsyth Street, S.W., Suite 23T85, Atlanta, Georgia 30303-3415, been notified that activities authorized by the license will be initiated.
22. Within 30 days of the date of a decision not to complete the facility, acquire equipment, or possess and use authorized materials, the licensee must notify the NRC, in writing, of that decision.

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CONDITIONS

(continued)

23. 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 December 27, 1994 [new license]

B. Letters dated:

- January 2, 1995 [I-131 capsules only]
- March 1, 1995 [facsimile forwarding copy of West Virginia Pharmacy License]
- March 21, 1995 [receipt of radioactive material]
- April 20, 1995 [add authorized user]
- March 5, 1996 [authorized user verification]
- April 2, 1996 [add authorized user]
- February 24, 1997 [change RSO, delete use Syncor sharps container]

C. NRC letter dated March 1, 1996 (extends expiration date in accordance with 10 CFR 30.36)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

HECTOR BERMUDEZ

Date MAY 13 1997

[Signature] 5/13/97

n:\mlicense\47-25322-A01

By

[Signature]

Region II, Division of Nuclear Materials Safety
61 Forsyth Street, S.W., Suite 23T85
Atlanta, Georgia 30303-3415



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION II
ATLANTA FEDERAL CENTER
61 FORSYTH STREET, SW, SUITE 23T85
ATLANTA, GEORGIA 30303

MAY 14 1997

INFORMATION FOR NRC MATERIAL LICENSEES

Please find enclosed:

- ☒ Your NRC material license
- ☒ Amendment to your NRC material license
- ☐ Amendment renewing your NRC material license
- ☐ Amendment terminating your NRC material license
- ☐ Notice for Radiographer Quality Assurance Approval Program

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify this office (ATTN: Ms. Diane Heim at (404) 562-4723) 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 19, "Notice, 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 II, ATTN: Materials Licensing/Inspection Branch, in writing, that activities authorized by the license will be initiated.
 - c. you have submitted and certified implementation of a Quality Management Program (10 CFR 35.32) for radiotherapy, or for administering > 30 uCi of I-125 or I-131.
3. Notify NRC, in writing, within 30 days:
 - a. when an authorized user, Radiation Safety Officer, or Teletherapy Physicist 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).
4. In accordance with 10 CFR 30.33(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. receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this part.
 - b. permit anyone, not authorized under 10 CFR 35, Subpart J, to work as an authorized user under a license for medical use of byproduct material.
 - c. permit anyone, not authorized under 10 CFR 35, Subpart J, to work as a Radiation Safety Officer, Teletherapy Physicist, or Nuclear Pharmacist, under a license for medical use of byproduct material.
 - d. order byproduct material in excess of the amount, or a different radionuclide or form, other than authorized on the license;
 - e. add or change the areas of use or address (or addresses) of use identified in the license application or on the license; or
 - f. 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. Transfer of licensed materials must be consistent with 10 CFR 30.41, 40.51 or 70.42, as applicable. 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 "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, (7/95). 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 against those who do not achieve the necessary attention to detail and standard of compliance expected of licensees.

Thank you for your cooperation.

Enclosures:

1. NRC License
2. Category Marked Below for:
 - ☐ New licenses: NUREG-1600 (7/95); 19; 20; 30; 40 or 70, as appropriate; 71; 170; NRC Form 3; Agreement State list; and NRC Form 313.
 - ☐ New radiography licenses: Parts 34; 150.
 - ☐ New medical and teletherapy licenses: Part 35.
 - ☐ Amendments and renewals: NRC Form 313.

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CONVERSATION RECORD

TIME

2:34 p

DATE

5/15/97

TYPE

☐ VISIT

☐ CONFERENCE

☒ TELEPHONE

ROUTING

NAME/SYMBOL INT

Location of Visit/Conference:

☐ INCOMING

☒ OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

ORGANIZATION (Office, dept., bureau, etc.)

TELEPHONE NO.

David Mc Leland RHP

Princeton Diag.

304-487-5600

SUBJECT

Deletion of reference TO 10CFR 32.73
from item T.A. of License

SUMMARY

Mr. Leland told me he
has no objection TO This
since 32.73 is no longer
in the regulations.

gfw

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

ACTION TAKEN

SIGNATURE

TITLE

DATE

Licensing Telephone Conversation Record

Page 2

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----

: Program Code: 02500
: Status Code: 0
: Fee Category: 3C 2B
: Exp. Date: 20050331
: Fee Comments: _____
: Decom Fin Assur Req'd: N
:

1997 MAR -3 AM 11:49

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED

Applicant/Licensee: PRINCETON DIAGNOSTIC ISOTOPES, INC.
Received Date: 970225
Docket No: 3033758
Control No.: 257403
License No.: 47-25322-01MD
Action Type: Amendment

2. FEE ATTACHED

Amount: 520.00
Check No.: 1303

3. COMMENTS

Signed DIANE HEIM
Date 2/26/97

8. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered ✓)

1. Fee Category and Amount: 3C 2B \$520

2. Correct Fee Paid. Application may be processed for:

Amendment ✓
Renewal _____
License _____

3. OTHER _____

Signed Rita Messier
Date 3/4/97

Log	<u>Mar 1 II</u>
Remitter	_____
Check No.	<u>1303</u>
Amount	<u>\$520</u>
Fee Category	<u>3C 2B</u>
Type of Fee	<u>Amend</u>
Date Check Rec'd.	<u>3/4/97</u>
Date Completed	<u>3/4/97</u>
By:	<u>Lee</u>



Princeton Diagnostic Isotopes, Inc.

USNRC
REGION II
101 Marietta Street N.W.
Atlanta, GA 30323-0199

RE: License #47-25322-01MD

To Whom It May Concern,

Please allow this amendment application to reflect the following changes:

1. Change the Radiation Safety Officer to Jeffrey A. Clanton, RPh. Please reference the license application letter dated April 20, 1995 for verification of Mr. Clanton's training and experience.

We confirm that the new Radiation Safety Officer will be available to oversee the Radiation Safety Program however, when the RSO is not on site, the Radiopharmacist on duty will monitor the program. Any and all emergencies will be immediately referred to the RSO by the Radiopharmacist on duty.

2. Please change the section of our current package return procedure labeled as Item 10.9 (A). We request to discontinue the use of the Syncor sharps container insert for retrieving radioactive waste which may be defined as medical waste. There will be no change in the type or amount of shielding used in the retrieval system.

Empty lead syringe shields will be monitored prior to reuse to assure that no contamination is present.

No other changes to our license are requested at this time.

Thank you for your attention to this matter.

Sincerely,

Pam Clanton, President

2-24-97

257403

NRC FORM 313
(6-83)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-86

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST, 8 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 (MNB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20545-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

APPLICATION FOR MATERIAL LICENSE

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 WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20545-001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MA., AND, 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
476 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1416

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 2000
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

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

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, IL 60532-4361

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
1460 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 47-25322-01MD
☐ C. RENEWAL OF LICENSE NUMBER _____

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

Princeton Diagnostic Isotopes, Inc.
34 New Hope Road
Princeton, NJ 08540

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

Same

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Sharon L. Long
National Physics Consultants

TELEPHONE # 330-866-7548

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2" X 11" PAPER. THE TYPE AND AMOUNT 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. INDIVIDUALS 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. LICENSE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY <u>3C</u> AMOUNT ENCLOSED \$ <u>520.00</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. 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 26, 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 - TYPE/PRINTED NAME AND TITLE

Pam Clanton, President

SIGNATURE

Pam Clanton

DATE

2-24-97

FOR NRC USE ONLY

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

257403



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

April 10, 1996

Princeton Diagnostic Isotopes, Inc.
ATTN: David L. McLeland
34 New Hope Road
Princeton, West Virginia 24740

SUBJECT: ACKNOWLEDGEMENT OF NOTIFICATION OF SELECTION OF AUTHORIZED USERS
UNDER 10 CFR 35.14

Gentlemen:

We have received your subject notification dated April 2, 1996 but will not amend your license at the present time. We will add (or delete) the Authorized Users designated in your letter during the next amendment or renewal of your license. You should retain copies of your Radiation Safety Committee records on this matter for review during our next inspection.

We appreciate your cooperation in this matter. If you have questions, please call me at (404) 331-4673. Our fax numbers are (404) 331-7437/4449. A copy of this letter and your letter will be placed in the Public Document Room in accordance with 10 CFR 2.790.

Sincerely,

Diane M. Heim
Licensing Assistant
Division of Nuclear Materials Safety



Princeton Diagnostic Isotopes, Inc.

April 2, 1996

United States Nuclear Regulatory Commission
Region II
101 Marietta Street, N.W., Suite 2900
Atlanta, GA 30323-0199
Attn: Jay Henson

Subject: Addition of an authorized User to License #47-25322-01MD

Dear Jay,

This letter is to inform you that Gregory E. Green has begun to work in a relief capacity as an authorized user. Enclosed is a letter from the Board of Pharmaceutical Specialties documenting his Board Certified status.

If you have any questions or need further assistance, please feel free to contact me at (304) 487-5600

Sincerely,

David L. McLeland
Princeton Diagnostic Isotopes

257030

bps Board of Pharmaceutical Specialties

March 5, 1996

Gregory E. Green, BCNP
c/o 34 New Hope Road #4
Princeton, WV 24740

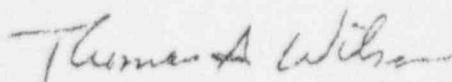
To Whom It May Concern:

This is to verify that Gregory E. Green (SSN 307 72 4264) is board certified in nuclear pharmacy by the Board of Pharmaceutical Specialties (BPS). Certification was granted in 1991 and is valid for seven (7) years.

The Board of Pharmaceutical Specialties is that agency within pharmacy through which specialty practice areas are formally recognized and specialists are certified. BPS was founded by American Pharmaceutical Association (APhA) on January 5, 1976. Nuclear Pharmacy was recognized as a specialty in 1978 and the certification process was initiated in 1982. Three other areas of specialized practice have been officially recognized by BPS: nutrition support pharmacy practice, pharmacotherapy, and psychiatric pharmacy practice. Currently, 1,649 pharmacists are certified by the Board.

If you have any questions, do not hesitate to contact the Board.

Sincerely,



Thomas A. Wilson
Certification Administrator

257030



Princeton Diagnostic Isotopes, Inc.

April 20, 1995

United States Nuclear Regulatory Commission
Region II
101 Marietta Street, N.W., Suite 2900
Atlanta, GA 30323-0199
Attn: Jay Henson

Subject: Addition of an Authorized User to License #47-25322-01MD

Dear Jay:

This letter is to notify you that I intend to allow Jeffrey A. Clanton, RPh to utilize radioactive materials under the above license number. Jeff currently is a Radiopharmacist for Vanderbilt University in Nashville, TN and is a Board Certified Nuclear Pharmacist. Current plans are for Jeff to provide weekend and emergency coverage as needed.

Enclosed is a copy of his Board Certification Certificate. If you require any additional documentation or need further information, please feel free to contact me at (304) 487-5600.

Sincerely,

David L. McLeland, RSO
Princeton Diagnostic Isotopes

bps

Certification in Nuclear Pharmacy

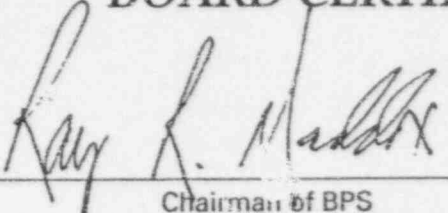
Board of Pharmaceutical Specialties

attests that

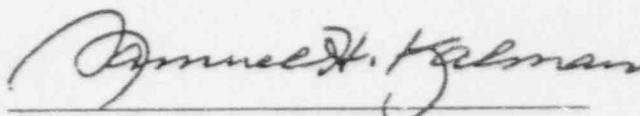
Jeffrey A. Clanton

having fulfilled all requirements for recertification, and having been recommended by
the Specialty Council on Nuclear Pharmacy, is reconfirmed as a

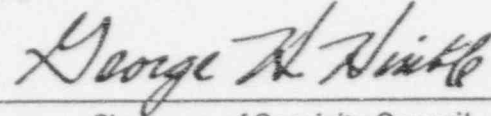
BOARD CERTIFIED NUCLEAR PHARMACIST



Chairman of BPS



Secretary of BPS



Chairman of Specialty Council

Date: July 1, 1991

BCNP# 82 128 41

First Certified: August 25, 1982

American Pharmaceutical Association