

MATERIALS LICENSE

Amendment No. 07

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, 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. Novo Laboratories, Inc.

2. 33 Turner Road
Danbury, Connecticut 06810In accordance with letter dated
March 22, 1989,3. License number 06-17718-01 is amended in
its entirety to read as follows:

4. Expiration date December 31, 1992

5. Docket or
Reference No. 030-132166. Byproduct, source, and/or
special nuclear material7. Chemical and/or physical
form8. Maximum amount that licensee
may possess at any one time
under this licenseA. Hydrogen 3
B. Carbon 14
C. Iodine 125
D. Iodine 125A. Any
B. Any
C. Any
D. Prepackaged Test Kits.A. 10 millicuries
B. 20 millicuries
C. 1 millicurie
D. 12 millicuries

9. Authorized use

A. through C. Research and development as defined in Section 30.4(q) of 10 CFR Part 30.
D. For the receipt, possession, storage and processing in vitro radioimmunoassay test kits for distribution to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State.★ ★ ★ ★ ★
CONDITIONS

10. Licensed material shall be used only at 33 Turner Road, Danbury, Connecticut.

11. A. Licensed material shall be used by, or under the supervision of,
Carol M. Beck, Ph.D., Robert J. Malley, Robert L. Starnes, Ph.D. or Rose Lance.

B. The Radiation Safety Officer for this license is Gregory B. Bidou.

OFFICIAL RECORD COPY ML 10

9003120634 890516
REG1 LIC30
MATLSLICENSING PDR11
9/4

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

06-17718-01

Docket or Reference number

030-13216

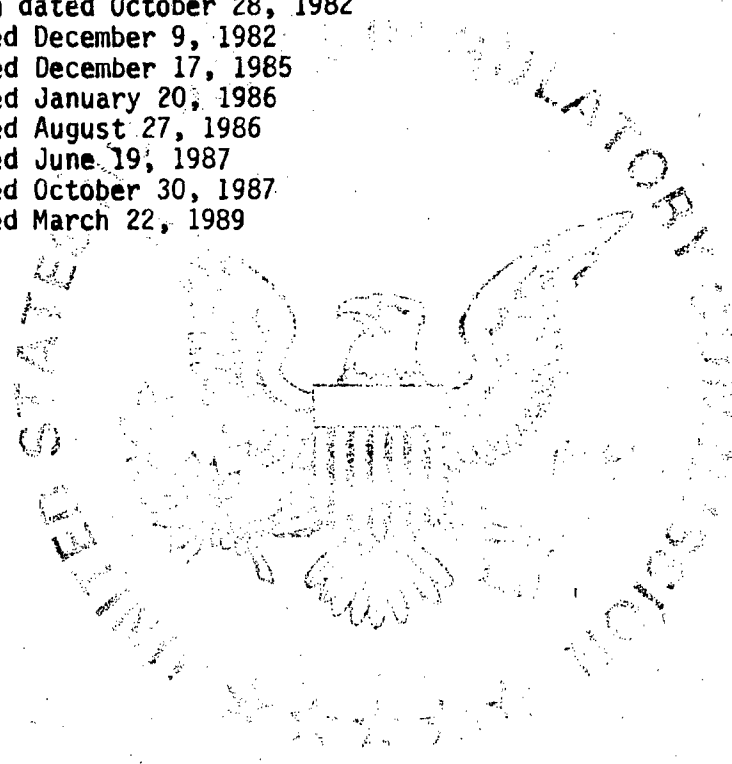
Amendment No. 07

(Continued)

CONDITIONS

12. 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 October 28, 1982
- B. Letter dated December 9, 1982
- C. Letter dated December 17, 1985
- D. Letter dated January 20, 1986
- E. Letter dated August 27, 1986
- F. Letter dated June 19, 1987
- G. Letter dated October 30, 1987
- H. Letter dated March 22, 1989



Date MAY 16 1989

For the U.S. Nuclear Regulatory Commission

Original Signed By:

By Thomas K. Thompson

Nuclear Materials Safety Branch

Region I

King of Prussia, Pennsylvania 19406

MAY 16 1989

License No. 06-17718-01
Docket No. 030-13216
Control No. 110509

Novo Laboratories, Incorporated
ATTN: Gregory B. Bidou, C.I.H.
Industrial Hygienist
33 Turner Road
Danbury, Connecticut 06810

Gentlemen:

Please find enclosed an amendment to 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) 337-5239, 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.

Novo Laboratories, Incorporated

2

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

Sincerely,

Original Signed By:
Thomas K. Thompson

Thomas K. Thompson, Health Physicist
Nuclear Materials Safety Section C
Division of Radiation Safety
and Safeguards

Enclosures:

1. Amendment No. 07
2. Requirements for Materials Licensees

DRSS:RI
Thompson/tlm

4/ /89

OFFICIAL RECORD COPY

ML 06-17718-01/LTR - 0002.0.0
04/17/89

APR 12 '89 16:28

P01

APR.12 '89 16:26 NOVO LABORATORIES, INC., USA

P.01

030-13216

06-17718-01

April 11, 1989

Mr. Thomas Thompson
United States Nuclear Regulatory Commission
Mail Control 110509
King of Prussia, PA

FAX: 215-337-5269

NOVO

Novo Laboratories, I

33 Turner Road
Danbury, CT
06810-5101
Tel. 203-790-2600
Fax. 203-790-2748

Dear Mr. Thompson:

Be advised that following our telephone conversation I contacted Rose Lance and inquired as to the specifics of her radioisotope safety training and handling experience. She related the following information to me regarding her past experience and safety training:

1981-1982 Southern Illinois University
H³ - Laboratory Technologist. Completed
University Radiation Safety Course (1981).



1983 Thomas Jefferson Medical Center
I¹³¹, I¹²⁵ Laboratory Technologist. Completed
Center's Radiation Safety Course (1983).

1984 Cooper Biomedical- Laboratory Technologist
radiolabeled DNA projects involving P³².

1985-1988 Boehrienger Mannheim- Laboratory Technologist
radiolabeled DNA projects involving P³².

Ms. Lance has joined our operation in the capacity of a Field Technical Sales Representative, which will require her to work with our prepackaged diagnostic kits containing I¹²⁵ radiolabeled material.

Although it is not expected that she will be called upon to actually manipulate radiolabeled material other than in the form of packaged kits, she will from time to time be required to re-box and/or display product for customers. We request that she be added to our license.

OFFICIAL RECORD COPY

ML 10

ADD 1 0 1000

110509

APR 12 '89 16:29

P02

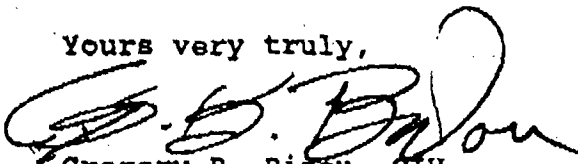
APR.12 '89 16:27 NOVO LABORATORIES, INC., USA

P.02

I do hope this short description will suffice and permit you to complete the processing of our amendment application. If you have any further requests, please call my Danbury office.

Best regards.

Yours very truly,

A handwritten signature in dark ink, appearing to read "G.B. Bidou", is written over the typed name.

Gregory B. Bidou, CIH
Industrial Hygienist
Dept. of Regulatory Affairs

GBB:jp

DATE

4/11/89

TELEPHONE OR VERBAL CONVERSATION RECORD

TIME

1550

☐ A.M.
☐ P.M.

☐ INCOMING CALL

☒ OUTGOING CALL

☐ VISIT

PERSON CALLING

TK Thompson

OFFICE/ADDRESS

RI

PHONE NUMBER

EXTENSION

5303

PERSON CALLED

Gregory B. Bidou

OFFICE/ADDRESS

Novo Laboratories, Inc

PHONE NUMBER

EXTENSION

(203) 790 2767

CONVERSATION

SUBJECT

Please indicate specific training with byproduct material ~~for~~ for Ms. Lance

SUMMARY

Mr. Bidou indicate he would send us specific training.

REFERRED TO:

ACTION REQUESTED

Letter to NRC

ACTION TAKEN

☐ ADVISE ME OF ACTION TAKEN.

INITIALS

TKT

DATE

4/14

INITIALS

DATE

ML 10

OFFICIAL RECORD COPY

030-13216

March 22, 1989

John E. Glenn, Ph.D.
Nuclear Regulatory Commission
Chief, Nuclear Materials Safety Section
Division of Radiation Safety and Safeguards
475 Allendale Rd.
King of Prussia, PA 19406

Log	Cape P
Remitter	
Check No.	007376
Amount	\$120
Fee Category	38
Type of Fee	AMD
Date Check Rec'd.	4/21/89
Date Completed	
By	[Signature]

NOVO

Novo Laboratories, Inc.

33 Turner Road
Danbury, CT
06810-5101
Tel. 203-790-2600
Fax. 203-790-2748

Dear Dr. Glenn:

As advised by a member of your staff during a recent telephone conversation (3/21/89) Novo Laboratories, Inc. 33 Turner Rd., Danbury, CT 06810 (NRC License #06-17718-01) requests by way of this letter the following amendment to our current license to reflect anticipated changes in our operations.

Novo requests that Rose Lance be added to the list of persons identified in the conditions section (Item 11) of our license.



We also request that the amount of prepackaged In Vitro I^{125} radiolabeled biochemicals (Section 6, Item D) allowed to be received, possessed, stored, and/or processed and distributed to persons authorized to receive the licensed material pursuant to the terms and conditions stipulated by the Nuclear Regulatory Commission or agreement state be increased to 12 millicurie.

We request these amendments because of an addition to our staff and a recent business acquisition.

Novo's recent acquisition will potentially result in an expansion of our I^{125} labeled RIA Test Kit product line. Pending approval by the appropriate federal agencies Novo intends to market I^{125} labeled RIA Test Kits for In Vitro human diagnostic purposes as well our existing R&D only RIA Kits. In advance of that time, we seek amendment to our license to address our projected on-site product storage needs.

We have attached the following:

- a) A check in the amount of \$120.00 for amendment fees.
- b) Curriculum Vitae (Rose Lance)
- c) Copy of NRC License #06-1771801

110509

OFFICIAL RECORD COPY ML 10

APR 03 1989

RECEIVED-REGION 1
APR 3 1989
APR 10 1989
P3:44
P3:42

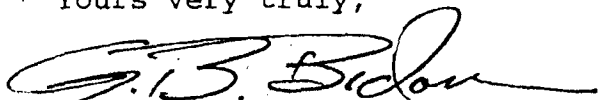
In as much as these products represent important technologies for medical diagnosis in the United States, we would greatly appreciate your efforts to expedite our amendment request.

NOVO

If you require any additional information please call my Danbury office at (203) 2767.

Thank you.

Yours very truly,



Gregory B. Bidou, CIH
Industrial Hygienist
Dept. of Regulatory Affairs

GBB:jp
attachments



ROSE A. LANCE

(b)(6)

PROFESSIONAL EXPERIENCE

BOEHRINGER MANNHEIM CORP.
Indianapolis, IN

9/85-present

BIOCHEMICAL SPECIALIST: Responsible for sales of Biochemical Division Products in territory consisting of New York City, Long Island, NY, Connecticut and Rhode Island. Product line spans Molecular Biology, Immunology, Biochemistry. Sales in 1986 increased 50% over 1985. AWARDS: Winner's Club for 1986 - Second Highest Sales in Division. Key Account Program. - Increased sales in Key Accounts by 53% for 1986 with goal being 30%.

COOPERBIOMEDICAL, INC.
Malvern, PA

8/83-9/85

TECHNICAL REPRESENTATIVE: Responsible for marketing and technical support for Scientific Division. Report to Vice President of Marketing on current pricing and product specifications on each product line as they are introduced. Advise of current research on products which should be introduced to current line. Implemented customer feedback system which has proven to be successful in improving product lines and increasing assistance. Responsible for custom and OEM sales to research institutions. Prepare technical newsletter which reaches entire customer base. Organize presentations and booths at major conventions and meetings.

THOMAS JEFFERSON SCHOOL OF MEDICINE
Philadelphia, PA

10/82-8/83

RESEARCH TECHNOLOGIST: Project Title: Characterization of Fibrinogen. Responsible for management and ordering of equipment and supplies and documentation of research data.

SOUTHERN ILLINOIS UNIVERSITY
Springfield, IL

6/81-6/82

RESEARCH TECHNOLOGIST: Project Titles: (I) Characterization of Immune Response to Ribosomal Vaccines from H. influenza type b. (II) Rifampin and Penicillin for Prevention of Rheumatic Fever. (III) Immunity to Experimental Histoplasmosis. Responsible for planning and performing experiments relating to projects, maintaining research data, instruction of high school students in summer research.

EDUCATION

Southern Illinois University
Carbondale, IL

Bachelor of Arts, Microbiology:

(b)(6)

Moraine Valley Community College
Palos Hills, IL

Associate in Applied Science, Medical Technology

(b)(6)

PROFESSIONAL AFFILIATIONS

American Society of Clinical Pathologists MLT (014411)
American Society for Microbiology

References furnished upon request.

MATERIALS LICENSE

Amendment No. 06

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Licensee

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Danbury, Connecticut 06810In accordance with letter dated
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Reference No. 4030-132166. 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
B. Carbon 14
C. Iodine 125
D. Iodine 125

- A. Any
B. Any
C. Any
D. Prepackaged Test Kits.

- A. 10 millicuries
B. 20 millicuries
C. 1 millicurie
D. 6 millicuries

9. Authorized use

- A. through C. Research and development as defined in Section 30.4(q) of 10 CFR Part 30.
D. For the receipt, possession, storage and processing in vitro radioimmunoassay test kits for distribution to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State.

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

06-17718-01

Docket or Reference number

030-13216

Amendment No. 06

(Continued)

CONDITIONS

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- C. Letter dated December 17, 1985
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- E. Letter dated August 27, 1986
- F. Letter dated June 19, 1987
- G. Letter dated October 30, 1987

110509

APR 03 1989

For the U.S. Nuclear Regulatory Commission

Original Signed By
John E. Glenn

Date

02 FEB 1988

By

Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406

OFFICIAL RECORD COPY ML 10

MS-10
89-04-05

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

: PROGRAM CODE: 03520
: STATUS CODE: 0
: FEE CATEGORY: 38
: EXP. DATE: 19921231
: FEE COMMENTS: EFF. 2/5/86
:

LICENSE FEE TRANSMITTAL

A. REGION T

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: NOVO LABS., INC.
RECEIVED DATE: 890403
DOCKET NO: 3013215
CONTROL NO.: 110509
LICENSE NO.: 06-17718-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: \$120.00
CHECK NO.: 009376

3. COMMENTS

SIGNED
DATE

R. L. Brown
89-04-05

5. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1-T)

1. FEE CATEGORY AND AMOUNT: 3B \$120

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

3. OTHER

SIGNED
DATE

A. Kimberly
4/21/89