NOVO LABORATORIES
INCORPORATED

59 DANBURY ROAD WILTON, Connecticut 06897 (203) 762-2401

L+W 17718

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

89495

C/1

Form AEC-313
(2-73)
10 CFR 30

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

Form approved
Budget Bureau No. 38-R0027

INSTRUCTIONS.—Complete Items 1 through 16 if this is an initial application or an application for renewal of a license. Information contained in previous applications filed with the Commission with respect to Items 8 through 15 may be incorporated by reference provided *references are clear and specific.* Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail two copies to: U.S. Atomic Energy Commission, Washington, D.C., 20545, Attention: Materials Branch, Directorate of Licensing. Upon approval of this application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Part 20, and the license fee provisions of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 16 and the appropriate fee enclosed. (See Note in Instruction Sheet).

1. (a) NAME AND STREET ADDRESS OF APPLICANT. *(Institution, firm, hospital person, etc. Include ZIP Code and telephone number.)*

Novo Laboratories, Inc.
59 Danbury Road
Wilton, Connecticut 06897

(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. *(If different from 1(a). Include ZIP Code.)*

Same

W+W 17718
030-13216
03620

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

Research Laboratory

3. PREVIOUS LICENSE NUMBER(S). *(If this is an application for renewal of a license, please indicate and give number.)*

None

4. INDIVIDUAL USER(S). *(Name and title of individual(s) who will use or directly supervise use of byproduct material. Give training and experience in Items 8 and 9.)*

Dr. M. K. Weibel
Director of Research & Development
Dr. D. Porter
Senior Research Scientist

5. RADIATION PROTECTION OFFICER. *(Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Items 8 and 9.)*

1. M. K. Weibel, D. Porter
2. G. R. Holeman, Certified Health Physicist (resume attached)

6. (a) BYPRODUCT MATERIAL. *(Elements and mass number of each.)*

H^3 C^{14} I^{125}

(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR PHYSICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME. *(If sealed source(s), also state name of manufacturer, model number, number of sources and maximum activity per source.)*

Any form - principally labeled biological materials

H^3 - 50 millicuries

C^{14} - 20 millicuries

I^{125} - 1 millicurie

Applicant.....
Check No. 2530 / 2686
Amount $125.00 (BK)
Date of Check 8-16-77 / 8-25-77
Date Check Rec'd 8-16-77 / 8-29-77
Received By AMJS

7. DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. *(If byproduct material is for "human use," supplement A (Form AEC-313a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source will be stored and/or used.)*

Research & Development: Immunoassay - proteins/enzymes
metabolic tracer - microbial

89495

(Continued on reverse side)

Aug 77 A-14

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 *(Use supplemental sheets if necessary)*

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection			Yes No	Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments	SEE ATTACHED SHEET		Yes No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity			Yes No	Yes No
d. Biological effects of radiation			Yes No	Yes No

9. EXPERIENCE WITH RADIATION. *(Actual use of radioisotopes or equivalent experience.)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
C^{14}	5 mC	Purdue University	4 years	research
H^{3}	5 mC	University of Pennsylvania	8 years	research
I^{125}	-	advice to be obtained from	consultant	-

10. RADIATION DETECTION INSTRUMENTS. *(Use supplemental sheets if necessary.)*

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm²)	USE (Monitoring, surveying, measuring)
liquid scintillation counter	1	B & Y	up to 900,000 cpm	-	sample analysis and monitoring

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE.

Commercially available standards; instrument to be calibrated routinely

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED. *(For film badges, specify method of calibrating and processing, or name of supplier.)*

None necessary - only u curie amounts of I^{125}, H^{3} and C^{14} to be handled

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS IN DUPLICATE

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached. (Circle answer) Yes (No) SEE ATTACHED DESCRIPTION

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.

SEE ATTACHED INFORMATION

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved. SEE ATTACHED INFORMATION

CERTIFICATE (This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1; CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

U.S. ATOMIC ENERGY COMMISSION
REGULATORY
MAIL SECTION

License Fee Category $ 3-K $225

Fee Enclosed $ 225

'77 AUG 30 PM 4 23

Novo Laboratories, Inc.
Applicant named in item 1

By: M. K. Weibel, Ph.D.

Director of Research & Development
Title of certifying official

Date August 1, 1977

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.

☆ U.S. GPO: 1973—543-126/515

Supplemental Sheet 10 CRF 30

Part 8 Training of I. . .dual Users

Page Two

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 *(Use supplemental sheets if necessary)*

8. TYPE OF TRAINING — M. K. Weibel	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	Purdue University University of Pennsylvania	12 yr.	(Yes) No	(Yes) No
b. Radioactivity measurement standardization and monitoring techniques and instruments	Purdue University University of Pennsylvania	12 yr.	(Yes) No	(Yes) No
c. Mathematics and calculations basic to the use and measurement of radioactivity	Purdue University University of Pennsylvania	12 yr.	(Yes) No	(Yes) No
d. Biological effects of radiation	Purdue University University of Pennsylvania	12	(Yes) No	(Yes) No

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TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 *(Use supplemental sheets if necessary)*

8. TYPE OF TRAINING — D. Porter	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	University of Pennsylvania	7 yr.	(Yes) No	(Yes) No
b. Radioactivity measurement standardization and monitoring techniques and instruments	University of Pennsylvania	7 yr.	(Yes) No	(Yes) No
c. Mathematics and calculations basic to the use and measurement of radioactivity	University of Pennsylvania	7 yr.	(Yes) No	(Yes) No
d. Biological effects of radiation	University of Pennsylvania	7 yr.	(Yes) No	(Yes) No

Supplemental Sheet 10 CRF 30

Part 13. Facilities & Equipment

The research laboratory facility consists of 15,000 sq. ft. It is equipped with modular two-man bays. Common work and equipment areas include 120 running feet of centrally located and completely serviced benches, 200 sq. ft. reagents preparation area, 12 linear ft. of high vent velocity enclosed hoods, separate flammable solvents area, 400 sq. ft. cold room and separate enclosed rooms for specialized work such as microbiology, light sensitive materials, etc.

The work area to be designated for handling of radioisotopes will include a 4 linear ft. high vent velocity enclosed stainless steel hood with adjacent 6 linear ft. completely serviced bench area including an inset 12 x 18 x 24" sink. Three cubic ft. of freezer space compartmentalized via sealed containers will be devoted solely to radioisotope sample storage. A segregated area including bench space is to be reserved in the cold room for radioisotope sample storage and low temperature work.

The entire laboratory area is protected by a class AAA ceiling mounted fire extinguisher system. All laboratory functions and facilities are in compliance with OSHA regulations and are inspected annually by an outside consultant.

Supplemental Sheet

Part 14. Radiation Protection Program

1. All protocols involving radioactive material will be reviewed and approved by the Radiation Safety Officer, (RSO).

2. All purchase orders for radioisotopes will be approved by the RSO.

3. Radioactive shipments will be monitored upon receipt to verify contents and to determine leaking or damaged shipments.

4. All users to handle radioactive samples will attend a seminar in which the training material required in 10CFR Part 19 will be presented.

5. Radioactive waste must be stored only in the designated area. Radioactive material may only be used in the designated areas.

6. Inventory records including a disposal log will be maintained.

7. Monitoring of experiments will be accomplished by smear techniques and the liquid scintillation counter. The consultant will perform quarterly surveys of work areas and reports will be maintained on file by the RSO.

8. In case of a spill or emergency involving radioactive material contact the RSO for advice immediately.

9. The Laboratory Safety Rules will include:

   a. Exposure to radioactive material shall be kept to a minimum consistent with the protocol.

   b. Contamination control techniques shall be practiced by all using radioisotopes.

   c. No eating, drinking or smoking is permitted in areas where radioactive material is used or stored.

   d. Mouth pipetting of radioactive material is not permitted.

   e. Gloves and lab coats shall be worn when using radioactive materials.

   f. Iodine waste shall be stored only in closed containers.

   g. Reference: 10CFR Part 20.

Supplemental Sheet 10 CRF 30

Part 15. Waste Disposal

A licensed commercial vendor is to be used for disposal of solid wastes. Liquid wastes will be diluted for sewer disposal in compliance with 10 CRF part 20. No use of radioisotopically labeled volatile materials such as solvents is contemplated.

SCIENCE CONSULTING SERVICES, INC. P.O. BOX 187 GUILFORD, CONN. 06437

AUG 1 1977

July 29, 1977

Dr. Michael K. Weibel
NOVO Laboratories, Incorporated
59 Danbury Road
Wilton, Connecticut 06897

Dear Dr. Weibel:

The local representatives of instrument manufacturers are:

Jose De Vallet
Sales Engineer
Packard Instrument Company, Inc.
85 Church Street
New Haven, Connecticut 06510 203/389-4234

Robert Mancini
Beckman Instruments, Inc.
32 Elm Street
New Haven, Connecticut 06510 203/787-3000

Thomas P. Cain
Searle Analytic
The Exchange Executive-Suite F
270 Farmington Avenue
Farmington, Connecticut 06032 203/677-8022

The suggested waste disposal vendor is:

Keith Foley
Radiac Research Corporation
261 Kent Avenue
Brooklyn, New York 11211 212/963-2233

Enclosed please find a copy of my Curriculum Vitae for including in your application.

Very truly yours,

George R. Holeman
Certified Health Physicist

GRH/jb
Enclosure

83495

GEORGE R. HOLEMAN

Business Address:
Yale University
Health Physics Division
314 Wright Nuclear Structure
Laboratory, West
260 Whitney Avenue
New Haven, Connecticut 06520

Home Address:
(b)(6)

EXPERIENCE - EDUCATIONAL

Degree/Year	Institution	Field of Study
B.A. (b)(6)	Centre College of Kentucky Danville, Kentucky	Physics/Math
A.M. - 1961	Harvard University Cambridge, Massachusetts	Engineering/Health Physics

EXPERIENCE - PROFESSIONAL

Organization	Years	Position
Harvard University Cambridge, Massachusetts	1960 - 1961	AEC Health Physics Fellow
Brookhaven National Laboratory Upton, Long Island, New York	1961	AEC Health Physics Fellow
General Electric Company Knolls Atomic Power Laboratory Schenectady, New York	1961 - 1963	Health Physicist
Yale University Department of University Health New Haven, Connecticut	1963 - 1971	Health Physicist (Responsible for Yale University Radiation Protection Program).
Yale University Department of Epidemiology and Public Health New Haven, Connecticut	1963 - Present	Lecturer in Public Health (Environmental Health).
Yale University Department of Epidemiology and Public Health New Haven, Connecticut	1964 - 1970	Co-Director - Graduate Radiological Health Training Project
The Travelers Research Corp. Hartford, Connecticut	1969 - 1970	Consultant
University of Connecticut Health Center Farmington, Connecticut	1969 - 1975	Consultant and Radiation Safety Officer. (Established Radiation Safety Program for new Medical Center).

William W. Backus Hospital Radiology Department Norwich, Connecticut	1971 - Present	Consultant, Radiation Physicist and Radiation Safety Officer
Yale University University Health Services New Haven, Connecticut	1971 - Present	Director, Health Physics Division
Windham Memorial Community Hospital Willimantic, Connecticut	1973 - Present	Consultant, Radiation Physicist and Radiation Safety Officer
Meriden-Wallingford Hospital Meriden, Connecticut	1973 - Present	Consultant, Radiation Physicist and Radiation Safety Officer
University of Connecticut	1974 - 1975	Consultant and Radiation Safety Officer (Established Centralized Radiation Safety Program for Broad Research Program).
Cancer Center Yale University New Haven, Connecticut	1974 - Present	Program Director Radioisotope Facility
Olin Research Corporation New Haven, Connecticut	1975 - Present	Consultant
United States Department of Agriculture, Forest Insect and Disease Laboratory Hamden, Connecticut	1975 - Present	Consultant
United States Veterans Administration Hospital West Haven, Connecticut	1976 - Present	Consultant

SOCIETIES

Member, Health Physics Society, New England Chapter, Greater New York Chapter, and Connecticut Chapter.
President, Connecticut Chapter of the Health Physics Society, (1967-68).
President-Elect, Connecticut Chapter of the Health Physics Society, (1975-76).
President, Connecticut Chapter of the Health Physics Society, (1975-76).
Fellow, American Public Health Association.
Member, American Nuclear Society and Connecticut Chapter.
Member, American Association of Physicists in Medicine.

COMMITTEES

Yale University:
Secretary, Yale University Radiation Safety Committee, (1963 - Present).
Member, Admissions and Degrees Committee, Yale School of Medicine, Department of Epidemiology and Public Health, (1965 - 1967).
Member, Safety Committee, Department of Physics, (1966 - Present).
Member, University Safety Policy Committee, (1968 - Present).

American Public Health Association:
Member, Committee on Status of Radiation Protection Personnel, (Chairman - University Sub-Committee), (1968 - 70).
Chairman, Radiological Health Section Nominating Committee, (1969 - 70).

Health Physics Society:
Member, Education and Training Committee, (1968 - 71).
Chairman, Education and Training Committee, (1970 - 71).
Consultant, Education and Training Committee, (1971 - 72).
Member, Membership Committee, (1974 - 1977).

American Nuclear Society:
Member, Executive Council, Connecticut Chapter, (1975 - 1977).

United States Atomic Energy Commission:
Member, USAEC Advisory Panel on Accelerator Radiation Safety, (1969 - 72).

Radiation Safety Committees:
Member, University of Connecticut Health Center, Farmington, Connecticut, (1969 - 75).
Member, University of Connecticut, Storrs, Connecticut, (1974 - 75).
Member, William W. Backus Hospital, Norwich, Connecticut,(1971 - Present).
Member, Meriden-Wallingford Hospital, Meriden, Connecticut, 1973 - Present).
Member, Yale-New Haven Hospital, New Haven, Connecticut, (1975 - Present).

PUBLICATIONS

G. R. Holeman, USAEC Report KAPL-Int-230, "Practical Radiation Protection Course", April, 1963.

J. C. Overly, G. R. Holeman, P. D. Parker, and D. A. Bromley, "Radiation Shielding for an MP Tandem Accelerator Instillation", Nucl. Inst. and Method, 53 (1967) 56.

G. R. Holeman, "A Method for Inferring Quality Factor Using the Bonner Spectrometer", USAEC Report, CONF-670305, Symposium on Biological Interpretation of Dose from Accelerator Produced Radiation, (1967) 225.

G. L. Watkins and G. R. Holeman, "The Evaluation of an Iterative Technique's Use in Unfolding Neutron Spectra Data", Health Phys., 15 (1968) 535.

G. R. Holeman, "Calibration of a GM Detector to Measure ^{15}O and ^{13}N in Air by Immersion in a Standardized ^{32}P Solution, Health Phys., 17 (1968) 158.

G. R. Holeman, D. McM. Shaw and K. W. Price, "Stray Neutron Spectra and Comparison of Measurements with Discrete Ordinates Calculations", USAEC Report, CONF-691101, Second International Symposium on Accelerator Radiation Dosimetry and Experience, (1970) 552.

G. R. Holeman, "Measurement of Accelerator Produced Stray Neutron Spectra" A.J.P.H., 60 (1970) 1824.

K. W. Price and G. R. Holeman, "A Technique for the Rapid Determination of Dose Equivalent Rates at Particle Accelerators Using the Bonner Spectrometer", in Health Physics Operational Monitoring, Edited by C. A. Willis and J. Handloser, Gordon & Breach, (1972) 429.

G. R. Holeman and D. McM. Shaw, "Radiation Exposure Record-Keeping by Time Sharing Computer", Health Phys., 27 (1974) 396.

K. W. Price and G. R. Holeman, "Health Physics Aspects of the Yale Heavy Ion Linear Accelerator Dismantling Project", Operational Health Physics, (Symposium Proceedings) Compiled by P. L. Carson, W. R. Hendee and D. C. Hunt, (1976) 499.

M. M. Gabel, K. W. Price and G. R. Holeman, "Thyroid Monitoring and Minimizing I-125 Uptake", Timely Topics (Proceedings of Campus Radiation Safety Officers' Conference, University of California, Irvine, California, August, 1975), Edited by William W. Wadman, III., (1976) 110.

M. M. Gabel, K. W. Price and G. R. Holeman, "Thyroid Monitoring and Minimizing I-125 Uptake", Measurements for the Safe Use of Radiation, NBS Special Publication 456, Edited by Sherman P. Fivozinsky, (1976) 371.

G. R. Holeman, K. W. Price, L. F. Friedman and R. Nath, "Neutron Spectra From a Sagittaire Medical Accelerator", Proceedings of IV. International Radiation Protection Association Congress, (1977) 827.

M. F. Johnson and G. R. Holeman, "The Health Effects of Exposure to Low-Level Radiation from Nuclear Power Plants: A Feasibility Study", (submitted to Health Physics Journal).

G. R. Holeman, K. W. Price, L. F. Friedman and R. Nath, "Neutron Spectral Measurements in an Intense Photon Field Associated with a High Energy X-Ray Radiotherapy Machine". (submitted to Medical Physics Journal).

K. W. Price, G. R. Holeman and R. Nath, "A Liquid Scintillation Counting Activation Technique for Determination of Fast and Slow Neutron Fluxes in Intense High Energy (8-30 MeV) Gamma Fields", (submitted to Health Physics Journal).

HONORS

Listed in Outstanding Young Men of America, 1968 Edition.

Listed in Community Leaders of America, 1969 Edition.

Listed in Two Thousand Men of Achievement, 1969 Edition, 1970 Edition.

Listed in American Men and Women of Science, 1976 Edition.

CERTIFICATIONS

Certified Health Physicist, American Board of Health Physics, 1969.

Certified Radiation Equipment Safety Officer, Department of Health, State of New York, 1973.