E. R. Squibb & Sons, Inc.

Georges Road
New Brunswick, N.J. 08903
201-545-1300

SQUIBB

July 11, 1983

Glenda Jackson
License Fee Management Branch
Silver Spring Office
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Ref: License No. 29-00139-02

Dear Ms. Jackson:

This is to request an amendment to Squibb's Byproduct Material License No. 29-00139-02 to have Dr. M. D. Loberg replace Dr. S. Barker as a member of the Radiation Safety Committee.

Enclosed for your information is Dr. Loberg's resumé. Also enclosed is a check for the amendment fee of $110.

Very truly yours,

John P. Gresh
Radiation Safety Officer

RECEIVED BY LFMB
Date 7/18/83
Log July 4 Amend
By Brown
Orig. To
Action Compl. 7/22/83

/rk
Enclosures

Applicant 52284
Check No. 110-3A
Amount Fee Category 3A
Type of Fee Amendment
Date Check Rec'd 7/18/83
Received By Brown

A110 refunded 3/27/84

E/5 6/30/83
3A
$52284
14876

CURRICULUM VITAE

I. PERSONAL

NAME: Michael Dewey Loberg, Ph.D.

DATE OF BIRTH: (b)(6)

PLACE OF BIRTH: (b)(6)

CITIZENSHIP: U.S.A.

MARITAL STATUS: (b)(6)

HOME ADDRESS: (b)(6)

Telephone: (b)(6)

II. EDUCATION

Undergraduate - B.S. degree in Chemistry - Trinity College, Hartford, Connecticut, (b)(6)

Graduate - M.S. degree in Chemistry - Washington University, St. Louis, Mo., (b)(6)

- Ph.D. degree in Chemistry - Washington University, St. Louis, Mo., (b)(6)

AWARDS:

Joseph V. Getlin Scholar, Trinity College 1965-1969
National Science Foundation Trainee 1969-1972
Radiation Research Society Travel Award 1972
Sigma Pi Sigma Honorary Physics Society
Best Scientific Paper Presented at the Mideastern Chapter Society of Nuclear Medicine Meeting, April 11-13, 1975

III. EMPLOYMENT EXPERIENCE

July 1979 - Present	Director, Radiopharmaceutical Research and Development, E. R. Squibb & Sons, Georges Road New Brunswick, N.J. 08903
July 1977 - July 1979	Director, University of Maryland Central Nuclear Pharmacy, 636 W. Lombard Street Baltimore, Maryland 21201
July 1976 - July 1979	Associate Professor of Medicine, Pharmacy, and Medicinal Chemistry, University of Maryland, 22 S. Greene Street, Baltimore, Maryland 21201

7/11/83

ADDENDUM #1

RADIATION SAFETY COMMITTEE MEMBERSHIP

1) Mr. P. A. Rava, Committee Chairman, Director, Quality Conrol Services

2) Mr. F. Golub, Director, Personnel and Industrial Relations

3) Mr. G. Thompson, Head, Radiopharmaceutical Manufacturing

4) Mr. H. R. Harrison, V.P. and Regulatory Counsel

5) Dr. E. Banta, Director, Medical Services

6) Dr. M. Loberg, Director, Radiopharmaceutical Research and Development

7) Dr. P. P. Roets, Manager, Personnel and Industrial Hygiene and Safety

8) Dr. D. Benson, Manager, Radiopharmaceutical Quality Control

9) Mr. J. P. Gresh, Manager, Health Physics Department

August 1973 - July 1976 Assistant Professor of Medicine and Assistant Professor of Pharmacy, University of Maryland, 22 S. Greene Street Baltimore, Maryland 21201

Sept. 1972 - Aug. 1973 Research Assistant, Washington University School of Medicine, St. Louis, Mo. 63110

IV. MEMBERSHIPS AND POSITIONS HELD IN SCIENTIFIC, PROFESSIONAL, AND SCHOLARLY SOCIETIES

Member - American Physical Society
Society of Nuclear Medicine
American Association for the Advancement of Science
Scientific Chairman for yearly Symposium on Radiopharmaceuticals sponsored by Mideastern Chapter, Society of Nuclear Medicine
Radiopharmaceutical Science Council, 1976-1980

Officer - Secretary/Treasurer, Mideastern Chapter, Society of Nuclear Medicine, 1978-1980

Member - Board of Directors, Radiopharmaceutical Science Council, 1978-1980

V. HONORS AND EXTRAMURAL AWARDS

1. Pharmacokinetics of a Radiolabeled Derivative of Lidocaine; M.D. Loberg; Baltimore Research Award; $910. Objective was to produce a gamma-emitting radiopharmaceutical capable of tracing the drug lidocaine in humans, 1974-1975.

2. Production of Radionuclidically Pure Iodine-123 Using a Medium Energy Cyclotron; M.D. Loberg; Bureau of Radiological Health; $2800. The objective was to establish a Regional Radionuclide Production Center for Iodine-123 within the University of Maryland involving the Cyclotron at College Park and the Radiopharmaceutical facilities at Baltimore, 1975-present.

3. Development of Bifunctional Radiopharmaceuticals; M.D. Loberg, Co-investigators - P. Callery, A. Fields, and E. Harvey; National Institute of Health; $160,000. The objective is to create a new class of radiopharmaceuticals in which a chelating group capable of binding gamma-emitting radiometals is attached to biologically active molecules thus forming a radioactive analog of the original compound, 1976-1978.

4. Development of Bifunctional Radiopharmaceuticals; Principal Investigator; Renewal of grant in Item 3; $130,000, 1978-1981.

VI. COMMITTEE SERVICE

Member - Human Use Subcommittee of the Radiation Safety Committee, UMBC, 1973-
Research Liason Committee, UMBC, 1974-1975
Graduate Programs, Cources, and Curricula Committee, School of Pharmacy, 1973-1976
Guest Lecturers Committee, School of Pharmacy, 1975-1977

VII. CONSULTING ACTIVITES AND SERVICE TO SCHOLARLY AND PROFESSIONAL SOCIETIES, EDUCATIONAL OR GOVERNMENTAL AGENCIES

Educational Consultant to the Nuclear Regulatory Commissions Program in Graduate Education, Washington, D.C. (1974-1975)
Educational Consultant to the U.S. Navy's Post-Graduate Residency Training Program, Bethesda, Maryland (1973-
Educational Consultant to Georgetown University's Post-Graduate Training Program, Georgetown, Maryland (1973-1975)
Educational Consultant to the Mideastern Chapter, Society of Nuclear Medicine's Continuing Education Program (1974-

VIII. TEACHING

A. Courses Taught

Pharmacy Practice, PHAR 450, 2 credits, 80 students, 8-10 contact hours on Radiopharmacy Practice, 1973-
Basic Nuclear Science, MCHM 470, 3 credits, Coursemaster.
Basic Nuclear Science Laboratory, MCHM 471, 1 credit, Coursemaster
Clinical Nuclear Science A-D, PHAR 472, 4 credits, Coursemaster
Clinical Nuclear Science Laboratory, PHAR 473, 1 credit, Coursemaster

B. Master and Doctoral Thesis Candidates

Mr. Steven Sikorski, Masters Thesis, Pharmacokinetics of Technetium-N-(2,6-dimethylphenylcarbamoylmethyl)iminodiacetic acid, 1976.
Mr. David Porter, Doctoral Thesis, Development of Tc-99m labeled hepatobiliary agents, expected summer of 1979.
Johanne Travis, Masters Thesis candidate

IX. PROFESSIONAL ACTIVITIES

A. Lectures and Seminars

1. M.D. Loberg, C. Coble, N. Mullani, M. Straatman, and M.J. Welch: The application of small computers to the analysis of radio-gas chromatographic data. Presented at the Sixth International Hot Atom Chemistry Symposium, Brookhaven, New York, September, 1971.

2. M.D. Loberg and M.J. Welch: The reactivity of iodine atoms formed by the decay of Xenon-123. Presented at the Sixth International Hot Atom Chemistry Symposium, Brookhaven, New York, September 1971.

3. M.D. Loberg: In-vivo and in-vitro evaluation of radiopharmaceutical kits. Nuclear Medicine Technology Symposium, Washington, D.C., November 10, 1973. Invited.

4. M.D. Loberg: Chemistry of technetium radiopharmaceuticals, Mideastern Section, Society of Nuclear Medicine, Washington, D.C., March 29, 1974. Invited.

5. M.D. Loberg: Chaired Symposium on Technetium Radiopharmaceuticals and presented paper entitled: Effective combinations of reducing and chelating agents, Mideastern Section, Society of Nuclear Medicine, Bethesda, Maryland, October 18, 1974.

6. M.D. Loberg: Role of the pharmacist in nuclear medicine. NABP - AACP District II Meeting, Albany, New York, October 24, 1974. Invited.

7. P.S. Callery, W.C. Faith, E.B. Harvey, and M.D. Loberg: Synthesis of a technetium-99m labeled analog of lidocaine for external imaging. Abstract, 169th Meeting of the American Chemical Society, Philadelphia, April, 1975.

8. M.D. Loberg, P.S. Callery, E.B. Harvey, W.C. Faith, and M.D. Cooper: Development of drug and biochemical analogues for use as radiopharmaceuticals. Presented at the 5th Annual Meeting of the Mideastern Chapter, Society of Nuclear Medicine, April, 1975.

9. E.B. Harvey, M.D. Loberg, and M.D. Cooper: ^{99m}Tc-labeled N-substituted iminodiacetic acid - A new radiopharmaceutical for hepatobiliary imaging. Presented at the 5th Annual Meeting of the Mideastern Chapter, Society of Nuclear Medicine, April, 1975.

10. M.D. Loberg: Quality control of radiopharmaceuticals Chesapeake Nuclear Medicine Technical Society, Mideastern Chapter, Society of Nuclear Medicine, April 2, 1975. Invited.

11. J. Quinlan, M. Loberg, R. Ollodart, M. Cooper, F. Dagher, and J. Frost: Detection of acute rejection in kidney transplants using radioiodinated autologous fibrinogen (RAF). 2nd Annual Scientific Session, The Kidney Foundation of Maryland, March, 1975.

12. M.D. Loberg, S. Wall, and M. Cooper: Feasibility study on the use of medium energy cyclotrons for the production of I-123. Bureau of Radiological Health Planning Symposium, May, 1975. Invited.

13. M.D. Loberg and M.D. Cooper: Performance and reproducibililty radiopharmaceuticals produced from kits for the labeling of autologous proteins and cells. Symposium on Standardization, Performance, and Quality Control in Nuclear Medicine, National Bureau of Standards, Gaithersburg, Maryland, June, 1975. Invited

14. M.D. Loberg: Design of radiopharmaceuticals. Teaching and Training Symposium sponsored by E.R. Squibb & Sons, Williamsburg Virginia, September, 1975. Invited.

15. M.D. Loberg: Chaired Symposium on Drug Analogs and presented a paper entitled: Current methodologies for the radiolabeling of drugs and biochemicals. Mideastern Chapter, Society of Nuclear Medicine, Silver Spring, Maryland, Nov. 21, 1975. Invited.

16. M.D. Loberg: Radiolabeling of drug and biochemical analogs, Johns Hopkins University, Medical School, November, 1975. Invited.

17. M.D. Loberg: Radiopharmaceuticals based on N-substitution of iminodiacetic acid, New England Nuclear, Billerica, Mass. January, 1976.

18. M.D. Loberg: Use of radiolabeled drug analogs for the measurement of regional pharmacokinetics. Vanderbilt University, Nashville, Tenn., January, 1976.

19. M.D. Loberg: Chemistry of radiopharmaceuticals. April, 1976 meeting of the Chesapeake Chapter of the American Chemical Society. Invited.

20. M.D. Loberg: Drug analogs based on N-substituted iminodiacetic acid. Symposium on the Chemistry of Radiopharmaceuticals, Hahnemann Medical College, Philadelphia, Pa., April, 1976. Invited.

21. M.D. Loberg and A.T. Fields: Kinetic and thermodynamic description of exchange reaction between ^{99m}Tc-HIDA and EDTA. Brookhaven National Laboratory, Long Island, New York, September, 1976.

22. M.D. Loberg: Comparison of Tc-99m labeled hepatobiliary agents. Annual Meeting of the Missouri Valley Chapter of the Society of Nuclear Medicine, St. Louis, Mo., October, 1977. Invited.

23. M.D. Loberg: Pharmacokinetics of Tc-99m labeled hepatobiliary agents. University of Chicago, Chicago, Ill., October, 1977. Invited.

24. M.D. Loberg: Clinical utility of various Tc-99m labeled hepatobiliary agents. Mid-winter Meeting, Mideastern Chapter, Society of Nuclear Medicine, October, 1977. Invited.

25. D. Porter, M.D. Loberg, E.B. Harvey and G.S. Johnston: Synthesis and biodistribution of Tc-99m-3α:7α:12α-trihydroxy-24-norcholanyl-23 iminodiacetate (Tc-CIDA): A potential liver scanning agent. Annual Mideastern Chapter Meeting, April, 1977.

26. M.D. Loberg: Development of Tc-99m labeled bifunctional radiopharmaceuticals. Mid-Atlantic Regional Meeting of the American Chemical Society, Hunt Valley, Md., April, 1978. Invited.

27. M.D. Loberg, A.T. Fields and D.W. Porter: Radiochemically pure Tc-99m labeled fatty acid analogs. Mideastern Chapter Meeting, Society of Nuclear Medicine, April, 1978.

28. M.D. Loberg: Radiopharmaceutical distribution by active transport: The implications of non-linear kinetics. 1st International Symposium on Radiopharmacology, Innsbruck, Austria, May, 1978. Invited.

29. M.D. Loberg: Recent advances in radiopharmaceuticals derived from bifunctional chelating agents. Northeast Regional Meeting of the American Chemical Society, Boston, Mass., June, 1978. Invited.

30. M.D. Loberg, P.S. Callery, D.W. Porter, and A.T. Fields: Chemistry of technetium radiopharmaceuticals derived from bifunctional chelating agents. 2nd International Symposium on Radiopharmaceutical Chemistry, Oxford, England, July, 1978. Invited.

31. M.D. Loberg, E.S. Hedlund, and P.S. Callery: Uptake of technetium labeled radiopharmaceuticals by normal brain tissue. 2nd International Congress of World Federation of Nuclear Medicine and Biology, Washington, D.C., September, 1978.

32. D.W. Porter, M.D. Loberg, A.T. Fields, and P.S. Callery: Structure activity relationships (SAR) of Tc-99m labeled N-substituted iminodiacetates. 2nd International Congress of World Federation of Nuclear Medicine and Biology, Washington, D.C., September, 1978.

33. D.W. Porter, M.D. Loberg, P.I. Eacho and M. Weiner: Comparison of hepatobiliary agents in an in-vitro model. IX Annual Mideastern Chapter Meeting, Society of Nuclear Medicine, Ocean City, Md., April, 1979.

B. Service to Editorial Boards of Journals

Reviewer for:

1. Journal of Nuclear Medicine
2. International Journal of Applied Radiation Isotopes
3. Radiation Research

XI. PUBLICATIONS - National Journals

1. M.D. Loberg: Ph.D. Thesis: The Chemical Reactions of Energetic Iodine Atoms with Simple Hydrocarbons, 1973.

2. M.D. Loberg, M.D. Phelps, and M.J. Welch: Preparation of pure carrier free Xenon-123 for rare gas washout studies. J. Nucl. Med., 14:733, 1973.

3. M.D. Loberg and M.J. Welch: The reaction of recoil iodine formed by the $^{123}Xe \rightarrow {}^{123}I$ system with simple hydrocarbons: The effect of additives on the reactivity. J. Am. Chem. Soc., 95:1075, 1973.

4. M.D. Loberg, K.A. Krohn, and M.J. Welch: The reactions of recoil iodine formed by the $^{123}Xe \rightarrow {}^{123}I$ system with simple hydrocarbons II. Pressure studies on the Methane and ethane systems. J. Am. Chem. Soc., 95:5496, 1973.

5. J.M.S. Henis, M.D. Loberg, and M.J. Welch: Ion molecule reactions in methyl halids. J. Am. Chem. Soc., 96:1665, 1974.

6. P. Hagan, M.D. Loberg, B.A. Rhodes, K. Harrison, M.D. Cooper: "Kit" preparation of radioiodinated autologous fibrinogen using iodine-131 monochloride. J. Nucl. Med., 15:974, 1974.

7. J. Quinlan, F. Dagher, R. Ollodart, M. Loberg, R. Mason, J. Frost, and M. Cooper: Early detection of acute rejection in renal allografts using radioiodinated autologous fibrinogen (RAF). Amer. J. Surg., 130:136, 1975.

8. M.D. Loberg, M.D. Cooper, E. Harvey, P. Callery, and B. Faith: Development of new radiopharmaceuticals based on N-substituted iminodiacetic acids. J. Nucl. Med., 17:633, 1976.

9. M.D. Loberg and A. Fields: Stability of ^{99m}Tc-labeled N-substituted iminodiacetic acids: Ligand exchange reaction between ^{99m}Tc-HIDA and EDTA. Int. J. Appl. Radiat., 28:687, 1977.

10. P. Callery, B. Faith, M. Loberg, E. Harvey, and M. Cooper: Tissue distribution of technetium-99m and carbon-14 labeled N-(2,6-dimethylphenylcarbamoylmethyl)iminodiacetic acid. J. Med. Chem., 19:952, 1976.

11. J. Ryan, M. Cooper, M. Loberg, E. Harvey, and S. Silorski: ^{99m}Tc-[N-(2,6-dimethylphenylcarbamoylmethyl)]iminodiacetic acid (Tc-HIDA): A new radiopharmaceutical for hepatobiliary imaging studies. J. Nucl. Med., 18:997, 1977.

12. M.D. Loberg, and A. Fields: Chemical structure of technetium-99m labeled N-(2,6-dimethylphenylcarbamoylmethyl)iminodiacetic acid (Tc-HIDA). Int. J. Appl. Radiat. & Isotopes., 29:167, 1978.

13. A.T. Fields, D. Porter, P.S. Callery, E. Harvey, and M.D. Loberg: Synthesis and radiolabeling of technetium radiopharmaceuticals based on N-substituted iminodiacetic acid: Effect of radiolabeling conditions on radiochemical purity. Radiopharm. and Labeled Compounds, 15:387, 1978.

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