



October 10, 1985

William J. Adam, PhD
Materials Licensing Section
United States Nuclear Regulatory
Commission, Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Dr. Adams,

Please find the additional information you requested on Mr. Hinkle and Ms. Bryant for adding their names under condition 12.A of our Toledo License No. 34-16654-01 MD. Our original request letter was submitted on July 22, 1985.

This is not a new amendment request, it is additional information which you requested in your letter of September 12, 1985.

Sincerely,

Frank M Comer

Frank M. Comer
Corporate Health Physicist
Syncor International Corp.

FMC/jm

Enclosures

cc: Randy Asmus
William Kemmel
Jay Simon

FEE EXEMPT
*continuation of
previous request*

RECEIVED BY LFMB

Date. *Oct. 23, 1985*
Log. *Oct. 16, 1985*
By. *SLK*
Orig. To
Action Compl. *J*

U.S. N.R.C.
12. FEE MGMT. BRANCH

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Syncor International Corporation
Health Physics Group
7586 Trade Street
San Diego, California 92121
(619) 578-8400

OCT 15 1985

CONTROL NO. 79936

Figure 1.

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

NAME Tracy Bryant

Location of Training	Date(s) of Attendance	Course Title	Total Clock Hours of Course	Breakdown of Course Content in Clock Hours*				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry
Lester E. Cox Medical Center Springfield, MO	6/1/80 to 5/30/82	Radiologic Technology	75	45 Rad 150	30 Rad 250			
St. Johns Mercy Medical Center St. Louis, MO	7/1/82 to 6/30/83	Nuclear Medicine Technology	115	30	10	40	5	30
TOTAL HOURS				75	40	40	5	30

*Note: Show a breakdown of hours by institutions, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)

DOCUMENTING RADIOISOTOPE HANDLING EXPERIENCE

NAME Tracy ByrantEXPERIENCE WITH RADIOACTIVE MATERIAL. (Actual Use of
Radioisotopes Under the Supervision of an Authorized User)

ISOTOPE	MAXIMUM AMOUNT USED AT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE (actual clock hours)	TYPE OF USE 1,2,3,4,5,6
Mo-99	16 Ci	St. Johns Mercy School of Nuclear Medicine 1982 - 83	75 hours	1,6
Tc-99m	14 Ci			3,4,5,6
I-131	150 mCi			1,3,4,5
Xe-133	1 Ci			1,3,4,5
Se-75	2 mCi	Syncor Corp. St. Louis, MO	March 1, 1985 October 1, 1985 1032 hours	1,3,4,5
I-125	100 uCi			1,3,4,5
Cr-51	500 uCi			1,3,4,5
Yb-169	15 mCi			1,3,4,5
P-32	10 mCi			1,3,4,5
Ga-67	10 mCi			1,3,4,5
Tl-201	10 mCi			1,3,4,5
Co-57	5 mCi			2
Cs-137	250 uCi			2
Ba-133	250 uCi			2

Key for "Type of Use"

The number or numbers entered under "Type of Use" correspond to experience in the following activities:

1. Ordering, receiving, and unpacking radioactive materials safely, including performance of related radiation surveys.
2. Calibration of dose calibrator, scintillation detectors, and survey meters.
3. Calculation, dispensing, and calibration of patient doses, including proper use of radiation shields.
4. Appropriate internal control procedures to prevent mislabeling errors.
5. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests.
6. Elution of Technetium-99m generator systems, assay and testing of the elute for Molybdenum-99 contamination, and processing the elute with reagent kits to prepare Technetium-99m labeled radiopharmaceuticals.

CONTROL NO. 79936

Figure 1.

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

NAME George H. Hinkle

Location of Training	Date(s) of Attendance	Course Title	Total Clock Hours of Course	Breakdown of Course Content in Clock Hours*				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry
Purdue University School of Pharmacy and Pharmacal Sciences West Lafayette, IN	Aug., 1970 through Dec., 1976 undergraduate and graduate degree program	Radiation Health Physics,BNUC 526	100	45	45	10		
		Applied Nuclear Pharmacy,BNUC 530	130			30		100
		Radiation Biology BNUC 540	50		5		45	
		Radiological Physics BNUC 690	50	20	30			
		Nuclear Pharmacy Experience,BNUC 690	40			10		30
		Bionucleonics Seminar,BNUC 696	50	10	10	10	10	10
		Radiochemistry, CHEM 548	100			50		50
TOTAL HOURS				75	90	110	55	190

*Note: Show a breakdown of hours by institutions, dates, and subjects. List each hour only once (i.e., under the most

DOCUMENTING RADIOISOTOPE HANDLING EXPERIENCE

NAME George H. Hinkle

EXPERIENCE WITH RADIOACTIVE MATERIAL. (Actual Use of Radioisotopes Under the Supervision of an Authorized User)

ISOTOPE	MAXIMUM AMOUNT USED AT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE (actual clock hours)	TYPE OF USE 1,2,3,4,5,6
Mo-90	16 Ci	Purdue University	3120 hours	1,6
Tc-99m	14 Ci	School of Pharmacy		3,4,5,6
I-131	150 mCi	West Lafayette, IN		1,3,4,5
Xe-133	1 Ci			1,3,4,5
Se-75	2 mCi	University of Oklahoma	3120 hours	1,3,4,5
I-125	100 uCi	College of Pharmacy		1,3,4,5
Cr-51	500 uCi	Nuclear Pharmacy		1,3,4,5
Yb-169	15 mCi	Oklahoma City, OK		1,3,4,5
P-32	10 mCi			1,3,4,5
Ga-67	10 mCi			1,3,4,5
Tl-201	10 mCi			1,3,4,5
Co-57	5 mCi			2
Cs-137	250 uCi			2
Ba-133	250 uCi			2

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1. Ordering, receiving, and unpacking radioactive materials safely, including performance of related radiation surveys.
2. Calibration of dose calibrator, scintillation detectors, and survey meters.
3. Calculation, dispensing, and calibration of patient doses, including proper use of radiation shields.
4. Appropriate internal control procedures to prevent mislabeling errors.
5. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests.
6. Elution of Technetium-99m generator systems, assay and testing of the elute for Molybdenum-99 contamination, and processing the elute with reagent kits to prepare Technetium-99m labeled radiopharmaceuticals.

GEORGE HENRY HINKLE, Jr.

BIOGRAPHICAL INFORMATION

Date of Birth: May 7, 1952
Marital Status: married to Cindy L. Kerby, July 29, 1972
Children: Cori Nicole, born September 9, 1975
Cammie Noelle, born April 26, 1978
Residence Address: 1795 Upper Chelsea Rd., Columbus, Ohio 43212
Business Address: Division of Nuclear Medicine
The Ohio State University Hospitals
410 West Tenth Avenue, Room N-159
Columbus, Ohio 43210

PROFESSIONAL TITLE

Director of Nuclear Pharmacy Services, The Ohio State University Hospitals
Clinical Assistant Professor, Department of Radiology
Clinical Assistant Professor, College of Pharmacy

EDUCATION

Undergraduate: B.S. in Pharmacy, Purdue University, May 1975
Graduate: M.S. in Nuclear Pharmacy, Purdue University, Department of
Bionucleonics School of Pharmacy and Pharmacal Sciences,
May 1977. Research thesis, "An Investigation of the Use of
Liposome Tc-99m DTPA as a New Radiopharmaceutical for Liver
Imaging, Stanley M. Shaw, major professor.

EXPERIENCE

May, 1981 to present: Served as Director of Nuclear Pharmacy Services at
The Ohio State University Hospitals Department of Pharmacy, Clinical Assistant
Professor Department of Radiology and Clinical Assistant Professor College of
Pharmacy.

February, 1978 to May, 1981: Served as Assistant Professor on the faculty of
the College of Pharmacy, The University of Oklahoma.

January, 1977 to February, 1978: Served as Instructor in Nuclear Pharmacy on
the faculty of the School of Pharmacy and Pharmacal Sciences, Purdue University.
Lectured on radiotracer methodology and nuclear pharmacy to undergraduate and
graduate students and instructed laboratory courses in these same disciplines.

May, 1975 to January, 1977: Served as Graduate Instructor in radiotracer
methodology and nuclear pharmacy at Purdue University. Instruction of
laboratory courses in these disciplines and various research responsibilities.

PROFESSIONAL RECOGNITION

Registered Pharmacist in Indiana, 1973-date

Registered Pharmacist in Ohio, 1981-date

Board Certified Nuclear Pharmacist, June 3, 1983 by American Pharmaceutical Association's Board of Pharmaceutical Specialties

SCIENTIFIC AND PROFESSIONAL HONORARIFS

Sigma Xi (Science Honorary)

Rho Chi (Pharmacy Honorary)

Kappa Psi (Professional Fraternity)

SCIENTIFIC AND PROFESSIONAL SOCIETIES

American Pharmaceutical Association

Academy of Pharmacy Practice

Section on Nuclear Pharmacy

Chairman, Educational Affairs Committee 1981-1984

Chairman, 1985-1986

Society of Nuclear Medicine

Radiopharmaceutical Science Council

RELEVANT GRADUATE COURSES

Introductory Bionucleonics

Applied Bionucleonics

Radiation Health Physics

Radiation Biology

Radiochemistry

Radiological Physics

Nuclear Pharmacy Experience

Parenteral Products

Essentials of Toxicology

Therapeutics

Experimental Statistics

MAJOR AREAS OF TEACHING AND RESEARCH INTERESTS

Primary interest is in teaching undergraduate and graduate students in the areas of radionuclide methodology and nuclear pharmacy. The use of isotopes in nuclear medicine. Interest in research in the development of new diagnostic radiopharmaceuticals and new methods of targeting diagnostic and therapeutic drugs to receptor sites. Formulation parameters of radiopharmaceuticals and the biological distribution and radiation dosimetry estimates for new compounds.

MAJOR AREAS OF INSTRUCTION

Radiopharmaceuticals, Nuclear Pharmacy, Applied Nuclear Pharmacy, Radionuclide Methodology, Diagnostic Pharmaceuticals, Tracer Methodology.

SCIENTIFIC PRESENTATIONS

1. "Preferential Localization of Liposomes Tc-99m DTPA in the Liver" presented at the Society of Nuclear Medicine annual meeting, 1977.
2. "Clinical Nuclear Pharmacy: Participation in the Investigational New Drug Application" presented at the American Pharmaceutical Association annual meeting, 1980.

3. "The Training of Specialists: Nuclear Pharmacy Residency Programs" presented as an invited speaker on a panel discussion before the American Society of Hospital Pharmacists' SIG on Radiopharmacy at the American Pharmaceutical Association annual meeting, 1980.
4. "Abnormal Biodistribution of Tc-99m Glucoptate Sodium" presented at the American Pharmaceutical Association annual meeting, 1981.
5. "Hepatobiliary Radiopharmaceuticals, From Dyes to Die Hards" presented as an invited speaker at the 25th Annual Meeting & Seminar in Diagnostic Imaging of the Oklahoma Society of Radiologic Technologists, April 11, 1981.
6. "Evaluation of Red Blood Cell Labeling Procedures in Cardiovascular Scintigraphy" presented at the American Pharmaceutical Association annual meeting, 1981.
7. "Nuclear Pharmacy Practice in the University Hospital" presented as an invited speaker at the Career Opportunities Day program held at the Purdue University School of Pharmacy and Pharmacal Sciences, September 9, 1982.
8. "Comparison of Labeling and Mouse Biodistribution of Tc-99m and In-111 Barium Calmette-Guerin (BCG) Vaccine" presented at the 130th American Pharmaceutical Association annual meeting, New Orleans, 1983.
9. "Update on Radiopharmaceuticals" presented as an invited speaker to the Society of Nuclear Medicine Central Chapter's "Update and Review of Nuclear Medicine" program, Columbus, Ohio, May 14, 1983.
10. "The Professions of Nuclear Pharmacy and Nuclear Medicine" participation in a radio broadcast discussion program entitled, "Access: Continuing Education by invitation, June 3, 1983.
11. "Radioimmuno-detection of Transplanted Colon Tumor by Use of a Portable Gamma Counting System" presented at the 69th Scientific Assembly of the Radiological Society of North America, Chicago, Illinois, November 1983.
12. "Radiopharmaceutical Update" presented at The Central Ohio Society of Nuclear Medicine Technologists meeting, Columbus, Ohio, November 9, 1983.
13. "Localization of Transplanted Colon Tumors Using Radioimmuno-detection with Polyclonal, Monoclonal and mixtures of anti-CEA Antibodies" presented at the 131st Annual Meeting of the American Pharmaceutical Association, Montreal, Canada, May 7, 1984.
14. "Use of Indium-111 Labeled Leukocytes in Diagnostic Nuclear Medicine" presented at the 6th Annual Spring Symposium of the Northern Ohio Society of Nuclear Technologists meeting, Cleveland, Ohio, May 19, 1984.
15. "Iodine-131 Labeled Anti-CEA Polyclonal Antibody Detection of Gastrointestinal Cancer," presented at the 31st annual meeting of the Society of Nuclear Medicine, Los Angeles, CA, June 7, 1984.

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Academy of Pharmacy Practice
Section on Nuclear Pharmacy
Chairman, Educational Affairs Committee 1981-1984
Chairman, 1985-1986
Society of Nuclear Medicine
Radiopharmaceutical Science Council

RELEVANT GRADUATE COURSES

Introductory Bionucleonics
Applied Bionucleonics
Radiation Health Physics
Radiation Biology
Radiochemistry
Radiological Physics
Nuclear Pharmacy Experience
Parenteral Products
Essentials of Toxicology
Therapeutics
Experimental Statistics

MAJOR AREAS OF TEACHING AND RESEARCH INTERESTS

Primary interest is in teaching undergraduate and graduate students in the areas of radionuclide methodology and nuclear pharmacy. The use of isotopes in nuclear medicine. Interest in research in the development of new diagnostic radiopharmaceuticals and new methods of targeting diagnostic and therapeutic drugs to receptor sites. Formulation parameters of radiopharmaceuticals and the biological distribution and radiation dosimetry estimates for new compounds.

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1. "Preferential Localization of Liposomes Tc-99m DTPA in the Liver" presented at the Society of Nuclear Medicine annual meeting, 1977.
2. "Clinical Nuclear Pharmacy: Participation in the Investigational New Drug Application" presented at the American Pharmaceutical Association annual meeting, 1980.

16. "Radiolabeling of Non-clonal Antibodies for Radioimmunoassay," presented as an invited lecture before the Cellular and Molecular Biology Section of Battelle Columbus Laboratories, Columbus, Ohio, February 4, 1985.
17. "Nuclear Pharmacy Services in an Institutional Setting," presented before Section on Nuclear Pharmacy of the Academy of Pharmacy Practice at the 132nd Annual Meeting of the American Pharmaceutical Association, San Antonio, TX, February 19, 1985.

SCIENTIFIC ABSTRACTS

1. "Preferential Localization of Liposomes Tc-99m DTPA in the Liver" G.H. Hinkle, G.S. Born, W.V. Kessler and S.M. Shaw, abstract published in the Contributed Papers of the 24th Annual Meeting section of the Journal of Nuclear Medicine Vol 18, No 6, June 1977, page 872.
2. "Evaluation of a Kit Preparation of Radioactive o-Iodohippuran" G.H. Hinkle, A.S. Nirschner, G.P. Basmadjian and R.D. Ice, abstract published in Abstracts of Contributed Papers of the 126th A. Ph.A. annual meeting, April 21-26, 1979.
3. "Clinical Nuclear Pharmacy: Participation in the Investigational New Drug Applications" G.H. Hinkle, K.K. Barker, G.P. Basmadjian and R.D. Ice, abstract published in Abstracts of Contributed Papers of the 127th A.Ph.A. annual meeting, April 19-24, 1980.
4. "Effect of Cardiac Drugs on Clinical Myocardial Thallium-201 Imaging" J.A. Waschek, G.P. Basmadjian, E.W. Allen, G.H. Hinkle and R.D. Ice, abstract published in the Contributed Papers of the 15th annual American Society of Hospital Pharmacists Midyear Clinical Meeting, San Francisco, December 7-11, 1980.
5. "Interdisciplinary and Participatory Approach to Radiopharmaceutical Drug Interaction Screening" L.J. Schaaf, G.P. Basmadjian, G.H. Hinkle and R.D. Ice, abstract published in the Contributed Papers of the 15th annual American Society of Hospital Pharmacists Midyear Clinical Meeting, San Francisco, December 7-11, 1980.
6. "Prostatic Lymph Scintigraphy with Tc-99m Sn-Phosphate" J.C. Leonard, G.P. Basmadjian, R.N. Isaacson, H.R. Lee, G.H. Hinkle, E.W. Allen and R.D. Ice, presented as a scientific exhibit at the 27th annual meeting of the Society of Nuclear Medicine, Detroit, 1980.
7. "Iodine Labeled Radiopharmaceuticals from Aryl Thallium bis(trifluoroacetate) Intermediates" D.R. Gilliland, G.P. Basmadjian, A.P. Marchand and G.H. Hinkle, abstract published in the Contributed Papers of the 68th annual meeting of the Oklahoma Academy of Science, November 13-14, 1980.
8. "Interdisciplinary Approach to Radiopharmaceutical-Pharmaceutical Interaction Screening" K.K. Barker, G.P. Basmadjian, G.H. Hinkle and R.D. Ice, abstract published in Abstracts of Contributed Papers of the 128th A.Ph.A. annual meeting, March 28-April 1, 1981.
9. "Evaluation of the Utility of Standard Imaging Technique in the Initial Evaluation of Patients with Acute Lymphocytic Leukemia" D.J. Kuntz, J.C. Leonard, E.W. Allen, R.M. Nitschke, J.J. Vanhoutte, G.P. Basmadjian, D.A. Wilson and G.H. Hinkle, presented at the 26th annual meeting of the Southwestern Chapter of the Society of Nuclear Medicine, New Orleans, March 26-29, 1981.
10. "Abnormal Biodistribution of Tc-99m Glucopate Sodium" G.H. Hinkle, G.P. Basmadjian, C. Peek, K.K. Barker and R.D. Ice, abstract published in Abstracts of Contributed Papers of the 128th A.Ph.A. annual meeting, March 28-April 1, 1981.
11. "Evaluation of RBC Labeling Procedures in Cardiovascular Scintigraphy: G.H. Hinkle, R. Reid, P.E. Shafer and J.O. Olsen, abstract published in Pharmacy Practice Vol 17, No 2, February, 1982, page A-14.

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12. "Comparison of Labeling and Tissue Distribution of Tc-99m and In-111 Labeled Calmette-Guérin (BCG) Vaccine" G.H. Hinkle, R.F. Barth and E. Brandage-Martin, abstract published in Pharmacy Practice Vol. 18, No. 2 February, 1983, page A-8.
13. "Radioimmunodetection of Transplanted Colon Tumor by Use of a Portable Gamma Counting System" G.H. Hinkle, J.O. Olsen, D.R. Aitken, M.O. Thurston and E.W. Martin, Jr. abstract published in Radiology Vol. 145 (p), November, 1983, page 279.
14. "Localization of Transplanted Colon Tumors Using Radioimmunodetection with Polyclonal, Monoclonal and Mixtures of Anti-CEA Antibodies" G.H. Hinkle, H.A. Nabi, J.O. Olsen, E.W. Martin, Jr., M.O. Thurston, abstract published in Pharmacy Practice Vol. 19, No. 3, March, 1984, page A-12.
15. "Iodine-131 Labeled Anti-CEA Polyclonal Antibody Detection of Gastrointestinal Cancer," H.A. Nabi, G.H. Hinkle, J.O. Olsen, D.A. Haapenssen, M.O. Thurston, C. Mottisik, D.P. Houchens, E.W. Martin, Jr., J. Nucl Med Vol. 25, No. 5, page P-113, May, 1984.

MAJOR UNIVERSITY AND COLLEGE OF PHARMACY POSITIONS

Member of Medical Radionuclide Committee, The Ohio State University Hospitals, June 1, 1981 - present.

Member of Nuclear Medicine Technology Educational Program Committee, The Ohio State University Hospitals, June 1, 1981 - present.

MAJOR COMMUNITY MEMBERSHIPS AND ACTIVITIES

Member Mountview Baptist Church

Member Purdue University Alumni Association

SOURCES AND LEVELS OF RESEARCH, TRAINING AND EQUIPMENT GRANTS

The University of Oklahoma Health Sciences Center Research Council grant for "Formulation of Kit for the Preparation of Sodium Iodine I-123 Iodohippurate" November 1, 1978-June 30, 1979. amount = \$1,800.00

The University of Oklahoma Health Sciences Center Research Council grant for Investigation of the Use of High Pressure Liquid Chromatography for Quality Assessment of Radiopharmaceuticals" December 1, 1980-June 30, 1981. amount = \$3,000.00

The Ohio State University College of Medicine Bremer Research Foundation grant for "Ultra-short Lived Radionuclide Generator" July 1, 1983-June 30, 1984. amount = \$5,000.00

American Cancer Society grant for project entitled, "Radioimmunodetection of CEA Producing Tumors with Indium-111 Labeled Anti-CEA Monoclonal Antibodies," July 1, 1984-June 30, 1985. amount = \$8,000.00

The Ohio State University seed-grant for project entitled, "Radiation Dose Estimates to Rat Thyroid Gland from Iodine - 131 Labeled Antibody Tumor Detection: An Experimental Animal Model to Test the Potency of SSKI, L-Thyroxine to Reduce Ionizing Radiation to the Thyroid Gland", July 1, 1984-June 30, 1985. Co-Investigator with Hani Abdel-Nabi, M.D., Ph.D. amount = \$14,000.00

Ohio Department of Development Thomas Alva Edison Partnership Program in conjunction with The Progenics Corporation grants for the project entitled, "Development of Radiolabeled Antibody Combinations and Improved Detection Equipment for Use in Intraoperative Detection of Cancer Sites", January 1, 1985-June 30, 1986. Co-Investigator with Edward W. Martin, Jr., M.D. amount = \$600,000.00

Department of Health and Human Services grant for project entitled, "Breast Cancer Lymphoscintigraphy", July 1, 1984-June, 1985. Co-Investigator with William B. Farrar, M.D. amount = \$5,000.00