EniChem Americas Inc.
Research & Development Center

July 6, 1989

030-30152

John E. Glenn, Ph. D., Chief
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Dear Dr. Glenn,

EniChem Americas, Inc., would like to request the following revisions to our license (License No. 29-28080-01, Docket No. 030-30152, Control No. 107635) effective immediately.

1. Receipt (p. 17, 26, 27 Radiation Safety Manual). The procedure for receipt and delivery of radioactive materials is proposed to be altered slightly in allowing the authorized user ordering radioactive materials to perform the necessary tests for contamination on the package and source container. The results of the tests will be forwarded to the RSO in a timely fashion for recording in the receipt log. The proposed wording to be substituted in Appendix III, Use of Radioisotopes, section 2 (Receipt, Transfer and Disposal of Radioactive Material) is as follows:

> All shipments containing radioactive materials are checked for radioactive contamination (package surface and interior) by an approved isotope user upon receipt by the receiving department. The radioisotope user ordering the radioactive materials is responsible for surveying the package and final isotope container for contamination and forwarding the survey results to the RSO. See Appendix IV for detailed procedures and forms.

Appendix IV. RADIOACTIVE MATERIAL RECEIPT, DELIVERY AND OPENING

I. <u>Package receipt by receiving department</u>.

A. Do not accept a radioisotope shipment that is damaged.

B. Since a contamination survey (eg. by G.M. meter) must be made within three (3) hours after receipt of a radioactive materials shipment (within 18 hours if the delivery is made after hours), record the date and time of receipt on the radioisotope delivery form and promptly notify the approved user ordering the materials.

C. Radioactive material shipments should be separated from the non-radioactive shipments upon receipt and secured.

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Monmouth Junction, NJ 08852

Note that shipments of radioactive materials must be secured at all times and are not to be left out unattended.

D. Ensure that the radioactive material shipment is received by the approved user in a timely fashion. If the shipment is not received an approved user within two (2) hours after receipt, **notify the RSO** <u>immediately</u> so that necessary surveys can be made.

E. Deliver the isotope shipment only to authorized radioactive materials users .

II. <u>Package opening by user receiving the shipment</u>.

A. Complete the contamination survey and return the results to the RSO. Note that the shipment <u>must</u> be surveyed for contamination within three hours of receipt by the shipping department.

B. Using a survey meter, measure and record the background radiation field as well as radiation fields at 3 feet from and at the package surface. **If radiation levels are found on the external surface of the package in excess of 200 millirem per hour , or at three feet from the external surface of the package in excess of 10 millirem per hour, contact the RSO immediately** to see whether, according to NRC regulations, (10 CFR 20.205), any formal notification of the NRC or shipper is necessary.

C. Wear gloves and protective clothing when opening the package.

D. Wipe the outside shipping container surface and count the wipes to check for contamination. Similarly, wipe test the final source container for the isotope (or the innermost non-sterile layer of the package if it is sterile-wrapped). The wipe tests should be counted in a liquid scintillation counter using an appropriate counting window. Record the results of the wipe tests (and background counting rate) on the radioactive materials receipt form and note any signs of damage to the package or vial. **If any of the wipe tests show greater than 22,000 dpm, contact the RSO immediately** to see whether, according to NRC regulations (10 CFR 20.205), any formal notification of either the NRC or shipper is necessary.

E. Sign the completed radioisotope receipt form and return it to the RSO.

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2. Calibration frequency, pp. 6,7 (Facilities and equipment) of original application. Calibration of the G.M. survey instruments will be done by any approved vendor. Calibration frequency will be at least yearly instead of at least every six months.

3. Note that the Radioisotope Lab, room 172, was built with a single fume hood instead of the two hoods described in page 4 of the original application.

4. Since our original application was submitted, we have added a Chemical Synthesis group to our organization. The group occupies laboratory 167 (see attached diagram). This laboratory is constructed similarly to the other general laboratories previously approved for radioisotope use. We request approval to synthesize radiolabeled peptides, enzyme inhibitors and metabolic substrates in this laboratory for use in studies on protein stability, enzyme kinetics and metabolic fates in plants and soils.

5. In the original application (item 11, p. 8), it was stated that ^{32}P would be disposed of by decay. We will also dispose of ^{32}P by transfer to a licensed radioactive materials broker.

6. We request approval to use ^{36}Cl (5 mCi maximum). The ^{36}Cl will be used as $^{36}ClO_3^-$ (an analog of NO_3^-) in studies of plant NO_3^- transport in laboratory experiments. The ^{36}Cl will be purchased as solutions of inorganic liquids ($^{36}ClO_3^-$ or $H^{36}Cl$ converted to $^{36}ClO_3^-$ by published (Deane-Drummond, C.E., 1981, Rapid method for the preparation of 36-Chlorate from 36-Chloride electrolysis. Int. J. Appl. Radiat. Isot. 32: 758-759) protocols or improvements thereon). Normal daily experimental usage will involve exposing plant tissue segments, isolated cells, or membrane vesicles to 0.2 to 10 uCi of the $^{36}ClO_3^-$ for 0.1 to 2.0 hours, washing the tissue or subcellular fraction, and counting the radioactivity taken up into the plant or cellular fraction by liquid scintillation spectroscopy. Waste ^{36}Cl will be disposed of by transfer to a licensed disposal vendor.

The maximum permissible concentration of soluble ^{36}Cl in air (from Table II of Appendix B to 10 CFR 20) is 1×10^{-8} uCi/ml. Assume a maximum of 5 mCi to be used over the course of an entire year, in all forms. For a conservative approximation, assume that all ^{36}Cl will escape from the laboratory area through the fume hood exhaust. The concentration of ^{36}Cl in the exhaust averaged over the year would be 2.6×10^{-10} uCi/ml. This concentration is two orders of magnitude less than the limit specified above (Table II, Appendix B, 10 CFR 20). Only a small fraction of the total ^{36}Cl used would be actually expected to be released in the effluent.

The individuals supervising the use of radioactive materials at EniChem Americas are the same as those identified in our initial

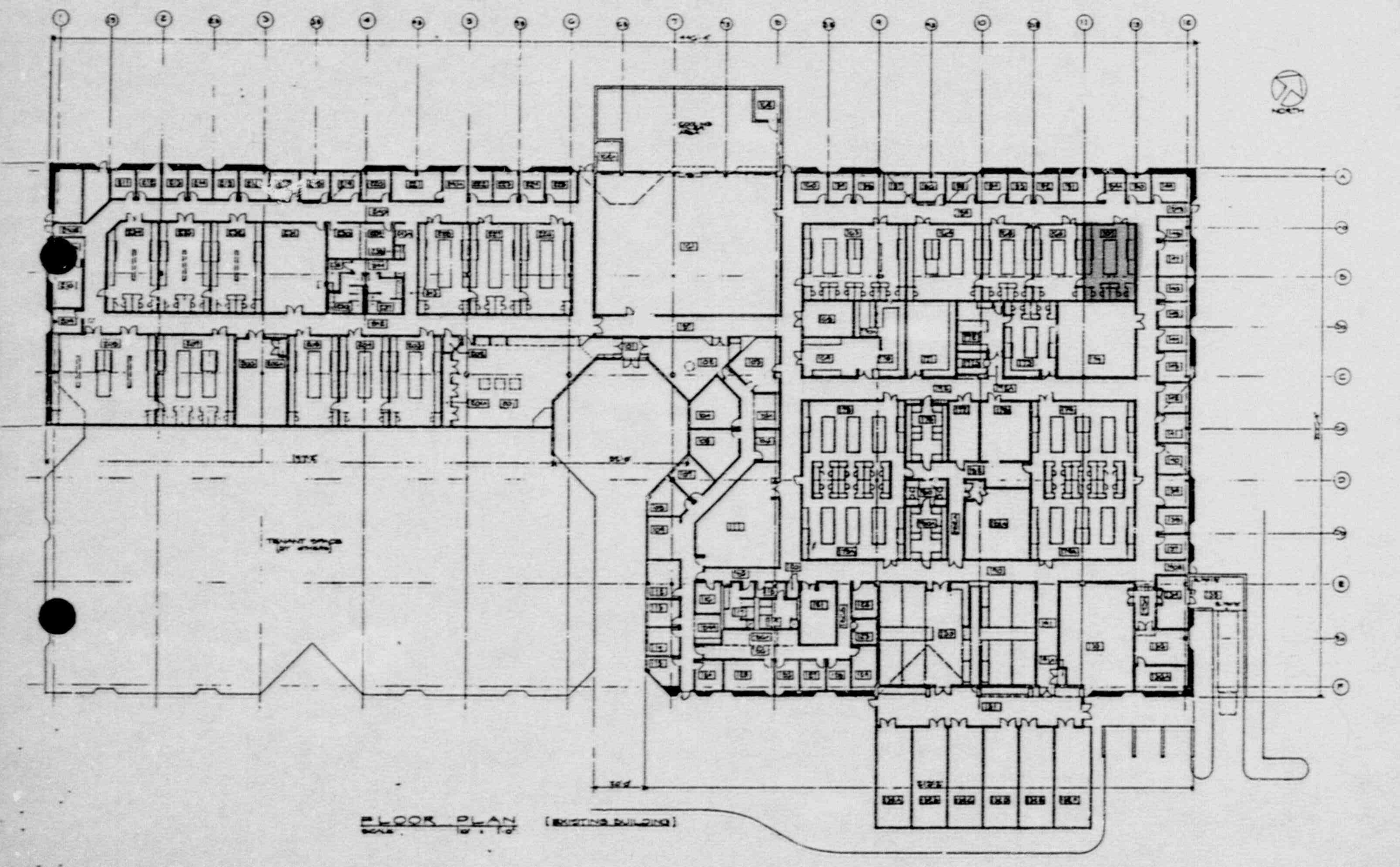
application (Mark R. Schmitt, Ph.D., Radiation Safety Officer; Dorothy A Pierce, Ph.D., Authorized User; Nicholas P. Everett, Ph.D., Authorized User; C.V.s attached).

If you need any clarification of matters relating to the requested changes in the license or to the new organization, please contact either Mark R. Schmitt, Radiation Safety Officer, or Frank Paul, the EniChem Research and Development Center Site Manager.

Sincerely yours,

Frank G. Paul
Site Manager

Mark R. Schmitt, Ph.D.
Radiation Safety Officer



FLOOR PLAN (EXISTING BUILDING)

Mark R. Schmitt, PhD
Principal Scientist/Radiation Safety Officer
Biotechnology Department
EniChem Americas, Inc.
2000 PrincetonPark Corporate Center
Monmouth Junction, NJ 08852

EDUCATION:

BSc, 1973	The Ohio State University, Columbus BSC with Distinction in Botany
MSc, 1977	The University of Wisconsin, Madison MS in Botany
PhD, 1983	The University of Wisconsin, Madison PhD in Horticulture and Botany

EXPERIENCE:

1988-Present	Biotechnology Research, EniChem Americas, Inc. Monmouth Junction, New Jersey Principal Scientist, Plant Physiology and Biochemistry Radiation Safety Officer
1986-1987	Biotechnology Research, EniChem Americas, Inc. Monmouth Junction, New Jersey Research Scientist, Plant Physiology and Biochemistry Radiation Safety Officer
1984-1986	Plant Sciences Department, Monsanto Agricultural Products Company St. Louis, Missouri Senior Research Biologist
1983-1984	Central Research Department, E.I. du Pont de Nemours and Company Wilmington, Delaware Visiting Scientist
1981-1983	Department of Botany, Washington State University Pullman, Washington Research Associate
1979-1980	Horticulture Department, University of Wisconsin Madison, Wisconsin Research Assistant

1977-1979	Horticulture Department, University of Wisconsin Madison, Wisconsin Research Assistant
1975-1977	Botany Department, University of Wisconsin Madison, Wisconsin Research Assistant
Summer 1975	Smithsonian Institution Scientific Exchange Program Montenegro, Yugoslavia Project Specialist
1973	Botany Department, The Ohio State University Columbus, Ohio Project Assistant

EXPERIENCE WITH RADIOACTIVE MATERIALS:

Nuclide	Maximum amount	Form	Location
^{3}H	5 mCi	THO Sugars Nucleosides	University of Wisconsin Washington State University DuPont Company Monsanto Company
^{14}C	25 mCi	$NaHCO_3$ Sugars Plant Hormones Organic acids	Ohio State University University of Wisconsin Washington State University DuPont Company Monsanto Company EniChem Americas
^{32}P	5 mCi	H_3PO_4	University of Wisconsin
^{45}Ca	1 mCi	$CaCl_2$	Ohio State University

RADIATION SAFETY TRAINING:

Formal training

University of Wisconsin, Madison -- Biochemical Techniques Course
3 one-hour lectures
- Types of radioactivity
- Biological effects of radiation
- Calculations/Mathematical relationships
- Detection instrumentation
- Autoradiography
- Safe handling procedures

2 four-hour laboratories
Liquid scintillation counting
Planchet counting
Radiation protection practices

Monsanto Agricultural Products Company, St. Louis, Missouri
2 three-hour lecture/discussions by Radiation Safety Officer
Types of radioactivity
Biological effects of radiation
Calculations
Detection instrumentation
Safe handling procedures
Disposal procedures

Princeton University, Princeton, New Jersey
1 two-hour presentation by Health Physics staff
Types of radioactivity
Biological effects of radiation
Detection instrumentation
Calculations
Safe handling procedures

Informal discussions with/presentations by Radiation Safety Officer/Health Physicist prior to initiating experimental work with radioactive materials

Departments of Botany and Horticulture, University of Wisconsin, Madison
Botany Department, Washington State University, Pullman, Washington
Central Research Department, E.I. du Pont de Nemours, and Co., Wilmington, Delaware

Practical experience with radioisotopes in biological laboratory research

Botany Department, The Ohio State University, 1972-1973
Botany Department, The University of Wisconsin, 1973-1977
Horticulture Department, The University of Wisconsin, 1977-1980
Botany Department, Washington State University, 1981-1982
Central Research Department, E.I. du Pont de Nemours, and Co., 1983-1984
Agricultural Products Department, Monsanto Company, 1985-1986
Biotechnology Department, EniChem Americas, Inc., 1987-1989

Nicholas P. Everett, PhD
Group Leader/Radioisotope Supervisor
Biotechnology Department
EniChem Americas, Inc.
2000 PrincetonPark Corporate Center
Monmouth Junction, NJ 08852

EDUCATION:

BSc, 1975	Kingston Polytechnic, Kingston-upon-Thames, England BSc in Applied Chemistry
PhD, 1978	University of Leicester, England PhD in Botany

EXPERIENCE:

1987-Present	Biotechnology Research, EniChem Americas, Inc. Monmouth Junction, New Jersey Group Leader, Cell Biology and Biochemistry
1985-1987	Biotechnology Research, Stauffer Chemical Co. Richmond, California Supervisor, Biochemical and Molecular Genetics Group Coordinator, Plant Biotechnology
1981-1985	Biotechnology Research, Stauffer Chemical Co. Richmond, California Research Biochemist/Senior Research Biochemist
1979-1981	Biochemistry Department, University of Liverpool Liverpool, England Senior Research Associate
1978-1979	Botany Department, University of Leicester Leicester, England Postdoctoral Research Associate

EXPERIENCE WITH RADIOACTIVE MATERIALS:

Nuclide	Maximum amount	Form	Location
^{3}H	50 μCi	Thymidine Estradiol	Kingston Polytechnic University of Liverpool
^{14}C	50 μCi	Amino Acids Plant Hormones	University of Leicester
^{86}Rb	50 μCi	$RbCl_2$	Kingston Polytechnic
^{203}Hg	50 μCi	$HgCl_2$	Kingston Polytechnic

At Stauffer Chemical Co., did not personally use radioactive material, but supervised staff use of a maximum or 1 mCi each of ^{14}C, ^{32}P, and ^{35}S.

RADIATION SAFETY TRAINING:

Formal training:

Kingston Polytechnic -- BSc in Applied Chemistry course
Formal instruction in the principles and practices of radiation protection, radioactivity measurements, standardization, monitoring techniques and instruments, calculation relating to use and measurement of radioactivity, and biological effects of radiation.

Practical experience with radioisotopes in laboratory research
Departments of Chemistry and Physics, Kingston Polytechnic, 1971-1975
Botany Department, University of Leicester, 1975-1977
Biochemistry Department, University of Liverpool, 1979-1981

Dorothy A. Pierce, PhD
Group Leader/Radioisotope Supervisor
Biotechnology Department
EniChem Americas, Inc.
2000 PrincetonPark Corporate Center
Monmouth Junction, New Jersey 08852

EDUCATION:

BA 1970	The Catholic University of America BA in Biology
PhD 1977	Brown University PhD in Developmental Biology

EXPERIENCE:

1987-Present	Biotechnology Research, EniChem Americas, Inc. Monmouth Junction, New Jersey Group Leader, Molecular Genetics
1985-1987	Biotechnology Research, Stauffer Chemical Co. Richmond, California Supervisor
1984-1985	Biotechnology Research, Stauffer Chemical Co. Richmond, California Senior Research Biologist/Project Leader/ Assistant Radiation Safety Officer
1981-1984	Biotechnology Research, Stauffer Chemical Co. Richmond, California Research Biologist/Assistant Radiation Safety Officer
1978-1981	Department of Zoology, University of North Carolina Chapel Hill, North Carolina Research Associate
1975-1978	Genetics Curriculum, University of North Carolina Chapel Hill, North Carolina NIH Postdoctoral trainee

EXPERIENCE WITH RADIOACTIVE MATERIALS:

Nuclide	Maximum amount	Form	Location
^{3}H	0.5 mCi	Nucleotides	Brown University
		Nucleotide precursors	University of North Carolina Stauffer Chemical Co.

^{14}C	0.5 mCi	Amino Acids	Brown University University of North Carolina Stauffer Chemical Co.
^{32}P	0.5 mCi	Nucleotides Nucleotide precursors	Brown University University of North Carolina
^{35}S	0.5 mCi	Amino Acids	University of North Carolina Stauffer Chemical Co.
^{125}I	10 μCi	Iodine	University of North Carolina

EXPERIENCE AS ASSISTANT RADIATION SAFETY OFFICER:

1981-1985 Stauffer Chemical Co.

Developed training procedures in use of radioisotopes
Organized/supervised ordering, storage, use and disposal of radioactive materials
Supervised safety monitoring of radioisotope laboratories

RADIATION SAFETY TRAINING:

Formal:

Orientation by radiation safety officer in use of radioactive materials
Yearly seminars on the use, detection, and biological effects of radioactive materials

Informal:

Inspection of facilities by consulting health physicist
On-the-job training tailored to individual isotopes and techniques.

MS=10

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03620
STATUS CODE: 0
FEE CATEGORY: 3M
EXP. DATE: 19921130
FEE COMMENTS: _____

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: ENICHEM AMERICAS, INC.
RECEIVED DATE: 890728
DOCKET NO: 3030152
CONTROL NO.: 111107
LICENSE NO.: 29-28080-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED $120
AMOUNT: 16296
CHECK NO.:

3. COMMENTS

SIGNED Jonte
DATE 8/3/89

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /__/)

1. FEE CATEGORY AND AMOUNT: 3M $120

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

3. OTHER _____
_____

SIGNED M. Maxwell
DATE 8/7/89