

## MATERIALS LICENSE

Amendment No. 14

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, 36, 39, 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	In accordance with application dated October 11, 1996	
1. Sigma Chemical Company	3. License Number 24-16273-01 is amended in its entirety to read as follows:	
2. P.O. Box 14508 St. Louis, MO 63178	4. Expiration Date October 31, 2001	
	5. Docket or Reference No. 030-10716	
6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Hydrogen-3	A. Any	A. 1000 curies
B. Carbon-14	B. Any	B. 800 curies
C. Phosphorus-32	C. Any	C. 1 curie
D. Sulfur-35	D. Any	D. 50 millicurie

## 9. Authorized Use:

- A. For research and development as defined in 10 CFR Part 30.4 and storage, processing and use in the production of labeled compounds for distribution to authorized recipients.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 11542 Fort Mims Drive, St. Louis, Missouri.
11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Thomas K. Spencer, Chairperson.
- B. The Radiation Protection Officer for the activities authorized by this license is Dennis W. Warner.
12. Licensed material shall not be used in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
24-16273-01

Docket or Reference Number  
030-10716

Amendment No. 14

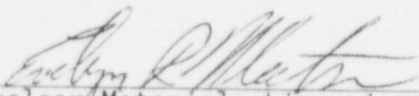
13. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
- A. Radioactive waste to be disposed of in this manner, shall be held for decay a minimum of 10 half-lives.
  - B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
14. This license does not authorize commercial distribution of licensed material.
15. The licensee shall maintain records of information important to safe and effective decommissioning at 11542 Fort Mims Drive, St. Louis, Missouri per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.
16. 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. Applications dated June 27, 1991 and October 11, 1996; and
  - B. Letters dated June 20, 1990, August 15, 1991, December 23, 1996 (with attachments), and March 7, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

MAR 21 1997

Date \_\_\_\_\_

By

  
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

(FOR LFMS USE)  
INFORMATION FROM LTS

Program Code: 03610  
Status Code: 0  
Fee Category: 3B  
Exp. Date: 20011031  
Fee Comments:  
Decom Fin Assur Req'd: Y

R9

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: SIGMA CHEMICAL COMPANY  
Received Date: 961015  
Docket No: 3010716  
Control No.: 301947  
License No.: 24-16273-01  
Action Type: Amendment

2. FEE ATTACHED

Amount: 580  
Check No.: 514371

3. COMMENTS

Signed D. Hersey  
Date 10-16-96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered ☒)

1. Fee Category and Amount: 3B \$580

2. Correct Fee Paid. Application may be processed for:  
Amendment ☒  
Renewal ☐  
License ☐

3. OTHER

Signed sc  
Date 10/22/96

1996 OCT 21 AM 11:41

OCT 28 1996

Log	<u>OCT 9 711</u>
Remitter	
Check No.	<u>514371</u>
Amount	<u>\$580</u>
Fee Category	<u>3B</u>
Type of Fee	<u>AmD</u>
Date Check Rec'd	<u>10/21/96</u>
Date Completed	<u>10/22/96</u>
By:	<u>sc</u>

A 580



(10-94)  
10 CFR 30, 32, 33  
34, 35, 36, 39 and 40

## APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-6 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

## APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY  
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS  
U.S. NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555-0001

## ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

## IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,  
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,  
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION  
NUCLEAR MATERIALS SAFETY BRANCH  
U.S. NUCLEAR REGULATORY COMMISSION, REGION I  
475 ALLEN DALE ROAD  
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO  
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,  
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION II  
101 MARIETTA STREET, NW, SUITE 2900  
ATLANTA, GA 30323-0199

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

## IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,  
SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION III  
801 WARRENVILLE RD.  
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,  
LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA,  
OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH,  
WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION  
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TX 76011-8064

## 1. THIS IS AN APPLICATION FOR (Check appropriate item)

☐ A  
☒ B  
☐ C

NEW LICENSE

AMENDMENT TO LICENSE NUMBER 24-16273-01

RENEWAL OF LICENSE NUMBER

## 2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

Sigma Chemical Company  
PO Box 14508  
St. Louis, MO 63178-9974

## 3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Sigma Chemical Company  
11542 Ft. Mims  
St. Louis, MO 63146-3510

## 4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dennis Warner

TELEPHONE NUMBER

(314) 771-5765

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

## 5. RADIOACTIVE MATERIAL

a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

## 6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

## 7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

## 8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

## 9. FACILITIES AND EQUIPMENT

## 10. RADIATION SAFETY PROGRAM

## 11. WASTE MANAGEMENT

## 12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3B

AMOUNT

ENCLOSED \$ 580

## 13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

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.

## CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Ronald Teller, Vice-President

## SIGNATURE

Ronald Teller

## DATE

10/11/96

## FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

AMOUNT RECEIVED

CHECK NUMBER

COMMENTS

\$

APPROVED BY

DATE

pm 10-11-96

OCT 15 1996

301947



**SIGMA**

CHEMICAL COMPANY



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TELEPHONE: USA/CANADA 1-800-325-3010  
OUTSIDE USA/CANADA call COLLECT 314-771-5750

October 11, 1996

APPLICATION FOR MATERIALS LICENSE AMENDMENT

License #: 24-16273-01

Sigma Chemical Company  
11542 Ft. Mims

- Item 5: No changes to this section are requested.
- Item 6: No changes to this section are requested.
- Item 7: See attached information.
- Item 8: No changes to this section are requested.
- Item 9: No changes to this section are requested.
- Item 10: Our updated Radiation Safety Program is attached.
- Item 11: No changes to this section are requested.
- Item 12: License type: 3B                      Fee enclosed: \$580

DENNIS W. WARNER  
Radiation Safety Officer

Mr. Warner has been with Sigma since 1984. He has worked at the Radiochemicals facility since 1987. He has a bachelors degree in Biology with a minor in chemistry from Marryville University in St. Louis, MO, and a Masters of Science in Industrial Hygiene from Central Missouri State University in Warrensburg , MO.

He has had production experience with Tritium and with Carbon-14 at the 5 Curie level. He has worked in all phases of the health physics program at the radiochemicals facility, and was primarily responsible for developing the format of many of the records systems currently in use at the facility.

Dennis was involved in the development of packages for certification testing and in the shipment of products from Radiochemicals. He has been involved in and is familiar with the preparation and shipment of materials for treatment or disposal.

THOMAS K. SPENCER  
Chairman, Radiation Safety Committee

Mr. Spencer received a B.A. degree in chemistry in 1975 from Central Methodist College, Fayette, Missouri, and a M.S. degree in organic chemistry from Bowling Green State University in 1980.

Mr. Spencer held the position of Associate Scientist with Polaroid Corporation in Cambridge, Massachusetts, from 1979 to 1986, where he was responsible for the synthesis of compounds important in color imaging processes. He then joined the staff at Chemsyn Laboratories in Lenexa, Kansas, as a Scientist responsible for the synthesis of tritium and carbon-14 labeled compounds. He spent over 2 ½ years at Chemsyn, during which time he became Acting Group Leader of a radio-synthesis group. Mr. Spencer then took a position as Senior Staff Scientist with Oread Laboratories in Lawrence, Kansas, where he became Group Leader. During his 6 ½ years with Oread, he was responsible for the overall management of the company's synthesis program, which included stable- and radio-isotope synthesis, including tritium, carbon-14, iodine-125 and zinc-65.

Mr. Spencer joined Sigma Radiochemicals in May of 1994, where he currently holds the position of Production Manager.

## RADIATION PROGRAM COMPARISON TABLE

License Number: 24-16273-01

Page Number of Old Version	Old Version	New Version
	Table of Contents	Sections identified in Table of Contents remained unchanged. However, Appendix A through C were listed as additions to Section XXI. Page Numbers changed accordingly.
Page 1	Section I, Table of Abbreviations.	Added three more abbreviations in the alphabetic listing. "CFR: Code of Federal Regulations; GM: Geiger-Mueller; Sv: Sievert"
Page 2	Section II, ALARA Philosophy (paragraph 4): "A Radiation Safety Committee shall be established to review and evaluate both the ALARA efforts of the Radiation Safety Staff and laboratory personnel, and the effectiveness of the radiation safety program....."	Replaced with, "A Radiation Safety Committee, (RSC), shall be established to review and evaluate both the ALARA efforts of the Safety Department, Department Management and Supervisors, operations personnel and the effectiveness of the radiation safety program....."
Page 3	Section III, Radiation Safety Committee. (paragraph 2): ".....The RSC shall meet quarterly to review and evaluate the ALARA efforts of the Radiation Safety staff and laboratory personnel as well as the overall effectiveness of the program."	Replaced with: "The RSC shall meet quarterly to review and evaluate the ALARA efforts of the Safety Department, Department Management and Supervisors, Operations personnel, and the effectiveness of the radiation safety program."
Page 3	Section III. The RSC membership shall be comprised of personnel from the following positions: Radiation Safety Officer - Harold Jackson Company Officer - Ron Wolfe Safety Director - Fred Shaffstall Compliance Officer - Elsa Steward Chairman, Radiochemicals Site Committee - Paul Spangler Chairman, Cherokee Site Committee-Al Fasching Chairman, Dekalb Site Committee-Brian Delmez Management Alternate -Steve Doelger	Replaced with: Radiation Safety Officer Senior Management Representative Safety Director Compliance Representative Chairperson, Radiochemicals Site Committee Chairperson, Cherokee Site Committee Chairperson, Dekalb Site Committee Additional Members  Note: Names of the membership were changed and moved to Appendix A.
Page 3	Section III (Item #2), "Provide guidance to the RSO and operations personnel"	Replaced with "Provide guidance to Safety and operations personnel."



**SIGMA CHEMICAL COMPANY**  
**LICENSE NO: 24-16273-01**

Page 3	Section III, (Item #4): "Approve plans for additional laboratories"	Replaced with: "Approve plans for new or revised facilities or equipment"
Page 3	Section III, (Item #8): "A quorum shall require the presence of the RSO, a company officer, the Compliance Officer, and a representative from each of the site committees"	Replaced with: "A quorum shall require the presence of the RSC chairman, the RSO, a Senior Management Representative, and a representative from each of the site committees."
Page 4	Section III, Item #9 list the names of the employees that are on the site committees for Cherokee, Dekalb, Radiochemicals and Spruce.	The list of names have changed for all sites and moved to Appendix B.
Page 5	Section IV, Radiation Safety Officer (first paragraph), "The Radiation Safety Officer reports directly to the Radiation Safety Committee. The RSO shall be responsible for the implementation and completeness of the radiation safety program. Through his efforts and direction the radiation safety program shall be the primary guideline utilized by all employees to assure their safety while radioactive materials are present. His duties shall include, but not limited to the following:" 1. Implement the policies and recommendations of the RSC."	Replaced with, "The Radiation Safety Officer reports directly to the Radiation Safety Committee on all matters concerning the ALARA program. The RSC, acting through the RSO, shall be responsible for the implementation and completeness of the radiation safety program. Through the efforts and direction of the RSO, the radiation safety program shall be the primary guideline utilized by all employees to assure their safety while radioactive materials are present. RSO duties shall include, but not limited to the following: (1). Assist Department Management in implementing the policies and recommendations of the RSC."
Page 7	Section VI, Personnel Exposure -	This section was changed to reflect the new regulations effective Jan 1994 (10 CFR 20)
Page 7	Section VII, Prenatal Exposure (paragraph 2)	This section was reworded.
Page 7	Section VII Prenatal Exposure (paragraph 3): "If the integrated exposure totals 300 mrem within 6 months or less, the work load of the individual will be critically reviewed." .....	Changed last part of the sentence "If the integrated exposure totals 300 mrem within 6 months or less, the work load of the individual will be reviewed by Department Management and the RSO" .....
Page 8	Section VIII, Posting Requirements. (bottom of page) "As an alternative, a notice may be attached to the NRC-3 describing the location where items three thru six may be found and are available for review."	Add to the sentence at the bottom of the page, "The site committee is responsible for ensuring the required information is posted."

**SIGMA CHEMICAL COMPANY**  
**LICENSE NO: 24-16273-01**

Page 9	Section, IX Maintenance and Housekeeping, (Item #1): "Permission is required from the RSO or radiation supervisor before any maintenance or housekeeping activities....."	Replace with: "Permission is required from the RSO, the area radiation supervisor, or at radiochemicals, department management before any maintenance....."
Page 9	Section IX, Maintenance and Housekeeping, (Item # 2): "Before permission will be issued, the RSO or radiation supervisor will:....."	Replaced with " Before permission will be issued, the RSO , area radiation supervisor, or at radiochemicals, department manager will....."
Page 9	Section IX, (Item #3), "Upon completion of the work, the RSO will inspect the area to assure that any work performed has not caused a reduction in the effective of any safety program or equipment....."	Replace with, "Upon completion of the work, the RSO will ensure that any work performed has not caused a reduction in the effectiveness of any safety program or equipment....."
Page 10	Section X, Personnel Training, "All personnel will be provided with annual refresher training covering the following:....."	Replaced with "All personnel will be provided with initial and annual refresher training covering the following:....."
Page 11	Section XI, Responsibility of Individuals Working with Radioactive Material.	Combined #2 and #7. Item #11 was added to the bottom of the list: "11. Following required radiation procedures"
Page 12	Section XII, General Rules for Safe Handling of Radioactive Material. (Item #5): "All spills of radioactive material must be reported to the supervisor of the area involved and decontaminated immediately"	Replaced with, "All spills of radioactive material must be reported immediately to the area radiation supervisor or the RSO."
Page 12	Section XII,	Item #4 was combined with Item #3. Item #12 was added to the list: "12. Follow required radiation procedures."
Page 12	Section XII, (Item #9): "Disposal of radioactive waste into sanitary sewers is not permitted."	Replaced with, "Disposal of radioactive waste into sewer system is not permitted unless specifically approved by the Radiation Safety Committee."
Page 12	Section XII, (Item #11): "Each person must wash and survey their hands upon leaving any area where radioactive material is used or stored."	Add another sentence to Item #11, "Contamination must be reported to the RSO immediately."
Page 13	Section XIII, Personnel Monitoring (Health Physics Program), (Section A): "Each individual using radioactive materials shall be furnished with a commercial film badge on a monthly basis from a vendor that is an NRC approved and appropriately licensed....."	Replaced with : "Each individual using radioactive materials at the Dekalb and Cherokee facilities, shall be furnished with a commercial film badge....."

**SIGMA CHEMICAL COMPANY**  
**LICENSE NO: 24-16273-01**

Page 13	Section XIII, (Section C): "All persons working at the Radiochemicals facility, including contract guards, shall be required to participate in a bioassay program."	Replaced with: "All persons working at the Radiochemicals facility, including contract Security Officers, shall be required to participate in a bioassay program. Radiochemicals Department are not required to wear film badges."
Page 15	Section XV, Radioactive Material Ordering and Inventory. (Paragraph 1), "The RSO is responsible for ensuring that the radioactive material inventory does not exceed license limits."	Replaced with: "The RSC through the RSO is responsible for ensuring that the radioactive material inventory does not exceed license limits. The RSO is responsible for monitoring the radioactive materials inventory."
Page 15	Section XVI, Procedures for Shipping Radioactive Material, "All shipments of radioactive material shall be made under the authority of the RSO. All radioactive material.....Sigma Chemical company drivers assigned to this function shall be trained to respond to emergency situations involving radioactive materials."	Last sentence was changed to "Sigma Chemical Company drivers assigned to this function shall be trained to respond to emergency situations involving all classes of hazardous materials."
Page 16	Section XVII, Receiving and Opening Radioactive Material Packages, (paragraph 2): "Upon arrival of all packages of radioactive material, the RSO or designate shall be notified. The RSO or designate will then ensure:....."	Replaced with, "Upon arrival of any package of radioactive material, the RSO or a site committee member shall be notified. The RSO or site committee member will then ensure:....."
Page 16	Section XVII, (paragraph 3) references 10 CFR 20.205	This section was changed to reflect the new regulations effective Jan 1994 (10 CFR Part 20). Replaced with new reference 10 CFR 20.1906
Page 16 and 17	Section XVII, Section A & B	Section A & B were combined into Section A.
Page 18	Section XVIII, Emergency Procedures. Minor and Major spills were specifically separated in Section B.	Combined Minor and Major spill sections into one, under Section B.
Page 20	Section XIX, Record Management. (paragraph 1): "The following records should be audited quarterly by the RSO and reported to the RSC....."	Replaced with, "The following records should be reviewed by the RSO and reported to the RSC."



**SIGMA CHEMICAL COMPANY**  
**LICENSE NO: 24-16273-01**

Page 21	Section XXI, Approval of Employees to Use Byproduct, (paragraph 3), "Employees considered for "approved employee" status must be recommended by their department head and approved by a committee established by the Radiation Safety Committee. The committee shall consist of the RSO, the Safety Director and the Radiation Supervisor from the primary work area. Employees approved to work with licensed materials will receive a copy of this manual along with training as outlined in Section X of the Program."	Replaced with, "Employees considered for "approved employee" status must be recommended by their department head, receive medical approval, be approved by the Radiation Supervisor from the primary work area, and by the RSO. These employees will be submitted to the RSC for confirmation. All employees approved to work with licensed materials will receive a copy of this manual along with training as outlined in Section X of the Program."
Page 21	Section XXI, Approval of Employees to Use Byproduct Material. (paragraph 4), "Employees considered for authorized user status shall be recommended to the RSO by their Radiation Supervisor. The RSO will provide the necessary information to the RSC for their review and consideration."	Replaced with, " "Approved employees" considered for "authorized user" status shall be recommended by the RSO. The RSO will provide the necessary information to the RSC for their review and confirmation."

CLARIFICATIONS REQUESTED BY MR. JAMES MULLAUER, NRC ARE IN BOLD

February 22, 1995  
October 1, 1996

SIGMA CHEMICAL  
RADIATION SAFETY PROGRAM MANUAL  
ALL FACILITIES

Copy No.

Issued to:

## TABLE OF CONTENTS

I.	Table of Abbreviations	1
II.	ALARA Philosophy	2
III.	Radiation Safety Committee	3
IV.	Radiation Safety Officer	5
V.	Classification of Areas	6
VI.	Personnel Exposure	6
VII.	Prenatal Exposure	6
VIII.	Posting Requirements	7
IX.	Maintenance and Housekeeping	8
X.	Personnel Training	9
XI.	Responsibility of Individuals Working With Radioactive Material	10
XII.	General Rules for Safe Handling of Radioactive Material	11
XIII.	Personnel Monitoring (Health Physics Program)	12
XIV.	Area Survey Procedures	13
XV.	Radioactive Materials Ordering and Inventory	14
XVI.	Shipping Radioactive Material	14
XVII.	Receiving and Opening Radioactive Material Packages	15
XVIII.	Emergency Procedures	16
XIX.	Record Management	17
XX.	Approval of Laboratories for Use of Byproduct Material	17
XXI.	Approval of Employees to Use Byproduct Material	18
	Approvals	19
	Appendix A - RSC Membership	20
	Appendix B - Site Committee Membership	20
	Appendix C - Radiochemicals Department Supplement	21



# I. Table of Abbreviations

The following are abbreviations used in this manual. They are as follows:

ALARA:	As Low as Reasonably Achievable
CFR:	Code of Federal Regulations
GM:	Geiger-Mueller
mCi:	Millicurie
MPC:	Maximum Permissible Concentration
mrem:	Millirem
NBS:	National Bureau of Standards
NCRP:	National Council on Radiation Protection and Measurements
NRC:	Nuclear Regulatory Commission
RSC:	Radiation Safety Committee
RSO:	Radiation Safety Officer
Sv:	Sievert
uCi:	Microcurie

## II. ALARA Philosophy

The management of Sigma Chemical Company, Inc. is committed to the policy of keeping individual and collective exposures As Low As Reasonably Achievable, (ALARA). The management has established the support necessary to administer a program that promotes the concept of ALARA.

An annual formal review of the Radiation Safety Program shall be conducted which will include the operating procedures, past exposures and a review of the corrective actions taken in the past and their effectiveness.

Modifications that were made at the time of need may have been as temporary measures to determine their effectiveness. Permanent modifications to operating procedures, equipment and facilities will be made where such changes will reduce exposures, unless, in our judgement, the cost is unjustified. Whenever modifications are recommended but not implemented, the reasons shall be documented.

A Radiation Safety Committee, (RSC), shall be established to review and evaluate both the ALARA efforts of the Safety Department, Department Management and Supervisors, operations personnel and the effectiveness of the radiation safety program. The RSC delegates enforcement authority for the ALARA program to the Radiation Safety Officer, (RSO), and supports necessary assertion of the authority.

The Radiation Safety Officer shall review all operational elements of the ALARA program annually. A quarterly review will be conducted of occupational exposures and investigations into determined elevated levels. All findings shall be documented and reported to the RSC.

The RSO shall ensure development of the ALARA program and promote its growth with the laboratory personnel.

III. Radiation Safety Committee

Sigma Chemical Company has established a radiation safety program which promotes the ALARA concept. This program is the responsibility of the Radiation Safety Committee.

The RSC shall delegate enforcement authority to the Radiation Safety Officer for the program, and supports necessary assertion of that authority. The RSC shall meet quarterly to review and evaluate the ALARA efforts of the Safety Department, Department Management and Supervisors, operations personnel, and the effectiveness of the radiation safety program.

RSC membership shall be comprised of the following positions:

- Radiation Safety Officer
- Senior Management Representatives
- Safety Director
- Compliance Representative
- Chairperson, Radiochemicals Site Committee
- Chairperson, Cherokee Site Committee
- Chairperson, DeKalb Site Committee
- Additional Members

The RSO shall be appointed by the RSC and shall be qualified to perform the duties of the RSO by a combination of education and experience. This will typically include a related degree in the sciences and experience relative to the materials being handled. The RSO is named on the materials licenses. The name and qualifications of the RSO must be submitted to the NRC.

The Chairman of the RSC is also named on the materials licenses. The Chairman of the RSC must be qualified to understand the nature and scope of the materials operations. Like the RSO, The name and qualifications of the chairman must be submitted to the NRC.

If either of the above positions shall become vacant the RSC shall name an acting Chair or RSO. The RSC shall continue to direct program operations during submission of the qualifications of the individual to NRC.

The membership of this committee may change due to such things as promotions and assignment changes. Each new member shall have sufficient qualifications through training and experience so that the overall effectiveness of the radiation safety program shall not be diminished. The current RSC membership is listed in Appendix A.



Duties of Radiation Safety Committee:

1. Establish policies for the safe use and handling of radioactive materials, including this Radiation Safety Program and revisions.
2. Provide guidance to Safety and operations personnel.
3. Review audits and safety evaluations.
4. Approve plans for new or revised facilities or equipment.
5. Approve Standard Operating Procedures.
6. A secretary shall keep minutes of all meetings. The minutes shall be approved at the next meeting of the RSC and be retained for the duration of the license.
7. Annual review of all aspects of the program.
8. A quorum shall require the presence of the RSC chairman, the RSO, a Senior Management Representative, and a representative from each of the site committees.
9. Site radiation committees shall be formed to deal with the daily operational needs of each facility. The RSO shall be a member of each site committee. The site committee shall meet as necessary to carry out the ALARA program, but no less than Quarterly. Each site committee shall elect a chairman to represent it at Radiation Safety Committee meetings and a secretary to keep minutes of the meetings.

The current membership of each site committee is listed in Appendix B. Any change in membership of a site committee shall meet the same guidelines as the RSC and shall be approved by the RSC.

#### IV. Radiation Safety Officer

The Radiation Safety Officer reports directly to the Radiation Safety Committee on all matters concerning the ALARA program. The RSC, acting through the RSO, shall be responsible for the implementation and completeness of the radiation safety program. Through the efforts and direction of the RSO, the radiation safety program shall be the primary guideline utilized by all employees to assure their safety while radioactive materials are present. RSO duties shall include, but not be limited to the following:

1. Assist Department Management in implementing the policies and recommendations of the RSC.
2. Prepare and maintain pertinent records of personnel exposures, radioactive material receipt, radioactive waste disposal, laboratory surveys and evaluations, equipment evaluations, leak testing of sealed sources, approved users of radioactive material, relevant State and Federal regulations, licenses and licensing correspondence.
3. Approve, process and record orders for all radioactive material.
4. Establish procedures for regular area monitoring, facility surveys, leak testing of sealed sources of radioactive material, personnel monitoring, waste disposal, package monitoring and survey instrument calibration.
5. Establish and maintain a program to receive and monitor incoming shipments of radioactive material.
6. Establish and maintain a program to monitor and approve outgoing shipments of radioactive material.
7. Coordinate a continuing program of instruction for personnel regarding the safe use of ionizing radiation as required by 10 CFR Part 19.
8. Maintain the radiation safety equipment used by the Radiation Safety Officer.
9. Provide consultation and assistance, covering:
  - a) Decontamination of personnel and areas subsequent to accidental spills of radioactive material.
  - b) Prenatal radiation exposure.
  - c) Preparation and audits of radiation safety evaluation reports for the RSC.
10. Immediately terminate any operation found to be unsafe or in violation of NRC and/or RSC rules and regulations.
11. Report all serious problems to the RSC promptly.
12. Conduct annual audits of all operations to determine that they are in compliance with NRC requirements and RSC authorization.

**NOTE: The RSO is responsible for the completion of the above duties, but is not required to personally perform all of them. The RSO may utilize qualified personnel to assist in the performance of these duties.**

## V. Classification of Areas

The following classifications pertain to the various laboratories and other areas in the facilities.

1. **UNRESTRICTED AREA-** Any area, access to which is not controlled by Sigma for purposes of protection of individuals from exposure to radiation and radioactive materials.
2. **RESTRICTED AREA-** Any area, access to which is controlled by Sigma for purposes of protection of individuals from exposure to radiation and radioactive materials.

All restricted areas shall be identified by the presence of appropriate signs posted at each entrance to the area.

## VI. Personnel Exposures

Control and safety procedures for restricted areas must be such that exposure of any individual 18 or more years of age shall not exceed the annual limitations of 10 CFR Part 20, Subpart C.

1. The annual limit, which is the more limiting of -
  - i) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or
  - ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).
2. The annual limits to the lens of the eye, to the skin, and to the extremities, which are:
  - i) An eye dose equivalent of 15 rems (0.15 Sv), and
  - ii) A shallow dose equivalent of 50 rems (0.50 Sv) to the skin or to any extremity.
3. The whole body exposure of any individual under 18 years of age is limited to 10% of the doses listed above.

## VII. Prenatal Exposure

All radiation workers should be aware and understand the special precautions concerning exposure during pregnancy, and the reasons for this recommendation, especially that the dose equivalent to the embryo or fetus from occupational exposure of the expectant mother should not exceed 500 mrem. The required information is available as NRC Regulatory Guide 8.13 (rev. 2, or as current). A copy of this guide may be obtained by contacting the RSO.

Additional limits and protective measures are required for a "declared pregnant woman" by 10 CFR 20.1208. At the time of her choosing, a pregnant radiation worker should inform the RSO of her condition. The employee's work assignments will be discussed, taking into account her past exposure record. An evaluation will be made to determine whether the employee's work assignment and personal monitoring program needs to be modified.

If the integrated exposure totals 300 mrem within 6 months or less, the work load of the individual will be reviewed by Department Management and the RSO. Unless work assignment changes resulting in a substantial reduction of radiation exposure are feasible, the employee will be advised to request a transfer or a leave of absence. If the integrated exposure approaches 500 mrem, a transfer or leave of absence is mandatory.



## VIII. Posting Requirements

Signs are required to denote certain areas or containers as follows:

"Caution Radioactive Material" signs are required to signify areas in which radioactive material is used or stored in amounts exceeding ten times the quantity of such material specified in Appendix C of 10 CFR Part 20.

A "Caution Radioactive Material" label must be affixed to any container used to store radioactive material.

Exceptions:

1. Containers in which contents are less than the quantities specified in Appendix C of 10 CFR Part 20.
2. Containers when they are attended by the user, e.g., beakers, flasks, etc. used transiently in laboratory procedures.

When containers are used for storage of radioactive material, the label must state the radionuclide, chemical composition, hazard classification, activity, and date.

### Notices to Workers

The NRC requires each licensee to post current copies of the following documents:

1. NRC-3 "Notice to Employees"
2. Any notices of violation involving licensed activities.
3. The regulations of 10 CFR Part 19, "Notices, Instructions, and Reports to Workers: Inspections and Investigations".
4. The regulations of 10 CFR Part 20, "Standards for Protection Against Radiation".
5. The NRC license, license conditions and amendments.
6. The operating procedures applicable to licensed activities.

As an alternative, a notice may be posted with the NRC-3 form describing the location where items three through six may be found or are available for review. The site committee is responsible for ensuring the required information is posted.

IX. Maintenance and Housekeeping

In order to control access to restricted areas, the following policies will apply:

1. Permission is required from the RSO, the area radiation supervisor, or at Radiochemicals, department management before any maintenance or housekeeping activities can be carried out in the restricted area, so that the RSO or radiation supervisor can provide appropriate surveys and personnel monitoring. This does not apply to routine activities of the RSO, radiation supervisors, or other individuals approved to work with radioactive materials.

Emergency repairs be undertaken at any time; however, the RSO, area radiation supervisor or at Radiochemicals, department management must be notified immediately.

2. Before permission will be issued, the RSO, area radiation supervisor or at Radiochemicals, department management will:
  - a) review with the Maintenance or Facility Services personnel the type of work that will be done;
  - b) determine that the restricted area is safe, and
  - c) check any equipment being worked on for possible internal as well as external contamination.
3. Upon completion of the work, the RSO will ensure that any work performed has not caused a reduction in the effectiveness of any safety program or equipment. Any work performed that may have caused such reduction will not be approved, and corrective actions must be taken.
4. The personnel involved may be required to participate in an appropriate exposure evaluation.

X. Personnel Training

All personnel will be provided with initial and annual refresher training covering the following:

1. Areas where radioactive material is used or stored.
2. Potential hazards associated with particular radioactive isotopes.
3. Radiological safety procedures appropriate to the duties of the participants.
4. Pertinent conditions of the NRC license.
5. Rules and regulations of the NRC license.
6. Employees' obligations to report unsafe conditions.
7. Appropriate response to emergencies involving radioactive material.
8. Employees' right to be informed of their radiation exposure and bioassay results.
9. Locations where the licensee has posted or made available notices, copies of regulations, and copies of the license and license conditions as required by 10 CFR Part 19.
10. The ALARA exposure philosophy.
11. A review of their responsibilities under the program, Section XI, and the general rules in Section XII.



XI. Responsibility of Individuals Working with Radioactive Material

Those persons assigned work that includes handling radioactive material are responsible for the safe use of the material. Their responsibilities include, but are not limited to:

1. Complying with Company, State, and Federal regulations pertaining to ionizing radiation.
2. Complying with bioassay requirements and / or wearing a personal radiation . or when required.
3. Maintaining adequate survey records, radioactive materials use records, and radioactive waste records.
4. Preparing routine inventories of radionuclides in their possession or under their control.
5. Knowing the locations where radioactive material is used or stored.
6. Maintaining their radiation exposure as low as reasonably achievable, (ALARA).
7. Using all recommended protective equipment and practices while working with ionizing radiation.
8. NO smoking, eating, and drinking in areas in which radioactive material is stored or used, as well as, strict observance of other good laboratory practices.
9. Reporting all radioactive spills or accidents and unsafe conditions.
10. Knowing the appropriate response to an emergency involving radioactive material.
11. Following required radiation procedures.

XII. General Rules for Safe Handling of Radioactive Material

1. All areas where radioactive materials are used or stored shall be posted with appropriate signs in accordance with relevant sections of 10 CFR Part 20 Subpart J.
2. Eating, storing or preparing food, smoking, or applying cosmetics is forbidden in any area where radioactive material is stored or used.
3. Direct contact with radioactive material must be avoided by using protective laboratory coats, wearing appropriate disposable gloves, and employing safety pipetters. Pipetting by mouth is not permitted at any time.
4. All spills of radioactive material must be reported immediately to the area radiation supervisor or the RSO.
5. Complete records of use and disposal of radioactive material must be kept.
6. Work should be carried out in a hood in all cases where radioactive material may be lost by volatilization, dispersion of dust, or by spraying or splattering. Whenever possible, work should be done in closed containers.
7. All radioactive samples should be kept in closed containers which are properly labeled showing the radionuclide, activity, chemical composition, hazard classification and date.
8. Disposal of radioactive waste into sewer systems is not permitted unless specifically approved by the Radiation Safety Committee
9. Contaminated solid waste must be placed into designated labeled waste containers, never into ordinary trash receptacles.
10. Each person must do a preliminary survey of their hands upon leaving any area where radioactive material is used or stored. After the preliminary survey employees must wash and resurvey their hands. Contamination detected during either survey must be reported to the RSO immediately.
11. All laboratory glassware and equipment shall be properly decontaminated after use.
12. Follow required radiation procedures.

XIII. Personnel Monitoring (Health Physics Program)

- A. Each individual using radioactive materials at the DeKalb and Cherokee facilities, shall be furnished with a commercial film badge on a monthly basis from a vendor that is an NRC approved and appropriately licensed commercial service, or participate in a bioassay program. Any elevated exposure will result in an immediate evaluation by the RSO. Personnel at Spruce, who handle only prepackaged products, shall participate in a bioassay program only in the event of a spill, and are not required to wear film badges.
- B. A bioassay program is required for employees working under the following conditions:
  - 1) Whenever working with quantities in excess of 100  $\mu\text{Ci}$  of I-125 in volatile or dispersible form, or with quantities greater than 1 mCi of I-125 bound to a nonvolatile agent.
  - 2) Whenever working with quantities in excess of 100  $\mu\text{Ci}$  of H-3, C-14 or P-32 in volatile form, or with quantities greater than 1 mCi in nonvolatile form.
- C. All persons working at the Radiochemicals facility, including contract security officers, shall be required to participate in a bioassay program. Radiochemicals Department personnel are not required to wear film badges **when working only with Tritium or Carbon-14.**



#### XIV. Area Survey Procedures

##### Frequency of Surveys

Laboratory areas shall be surveyed at least monthly. The RSC will designate those areas which require surveys on a weekly basis.

A survey shall consist of:

1. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mrem/hour, and/or,
2. A series of wipe tests to measure removable contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 220 dpm per 100 cm<sup>2</sup> for the contaminant involved.
3. Decontamination of area(s) found to be in excess of 220 dpm per 100 cm<sup>2</sup>, except the restricted area at Radiochemicals which is allowed 2200 dpm per 100 cm<sup>2</sup>.
4. Air sampling is required only when using quantities greater than 100 uCi of H-3, C-14, P-32 or I-125 in volatile form or quantities greater than 1 mCi in nonvolatile form.

A permanent record shall be kept of all survey results. The record shall include:

1. Location, date and name of the surveyor.
2. Drawing of area surveyed to identify relevant features such as active storage areas, active waste areas, etc.
3. Measured exposure rates, keyed to locations on the drawing. Rates that require corrective actions are identified.
4. Detected contamination levels, keyed to locations on drawing.
5. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

XV. Radioactive Material Ordering and Inventory

The RSC through the RSO is responsible for ensuring that the radioactive material inventory does not exceed license limits. The RSO is responsible for monitoring the radioactive materials inventory.

As a result:

1. All orders for radioactive material shall be submitted to the RSO, or the Safety Director in his absence, for approval, regardless if it is from an outside source or an inter-departmental transfer.
2. A complete, physical inventory of all radioactive material shall be conducted on an annual basis under the direction of the RSO.

Before approving any request for additional material, the RSO shall consider the amount of radioactivity being requested, the current inventory, material received since the latest inventory, the amount of radioactivity shipped and the amount of material released as waste.

XVI. Procedures for Shipping Radioactive Material

All shipments of radioactive material shall be made under the authority of the RSO. All radioactive material shall be packaged, labeled and transported in a manner consistent with NRC and DOT regulations. This includes all interplant material transfers. Sigma Chemical Company drivers assigned to this function shall be trained to respond to emergency situations involving all classes of hazardous materials.

## XVII. Receiving and Opening Radioactive Material Packages

Radioactive material shall be received only during normal working hours.

Upon arrival of any package of radioactive material, the RSO or a site committee member shall be notified. The RSO or site committee member will then ensure:

1. That the order is as placed,
2. That the package appears to be undamaged, and
3. When required by 10 CFR 20.1906, that the levels of surface contamination and external exposure are within acceptable limits.

If at any time during this procedure, the package is determined to have radiation levels or external levels of contamination in excess of those permitted by 10 CFR 20.1906, the RSO shall notify the final delivering carrier and the Region III NRC Inspection and Enforcement Office.

The following procedures for opening packages containing radioactive material have been developed for use by the RSO or designate to assure compliance with 10 CFR 20.1906.

### A. Packages where no damage is present or suspected:

1. Put on appropriate disposable gloves.
2. Visually inspect package for any sign of damage (e.g., wetness, crushed, etc.). If the package is damaged, place it in a strong tight container and transport to a fume hood.
3. Measure and record exposure rate at three feet from package surface using a Geiger-Mueller, (GM), meter.
4. Measure surface exposure rate using a GM meter and record.
5. Open the outer package (following manufacturer's direction if available) and remove packing slip. Open inner package to verify contents (compare requisition packing slip and label on bottle), and check integrity of final source container (inspecting for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
6. Wipe external surface of the final source container with cotton swab or filter paper and assay by liquid scintillation counting. Survey using a GM meter. Record all results.
7. Monitor the packing material and packages for contamination before discarding. If contaminated, treat as radioactive waste. If not contaminated, obliterate radiation labels before discarding in regular trash.

### B. Packages where damage is present or suspected:

1. Inform the RSO immediately, to permit any required notifications to be made.



## XVIII. Emergency Procedures

### A. Posting of Emergency Instructions

Emergency instructions are posted in all areas where radioactive materials are stored or handled. These instructions shall describe immediate action to be taken in order to prevent contamination of personnel and work areas, as well as state the names and telephone numbers of the responsible persons to be notified in case of an emergency.

### B. Emergency Procedures Involving Spills

Any spill may present a risk of exposure or chemical hazard.

1. Notify personnel not involved to vacate the area.
2. Notify Department Management and the RSO or Safety Director immediately.
3. Restrict the movement of any potentially contaminated personnel to prevent the spread of contamination.
4. Prevent spreading by covering the spill with absorbent material, or shield the spill appropriately if this can be accomplished without further spread of contamination or significantly increasing your radiation exposure.
5. Leave the area and lock or post the door(s) to prevent entry.
6. Contaminated clothing should be removed and stored for further evaluation. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

All corrective action, incident reports, monitoring, decontamination efforts, and notifications shall be the responsibility of and directed by the RSO, or other safety department personnel.

### C. Fire Emergency Procedure

Follow instructions in the Facility Emergency Plan. The local Fire Departments have been notified and are aware of the materials utilized at our facilities.

XIX. Record Management

The following records **shall** be reviewed quarterly by the RSO and reported to the RSC.

1. Personnel exposures.
2. Personnel training and refresher courses (required annually).
3. Shipping and receiving records.
4. Area survey records.
5. Radioactive material inventory (required annually).
6. Radioactive material disposal records.
7. Instrumentation calibration records (required annually).
8. Emergency procedures - posting of notices and other required signs.
9. Approved procedures (Reapproval required annually).
10. Approved minutes of RSC meetings.
11. Customer service file, (Safety or regulatory problems)

XX. Approval of Laboratories for Use of Byproducts Material

Review of new laboratories and equipment shall be the responsibility of the RSC. Additionally, all major plant modifications require Safety Department approval.

Laboratories will be evaluated to ensure that the ALARA philosophy is maintained and that any emission or exposure is within regulations. The following shall be considered:

1. Type of operation and scale
2. Utilization of adjacent areas
3. Required shielding
4. Adequacy of exhaust and containment
5. Sewers and containment
6. General plant safety
7. Waste generated and proposed disposal methods

## XXI. Approval of Employees to Use Byproduct Materials

Sigma has established program controls over radioactive materials such that we consider all employees working with licensed materials to be working in a supervised environment.

We have developed a two level approval system. The first level of approval is an "approved employee". This person is allowed to work with licensed material on a direct supervision basis. The second level of approval is an "authorized user". An authorized user has met more stringent requirements, will be subject to less supervision, and may have additional responsibilities in the program.

Employees considered for "approved employee" status must be recommended by their department head, receive medical approval, be approved by the Radiation Supervisor from the primary work area, and by the RSO. **The names and qualifications of these employees will be submitted to the RSC.** All employees approved to work with licensed materials will receive a copy of this manual along with training as outlined in Section X of the Program.

"Approved employees" considered for "authorized user" status shall be recommended by the RSO. The RSO will provide the necessary information to the RSC for their review and confirmation.

The following guidelines will be used to evaluate individuals considered for authorized user status:

1. A college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences, or in engineering; and
2. At least forty hours of training and experience in the safe handling of radioactive materials, characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the quantity, type and forms of byproduct material to be used.
3. Sufficient participation in our program to allow for proper skills evaluation.



SIGMA CHEMICAL COMPANY  
RADIATION SAFETY PROGRAM MANUAL  
ALL FACILITIES

Manual revision dated: October 1, 1996

APPROVALS PAGE

Prepared by: \_\_\_\_\_ Date \_\_\_\_\_

Radiation Safety Committee

Approved by: \_\_\_\_\_ Date \_\_\_\_\_

Chairman, Radiation Safety Committee

Approved by: \_\_\_\_\_ Date \_\_\_\_\_

Safety Director

Approved by: \_\_\_\_\_ Date \_\_\_\_\_

President, Sigma Chemical Company

Appendix A

CURRENT RADIATION SAFETY COMMITTEE MEMBERSHIP

Radiation Safety Officer - Dennis Warner  
Senior Management representative - Ron Teller  
Safety Director - George Bleazard  
Compliance Representative - Bernadette Yuhas  
Chairman, Radiation Safety Committee - Tom Spencer  
Chairman, Radiochemicals Site Committee - Paul Spangler  
Chairman, Cherokee Site Committee - Doris Dixon  
Chairman, DeKalb Site Committee - Brian Delmez  
Members - Steve Crump, Eric Edwards, Harold Jackson

Appendix B

CURRENT SITE COMMITTEE MEMBERSHIP

Cherokee

Christopher Bork  
Doris Dixon  
Tom Stanton  
RSO

Radiochemicals

Eric Edwards  
Paul Spangler  
Tom Spencer  
Bernadette Yuhas  
Lab. Rep.  
RSO

DeKalb

Steve Crump  
Brian Delmez  
Rich Klaas  
Vernon Reisenbichler  
RSO

Spruce

Harold Jackson  
RSO

## Appendix C

### RADIOCHEMICALS DEPARTMENT SUPPLEMENT

#### I Personal Protective Equipment

As part of our ALARA program the following requirements for the use of personal protective equipment are incorporated into the Radiation Safety Program for all Radiochemicals department employees.

##### A) Safety Glasses:

Approved safety glasses represent the minimum degree of eye protection required of any employee in any restricted area or while performing other tasks where eye protection is required by SOP 1.04. New employees who need prescription glasses may use approved safety glasses over their personal glasses while safety glasses are on order. Contractors shall supply their own safety glasses and visitors shall be provided with visitors glasses.

An employee observed in a restricted area without safety glasses or previously approved alternative shall be subject to disciplinary action up to and including termination.

##### B) Lab Coats:

Any person entering a restricted area shall be required to wear a lab coat or other previously approved apparel. The RSO and Safety Director shall be responsible for reviewing any job or operation to determine if a suitable alternative exists. This policy will apply to security officers, visitors, and contractors as well as Sigma employees.

An employee observed in a restricted area without a lab coat or previously approved alternative apparel shall be subject to disciplinary action up to and including termination.

##### C) Gloves:

Any employee working with radioactive materials in a restricted area or involved in any other operation which might involve contact with radioactive contamination must wear gloves to avoid direct contact with radioactive materials. Operations may require the use of multiple pairs or types of gloves in order to prevent contact.

Any employee observed working with radioactive materials without the use of gloves to avoid contact shall be subject to disciplinary action up to and including termination.

##### D) Shoe Covers:

Any person entering any restricted area shall wear shoe covers which are provided, in order to prevent contamination of personal shoes and prevent the possible migration of material out the restricted areas. Department employees are to use the heavy duty rubber shoe covers which are more durable and are not subject to walking out. Disposable vinyl shoe covers are provided for visitors only.

An employee observed in the restricted area without proper shoe covers shall be subject to disciplinary action up to and including termination.



- II In order to control radioactive materials any article known or suspected to (1) be radioactive or (2) have radioactive contamination must be handled as described below. This means that any clothing or shoes which are contaminated must remain in the restricted area for proper disposal. Any equipment which has been used in the restricted area must pass a wipe test by the Radiation Safety Staff before disposal as other than radioactive, or before leaving the restricted area.
- III Training will be held during the first quarter of each year. The training will cover those items listed in section X of this manual as well as a review of the manual itself. A general discussion period will be included to allow employees to raise questions of their choosing. All department employees must attend in order to continue working with radioactive materials. A signed attendance list and a class agenda will be maintained for documentation.
- IV The Radiochemicals Department Managers maintain a file of complaints of a Safety or regulatory nature, i.e., shipping, packaging or contamination problems or license questions. Complaints of this nature will be brought to the attention of the RSO immediately.
- V In order to maintain our records and in compliance with our license the RSO must perform audits of several areas on a regular basis. This requires that all records be maintained in a current status at all times. The Radiochemicals Record System Monthly Compliance form will be used for this routine audit function. It is to be completed and filed on a monthly basis. An annual physical inventory and audit are to be completed during the third quarter of each year.
- VI A locked restricted area has been constructed for the storage of contaminated equipment and supplies prior to decontamination or final disposal as radioactive waste. Employees must obtain Department Management approval before transferring items to the area. Absolutely no items are to be deposited outside the area. Personnel working in the area are required to: 1) wear approved safety glasses, shoe covers, gloves and a lab coat; 2) monitor activity using a survey meter when working on decontaminating or packing up material and; 3) to wash and monitor hands and clothing when leaving the area.
- VII Any of the following situations require immediate notification of department management and the RSO or Safety Director.
1. Injury involving radioactive materials requiring other than first-aid.
  2. Unplanned loss of control of radioactive material greater than 50 mci.
  3. Average Bioassay over 5 times the action level for any period longer than 24 hours.
  4. Situation involving radioactive materials resulting in a general building evacuation.
  5. Any unplanned radioactive release off company property (ie. air or sewer). This also requires immediate notification of the Compliance Director and the completion of a spill report.
  6. Any near-miss incident which could have resulted in any of the above.

An incident report must be completed by the site committee and returned to the RSO or Safety Director within 24 hours.

## VIII Responsibilities

- A. Department Managers and Supervisors shall be responsible for training of their personnel and enforcement of this program.
- B. The RSC through the RSO is responsible for administering the bioassay program and periodically auditing compliance with this program
- C. The Site Committee is responsible for investigating incidents and preparing an investigation report.



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OUTSIDE USA/CANADA call COLLECT 314-771-5750

United States Nuclear Regulatory Commission  
Region III  
Mr. James Mullauer  
801 Warrensville Road  
Lisle IL, 60532 - 4351

October 11, 1996  
Control Number 399582

Dear Mr. Mullauer,

Enclosed are three separate license amendments covering the personnel changes and updated Radiation Safety Program manual which were referenced in our letter of September 27, 1996. The Radiation Safety Committee is responsible for oversight of all Sigma materials licenses and activities.

The Qualifications for Mr. Warner and Mr. Spencer are attached.

I have included with the program manual the comparison table from the previous manual edition to the current version. The clarifications which you requested in our phone conversation of September 20, 1996 are included in bold in the manual. They are located on pages 3, 5, 11, 12, 17, and 18.

If we can provide any additional information do not hesitate to call.

Sigma Chemical Co.

*Harold Jackson*  
Harold Jackson



MAR 21 1997

Dennis W. Warner  
Radiation Safety Officer  
Sigma Chemical Company  
P. O. Box 14508  
St. Louis, MO 63178

Dear Mr. Warner:

Enclosed is Amendment No. 14 to your NRC Material License No. 24-16273-01, Amendment No. 4 to your License No. 24-16607-02 and Amendment No. 04 to your License No. 24-16607-03 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
  - a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
  - b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.
4. Request and obtain a license amendment before you:
  - a. Change Radiation Safety Officers;
  - b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

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- c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
  - d. Change ownership of your organization.
5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or 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. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,  
Original Signed By  
Evelyn R. Matson  
Nuclear Materials Licensing Branch

License No.: 24-16273-01  
Docket No.: 030-10716

Enclosures: 1. License No. 24-16273-01;  
030-10716; Amendment No. 14  
2. License No. 24-16607-02;  
030-28732; Amendment No. 04  
3. License No. 24-16607-03;  
030-28992; Amendment No. 04

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OUTSIDE USA/CANADA call COLLECT 314-771-5750

United States Nuclear Regulatory Commission  
Region III  
Ms. Evelyn R. Matson  
801 Warrensville Road  
Lisle IL, 60535 - 4351

March 7, 1997

Control Number 301947  
Control Number 301948  
Control Number 301949

Dear Ms. Matson,

This letter is in response to your letter dated January 14, 1997 requesting additional information for the pending amendment of NRC Licenses No. 24-16273-01, 24-16607-02, and 24-16607-03. In your correspondence there appears to be a typographical error in which incorrect license numbers have inadvertently been referenced, (24-16273-02 and 24-16273-03).

Mr. Warner's training and education consists of the following. He has a B.S. degree in Biology with a chemistry minor. In addition he has attended the Occupational and Environmental Radiation Protection class at Harvard School of Public Health, consisting of approximately forty hours of class room training. He also has attended a 40 hour Hazwoper training class as described in 29 CFR 1910.120. In 1994 he completed the requirements and received a Masters degree in Industrial Hygiene. Throughout his nine year association with our radiation safety program he has participated in both initial and the annual training sessions. In 1996 he presented the Annual Radiation Safety Training to the participants in our materials program under the supervision of the RSO.

Mr. Warner's applied health physics experience consists of the following. He held the position of Health Physics Chemist at our Radiochemicals facility from 1987 - 1993. During this time he was responsible for conducting the weekly bioassays, air monitoring, chemical hood flows, and facility wipe test. He assisted the RSO in development of the current format of the reports and record system. This work required communication and interaction with both the RSO, departmental management and operations personnel.

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MAR 10 1997

REGION III



work provided hands on experience with all types of our current Health Physics equipment. He has sufficient knowledge and familiarity with the equipment to determine if it is the proper equipment for the task and that it is operating properly. All maintenance and calibration of the equipment is conducted by qualified independent third parties.

Other experience has included packaging products for shipment to customers, ensuring compliance with NRC and DOT regulations based on his knowledge and working closely with other transportation personnel within the company. He has also been involved with the preparation of all waste streams for proper shipment. For approximately two years (1993-1995) Mr. Warner was a Production Chemist involved in the synthesis and purification of Carbon 14 and Tritium products, working with quantities up to 5 curies in a single production run. He is very familiar with the production equipment currently being used, methods of controlling contamination and proper decontamination procedures. Because he has been involved in developing production safety procedures, his experience gives him first hand knowledge of situations and needs that may occur in the synthesis of labeled compounds. His industrial hygiene training has prepared him to deal with the proper selection of the many forms of personal protective equipment. He is thoroughly familiar with our respiratory protection program.

Mr. Warner transferred to the Safety department in May 1995. At this time he resumed the health physics duties at the Radiochemicals facility. He has been very involved with all aspects of our monitoring and bioassay programs and is familiar with the associated dose calculations. He understands the properties of the current isotopes used at our facilities and the appropriate monitoring and safety procedure processes. Our current isotopes of use have simple decay pathways and generally do not require additional shielding. Mr. Warner's educational background covered shielding methodology. He has developed a good working knowledge of NRC and DOT regulations.

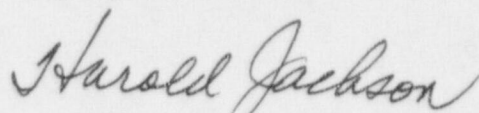
While Mr. Warner will have some other general safety related responsibilities in addition to the Radiation Safety Program, however Radiation Safety will be his primary responsibility.

The area radiation supervisors are employees who have been approved for work with radioactive materials. They have oversight responsibilities for operations in their area, working through the RSO. An area radiation supervisor may also have additional duties supporting the RSO such as receiving incoming materials and completing the receiving form to forward to the RSO, checking survey logs and in general being an additional set of eyes and ears for the RSO. Departmental management is responsible for overall safe operation in their area. The Radiation Safety Committee with Departmental Management from the areas as members is responsible for Sigma's Radiation Safety Program.

The statement in Section XIX "Records Management" of the Radiation Safety Program Manual is correct as written, and will remain, "The following records shall be reviewed quarterly by the RSO and reported to the RSC." Our intent is to review the records quarterly the comparison table statement inadvertently left out the frequency of review.

I have included a completed Supplement A (attachment 1) for Mr. Warner along with a tabular form response to the Appendix A qualifications (attachment 2).  
If you have any further questions please feel free to contact us.

Sigma Chemical Co.

A handwritten signature in cursive script that reads "Harold Jackson". The signature is written in dark ink and is positioned above the printed name.

Harold Jackson

EXHIBIT 2  
SUPPLEMENT A

SUPPLEMENT		U.S. NUCLEAR REGULATORY COMMISSION		
TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER				
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER  Dennis w. Warner		2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED		
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
N/A				
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES				
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING		
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE	
a. RADIATION PHYSICS AND INSTRUMENTATION	1) OERP - Harvard School of Public Health, 1989, 5days 2) St. Louis Chpt. H.P. Soc.	20	10	
b. RADIATION PROTECTION	10 CFR 20 review, 1992, 1 day 3) Central Missouri State Univ. M. S. Industrial Hygiene, 1994 4) Sigma Chemical Co. training programs	40	100	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY		20	100	
d. RADIATION BIOLOGY		20	--	
e. RADIOPHARMACEUTICAL CHEMISTRY	N/A			
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	Q1 USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
H-3	150	Sigma Chemical	> 1000	Synthesis and
C-14	5000	Sigma Chemical	> 500	Quality Control



3/7/97

- 1) Good communication skills, both written and verbal are a requirement for Mr. Warner's position. He has demonstrated this ability with satisfactory performance in his current position and in the health physics chemist position.
- 2) Mr Warner has recently completed the course of study and received a Masters of Science degree in Industrial Hygiene. This is in addition to his Bachelors degree in Biology with a Chemistry minor.
- 3) Mr. Warner has reviewed and applied pertinent current standards, guides and reports published by ICRP, NCRP and other various organizations that have been available.
- 4) Mr. Warner has a good working knowledge of applicable NRC regulations, regulatory guides and NUREG series reports. He reviews information updates received through NRC mailings and other sources.
- 5) Mr Warner has experience in the use of all of our current radiation measurement instruments both from a health physics and production usage basis. He used the results of these measurements in the determination of activity, contamination and exposure levels, in his health physics activities. He has received training provided at Sigma relative to our program as well as classroom demonstrations for other types of usage during the OERP class at Harvard.
- 6) Mr. Warner has the knowledge and ability to determine if monitoring equipment is operating properly, as demonstrated in the performance of his health physics activities. Sigma has a program for the regular maintenance and calibration of all health physics instrumentation by a qualified third party vendor.
- 7) Mr. Warner's training, education and experience as a health physics chemist provide him with the knowledge and ability necessary for the proper selection of equipment for a given radiation monitoring task.
- 8) Through his training at the Harvard School of Public Health, Mr Warner has the ability to evaluate the need for additional shielding for any of our materials operations. Our current primary isotopes of use do not require the use of additional external shielding.
- 9) Mr Warner has the ability to calculate radioactive decay and to interpret the decay diagrams for various isotopes. The current isotopes of use have simple decay paths with readily calculated decay levels.
- 10) Mr Warner's training and experience coupled with his knowledge of and participation in all aspects of our bioassay and monitoring programs indicates his ability to perform appropriate dose calculations.

- 11) Mr. Warner's education and training have provided him with a strong background for the proper selection of monitoring devices. He has gained valuable hands on experience with our program utilizing film badges, ring badges and bioassay monitoring.
- 12) Mr Warner routinely updates, develops and conducts training sessions on radioactive materials and safety topics based on his education knowledge and experience.
- 13) Mr. Warner's education, training and broad range of experience within our program provides an understanding of operational needs and the ability to recognize existing and anticipate possible safety problems.
- 14) Mr. Warner's training would allow him to anticipate and deal with these issues although these problems are not associated with the current isotopes of use.
- 15) Mr. Warner's previous responsibilities in the program included the proper preparation of radioactive waste materials for shipment and disposal and current radioactive effluent treatment methods, equipment and procedures.
- 16) Mr. Warner's education and production experience coupled with health physics activities has prepared him well for all aspects of dealing with contamination situations. He has considerable experience in the decontamination of areas and equipment. He also has 40 hour Hazwoper training which provided training in decontamination procedures.
- 17) Mr. Warner's education, training and demonstrated experience provides him with the knowledge and ability to develop and implement an emergency action plan. He assisted in the development of our current emergency plan. He has also participated in training on the incident command system for dealing with emergency situations.
- 18) Mr. Warner's education, training provide him with the ability to evaluate and select respiratory protective equipment. His two years of administering the respiratory protection program has provided a thorough understanding of respiratory protection equipment training and use.
- 19) Mr. Warner's education, experience, and training in Industrial Hygiene have given him the knowledge and ability to properly evaluate and select all forms of personal protective equipment.
- 20) The combination of Mr. Warner's education and training along with his personal experience using process control and containment equipment provides the necessary knowledge and ability to properly evaluate, test, maintain and supervise the maintenance of this type of equipment.
- 21) Mr. Warner's education and training provides him with the knowledge and ability to deal with sealed source operations. Our program does not utilize sealed sources other than small check sources and two general licensed ionization detectors..

- 22) Mr Warner has knowledge and ability to evaluate, use, maintain and supervise the use of a wide variety of waste collection and treatment equipment. He has demonstrated this in his previous responsibilities dealing with all phases of our radioactive waste disposal program.
- 23) Mr. Warner has demonstrated a good working knowledge of transportation regulations. In his previous position he was responsible for packaging materials for shipment in accordance with all applicable regulations.
- 24) Mr. Warner's education and training and experience have provided him with a solid basis for bioassay program operation. He has demonstrated a thorough knowledge and understanding of our bioassay program through past performance, including NRC inspections.
- 25) Mr. Warner has the necessary knowledge and ability, including maturity of judgement, to perform the job of radiation safety officer. This has been acquired through his education in Industrial Hygiene, additional training activities such as OERP and Hazwoper, and his 9 years of experience with the Sigma radioactive materials program. His experience has included all phases of safety, health physics and production..



JAN 14 1997

Harold Jackson  
Radiation Safety Officer  
Sigma Chemical Company  
P.O. Box 14508  
St. Louis, MO 63178

Dear Mr. Jackson:

We have reviewed your applications dated October 11, 1996, requesting amendments to your NRC Licenses No. 24-16273-01, 24-16273-02, and 24-16273-03. We need the following additional information to complete our review:

1. Radiation Safety Officer
  - A. Please describe in more detail the training that Mr. Warner has received in radiation safety. Training should include some formal classroom and laboratory instruction. Please use the attached Supplement A to indicate the topics covered, where the training was obtained and the number of hours.
  - B. Please provide additional information on Mr. Warner's applied health physics experience. Describing the positions he has held at Sigma and their associated duties will be very helpful. You should provide enough information to show that he has sufficient experience to meet the characteristics described in Appendix A, of the enclosed guide entitled "Qualification For The Radiation Safety Officer in a Large Scale Non-Fuel-Cycle Radionuclide Program."
  - C. Please indicate if Mr. Warner has duties other than radiation safety. If so, justify the time he will spend on radiation safety with the size and radiation safety risks associated with your use of radioactive materials.
2. We have noted in the changes to the radiation safety program that department managers and area radiation supervisors have radiation safety responsibilities. Please describe the training and experience people in these positions typically have in radiation safety. Their training and experience should be commensurate with their responsibilities.
3. There appears to be a discrepancy between the Radiation Program Comparison Table that you submitted and the Radiation Safety Program Manual. Specifically, on page 4 of the table, the item "Page 20", column 2, states "Replace with, "The following records should be reviewed by the RSO and reported to the RSC." However, Section XIX "Records Management" of the manual states "The following

H. Jackson

-2-

records shall be reviewed quarterly by the RSO and reported to the RSC." Please clarify your intent. We will approve the current statements and frequencies stated in the manual. We will request that you specify a frequency of review if you intend to implement the version stated in the table which appears to omit a stated frequency for review.

We will continue our review of your request when we receive this additional information. Please reply in writing, provide two copies and refer to Control Nos. 301947, 301948 and 301949.

If you have any questions or require clarification on any of the information stated above, please contact us at (630) 829-9822.

Sincerely,

Original Signed By  
Evelyn R. Matson  
Health Physicist  
Nuclear Materials Licensing Branch

Licenses No. 24-16273-01, 24-16273-02, and 24-16273-03

Enclosures: 1. Supplement A, Training and Experience,  
Authorized User or Radiation Safety Officer  
2. Qualification For The Radiation Safety Officer  
in a Large Scale Non-Fuel-Cycle Radionuclide  
Program

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

October 22, 1996

Dennis W. Warner  
Radiation Safety Officer  
Sigma Chemical Company  
P. O. Box 14508  
St. Louis, MO 63178

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE  
(Letter & Applications Dated 10/11/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☐ New License                      ☒ Amendment                      ☐ Renewal  
☐ Termination                      ☐ Auth User (Amendment not required)  
☐ Other \_\_\_\_\_

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301947, 301948, 301949  
License No. 24-16273-01, 24-16607-02, 24-16607-03