

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Reports No. 030-11303/90001(DRSS); 030-28992/90001(DRSS)

Docket Nos. 030-11303; 030-28992

License No. 24-16607-01
License No. 24-16607-03

Priority II
Priority II

Category E1A
Category E1A

Licensee: Sigma Chemical Company
3500 Dekalb Street
St. Louis, MO 63118

Inspection Conducted: November 8-9, 1990

Inspector: *Evelyn R. Matson*
Evelyn R. Matson
Radiation Specialist

Nov 26, 1990
Date

Approved By: *Roy J. Caniano*
Roy J. Caniano, Chief
Nuclear Materials Safety
Section 2

11/26/90
Date

Inspection Summary

Inspection on November 8-9, 1990 (Reports No. 030-11303/90001(DRSS);
No. 030-28992/90001(DRSS))

Areas Inspected: This routine, unannounced safety inspection included a review of the licensee's organization; scope of program; training; radiological protection procedures; facilities; instrumentation; receipt and transfer; personnel radiation protection; waste disposal; independent measurements; posting and labeling; transportation; and notifications and reports.

Results: Of the areas inspected, no violations of NRC requirements were identified.

9012110120 901127
REG3 LIC30
24-16607-01 PDC

DETAILS

1. Persons Contacted

*Ronald Wolfe, Vice President of Operations
*Harold Jackson, Radiation Safety Officer
*Elsa Steward, Compliance Officer
Dennis Murrey, Laboratory Supervisor, Cherokee
Al Flashing, Laboratory Supervisor, Cherokee
Brian Delmez, Production Chemist Supervisor, Dekalb
Ed Haas, Production Chemist, Dekalb

*Present at the exit meeting held on November 9, 1990.

2. Inspection History

Sigma Chemical Company currently holds four byproduct materials licenses. One license is a distribution license while the other three cover research, development, and production of radiochemicals. The three licenses cover three different locations within the St. Louis area, Ft. Mims, Dekalb, and Cherokee. This inspection covered only the Cherokee and Dekalb facilities but did include a review of issues identified recently at the Ft. Mims facility to determine whether they also occurred at the inspected locations.

Two inspections were performed in 1990 at the Ft. Mims facility (License No. 24-16273-01). These inspections were conducted as a result of allegations received and a carbon-14 contamination incident. As a result of the inspections conducted on February 6, 1990, and on April 25, 1990, the following violations were identified: (1) failure to store contaminated equipment in a restricted area; (2) failure to remove and store contaminated clothing; (3) failure to retrain individuals working in or frequenting any portion of a restricted area annually; (4) the licensee permitted an individual working in a restricted area to be exposed to radioactive material such that a carbon-14 uptake exceeded the limits specified in Part 20, and (5) failure of an individual to wear a protective laboratory coat. This inspection included a review to determine if these violations exist and if the allegations were substantiated at these other licensee facilities. In summary and as described throughout this inspection report, it appears that the violations either were corrected at these other facilities or did not exist. In addition, the allegations were not substantiated at the Cherokee and Dekalb facilities.

License No. 24-16607-01 (Dekalb) was last inspected on December 12, 1985. Three violations were identified: (1) failure to perform wipe tests on final source container of packages upon receipt; (2) failure to conduct annual training; and (3) failure to perform inventory as required. These previous violations appear to have been corrected and have not recurred.

License No. 24-16607-03 (Cherokee) was last inspected on August 14-16, 1989. This was a special inspection to look into the licensee's report of leaking waste disposal drums shipped by ADCO. Three violations were identified: (1) failure of the Radiation Safety Committee (RSC) to approve authorized users; (2) failure of the RSC to apply user approval criteria stated in 10 CFR 33.15; and (3) failure to conduct an annual review of the radiation safety program. Two concerns were also addressed: (1) incomplete documentation of quarterly audits; and (2) incomplete records of personnel training.

These previous violations and concerns appear to have been corrected and have not recurred as noted in this report.

3. Licensed Program Summary

License No. 24-16607-01 authorizes laboratory research and development at 3500 Dekalb Street. This license allows the use of any byproduct material listed in 10 CFR 33.11(b), Type B license of broad scope, with possession limits specified in 10 CFR 33.100, Schedule A, Column 1. Currently, quantities less than 1 millicurie per procedure are used for in-vitro analytical studies in two laboratories that are dedicated to radioactive materials. The radionuclides in use are carbon-14, hydrogen-3, phosphorus-32 and iodine-125. Approximately 10 persons are approved by the RSC as authorized users at this location.

License No. 24-16607-03 authorizes research and development and the manufacturing of products at 3300 South Second Street (referred to as the Cherokee facility by the licensee). License authorization includes possession of 120 curies total of byproduct materials with Atomic Numbers from 3 through 83. Currently, the licensee is not performing any production at this facility and uses only millicuries quantities per year for in-vitro bench chemistry. The Cherokee facility has two laboratories dedicated for the use of radioactive material and approximately 25 persons are approved as authorized users. Most are not actively handling material on a routine basis.

At the present time, the licensee does not possess any sealed sources under these two licenses.

The quantities, kinds, uses and locations of radioactive material are as authorized by the license.

No violations of NRC requirements were identified.

4. Organization

Sigma Chemical Company has established a Radiation Safety Committee (RSC). One committee provides scientific review and approval of all uses of radioactive materials at both the Dekalb and Cherokee facilities. It also oversees implementation of the safety requirements for the possession, use and administration of radioactive materials.

The inspector determined through interviews with personnel and a review of the RSC meeting minutes for 1990 that the membership, the topics covered, and the meeting frequency are as required. In response to the violations identified in 1989 regarding approval of authorized users, in January 1990, the RSC reviewed and approved all 34 users and approved six persons to be supervised pending additional experience. The RSO stated that each user was required to complete and submit a training and experience form. The PSO and RSC approved only applicants who had at least 40 hours of training and experience and a college degree at the bachelor level in the physical or biological sciences or in engineering. New applicants are reviewed and approved prior to working independently in the radiation labs.

The RSC approves experiment protocols. During the inspection, the inspector observed that a supervisor in charge of radioactive materials laboratories maintains a file of RSC approved protocols. The supervisor assures that RSC reviews and approvals have been granted before new users and new protocols are permitted in the labs.

No violations of NRC requirements were identified.

5. Training

Licensee representatives stated and a review of training records confirmed that personnel entering restricted areas received training in May 1990. However, not all personnel were available to attend the training. During the inspection, the RSO, compliance officer and management representative stated that the remaining personnel will receive training within the next two months. Several persons were interviewed by the inspector and they confirmed that they had attended the training as described. In addition, personnel appeared to be knowledgeable about radiation safety procedures.

No violations of NRC requirements were identified.

6. Radiological Protection Procedures

Small quantities of radionuclides are used for in-vitro research. Radionuclides are used in adequately designed chemical laboratories. These labs are separated from other use areas and secured by locked doors. The laboratory supervisors control the keys and supervise entry. Each lab is provided with non-porous work surfaces which are covered with absorbent paper and trays. During the inspection, the inspector observed the availability and use of gloves, remote pipettes, lab coats, safety glasses, and Plexiglas and lead shielding. The inspector observed that all persons in the laboratories were wearing laboratory coats and safety glasses.

Radioactive materials in storage and as waste are secured in restricted areas. No radioactive material is used or stored in unrestricted areas.

No violations of NRC requirements were identified.

7. Facilities

The inspector toured the licensee's facilities and determined that they are as described in the license application and appear adequate for the safe use of radioactive materials.

No violations of NRC requirements were identified.

8. Instrumentation

The laboratories at Dekalb Street and Cherokee are equipped with G-M survey meters with thin window pancake probes. Each meter was operational during the inspection and stickers showed that all were calibrated by an authorized vendor within the last 12 months as required. In addition, the labs have liquid scintillation and gamma counters available for analysis of removable contamination wipe tests.

No violations of NRC requirements were identified.

9. Receipt and Transfer of Radioactive Material

The RSO controls all ordering and transfers of radioactive materials. Authorized users contact him when they want to place an order. The RSO obtains a purchase order number from the purchasing department and places the order with the vendor personally. Packages containing radioactive material are delivered to the receiving dock at each facility. Receiving personnel notify lab supervisors who are responsible for picking up the package and performing the opening procedures. Interviews with lab supervisors and a review of receipt records indicated that packages are surveyed and records are kept as required.

When radioactive materials need to be transferred, the RSO is notified. He is responsible for determining that the material is properly packaged and labeled in accordance with Department of Transportation procedures. The inspector observed packaging materials and labels that were on hand. For transfers between Sigma Chemical Company facilities, the RSO stated that he personally delivers the prepared packages.

No violations of NRC requirements were identified.

10. Personnel Radiation Protection

a. External

Whole body film badges are issued to and worn by authorized users when handling radioactive materials. The inspector observed personnel in the radiation labs wearing their film badges. During the last inspection, it was noted that film badges were exchanged between users. The RSO stated that he personally collects and exchanges the film badges monthly and has observed that users leave their badges on

their lab coats and that each person stores his lab coat at his own desk to avoid mix-ups. He stated that he has observed that film badges are worn by the persons to whom they are assigned.

The inspector reviewed the exposure results for the period of January 15, 1987 through September 14, 1990. The maximum exposure recorded for this period was 20 millirem and the average recorded exposure was minimal.

The RSO stated that he reviews the film badge reports on a monthly basis for ALARA action levels. He stated and a review of RSC meeting minutes confirmed that exposures are reviewed by the RSC quarterly. All exposures reviewed were below the ALARA action levels. Even so, the RSO stated that he investigates each exposure above minimal to determine its cause.

Laboratory supervisors stated and a review of records confirmed that laboratory areas are surveyed monthly for ambient dose rates and for removable contamination. When levels above background are detected the area is cleaned and resurveyed with records kept of the results.

Licensee representatives stated that removable contamination wipe tests are analyzed for beta and gamma components. However, the records maintained showed only one numerical result for each wiped location recorded in counts per minute. As discussed with the RSO and lab supervisors, records should be kept in unit of disintegrations per minute and should show the results for each type of radionuclide.

The inspector also recommended that at Dekalb Street, the waste storage location should be included in the monthly survey program to assure adequate control of contamination.

b. Internal

The licensee has established a bioassay program, however, since all radioactive materials are handled in microcurie quantities only, are confined, and are non-volatile, bioassays have not been required or implemented. The potential for internal exposure of individuals to airborne radioactive material is negligible and the RSO and lab supervisors stated that no major spills or personnel contamination have occurred.

In addition, the RSO stated that he inspects the labs for the proper use of remote pipettes, gloves, lab coats, and paper coverings to prevent the spread of contamination and possible ingestion of radioactive materials. The inspector observed the use of laboratory coats and safety glasses by individuals in the labs.

No violations of NRC requirements were identified.

11. Radioactive Waste Disposal

Contaminated waste materials generated from the use of radioactive material is currently being stored. The RSO stated that the last shipment of radioactive waste from these two licensed locations was in 1979. Currently, dry contaminated waste is stored in small plastic cans in designated storage locations at Cherokee and Dekalb Streets.

Laboratory supervisors and the RSO stated that no radioactive material is disposed of in the sanitary sewerage system. Sink traps and drains are surveyed during the monthly surveys and the results are all negligible.

For the Cherokee and the Dekalb locations, the RSO made an assessment of the radioactive concentration of carbon-14 and hydrogen-3 contained in liquid scintillation medium. Based on the amount used and the dilution, it appears that the levels are less than the limits specified for these materials in 10 CFR 20.306 (0.05 microcuries per gram). Therefore, the medium is disposed of without regard to its radioactivity. It is transferred to an industrial incinerator which is licensed by other agencies.

Even though the license at Sigma Chemical Company's Ft. Mims location was not inspected at this time, the inspector did review the corrective actions taken by the licensee as the result of an incident of a leaking waste drum that occurred in 1988. A drum containing liquid scintillation medium was shipped from the Ft. Mims location and was discovered to be leaking by ADCO. This event was reviewed by the NRC during a previous inspection. During this inspection, the inspector determined through interviews with RSO and the compliance officer and a review of records that all shipments of liquid scintillation medium are packed in 30 gallon drums and then overpacked with dry absorbent and a 55 gallon drum. This step was taken to assure that rough handling (thought to be the cause of the 1988 leak) would not result in a rupture of the 30 gallon container. In addition, as recommended to them, Sigma Chemical Company now maintains complete Department of Transportation shipping documents. The licensee representatives stated that no leaking drums have been reported since the 1988 incident.

No violations of NRC requirements were identified.

12. Independent Measurements

Radiation measurements were made by the NRC inspector using a Xetex Model 305B survey meter calibrated on May 5, 1990, and using the licensee's Ludlum Model 3 meter with Model 44-9 thin window pancake probe. Areas surveyed included the radiochemical laboratories at Dekalb and Cherokee Streets as well as the waste storage areas at each. Gamma and energetic beta radiation levels in restricted and unrestricted areas were found to be well below 10 CFR Part 20 limits.

No violations of NRC requirements were identified.

13. Posting and Labeling

An inspection of various areas in the licensee's facility showed that restricted areas and storage areas were posted with Caution Radioactive Materials signs as required. Containers and articles were labeled as well. In addition, NRC-3 "Notice to Employees" forms were posted as required by 10 CFR 19.11.

No violations of NRC requirements were identified.

14. Notifications and Reports

A review of film badge records revealed that no overexposures to personnel occurred. Licensee representatives stated that no incidents, loss or theft of radioactive material occurred during the inspection period. Therefore, no notifications or reports were required during this inspection period.

No violations of NRC requirements were identified.

16. Exit Meeting

At the conclusion of the inspection on November 9, 1990, the inspector met with those individuals identified in Section 1 of this report. A summary of the areas inspected, the apparent inspection results, the licensee's previous corrective actions, and the NRC enforcement policy, the forthcoming letter and report were discussed. The licensee indicated that the information discussed in this report is not proprietary in nature. No written material was left with the licensee. The participants also discussed the advantages and disadvantages of the licensee maintaining three separate licenses which are in fact managed by a common RSO, RSC and managers at the top levels of the organization. The inspector strongly recommended consolidating licenses.