

Appendix A

NOTICE OF VIOLATION

Sigma Chemical Company

License No. 24-16607-03

License No. 24-16607-02

As a result of the inspection conducted on August 14 through August 16, 1989, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (1989) (Enforcement Policy) the following violations were identified:

1. License No. 24-16607-02

License Condition No. 13 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in certain referenced documents.

- a. The referenced application dated June 5, 1985, describes in Item No. 8 the training an individual must receive before being cleared to work in a restricted area. It outlines the topics to be covered and provides for a refresher course as required, or at least annually.

Item No. 8 also requires that a written record be kept to show that the individual received training and understands the subject matter.

Contrary to the above, since the radioactive storage area became operational in December 1985, individuals who work in the restricted area have not had a refresher course. In addition, the licensee has failed to maintain records of initial training received by these individuals.

This is a Severity Level IV violation (Supplement VI).

- b. The licensee's Radiation Safety Program contained in the referenced application dated June 5, 1985, requires that an annual formal review of the Radiation Safety Program be conducted which will include the operating procedures, past exposures and a review of the corrective actions taken in the past and their effectiveness.

Contrary to the above, an annual formal review of the Radiation Safety Program has not been conducted since the facility became operational in December 1985.

This is a Severity Level IV violation (Supplement VI).

- c. The licensee's Radiation Safety Program contained in the referenced application dated June 5, 1985, requires that all packages containing radioactive materials, if delivered by truck, be monitored for radiation within three hours after receipt, or within 18 hours if received during non-working hours, before opening or moving from the receiving area.

Contrary to the above, since approximately December 1985, the licensee has not monitored all packages containing radioactive material that were delivered by truck. Specifically, the licensee monitors for radiation only those packages which are affixed with the Radioactive Yellow-II label.

This is a Severity Level IV violation (Supplement VI).

- d. The licensee's Radiation Safety Program, contained in the referenced application dated June 5, 1985, requires that surveys be performed in the restricted area and adjacent to the restricted area at least monthly or as experience requires. The procedures also require that a wipe be taken randomly in the surveyed area to cover approximately 100 square centimeters.

Contrary to the above, the licensee has not performed any radiation surveys or wipe tests in the restricted area or in areas adjacent to the restricted area since approximately December 1985.

This is a Severity Level IV violation (Supplement VI).

2. License No. 24-16607-03

- a. License Condition No. 11.A requires that licensed material be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.

Contrary to the above, licensed material was used by individuals who were not designated or under the supervision of individuals designated by the Radiation Safety Committee. Specifically, since approximately June 1987, licensed material has been used by individuals designated by the Laboratory Radiation Supervisor and by a team consisting of a Company Vice President, the Department Head, the Safety Officer, the Laboratory Radiation Supervisor, and the Radiation Safety Officer.

This is a Severity Level IV violation (Supplement VI).

b. License Condition No. 17 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in certain referenced documents.

(1) Item 1b(2) of the referenced letter dated March 12, 1986, states that personnel will be reviewed for approval (to participate in the Radioactive Program) under the criteria listed in 10 CFR Part 33.15(b).

Contrary to the above, since approximately June 1987, the criteria listed in 10 CFR Part 33.15(b) has not been used to approve individuals for participation in the Radioactive Program.

This is a Severity Level IV violation (Supplement VI).

(2) Item II of the referenced Radiation Safety Manual, dated March 12, 1986, requires that an annual formal review of the Radiation Safety Program be conducted which will include the operating procedures, past exposures and a review of the corrective actions taken in the past and their effectiveness.

Contrary to the above, as of August 16, 1989, an annual formal review of the Radiation Safety Program had not been conducted as required.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each violation: (1) the corrective steps that have been taken and the results achieved; (2) the corrective steps that will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

October 24, 1989
Dated

Bruce S. Malliett
Bruce S. Malliett, Ph.D., Chief
Nuclear Materials Safety Branch

Appendix B

MANAGEMENT CONTROL

In order to provide you with some guidance in assessing the adequacy of your management control program, the NRC Region III office provides the following as the acceptance criteria for adequate management control for materials licensees. "Management Control" is a system instituted by management to assure that licensed activities are performed safely and in accordance with regulatory requirements (license conditions and applicable regulations).

This will include:

- a. Delineation of duties and responsibilities of all persons involved in licensed activities.
- b. Providing for indoctrination and training of all personnel performing licensed activities, specifically in those areas directly affecting compliance with NRC regulations and license conditions.
- c. Verification, as by checking, auditing and inspecting, that activities affecting safety related functions have been correctly performed. The verifying process should be performed by individuals or groups other than those performing the safety related procedures.
- d. Insuring continued compliance of licensed activities throughout periods during which routine activities may be interrupted, such as changes in equipment, personnel or facilities.

Because of the many variables involved, such as the number of personnel, type of activity being performed and the location or locations where activities are performed, the organizational structure for executing the management control program may take various forms; however, irrespective of the organizational structure, the individual or group responsible for this control should have the flexibility and authority to institute changes or corrections as required to maintain compliance with NRC regulations and license conditions.