

NOTICE OF VIOLATION

Stolle Research and Development Corp.
Cincinnati, Ohio

License No. 34-26227-01
Docket No. 030-31847

During an NRC inspection conducted on May 22, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1992), the violations are listed below:

- A. Condition 18. of License No. 34-26227-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated July 17, 1990 (with attached Radiation Safety Manual dated March 1990) and a letter dated September 28, 1990 (with attachments).

Chapter 5, Section B.2.d., of the March 1990 Radiation Safety Manual, attached to the referenced application, requires that the Radiation Safety Office conduct an unannounced survey at least once a month of all laboratories using radioisotopes. The surveys will be performed in similar fashion to those done by the individual users (i.e., wipe test surveys for weak beta emitting isotopes, direct reading surveys for gamma and hard beta emitting isotopes), but will include checks of posting and laboratory safety.

Contrary to the above, from May 1991 through May 22, 1992, the Radiation Safety Officer did not conduct unannounced surveys at least once a month of all laboratories using radioisotopes. Specifically, from May 1991 through November 1991 and from January 1992 through April 1992, the Radiation Safety Officer did not perform any surveys in the Radiation Laboratory, an area where submillicurie quantities of hydrogen-3 were routinely used each month.

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

- B. Condition 18. of License No. 34-26227-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated July 17, 1990 (with attached Radiation Safety Manual dated March 1990) and a letter dated September 28, 1990 (with attachments).

Item 9 of the referenced application states that the use of radioisotopes shall be restricted to the Radiation Laboratory and to Laboratory #1, except for small analytical samples. A diagram of the licensee's facilities, submitted as part of the referenced application, further defines the boundaries of the Radiation Laboratory to the southwest-most corner of the ground floor of the facilities located at 6990 Cornell Road, Cincinnati, Ohio.

Contrary to the above, from May 1991 through May 22, 1992, the licensee has used submillicurie quantities of hydrogen-3 in the laboratory areas outside of the Radiation Laboratory and Laboratory #1. The unapproved areas of use are located east of the approved Radiation Laboratory.

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

- C. Condition 18. of License No. 34-26227-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated July 17, 1990 (with attached Radiation Safety Manual dated March 1990) and a letter dated September 28, 1990 (with attachments).

Chapter 4, Section C, of the March 1990 Radiation Safety Manual, attached to the referenced application, states that requisitions for radioisotopes received by the purchasing department that do not contain RSO (Radiation Safety Officer) approval will be returned unordered.

Contrary to the above, from May 1991 through May 22, 1992, approximately 50 percent of the requisitions for radioisotopes received by the purchasing department did not contain RSO approval and were not returned unordered. For example, on February 17, 1992, the licensee received a shipment of 5 millicuries of hydrogen-3 labelled thymidine that the RSO did not approve and the requisition was not returned unordered.

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

- D. Condition 18. of License No. 34-26227-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated July 17, 1990 (with attached Radiation Safety Manual dated March 1990) and a letter dated September 28, 1990 (with attachments).

Chapter 5, Section B.2, of the March 1990 Radiation Safety Manual, attached to the referenced application, requires that appropriate daily surveys be performed whenever radioisotopes are used. Wipe tests must be used for the detection of weak beta emitters such as hydrogen-3, carbon-14, and sulfur-35.

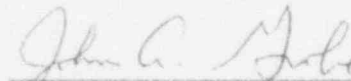
Contrary to the above, from May 1991 through May 21, 1992, the licensee did not perform any surveys when submillicurie quantities of hydrogen-3 were used. For example, on January 29, 1992, the licensee used 800 microcuries of hydrogen-3 in an experiment and a wipe test was not conducted.

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

Pursuant to the provisions of 10 CFR 2.201, Stolle Research & Development Corp. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

JUN 23 1992

Dated _____



John A. Grobe, Chief
Nuclear Materials Safety Branch

MANAGEMENT CONTROL

In order to provide you with some guidance in assessing the adequacy of your management control program, the NRC Region III office is providing the following as an acceptable criteria for adequate management control by 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 includes:

- a. Delineating duties and responsibilities of all persons involved in licensed activities.
- b. Providing indoctrination and training of all individuals performing licensed activities, specifically in those areas directly affecting compliance with NRC regulations and license conditions.
- c. Verifying by checking, auditing, and inspecting, that activities affecting safety related functions have been correctly performed. The verification process should be performed by individuals or groups other than those performing the safety related procedures.
- d. Insuring continued compliance of licensed activities during periods when 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, the individual or group responsible for this control should have the flexibility and authority to institute changes or corrections as needed to maintain compliance with NRC regulations and license conditions.