

APPENDIX A
NOTICE OF VIOLATION

Seragen, Inc.
Boston, Massachusetts 02122

Docket No. 030-17755
License No. 20-19478-01

As a result of the inspection conducted on December 11-12, 1985, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

- A. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

10 CFR 20.301 requires that no licensee dispose of licensed material except by certain specified procedures. 10 CFR 20.303 specifies the maximum permissible concentration (MPC) levels and form in which the licensed material is allowed to be discharged into a sanitary sewerage system.

Contrary to the above, as of May 1985, complete evaluations of the concentration levels of licensed material in liquid waste were not made at your Lexington facility. Specifically, the daily liquid sewerage volume leaving the facility was never determined in order to complete the calculations necessary to determine whether concentration levels for the licensed liquid waste leaving the facility were within the limits.

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

- B. 10 CFR 30.41(c) requires that, prior to transferring licensed material, each licensee verify that the transferee's license authorizes the receipt of the type, form and quantity of byproduct material to be transferred. 10 CFR 30.41(d) specifies the requirements for verifying authorization.

Contrary to the above, on December 11, 1985, in vitro test kits containing millicurie quantities of I-125 were transferred without utilizing one of the verification procedures. Specifically, the transferer did not have procedures in place for ensuring that the transferee possessed a license authorizing them to receive the type, form and quantity of byproduct material to be transferred

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

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- C. 10 CFR 32.71 requires that each person licensed to manufacture or distribute byproduct material for use under the general license of 10 CFR 31.11 enclose a leaflet or brochure with the package notifying the general licensee that they are authorized to receive, acquire, possess, use and transfer the byproduct material that has been delivered to them.

Contrary to the above, on December 11, 1985, the brochure designed to be enclosed with each package of byproduct material that has been manufactured for customers licensed under the general license of 10 CFR 31.11 did not contain any information to indicate that such general licensees could receive, acquire, possess, use or transfer such material enclosed in the package.

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

Pursuant to the provisions of 10 CFR 2.201, Seragen, Inc. is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.