

APPENDIX A

NOTICE OF VIOLATION

Biodevelopment Laboratories, Inc.  
Cambridge, Massachusetts 02140-2390

Docket No. 030-04605  
License No. 20-01489-01

During an NRC inspection conducted on April 28 and 29, 1994, 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, the violations are listed below:

1. Condition No. 20 of License No. 20-01489-01 requires, in part, that ash residues may be disposed of as ordinary waste provided that concentrations of licensed material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in Appendix B, Table II, 10 CFR 20.

Contrary to the above, on January 1, 1994, ash residues were disposed of as ordinary waste and it was not provided that concentrations of licensed material appearing in the ash residues did not exceed the concentrations (in terms of microcuries (uCi) per gram) specified for water in Appendix B, Table II, 10 CFR 20. Specifically, the licensee disposed of incinerator ash which contained 4.5 E-5 uCi per gram of carbon-14, an amount which exceeds 3 E-5 uCi per gram of carbon-14, the concentration specified for water in Appendix B, Table II, 10 CFR 20. Furthermore, the licensee's procedure for testing ash allowed for the disposal of ash containing up to 0.05 uCi per gram of carbon-14, amounts which exceeds 3 E-5 uCi per gram of carbon-14.

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

2. 10 CFR 20.106(a) requires that except as authorized by the Commission, no licensee may release radioactive material to an unrestricted area in concentrations which exceed the limits specified in 10 CFR Part 20, Appendix B, Table II, when averaged over a period not greater than one year.

Contrary to the above, from December 31, 1992 to December 31, 1993, the licensee released radioactive material to an unrestricted area in concentrations which exceed the limits specified in 10 CFR Part 20, Appendix B, Table II, when averaged over a period not greater than one year. Specifically, stack effluent in a concentration of 3 E-10 microcuries per milliliter (uCi/ml) of iodine-125 averaged over one year, a quantity exceeding 8 E-11 uCi/mL, the limit in 10 CFR Part 20, Appendix B, Table II, was released and this concentration was not authorized by the Commission.

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

OFFICIAL RECORD COPY - S:\PENDING\BIODEVEL.NOV - 05/09/94

RETURN ORIGINAL TO  
REGION I

RE-07

9405270193 940519  
PDR ADOCK 03004605  
C PDR

3. Condition No 20. of License No. 20-01489-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in an application dated January 27, 1988, and a letter received on March 17, 1989.

A. Page 3 of an application dated January 27, 1988 requires the Radiation Safety Committee to meet quarterly.

Contrary to the above, as of April 19, 1994, the Radiation Safety Committee (RSC) did not meet quarterly. Specifically, from January 1, 1993 to April 19, 1994, the RSC met on three occasions, a frequency less than quarterly.

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

B. Item 4 of a letter received on March 17, 1989 requires that an internal audit be conducted by the Radiation Safety Officer once every three months.

Contrary to the above, as of April 19, 1994, internal audits were not conducted by the Radiation Safety Officer once every three months. Specifically, from January 1, 1993 to April 19, 1994, two audits were conducted, a frequency less than once every three months.

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

Pursuant to the provisions of 10 CFR 2.201, Biodevelopment Laboratories, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, 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 to show cause 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.