

APPENDIX A

NOTICE OF VIOLATION

Biosurface Technology, Inc.
Cambridge, Massachusetts 02139

Docket No. 030-30125
License No. 20-28072-02

During an NRC inspection conducted on February 9, 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:

10 CFR 71.5(a) requires, in part, that no licensee shall transport any licensed material outside the confines of his plant or other place of use, or deliver any licensed material to a carrier for transport, unless the licensee complies with applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170-189.

1. 49 CFR 172.200(a) requires that each person who offers a hazardous material for transportation describe the hazardous material on the shipping paper.

Contrary to the above, on August 28, 1991, an AECL Model Gammacell 220 irradiator, serial number 208, containing approximately 4600 curies of cobalt-60, was transported from One Kendall Square in Cambridge, Massachusetts to 64 Sidney Street in Cambridge, Massachusetts, and shipping papers were not available for inspection.

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

2. 49 CFR 173.416 specifies, in part, the packages authorized for shipment of radioactive material in quantities exceeding the activity of special form radioactive material as listed in 49 CFR 173.435, and includes the requirement that the package or container be approved by the NRC.

49 CFR 173.435 establishes this value to be 7 curies for cobalt-60 in special form (the maximum A sub one quantity).

Contrary to the above, on August 28, 1991, approximately 4600 curies of cobalt-60 contained in an AECL Model Gammacell 220 irradiator, serial number 208, was transported from One Kendall Square in Cambridge, Massachusetts to 64 Sidney Street in Cambridge, Massachusetts and that package (container) was not approved by the NRC. Specifically, the Gammacell 220 had a foreign competent authority certificate, revalidated by the DOT, which allowed shipments made to or from locations outside the

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United States, but did not allow shipments to and from locations within the United States.

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

Pursuant to the provisions of 10 CFR 2.201, Biosurface Technology, 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.