

APPENDIX A

NOTICE OF VIOLATION

Zynaxis Cells Science, Inc.
Malvern, Pennsylvania 19355

Docket Nos. 030-30914
030-30915
License Nos. 37-28318-01
37-28318-02

During an NRC inspection conducted on November 30, 1993 and December 1, 1993, 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:

- A. Condition 13 of License No. 37-28318-01 requires that sealed sources or detector cells containing byproduct material be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, as of December 1, 1993, a sealed source containing 678 curies of cesium-137 had not been tested for contamination or leakage since February 21, 1990. Specifically, an AECL Gammacell 1000 Model A irradiator containing a cesium-137 source was used two times during May 1993 and had not been leak tested since February 21, 1990.

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

- B. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. 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.

Contrary to the above, as of December 1, 1993, the licensee did not make surveys to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the skin of the whole body. Specifically, there were three incidents dated September 12, 1990, November 19, 1992, and July 26, 1993 which resulted in skin contamination involving licensed radioactive material. The licensee performed reviews of each incident and recommended corrective action but did not perform dose assessments.

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

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Pursuant to the provisions of 10 CFR 2.201, Zynaxis Cell Science, 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.