

## NOTICE OF VIOLATION

Zynaxis, Inc.  
Malvern, PA 19355

Docket No. 030-30915  
License No. 37-28318-02

During an NRC inspection conducted on March 20, 1997, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600, the violations are listed below:

- A. 10 CFR 20.1904(a) requires the licensee to ensure that each container of licensed material bears a durable, clearly visible label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, etc.) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

Contrary to the above, on March 20, 1997, waste containers of tritium and sulfur-35 did not bear clearly visible labels bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL." Furthermore, they did not bear labels that identified the radionuclide(s) or the quantity of radioactivity, nor did they otherwise bear sufficient information to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposure.

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

- B. 10 CFR 20.1101(c) requires the licensee to periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, as of March 20, 1997, the licensee did not periodically (at least annually) review the radiation protection program content and implementation. Specifically, the licensee did not review the radiation protection program since approximately March 20, 1995, a period greater than annual.

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

- C. License Condition No. 19 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in an application dated February 24, 1994, and a letter dated August 1, 1994.

1. Page 14 of application dated February 24, 1994 requires, in part, that the licensee calibrate radiation survey meters annually.

Contrary to the above, as of March 20, 1997, the licensee did not calibrate its radiation survey meters annually. Specifically, the licensee used a Ludlum Model 3 sodium iodide radiation survey meter last calibrated on June 8, 1995 to perform radiation surveys, a period greater than annual.

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

2. Page 24 of application dated February 24, 1994 requires, in part, that the licensee provide radiation safety training to workers who use radioactive materials under the supervision of an authorized user.

Contrary to the above, from July 24, 1996 to March 20, 1997, the licensee did not provide radiation safety training to a worker who used radioactive materials under the supervision of an authorized user.

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

3. Page 24 of application dated February 24, 1997 requires, in part, that the licensee to provide instruction to ancillary personnel initially and annually thereafter on radiation hazards and appropriate precautions.

Specifically, as of March 20, 1997, the licensee did not provide instruction to ancillary personnel initially nor annually on radiation hazards and appropriate precautions. Specifically, ancillary personnel were last trained in March 1995, a period greater than annual.

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

Pursuant to the provisions of 10 CFR 2.201, Zynaxis, 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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. 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.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.