



March 29, 1994

US Nuclear Regulatory Commission
Document Control Desk
Washington, DC 20555

Reply to a Notice of Violation

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

Dear Sirs,

In reply to your letter and notice of violation dated March 9, 1994:

Violation A: Failure to Perform Leak Testing of Sealed Sources.

(1) Zynaxis, Inc. did not perform leak testing of the Cs-137 sealed source as the irradiator was considered to be in storage during the period in question (2/21/90 through 12/1/93). As stated in the violation the sealed source was used only twice during this period. Zynaxis, Inc. concedes that this constitutes a "use" and a leak test should have been done at that time.

(2) The Cs-137 sealed source has been leak tested three times since the NRC inspection of Dec. 1, 1993. The dates of the testing and the results are as follows: 12/3/93, 0.00003 μCi ; 1/31/94, 0 μCi ; 3/21/94, 0 μCi . (n.b.: 0 μCi indicates that the background counts are greater than the survey test results) These results confirm that the source is not leaking.

(3) An SOP has been developed and implemented (3/14/94) to assure that sealed sources are leak tested at intervals not exceeding 6 months.

(4) Full compliance with the requirements for periodic leak testing was met on 12/3/93.

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Violation B: Failure to Perform Surveys to Assure Compliance with 10 CFR 20.101.

(1) For the three incidents in question, Zynaxis, Inc. took immediate emergency action to decontaminate the skin, make measurements of the activity on the skin, initiate corrective measures, and documented each incident. In this process, Zynaxis, Inc. did not calculate the skin dose because the level of contamination was not thought to be severe enough that skin dose limits would be exceeded. (This ultimately proved to be the case.)

(2) Information regarding the three skin exposure incidents was supplied to Wesley R. Van Pelt, Ph.D. for determination of radiation skin dose shortly after discussing this with the NRC inspector during the Dec. 1, 1993 inspection. Dr. Van Pelt performed the skin dose calculations and reported the following results on the respective dates: i) 6.25 rem skin dose reported on 1/22/94 from Tc-99m exposure; ii) 0.7 rem skin dose reported on 1/24/94 from I-125 exposure; iii) 4.06 rem skin dose reported on 1/30/94 from Sm-153 exposure. None of these skin exposures exceeds NRC limits.

(3) Two steps have been implemented to avoid recurrence of this situation. First, an SOP has been developed and implemented (3/17/94) to assure that calculations of skin dose will be performed as part of the response to any skin exposure incident. Second, a training course has been established and implemented (3/16/94) and personnel have been informed about ways to avoid skin contamination and what actions should be taken in the event that an incident of personal contamination occurs.

(4) Full compliance was met on 3/17/94.

Sincerely,



Martyn D. Greenacre, CEO