April 21, 1978

Samuel J. Chilk, Secretary
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Chilk:

RE: General Electric Company
Vallecitos Nuclear Center
General Electric Test Reactor (G.E.T.R.)
Docket #50-70
Operating License #TR-1 (Show Cause Proceeding)

Racx is interested in making a limited appearance, either in person or by a written statement, at any public hearing which may be held concerning the above matter. Our interest in these proceedings results from a business arrangement with General Electric whereby Racx Corporation markets Xenon-133 in both one curie and one-half curie ampules. These ampules are manufactured by General Electric at the Vallecitos Nuclear Center.

We would appreciate notification of the time, date, and location of any hearings on this matter. Attached is a statement of our views concerning this matter, and we would appreciate it if this would be considered in the proceedings.

Sincerely,

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H. M. Williams
President

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BACKGROUND INFORMATION

Radx Corporation is the leading manufacturer and supplier of equipment for the administration to humans of Xenon-133 radioactive gas in a procedure called a lung ventilation study. A lung ventilation study is a lifesaving procedure allowing the nuclear medicine physician to make a differential diagnosis between chronic obstructive airway disease and pulmonary embolism. The differential diagnosis is extremely important, as it dictates the course of therapy.

The process of the pulmonary or lung ventilation study requires the rebreathing of a quantity of Xenon-133 gas. Historically, this material has been available in individual doses, which is relatively expensive, costing from $1.00 to $3.00 per millicurie. This means that an individual patient dose can be as much as $30.00. General Electric developed bulk ampules of Xenon-133, which could be purchased for as little as 22½ cents per millicurie, therefore reducing the cost per study to as little as $2.00 to $3.00. Radx manufactures a device which allows the user to crush and dispense the gas from these bulk ampules.

In May of 1977, Radx entered into a business arrangement with General Electric whereby Radx would promote and market the curie, and one-half curie ampule. Part of the program to reduce the cost of xenon ventilation studies and to increase the efficacy of the procedure was to provide the Radx complete system of xenon equipment plus sufficient quantities of xenon gas to perform the patient load at a fixed monthly fee, usually significantly less than what the hospital paid for individual doses of Xenon-133 alone.

These programs required long-term contracts, most of which are for five years. These programs require a considerable initial capital investment on the part of Radx due to the fact that $8,000 worth of equipment is shipped initially with a very low monthly payment, the equipment being amortized over the entire length of the contract, usually sixty months. The entire program is highly dependent on a good, consistent supply of Xenon-133 gas.

These programs were quite successful. Over fifty hospitals have taken advantage of our programs, in one way or another, resulting in a significant reduction in the cost of providing this important diagnostic procedure.

When notified of the potential shutdown of the G. E. Test Reactor at Vallecitos, Radx made immediate effort to obtain alternate supplies of this material because the financial involvement was such that a discontinuance in the supply would have caused a very severe financial hardship, which, if extended, would have eventually resulted in corporate failure.

Our search for alternate supplies revealed that General Electric was the only supplier of a product with an approved new drug application. Contact with the F.D.A. and the N.R.C. indicated that no exceptions could be made to their rules and regulations concerning approved new drugs, and that if General Electric could not supply the material under their license, the material could not be supplied from any other source.

General Electric arranged to procure raw material from another supplier, purify, and package the material under their approved N.D.A. However, this action, although significant, has produced a number of problems.

1. The increased cost associated with General Electric's outside procurement of raw material was passed on to Radx. Because of some of our contractual arrangements, these cost increases could not be fully passed on to the user. This resulted in financial hardships.

2. This vicarious supply of raw material created an inconsistent and unpredictable supply of F.D.A. approved Xenon-133 in curie and half curie ampules. It also resulted in a restricted shipping time schedule, meaning that ampules could only be shipped on Friday for Monday calibration and Monday for Wednesday calibration. Because of the cost involved, it could not be made available on a daily basis as it had been when the reactor was in operation. The inconsistency of supply and the inability to supply the xenon on a schedule necessary for the operation of a nuclear medicine department has meant that some patient studies were not performed, that the cost of these patient studies significantly increased, and the financial hardship that this has caused Radx has not abated with time. It has been erroneously reported that the shutdown of the G.E.T.R. has not significantly affected the supply of radionuclides in the United States. Radx does not concur with such a statement. Some shipments have been delayed, some have not been available at all, and it has affected at least one aspect of performance of nuclear medicine at a significant number of medical institutions in the United States.

It is our request, since the preponderance of evidence is that the G.E.T.R. facility was shutdown without cause and the effect on the Nuclear Medicine community has been significant, that it be allowed to reopen immediately.