



January 12, 1994

U.S. Nuclear Regulatory Commission
Document Control Desk
Washington, D.C. 20555

Re: Docket # 030-15009

REPLY TO A NOTICE OF VIOLATION

I. Background Information/Explanation

This letter confirms that a written request to amend our license is being finalized and will be submitted to the Region 1 office by January 31, 1994. It also addresses the two violations specified by Ms. Cahill relative to her recent inspection. Although these violations are not contested, I request the following information be considered with regard to these issues.

LifeChem is a clinical laboratory performing diagnostic testing for a growing number of dialysis patients nationwide. This service contributes significantly to the delivery of specialized medical treatment and an enhanced quality of life for these patients. Since certain diagnostic testing utilizes low-level radioactive methodology, LifeChem has been a responsible and registered generator of LLR waste for many years. But along with other responsible generators, LifeChem finds itself in a frustrating "Catch 22" situation.

The Federal government mandated that each state be responsible for managing the safe disposal of its LLRW as of 12/31/92. Out-of-state access to three primary LLRW sites was therefore curtailed on that date. (Exorbitant fees for "temporary" out-of-state access to the Barnwell, S.C. site could not be considered by LifeChem as a feasible option.)

Though the NJLLRW Disposal Facility Siting Board has been working diligently for several years, its objective cannot be realized in the short term since a suitable site has not yet been designated. It is probable that no State disposal facility will be

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operational by the January 1, 1996 deadline. Projections as to when a LLRW disposal facility will become operational remain pure speculation.

Based upon various articles in NMSS License Newsletters, the NRC recognizes that "many licensees...will need to store LLW on site until disposal capacity is available Although NRC encourages permanent disposal of LLW, and views storage as an option of last resort, the staff understands that on-site interim storage may be necessary in many cases."

LifeChem was compelled by external circumstances and conditions to initiate the "option of last resort," interim storage, as of January 1993. Be assured that LifeChem will continue to be a responsible generator and make every effort to remain in full compliance during the demanding times ahead. LifeChem is encouraged by the NRC's current posture regarding these sensitive issues and trusts it will extend a greater measure of understanding to well-intentioned licensees who find themselves in the frustrating position of being "between a rock and a hard place."

II. Response to Specifications -- Appendix A

A. Radioactive waste was stored in two trailers located behind the licensee's main facility and the trailers were not indicated as locations of storage on the floor plan.

1. Reason for the violation.

During 1991-1992, continued volume increases began to impact heavily on the storage space allocated for LLRW and other waste streams. Since it was also projected that the space would be inadequate by early 1993 and since access to disposal facilities for NJLLRW would be restricted as of January 1993, corporate approval was sought to renovate areas which would enhance wastestream management practices.

On December 2, 1992, Chinu Jani, our Director of Operations, and I contacted Mr. Tom Thompson at the USNRC Region 1 office and discussed renovation, waste minimization, and interim storage plans (trailers) with him. He indicated that our plans appeared to be acceptable and that an amendment should be filed upon completion of the project reflecting all changes made. Although Mr. Thompson's instructions were stated clearly, in retrospect, a notification of projected

plans should have been forwarded to the Region 1 office prior to the start of the project. Perhaps this Notice of Violation would then have been unnecessary.

Corporate approval was received during the first quarter of 1993 and a modest expansion project was undertaken in various phases throughout the year to provide separate processing areas for RMW/LLRW, to incorporate waste reduction equipment (as part of long-term interim storage practices, per NMSS Licensee Newsletters) and to add space for interim storage of LLRW utilizing trailers. For the project to proceed, the first trailer was acquired in February 1993 and LLRW was transferred into it. In late October 1993, a second trailer was acquired to complete the project.

A comprehensive description of the above changes to support a request for an amendment was begun in mid-November. As stated to Ms. Cahill, I projected its completion and submission by January 31, 1994.

2. Corrective steps taken and results achieved.

As previously stated, the NRC will be notified prior to or during any project or condition which relates to the licensing agreement terms. I understood the importance of keeping the Commission apprised of such activities but erred in believing that it was best to accurately reflect these changes after completion of the expansion project.

Revised site plans (internal/external) have been developed which clearly indicate storage locations and will be included in the amendment packet.

Clarification: Please note that during the period 2/93 - 10/93, only one trailer was used for interim storage. The second trailer was added in 10/93.

3. Corrective steps taken to avoid further violations.

Proactive communication with NRC's Region 1 office will avoid a recurrence of such problems.

It is not anticipated that additional trailers will be necessary to satisfy our interim storage needs.

4. Date of full compliance.

After dispatch of the amendment packet to the NRC, I anticipate attaining full compliance by the end of April. I will be available to promptly respond to any clarification or concern the NRC might have.

B. From February 1993 to November 1993, two trailers in which radioactive waste was stored were not served monthly.

1. Reason for the violation.

The requirement to survey exterior storage trailer and the frequency necessary had not been recognized until Ms. Cahill's comment during her inspection.

The implementation of this requirement does not present a problem. This procedure will be performed and documented on a monthly basis.

2. Corrective steps taken and results achieved.

A Ludlum rate meter and scintillator has been purchased to use expressly for this purpose. It is expected to arrive within two weeks.

Monthly surveys will be conducted by the Radiation Safety Officer and findings documented on an appropriate record log which will be developed.

3. Corrective steps taken to avoid further violations.

The Radiation Safety Officer will be responsible for complying with this requirement.

Clarification: Please note that both trailers are locked/secure, weathertight, and placarded with the appropriate radiation symbol; only one trailer was used during the period 2/93 - 10/93.

4. Date of full compliance.

The implementation date for this survey procedure is projected to be February 1994.

Thank you for your consideration in this matter. If I can be of further assistance, please contact me at 1-800-631-1599, extension 875.

Sincerely,



A. Sbaratta, Manager
Quality Improvement and Regulatory Affairs

cc: Jenny M. Johansen
Robyn Spycaboer