

MAR 15 1994

License No. 29-19918-01
Docket No. 030-19526
Control No. 114548

The Liposome Company, Incorporated
ATTN: Lee Buccheri
Radiation Safety Officer
Princeton Forrestal Center
1 Research Way
Princeton, New Jersey 08540

Dear Mr. Buccheri:

Subject: Financial Assurance

This is in reference to your letter dated March 18, 1991 with attached Decommissioning Funding Plan to provide financial assurance for License No. 29-19918-01. We have reviewed your submittal and request that you modify your submission to address the specific matters described below:

- i. You have adapted the cost estimating tables found in Appendix F to *Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70 and 72*, to derive the submitted cost estimate. You have not, however, substantiated the assumption in your cost estimate regarding the low levels of contamination in the facility. According to the cost estimate, the only items which may require decontamination during decommissioning are refrigerators, some sinks and drains, a liquid scintillation counter, centrifuges, fume hoods and laboratory benches. The cost estimate indicates that no other equipment or building surfaces in any of the 18 laboratories and associated rooms will require decontamination and decommissioning. The Decommissioning Funding Plans (DFP) states that this is due to the fact that: there is "minimal contamination of equipment and none to the facility"; "based on the history of the site ... there seems (to be) little reason to expect any major contamination of the facility"; and "monthly radiation surveys indicate no contamination of the facility."

Please substantiate these claims of minimal contamination to the facility.

- a. Describe the extent of the monthly surveys (instrumentation and degree of inclusion, overview versus in-depth survey) and state whether or not the sanitary sewer is included in the survey.

- b. Describe whether your assumption that there are no sewer disposals is based on tracking and recording of all disposal actions or on the assumption that the policy of not disposing radioactive material (RAM) in the sanitary sewer is followed consistently.
- c. Describe the extent of the preliminary surveys of the ductwork, ie. were all the ducts surveyed or was a representative sample chosen. If a representative sample was chosen, what percentage was selected as a representative sample.

You may further substantiate the assumption that there is routinely lower contamination found at the facility by presenting results of wipe tests, both average and maximum, and confirm that areas of increased potential for contamination, such as glove boxes, fume hoods, duct-work, laboratory benches and floors have low levels of contamination.

2. You provided estimates of volumes of equipment that may require decontamination and decommissioning, however, the number and types of components are not clear. Specifically, the estimates for fume hoods, laboratory benches and sinks and drains are expressed in volume without a clear indication of the actual number of units included in the cost estimate. We could not evaluate whether the cost estimate includes reasonable estimates of costs for decommissioning activities. Provide additional detail in Table 3 which clarifies the unit volume and number of units of contaminated equipment to allow the NRC to evaluate the cost estimate for major decommissioning activities.
3. It appears that you have not made any allowance in the cost estimate for contingencies. Regulatory Guide 3.66 recommends that a contingency factor be included in the decommissioning cost estimate. Incorporating a contingency factor in the cost estimate will help to ensure that you are prepared for unexpected circumstances that could raise decommissioning costs. *NUREG/CR-1754, "Technology, Safety and Costs of Decommissioning Reference Non-Fuel-Cycle Nuclear Facilities"* (enclosed) uses a contingency factor of 25 percent in its cost estimates for each of six reference laboratories. Please incorporate a contingency factor of 25 percent into the decommissioning cost estimate or you may choose to use a lower contingency factor if you can show why a lower factor is appropriate. In addition, confirm that you have not included in the cost estimate, credit for any salvage value that may be realized with the sale of potential assets after decommissioning.
4. 10 CFR 30.35(e) requires that you describe the means you will use to adjust decommissioning cost estimates and associated funding levels over the life of the facility. Regulatory Guide 3.66 provides a method for adjusting the cost estimates and suggests that adjustments be made for inflation and for site-specific factors at the time of license renewal, or when the amounts or types of material at the facility change. You may also need to make adjustments to account for inflation, for other changes in prices of goods and services, for changes in facility conditions, or for changes in expected

decommissioning procedures. Please provide the means you will use for adjusting your decommissioning funding levels.

5. You submitted a Letter of Credit which closely follows the recommended wording in Regulatory Guide 3.66, however, it is an unexecuted draft and does not provide financial assurance in its present form. An acceptable Letter of Credit must specify a financial institution which is authorized to issue a Letter of Credit and which is regulated by a state or federal agency. The Letter of Credit must also include: a letter of credit number; an effective date; an expiration date; and must be signed by an authorized representative of the issuing financial institution. Submit an originally signed duplicate (an executed copy) of the Letter of Credit as required by 10 CFR 30.35 and as recommended by Regulatory Guide 3.66.
6. 10CFR 30.35(f)(2)(ii) requires licensees using a surety method of financial assurance certification to make the financial assurance mechanism payable to a trust fund established for decommissioning costs since funds paid directly to NRC must be deposited in the U.S. Treasury and would not be available for decommissioning costs. To avoid the possibility that a trust fund will not be readily available if and when needed, Regulatory Guide 3.66 states that a standby trust fund should be established and submitted with the Letter of Credit. Please submit the standby trust fund, acknowledgement, and related documents and closely follow the recommended wording found on pages 4-18 through 4-27 of Regulatory Guide 3.66.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 114548. If you have any technical questions regarding this deficiency letter please call David Everhart at (215) 337-6936.

The Liposome Company, Inc.

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If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original Signed By:
Mohamed M. Shanbaky

Mohamed M. Shanbaky, Chief
Research and Development Section
Division of Radiation Safety
and Safeguards

Enclosures:

1. Regulatory Guide 3.66
2. NUREG\CR-1754
3. NUREG\CR-1754, Addendum 1