Ref: SA/KNS

David Axelrod, M.D., Commissioner New York State Department of Health Empire State Plaza Tower Building Albany, New York 12237

Dear Dr. Axelrod:

This confirms the discussion Mrs. Kathleen Schneider held with you concerning the results of our partial review and evaluation of the Department's program for regulation of agreement materials. The review covered organization, management and administration, personnel, regulations, licensing and portions of the compliance program. Since there are several problems with the adequacy of the inspection reports, we believe it is important that the review include as many field evaluations of the inspection staff as is possible. We plan to complete this part of the review later this year. Since the review is not complete, we are not prepared to make recommendations for findings of adequacy developed, however, that deserve your attention.

Since the last review meeting, the number of overdue inspections has increased from 17 to 66, the one licensee in the State Priority Category I is overdue by 14 months and 44 licenses in Category II overdue by 5 to 20 months. The program's staff attributed the increase in overdue inspection to personnel vacancies and lack of support for the inspectors in the regional office.

We understand that there is a vacant position in the Albany central office, a vacant position in the White Plains Regional Office, and the inspector in the Rochester Office is awaiting personnel action to upgrade her job position so that she can perform material inspections. We recommend that the Department take prompt action to fill the vacant positions and upgrade the position in Rochester as soon as possible and take action to reduce the number of overdue inspections for the higher priority licenses.

We are concerned over the difficulty that the regional inspectors are encountering. There appears to be a lack of management support for the agreement material inspectors in various regional offices. In one region, the inspector has difficulty in engaging a State car for a reasonable length of time to perform materials inspections. The inspectors do not always have laboratory support for analyzing samples taken during the course of an inspection. The survey basis. Also, in one region, mail sent to the inspector from the central office staff has been forced to send all written communication to the inspectors home address. We believe these problems have had an undesirable impact on the compliance that these various problems be addressed by the Department as soon as possible.

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We noted that four recommendations made following the last review had not been implemented and are again included in this year's recommendations in the enclosed letter to Mr. Goldman. I am also enclosing a second copy of both letters which should be placed in the State Public Document Room, or otherwise be made available for public review.

I appreciate the courtesy and assistance extended Mrs. Schneider during the meeting with your staff. I would appreciate your review of these recommendations and your comments on them.

Sincerely.

G. Wayne Kerr, Acting Director Office of State Programs

Enclosure: As stated

CC: T. K. DeBoer

NRC Public Document Room

State Public Document Room)

H. Goldman, w/o enclosure

w/enclosure

bcc: T. Elsasser w/enclosure

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