

July 17, 1997

Docket No. 030-30876

License No. 31-28300-01

George H. Boone
Director
Department of Health & Human Services
Public Health Service
Food and Drug Administration
850 Third Avenue - 7th Floor
Brooklyn, New York 11232

SUBJECT: INSPECTION NO. 030-30876/97-001

Dear Mr. Boone:

On June 23, 1997, Richard Gibson, Jr., of this office conducted a safety inspection at the Department of Health & Human Services' Northeast Regional Laboratory, Brooklyn, New York of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with you and other members of your staff, at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

The violation described in the Notice of Violation enclosed with this letter was identified during a previous inspection of your licensed activities and documented in our NRC Form 591 dated May 15, 1992. From this inspection, it appears that your corrective actions were not effective since this item has recurred. Recurrent and uncorrected violations are given additional weight in the consideration and selection of

OFFICIAL RECORD COPY

RETURN ORIGINAL TO
REGION I

9707220403 970717
PDR ADOCK 03030876
C PDR



1E:07

George H. Boone, Director
Department of Health & Human Services

-2-

appropriate enforcement action. Therefore, in your response to this letter, you should give particular attention to those actions taken or planned to ensure that identified items of noncompliance will be completely corrected and will not recur.

In accordance with Section 2.790 of NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public. The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Your cooperation with us is appreciated.

Sincerely,

ORIGINAL SIGNED BY:
JOHN D. KINNEMAN

John D. Kinneman, Chief
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Docket No.: 030-30876
License No.: 31-28300-01

Enclosure:
Notice of Violation

cc w/enclosure:
Michael J. Palmieri, Radiation Safety Officer
State of New York

OFFICIAL RECORD COPY

George H. Boone, Director
Department of Health & Human Services

-3-

Distribution: w/encl

PUBLIC

Nuclear Safety Information Center (NSIC)

Region I Docket Room (w/concurrences)

D. J. Holody, RI

DOCUMENT NAME: R:\WPS\MLDL\L3128300.01

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	<input checked="" type="checkbox"/> N	DNMS/RI	<input checked="" type="checkbox"/> W			
NAME	RGibson/rxg		J. M. Merman				
DATE	07/16/97		07/16/97		07/ /97		07/ /97

OFFICIAL RECORD COPY