



JAN 14 1986

Mr. J. Nelson Grace  
Regional Administrator  
United States Nuclear Regulatory Commission  
101 Marietta Street, N.W.  
Atlanta, Georgia 30323

Dear Mr. Grace:

This is in response to your letter regarding the October 28-29, 1985 inspection of the Centers for Disease Control (CDC) Radiation Safety Program by members of your staff and the enforcement conference held on November 19 to discuss the findings of that inspection. We accept that the violations occurred as outlined in the Notice of Violation, and we believe that the actions listed in our letters of November 19 and December 23 (copies enclosed) represent appropriate corrective action.

We have prepared a point-by-point response to the deficiencies noted for each of the two licenses we currently hold. We believe these responses reflect our commitment to carry out an exemplary radiation protection program for our employees. Our specific comments are as follows:

1. License Number 10-06772-01

- a. Severity Level IV Violation: Office of Biosafety (OBS) personnel did not conduct routine surveys of all laboratories on a quarterly basis during 1985.

Response: The fourth quarter monitoring surveys of the 66 laboratories using radioisotopes were completed on December 19. The completion of all monitoring surveys is a high priority in our efforts to strengthen our radiation safety program. To insure that all surveys are completed on a timely basis in the future, we have assigned an existing OBS staff member to assist the Radiation Safety Officer in performing the necessary monitoring. We have requested that the Nuclear Regulatory Commission amend our license to allow the monitoring to be done every 4 months, rather than quarterly as is presently required. We understand that such a schedule is acceptable since none of our laboratorians currently use more than 5 millicuries of radioactive material per quarter.

03004001  
03013103

8601290066 860114  
REG2 LIC30 PDR  
10-06772-01

IE07

- b. Severity Level IV Violation: On various occasions during 1985, the licensee had transported materials from the Clifton Road facility to the Chamblee facility without being authorized in a general or specific license to do so.

Response: We have implemented a procedure whereby all incoming radioactive material shipments destined for laboratorians at Chamblee will be taken by common carrier directly to that facility. This will obviate the need for transfer of radioactive materials via the CDC mail service. Each of these packages will be monitored at Chamblee by individuals who have been trained by the Radiation Safety Officer.

- c. Severity Level IV Violation: The licensee did not test the chromatograph detectors containing Nickel-63 between October 1984 and August 1985, an interval of more than 6 months.

Response: A new schedule for testing the gas chromatograph detectors has been established, requiring wipe samples to be collected in August and February of each year. OBS will send instructions on performing the wipe tests to laboratorians in July and January of each year; laboratorians will be required to perform the sampling and return the wipes within 30 calendar days.

- d. Severity Level V Violation: Records of leak test results from October 1984 were not available during the inspection on October 28 and 29, 1985.

Response: CDC has contracted with the National Leak Test Center in North Tonawanda, New York, to perform the analysis on the gas chromatographic wipe samples. We have developed internal procedures to eliminate the delays which have existed in the past in obtaining the sample test results on a timely basis.

- e. Severity Level V Violation: On October 28 and 29, 1985, the licensee had posted neither 10 CFR 19 and other documents nor the notice where the documents might be examined.

Response: On November 18, 1985, OBS completed the posting of the notices informing laboratorians who work with radioactive materials of the location of all documents relating to CDC's Radiation Safety Program. Laboratorians also have an open invitation to come to OBS at any time to examine documents on the use of radioactive materials.

- f. Severity Level V Violation: On October 29, 1985, the licensee had not posted Forms NRC-3 as prescribed in or near laboratories utilizing radioactive materials at the Chamblee location.

Response: OBS completed the posting of Form NRC-3 at eight different locations in which radioactive materials are utilized at the Chamblee facility on November 18, 1985. On the same date, forms were posted at 16 locations at Clifton Road.

2. License Number 10-06772-02

- a. Severity Level IV Violation: On numerous occasions in 1985, the licensee permitted individuals not named in License Condition 12 to use the Co-60 AECL Gammacell Self-Contained Irradiator when none of the individuals named in Condition 12 were present.

Response: On December 9, OBS conducted an 8-hour training course on the use of the gammacell for 27 CDC laboratorians, all of whom passed the course with a grade of 75 or higher. The syllabus and the examination questions had been approved by your office earlier. The names of the persons who passed the course were listed in an enclosure to our December 23 letter. On December 16, a digital card-access reader was installed on the entrance to the room which houses the gammacell in order to control and monitor access to that unit. Only authorized gammacell users have received card-entry keys and the numerical password required for entry, thus providing two levels of security.

- b. Severity Level IV Violation: The irradiator room keys were left in the log book in a laboratory instead of being held by the guard force, Radiation Safety Officer, or authorized supervisors.

Response: As noted in item (a) above, the process for entry to the gammacell room has been changed significantly. The conventional door locks have been removed and a computer-controlled card access reader has been installed. The primary advantage of this system is that the computer records on a log the card number and time of entry of each laboratorian who enters the room. This information can be compared with the user's log book inside the room.

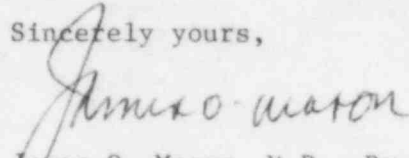
- c. Severity Level V Violation: On October 28, 1985, the licensee had posted neither 10 CFR 19 and other documents nor the notice of where the documents might be examined.

Response: On November 18, 1985, the notice was posted on the bulletin board in the irradiator room stating the location and availability of all documents related to the use of the irradiator. Authorized users may at any time review and examine any of the documents related to our radiation safety program.

Page 4 - Mr. J. Nelson Grace

We sincerely hope that we have provided a timely and appropriate response to each of the deficiencies noted during the October 28-29 inspection. We plan to continue to strengthen our radiation safety program and are striving toward the absence of any violations regardless of the severity level. In that regard, we welcome continuing assistance from the radiation specialists in your office.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "James O. Mason".

James O. Mason, M.D., Dr.P.H.  
Assistant Surgeon General  
Director

Enclosures