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May 28, 1991

Re: Indian Point Unit No. 2  
Docket No. 50-247

Document Control Desk  
US Nuclear Regulatory Commission  
Mail Station P1-137  
Washington, DC 20555

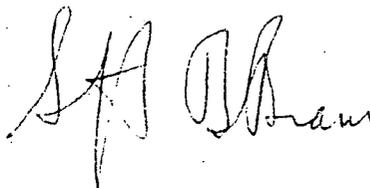
SUBJECT: Response to Notice of Violation, NRC Inspection  
Report No. 50-247/91-08

This letter is in response to the subject Notice of Violation transmitted to us by letter dated April 25, 1991. Our response is provided in Attachment A to this letter.

You also requested that we provide the current status of the items in the Inspection Report that were identified as unresolved. The status of those items is provided in Attachment B.

Should you have any questions regarding this matter, please contact Mr. Charles W. Jackson, Manager, Nuclear Safety and Licensing.

Very truly yours,



attachment

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ATTACHMENT A  
RESPONSE TO NOTICE OF VIOLATION

CONSOLIDATED EDISON COMPANY OF NEW YORK, INC.  
INDIAN POINT UNIT NO. 2  
DOCKET NO. 50-247  
MAY, 1991

Notice of Violation

1. Section 2.4(g)(14) of Appendix A to 10 CFR Part 26 states, in part, that if the temperature of a urine specimen is outside the range of 90.5 degrees to 99.8 degrees Fahrenheit, that is a reason to believe that the individual may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collection site person and both specimens shall be forwarded to the laboratory for testing. An individual may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

Contrary to the above, on March 19, 1990, a collection site person failed to require that an observed specimen be given or suggest that an oral temperature be taken to substantiate the temperature of the specimen, when the specimen was found to be outside the prescribed temperature range.

Response

In March, 1990, Con Edison's contractor Collection Agent had made note of the temperature discrepancy of the collected specimen referenced in the Notice of Violation. However, there is no documentation indicating that a second sample was collected. Further efforts to reconstruct the background of this procedural discrepancy have been limited by Con Edison's subsequent termination of the contractor responsible for this collection and the unavailability of the individual collection agent, who we are informed is no longer residing in the United States.

Nevertheless, certain immediate corrective actions were taken. Procedures were revised to require further documentation of the appropriate steps to be taken by a collector should he/she collect a specimen that is not within the acceptable temperature range as specified in Appendix A to 10 CFR Part 26, Section 2.4(g)(14). In addition, the current collection agent contractor has given additional training to its individual collection agents on collection procedures, emphasizing reasons for unacceptable specimens and actions to be taken if the situation is encountered.

Furthermore, we have implemented a new collection log format. It includes a column for the collector to indicate "sample acceptable" by entering a "Y" or an "N".

Collection log instructions are affixed to page one of every log book. The contractor has been instructed, in writing, to inform all collectors of the collection log instructions. The contractor has documented that this is being done.

Additionally, it is now procedurally required that a Con Edison Occupational Health employee (Medical Technician or Nurse) report any collections recorded in the collector's log as "unacceptable" to the Manager, Quality Assurance at Occupational Health for audit. Occupational Health will inspect the log weekly.

These procedural improvements reflect a heightened awareness of the correct collection procedure, specifically with regard to temperature deviations, by contractor collectors.

#### Notice of Violation

2. Section 1.2 of Appendix A to 10 CFR Part 26 defines the permanent record book as a permanently bound book in which identifying data on each specimen collected at a collection site are permanently recorded in the sequence of collection. Section 2.4(g)(24) of Appendix A to 10 CFR Part 26 states, in part, that the collection site person shall sign the permanent record book next to the identifying information. Section 2.7(n) of Appendix A to 10 CFR Part 26 states, in part, that the licensee's testing facility shall maintain and make available for at least 2 years documentation of all aspects of the testing process.

Contrary to the above, the licensee could not provide permanent record books for the first four months of program implementation. In addition, the inspector determined that collection site personnel were not signing the currently existing permanent record books next to the identifying information, and that one individual who provided a sample was never recorded in the permanent record book.

#### Response

The situation regarding missing record books for the first four months of 1990 is directly related to Con Edison's decision to terminate the services of the collection contractor being used at that time. Upon termination of the contract, the record books that were kept up to that date by the contractor were not returned to Con Edison. When a Con Edison employee attempted to retrieve the log books, he was provided only with those logs commencing 5/3/90. The former contractor could not produce any earlier log books.

An attempt was made to reconstruct the log books from available documentation, but the result was incomplete and not in a bound form. The present contract collection agent has acknowledged its clear understanding of the requirements of section 2.7(n) of Appendix A to 10 CFR Part 26 in regard to maintaining and making available for at least 2 years documentation of all aspects of the testing process. This documentation includes all collection log books.

The format for the original collection logs did not include a column for the collector's signature based on Con Edison's understanding at the time that the collector's signature was not a testing requirement under 10 CFR Part 26. The log books have been replaced at the collection sites with a bound book utilizing a format that is in compliance with section 2.4 (g)(24) of Appendix A to 10 CFR Part 26. The format clearly requires collector signature. To insure compliance, a Con Edison Occupational Health employee (Medical Technician or Nurse) inspects the books weekly and reports deviations to the Manager, Quality Assurance at Occupational Health for resolution. The collection log instructions attached to page one of each collection log also reinforce proper log entry procedure.

Failure to document the event when an employee gave a specimen was due to collector oversight. Con Edison has recently put into place a computer system that tracks each specimen from collection to resolution. The "All Collected File" is a data file of all specimens collected. The data is input into the file by the collector via an onsite mainframe terminal. A collection that is not entered in the log book and not entered on the terminal will be picked up by the FFD Tracking System when it compares collected results to the All Collected File. Any specimen with a result that is not in the All Collected File will appear on a computer generated Exception Report for resolution by Occupational Health.

It is anticipated that these corrective actions will preclude further violations of this nature.

ATTACHMENT B

CURRENT STATUS OF UNRESOLVED ITEMS

CONSOLIDATED EDISON COMPANY OF NEW YORK, INC.  
INDIAN POINT UNIT NO. 2  
DOCKET NO. 50-247  
MAY, 1991

Unresolved Items

1. During the inspection at the Indian Point Unit 2 Station, the inspector was provided with testing data that the licensee had compiled for the first year of program implementation which reflected: (1) gas chromatography/mass spectrometry (GC/MS) confirmatory positive test results; (2) MRO confirmed positive test results; and (3) blind performance positive test results. Since the testing data could not be reconciled against HHS-laboratory statistical summaries for the entire year, the inspector decided to conduct an audit of all laboratory confirmatory positive test results at the licensee's offices in Brooklyn, New York, where all of the FFD test results are maintained. Prior to the audit, the licensee presented the inspector with a revision to the licensee compiled testing data that was provided during the inspection at the Indian Point Unit 2 Station. The licensee provided the inspector with what it purported to be all of the confirmatory positive tests results for the first year of program implementation.

The inspector conducted a 100 percent audit of the records that were provided. The inspector was still not able to reconcile the records completely against the testing data that was provided. The MRO confirmed positives and the blind performance data were found to be in error. As a result, the licensee stated that the performance data that it reported to the Commission for the first year of program implementation would be revised and resubmitted. Therefore, this matter is considered an unresolved item (UNR 50-247/91-08-01) and will be reviewed during a subsequent inspection.

Current Status:

Efforts to resolve discrepancies in the Fitness for Duty Performance data have concentrated on the second half of 1990, after substitution of the collection contractor. By the time of the inspection we had self-identified some errors occurring in this time period. As a result, an amended semiannual report has been submitted by letter dated May 23, 1991. This effort represented the results of an intensive review of all records in that time period and documented the corrected statistics found therein.

Unresolved Items

2. On April 30, 1990, an individual completed random testing at the Indian Point Station collection facility. Within a day or two, the urine specimen was shipped to an HHS-certified laboratory for testing. The licensee's MRO received the laboratory results on June 11, 1990. The test results indicated a positive for cocaine by GC/MS analyses but were not accompanied by the chain-of-custody form. Because of the missing chain-of-custody form, the MRO considered this as a break in the chain-of-custody and decided to treat the test results as negative. The MRO required the individual to be retested on June 26, 1990. The results of that retest were negative.

While it is prudent for an MRO to invalidate laboratory test results when there is an apparent break in the chain-of-custody, the NRC has an expectation that the MRO will investigate a missing chain-of-custody form and take prompt corrective action. This was not done in that case. From a review of the MRO's desk (detailed) procedures, the inspector determined that the procedures were lacking in the essential elements to ensure that chain-of-custody issues are properly addressed. The licensee committed to take corrective action in this area. Therefore, this matter is considered an unresolved item (UNR 50-247/91-08-03) and will be reviewed during a subsequent inspection.

Current Status

The responsible contractor MRO has been terminated from the program. In addition, the computerized FFD Tracking Program which has recently been installed will identify lab positives that have not been resolved within (8) days of the collection date. This gives Occupational Health two days to resolve potential problem cases.

The present MRO's are aware of their responsibilities regarding Chain-of-Custody issues (i.e., missing Chain-of-Custody Form) and the detailed procedures have been upgraded to ensure that chain-of-custody issues are properly addressed.