



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

JUL 13 1992

Docket No. 99901250

Mr. Michael S. Morris
President
Bridgeport Testing Laboratory, Inc.
23 Willow Street
Bridgeport, Connecticut 06610

Dear Mr. Morris:

SUBJECT: RESPONSE TO 10 CFR PART 21 INQUIRY

By letter dated April 8, 1992, to Mr. Gregory Cwalina, you requested clarification on the NRC's position as described in a letter dated April 26, 1991, to the James C. White Company. The April 26 letter responded to several Part 21 related inquiries including the need to audit suppliers of calibration services for measuring and test equipment used on safety-related items. We have clarified our position, as well as addressed the limited application you described in your letter, in an enclosure to this letter.

Please note that our response is limited to the NRC responsibilities of Title 10 of the Code of Federal Regulations (10 CFR) and does not address the American Society of Mechanical Engineers (ASME) code requirements. Official positions regarding compliance with standard industry codes should be obtained from the affected organizations. Should you have any further questions, please contact Mr. Gregory Cwalina of my staff at (301) 504-2984.

Sincerely,

A handwritten signature in dark ink, appearing to read "Leif J. Norrholm", is written over the typed name.

Leif J. Norrholm, Chief
Vendor Inspection Branch
Division of Reactor Inspection
and Safeguards
Office of Nuclear Reactor Regulation

Enclosure:
Response to Questions

RESPONSE TO BRIDGEPORT TESTING LABORATORY LETTER

QUESTION:

What is the requirement for on site audits under the following limited situation:

- 1) Service being supplied is a calibration service
- 2) Service is being supplied to equipment located in our premises, and the service is performed on our premises
- 3) Supplier has his records concerning traceability to NIST in his possession at the time service is supplied
- 4) Supplier has in his possession at the time service is being performed the written procedures to which he operates
- 5) Our Quality Control Department monitors his actions during the calibration process to assure that the written procedures are followed
- 6) Comprehensive documents supporting the calibration performed (ie Strain charts) are retained at our facility pending receipt of the written calibration report

NRC RESPONSE:

Several of the quality assurance requirements specified by Appendix B to Part 50 of Title 10 of the Code of Federal Regulations (10 CFR Part 50) relate to calibration services. Criterion XVIII states, in part, that planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance (QA) program. If the scope of services is limited to calibration of equipment on your premises only, a complete audit at the offices of the calibration company may not be necessary to adequately evaluate compliance with their QA program. A review of their QA manual, written procedures, personnel qualifications, and documentation confirming traceability to the National Institute of Standards and Technology (NIST) may constitute the basis for a sufficient audit. Additional measures, such as telephone checks, may be necessary to establish the integrity of the traceability documentation. A further review of the calibration company's internal audits should provide insight into the effectiveness of their overall QA program.

Those activities affecting quality should also be observed in process to assure the written instructions are being followed. The audit results must be documented and available for review. Sufficient records must also be maintained supporting each calibration service performed, including documentation that the services conform with the specific requirements as stated on the procurement documents.