

INSPECTION REPORT

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR INSPECTION
AND LICENSEE PERFORMANCE

ORGANIZATION: GULTON-STATHAM TRANSDUCERS, INCORPORATED
1644 WHITTIER AVENUE
COSTA MESA, CALIFORNIA 92627

REPORT NO.: 99901261/94-01

CORRESPONDENCE ADDRESS: Steven S. Pirrone, President
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ORGANIZATIONAL CONTACT: Paul Mesmer, Vice President of Quality Assurance
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NUCLEAR INDUSTRY ACTIVITY: Pressure and differential pressure transmitters

INSPECTION CONDUCTED: March 7-10, 1994

TEAM LEADER: *Richard C. Wilson* 4/11/94
Richard C. Wilson, Senior Engineer Date
Reactive Inspection Section 2 (RIS2)
Vendor Inspection Branch (VIB)

OTHER INSPECTOR: Ronald K. Frahm Jr., RIS2, VIB

APPROVED: *Gregory C. Cwalina* 4/11/94
Gregory C. Cwalina, Chief Date
Reactive Inspection Section 2
Vendor Inspection Branch

INSPECTION BASES: 10 CFR Part 21 and 10 CFR Part 50, Appendix B

INSPECTION SCOPE: To selectively review the implementation of G-S's quality assurance program for supplying nuclear safety-related equipment, with emphasis on calibration

PLANT SITE APPLICABILITY: Numerous

1 INSPECTION SUMMARY

1.1 Violation 99901261/94-01-01 (Open)

Contrary to the requirements of 10 CFR Part 21, Gulton-Statham Transducers, Incorporated's (G-S's) implementation procedure was not adequate to ensure the completion of the required evaluations of deviations and potential reporting of defects (see Section 3.8 of this inspection report).

1.2 Violation 99901261/94-01-02 (Open)

Contrary to the requirements of 10 CFR Part 21, G-S had not posted a current copy of the regulations or a notice which describes the regulations (see Section 3.8 of this inspection report).

1.3 Nonconformance 99901261/94-01-03 (Open)

Contrary to criteria XII and VII of Appendix B to 10 CFR Part 50, which was invoked on G-S by licensee purchase orders, G-S did not assure that QA surveys of calibration service suppliers were adequate for nuclear safety-related use (see Section 3.5 of this inspection report).

1.4 Nonconformance 99901261/94-01-04 (Open)

Contrary to criterion XII of Appendix B to 10 CFR Part 50, which was invoked on G-S by licensee purchase orders, a megohmmeter being used on the production line was past due for calibration (see Section 3.7 of this inspection report).

1.5 Nonconformance 99901261/94-01-05 (Open)

Contrary to criterion V of Appendix B to 10 CFR Part 50, which was invoked on G-S by licensee purchase orders, G-S did not follow its prescribed procedures for issuing a monthly report of items past due for calibration (see Section 3.7 of this inspection report).

2 STATUS OF PREVIOUS INSPECTION FINDINGS

There was no previous NRC inspection of this facility.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Entrance and Exit Meetings

In the entrance meeting on March 7, 1994, the NRC inspectors discussed the scope of the inspection, outlined the areas to be

inspected, and established interfaces with G-S management and staff. In the exit meeting on March 10, 1994, the inspectors discussed their findings and concerns with G-S management and staff.

3.2 Inspection Scope

The Statham and Gulton divisions of Mark IV Industries, Inc. were merged in 1992. The Statham operation in Oxnard, California, was moved to Gulton's Costa Mesa location in 1993. Gulton-Statham Transducers, Inc., (G-S) products include pressure and position transducers for aerospace, aviation, and industrial use. The Costa Mesa facility includes over 80,000 square feet, and employs about 250. Domestic nuclear sales of about \$300,000 per year comprise about 1% of sales, and foreign nuclear about 10%. The single quality assurance (QA) program used for all G-S activities is based heavily on MIL specifications, which account for about 60% of sales.

The G-S product line includes the 3200 Series pressure and differential pressure transmitters previously supplied by Statham. These transmitters are used in nuclear power plants in environmentally qualified, safety-related applications. The transmitter sensing element consists of a thin film strain gauge bridge that is sputter deposited on a small stainless steel beam. Process fluid pressure on a diaphragm forces a steel pin against the cantilevered beam, causing tensile and compressive stresses on the bridge elements. The transmitter includes a solid state amplifier that converts the bridge output to a 4-20 mA signal. The specified transmitter accuracy is $\pm 0.25\%$ of calibrated span, including linearity, hysteresis, and repeatability.

The inspection covered selected aspects of G-S's 10 CFR Part 50, Appendix B quality assurance program for supplying safety-related transmitters for commercial nuclear power plants, with emphasis on calibration. The inspectors also reviewed G-S's program for meeting the reporting requirements of 10 CFR Part 21, and observed G-S's facilities, again with emphasis on calibration. The NRC inspectors selectively reviewed all of the on-hand nuclear safety-related purchase orders (POs) for complete transmitters or associated piece-parts that have been (or will be) shipped from the Costa Mesa facility.

3.3 Quality Assurance Program

G-S had a single quality assurance (QA) program that applied to all work performed at the facility. The program was delineated in manual QAP-0100, "Quality Assurance Policy and Procedure Manual," Revision L, dated February 4, 1994. The manual followed the ISO-9001 QA program arrangement, and appeared to meet the applicable requirements of Appendix B to 10 CFR Part 50. The inspectors noted that the QA department had sufficient authority

and organizational freedom to adequately perform its QA functions. The vice president of Quality Assurance reported directly to the president of G-S, and had sufficient independence from cost and schedule when opposed to safety considerations.

G-S indicated to the NRC inspectors that they presently procure all components as commercial grade, with no special nuclear requirements imposed in purchase orders (POs) to their suppliers. While reviewing POs for replacement piece-parts (O-rings and junction box assemblies), the NRC inspectors found that G-S's parts traceability program provided effective control of lots and batches for both manufactured and procured components.

Procedure, SSP-345, "Dedication of Commercial Grade Items," Revision [none], dated March 7, 1994, covered dedication of commercial grade items for nuclear safety-related applications. Since this procedure was issued on the date of the entrance meeting and had not been implemented, the inspectors did not review it. The inspectors did note, however, that the procedure was not directly tied into G-S's QA program. The vice president of QA acknowledged this oversight, and committed to revising manual QAP-0100 to reference the dedication procedure.

3.4 Transmitter Calibration

The NRC inspectors reviewed the calibration records for a differential pressure transmitter shipped to the Millstone site under Northeast Utilities (NU) PO 889594 dated July 27, 1993 (G-S Sales Order 028333-07). The PO stated that the procurement was nuclear safety-related, and imposed 10 CFR Part 21 and Appendix B to 10 CFR Part 50. The transmitter was serial number R3386, model no. PD3200-400-L8-22-36-XX, calibrated from 56 to 316 inches of water. This transmitter was one of the first that was shipped from the Costa Mesa facility since Statham moved to that location in late 1993. Documentation indicated that the transmitter had been assembled and tested at Oxnard in 1991, and the amplifier board was found to be defective during in-process elevated temperature testing. Additional testing at Oxnard in 1992 showed the repaired transmitter to be acceptable. G-S then performed further in-process elevated temperature testing and final acceptance testing at Costa Mesa in January 1994, and shipped the transmitter on February 9, 1994.

G-S performs considerable in-process testing on transmitters before, during, and after assembly, including elevated temperature testing, and subjects each unit to a 168 hour burnin. The NRC inspector regarded the in-process testing as primarily precautionary in nature, and not a part of calibration. The inspector examined in detail the calibration traceability for the instruments used to measure input pressure and output voltage during final calibration on January 29, 1994.

Acceptance testing was performed in accordance with Drawing No. ATP 2508, "Acceptance Test Procedure for Statham Division Pressure Transmitters Model PD3200," Revision F, dated January 21, 1993, using Acceptance Test Data Sheet No. 1508. For final calibration, the procedure specified the types of pressure calibrator and digital voltmeter to be used, with required accuracies. The procedure did not require recording the identification number (ID) of the specific calibrating equipment used, nor did the data sheet provide for recording that information. However, for transmitter serial number R3386 the technician recorded on the data sheet the ID for the Ruska pressure gauge and interface as 2-201-016, and the test date as January 29, 1994. When the NRC inspector observed the test setup, the pressure gauge and interface were Ruska model DDR 6000 and 6005 with the same ID noted on the data sheet, and the digital multimeter was a Fluke model 8810A with ID 1-504-181. Both instruments were within their calibrated intervals.

In response to the NRC inspector's concern about recording specific calibration test instrument identification and test dates, G-S committed by fax dated March 31, 1994, to add a note to shop travellers requiring this information to be recorded on the acceptance test data sheets.

(NOTE: The G-S metrology laboratory was in the process of converting G-S identification (ID) numbers from the system that had been used by Statham at Oxnard to the G-S Costa Mesa system. Even though the electrical metrology technician was not present during the file search, the mechanical technician readily retrieved all pertinent records.)

G-S metrology laboratory records showed that the Ruska digital direct reading pressure gauge and interface had been calibrated against the laboratory standard Ruska model 2465A piston gauge dead weight tester, ID 0-201-001. The laboratory standard had been calibrated at G-S by the Gauge Repair Service (GRS) company against a DH Instruments model 5201 piston gauge, serial number 3662, provided by GRS. The GRS documentation stated that the DH instrument calibration was traceable to National Institute of Standards and Technology (NIST) test number TN-243399-89, but the G-S files did not contain copies of the supporting calibration reports or evidence that the reports had been reviewed to verify traceability. All of the instruments used for calibration had acceptable accuracies and were within their calibration intervals.

G-S metrology laboratory records showed that the Fluke digital multimeter used for acceptance testing had been calibrated against three laboratory standards: (a) a Fluke model 5700A multifunction calibrator, old ID 0-501-023, new ID 0-704-001; (b) a Datron model 1062 digital multimeter, ID 0-502-006; and

(c) a Valhalla Scientific model 2724 programmable resistance standard, old ID 0-101-007, new ID 0-101-001.

The Fluke and Datron standards were calibrated against the following standards in the G-S metrology laboratory: (a) a Fluke model 732B standard DC reference, ID 0-501-024; (b) a Fluke model 742A-10k resistor standard, ID 0-101-023; (c) a Fluke model 742A-1 resistor standard, ID 0-101-022; and (d) the Valhalla Scientific model 2724 programmable resistor, old ID 0-101-007, new ID 0-101-001. All four of these standards were calibrated at Teledyne Systems Company, Inc. The Teledyne metrology laboratory reports provided test data and identified the specific Teledyne standards used, with applicable NIST test numbers and dates. The G-S files did not contain copies of the supporting calibration reports or evidence that the reports had been reviewed to verify traceability. All of the instruments used for calibration had acceptable accuracies and were within their calibration intervals.

3.5 External Suppliers of Calibration Services

G-S personnel provided the NRC inspectors with a copy of an internal memorandum dated March 2, 1994, from the quality program manager to the vice president of QA. The memo listed six metrology laboratories, including the Gauge Repair Service company (GRS) and the Teledyne Systems Company, that were used for nuclear product calibration and needed facility surveys. Both GRS and Teledyne are suppliers of commercial grade calibration services, and the services are dedicated by G-S by means of vendor surveys combined with experience.

The NRC inspector reviewed the G-S QA vendor files for GRS and Teledyne. The indicated bases for accepting GRS as a supplier of calibration services were (a) a 1984 survey, (b) questionnaires, and (c) historical data (although no specific data on supplier performance were included in the file). For Teledyne, acceptance was based on (a) a 1994 questionnaire that was signed without comment by the G-S quality engineer on February 16, 1994, and (b) a September 8, 1992, survey by a Statham Oxnard quality control inspector. The survey report was a general checklist that did not provide objective evidence that the inspector had performed a dedication of the specific type of commercial grade calibration services performed for Statham and G-S by Teledyne.

Criterion XII of 10 CFR Part 50 requires proper control and calibration of instruments affecting quality, and criterion VII requires assessing the effectiveness of the control of quality by contractors. G-S's failure to perform adequate commercial grade surveys of GRS and Teledyne sufficient for dedication of their calibration services, and to enforce relevant requirements in POs to those suppliers, constitute Nonconformance 99901261/94-01-03.

3.6 Customer Interfacing

The NU PO required a certificate of conformance stating that the equipment was Class 1E and was qualified to environmental and seismic requirements based on "Gould Nuclear Qualification Report #10C6 Rev C." The G-S certificate of compliance was dated January 31, 1994; it referenced Revision D of the qualification report, dated October 2, 1992. The date of Revision C was January 17, 1990. Revision D described and evaluated certain changes to the transmitter design that was originally type tested in 1984. These changes were incorporated in production and applied to the transmitter actually shipped under this PO, so Revision D was applicable to the hardware.

This discrepancy should have been identified during preparation and QA review of the G-S sales order. It appears to be an isolated case associated with the transfer of activities from Oxnard to Costa Mesa. In response to the inspector's concerns, G-S contacted the licensee, who stated that they had identified the revision change and planned to issue a PO change. To help prevent recurrence, G-S sales personnel plan to notify all customers of such conflicts prior to PO issuance, and to identify current information in blanket mailings.

The two PD3200 transmitters (PO line item 2) were shipped to NU on January 31 and February 8, 1994. The licensee's PO did not require shipping a copy of the acceptance test data, although such data might well be useful to nuclear plant instrumentation and control personnel. G-S also had no record of the licensee witnessing acceptance testing. G-S's quality engineer applied Code DA1 to the sales order, which required shipping the calibration test data, and the final inspector believed that the data were shipped. The appropriate box on the shipping papers was not checked, but that was regarded as an isolated oversight. G-S advised the NRC inspectors on March 31, 1994, that the licensee had received the test data.

3.7 Work in Process - Use of Test and Measuring Equipment

Illinois Power Company PO 545618 (G-S Sales Order 028311-02) dated June 28, 1993, covered two PD3218 pressure transmitters for the Clinton nuclear plant. The PO imposed 10 CFR Part 21 and Appendix B to 10 CFR Part 50. While observing work in process on March 9, 1994, the NRC inspectors saw a megohmmeter (ID 1-508-005) being used on the production line that was past due for calibration. The meter was due to be calibrated on February 10, 1994. The cognizant supervisor indicated that this meter was used on March 8, 1994, to perform the in-process insulation resistance verification (operation 130) for a transmitter being manufactured for the Illinois Power Company PO. G-S recalibrated the meter on March 10, 1994 and found it to be within tolerance with no adjustment needed.

Criterion XII of Appendix B to 10 CFR Part 50 requires that instruments used in activities affecting quality must be calibrated at specified periods to maintain accuracy within necessary limits. Use of the meter outside its calibration interval constitutes Nonconformance 99901261/94-01-04.

Paragraph 5.1.4.1 of procedure SQP-0123, "Metrology Laboratory Operating Practices and Procedures," Revision AB, dated December 18, 1993, stated that the metrology lab provides a listing of items due for calibration during the upcoming month on the first day of each month. Contrary to the above, the NRC inspectors found that G-S had not issued the overdue listing for the past several months. The inspectors believe this deficiency to be a contributing factor to finding test equipment on the shop floor which was past due for calibration.

In response to this concern, on March 16, 1994, G-S QA issued QA alert notices to the shop supervisors noting all of the test and measuring equipment that was past due for calibration and could not be located. The March 31, 1994, Equipment Master List identified test equipment that could not be located by code "CNL" in the Status field. G-S faxed copies of these documents to the NRC inspectors.

Criterion V of Appendix B to 10 CFR Part 50 requires that activities affecting quality be prescribed by documented instructions and be accomplished in accordance with them. Failure to issue the listings of items due for calibration constitutes Nonconformance 99901261/94-01-05.

3.8 10 CFR Part 21 Program

The NRC inspectors reviewed G-S procedure SQP-0228, "Reporting Potentially Significant Conditions - Nuclear Safety Related Production," Revision B, dated August 30, 1993. This was G-S's current procedure for reporting defects and noncompliances pursuant to 10 CFR Part 21. The inspector noted that this procedure was not sufficient to ensure the completion of the required evaluations of deviations and potential reporting of defects as required by 10 CFR 21.21. Specifically, the procedure did not clearly distinguish between deviations and defects in a manner that encouraged employees to report potential conditions adverse to quality. The definition of basic component in paragraph 3.4 of the procedure was inconsistent with that specified in 10 CFR 21.3(a). The procedure did not identify the responsible officer as defined by 10 CFR 21.3(l), or state that this individual must be informed within five working days after completion of an evaluation which concludes that there is a defect or failure to comply relating to a substantial safety hazard. Finally, The procedure failed to mention that if G-S determined they did not have the capability to perform an

evaluation, they must inform the purchasers or affected licensees within five working days of this determination so that they may evaluate the deviation to identify potential defects in accordance with 10 CFR 21.21(b).

Based on these deficiencies, the NRC inspectors concluded that QA procedure SQP-0228 did not ensure that deviations would be evaluated, that defects or failures to comply would be reported to the responsible officer, or that all affected purchasers or licensees would be informed of deviations when G-S cannot perform the evaluation. These deficiencies constitute Violation 99901261/94-01-01.

The NRC inspectors also evaluated whether G-S had complied with the posting requirements of 10 CFR 21.6. The inspectors found that G-S had posted notices which included a copy of Section 206 of the Energy Reorganization Act of 1974, the name of the individual to whom a report should be made (the vice president of QA), and a reference to G-S's implementing procedure SQP-0228. G-S had not posted a current copy of 10 CFR Part 21, or a notice describing its contents and where it may be viewed, as required by 10 CFR 21.6. This deficiency constitutes Violation 99901261/94-01-02.

As a result of the inspectors' concerns, the vice president of QA committed to revise procedure SQP-0228 to more accurately reflect the evaluation and reporting requirements of 10 CFR Part 21, and G-S posted current copies of 10 CFR Part 21 alongside its previously posted notices during the inspection.

4 PERSONNEL CONTACTED

- * S.S. Pirrone, President
- + * P. Mesmer, Vice President of QA
- + * F. Friberg, Vice President of Operations
- + * S.E. Kim, Director of Engineering
- + * D.A. Norkus, Director of Program and Contract Management
- * J. Cox, Director of Marketing and Sales
- D.J. Bucka, Manager of Mechanical Engineering
- R. Edes, Quality Program Manager
- W. Foltz, Quality Control Manager
- + * P. Blanchard, Quality Engineer
- B. Jewell, QA Metrology Lab Technician, Mechanical
- J. Eggebeen, Senior Process Engineer

+ Attended the entrance meeting on March 7, 1994

* Attended the exit meeting on March 10, 1994