

EXELON CORPORATION
VENDOR CG CALIBRATION SURVEY REPORT
CG-2003-14

Supplier Name / Address / Phone Number

Process Instruments Inc.
615 E. Carson St.
Pittsburgh, PA 15203
Phone: (6412) 431-4600

Audit Dates:

February 26 –27, 2003

Audit Purpose / Scope

The purpose of this Commercial Grade Calibration Survey was to verify the adequacy and implementation of the Process Instruments Inc. Quality Manual, Revision 4, dated July 2002, and supplemental procedures, which are used to provide control of calibration services for resistance standards owned by the Exelon Power Labs.

Background

Process Instrument Inc. is a small company that employees approximately twenty (20) people. The facility consist of various laboratories capable of performing electronic, electrical and mechanical calibrations and tests including but not limited to: dimensions, force, torque, mass, length, angular, level, time, resistance, temperature, humidity, PH, conductivity, pressure, color resistance, and optics. The company also performs manufacturing / repairs of commercial electronic /electrical equipment. At the request of Exelon Power Labs, Process Instruments was added to the Exelon Evaluated Vendors List in 2002. A 2000 survey performed by Southern Nuclear Operating Company was reviewed along with their Quality Manual and used as the initial basis for adding this vendor to the EVL.

Summary

The Calibration Survey was performed at the Process Instruments Inc. Pittsburgh, PA facility. Using Revision 1 of the NUPIC Commercial Grade Survey checklist for Calibration Services, the survey was accomplished by review of procedures, discussions of work activities with responsible personnel, oversight of Laboratory facilities, standards, M&TE, and processes utilized for performance of resistance calibration activities. The reviews, discussions and observations conducted at the Pittsburgh, PA facility established that the calibration services performed by Process Instruments Inc. are being accomplished in a satisfactory and controlled manner. Details of audit areas reviewed are provided in the Investigative Summary section below as well as the survey checklist. No findings were issued as a result of this survey.

There were no new special order entry requirements identified needing to be imposed as a result of this survey. It should also be noted that the Process Instrument's quality system does not address 10CFR50 Appendix B or 10CFR21. Process Instruments Inc. does accept special requirements to notify clients when problems or nonconformances are identified with equipment that they qualify or programs that they encounter.

Based on survey results, the Process Instruments Inc. Quality Program was determined to be effectively implemented for the services that they are currently providing to Exelon.

Previous Survey Findings / NUREG 0040

The previous NUPIC Member Commercial Grade Survey performed by led by Southern Nuclear Operating Company performed February 29, 2000. There were no findings issued as a result of the survey.

There are no NUREG 0040 listings for Process Instruments Inc.

Investigative Summary

Section I – Training/Qualification of Personnel

In accordance with section 18 of the Quality Manual, Process Instruments provides on the job and third party training. Records of the training are maintained. Procedures specify that only adequately trained personnel are authorized to perform requisite tasks.

Review of PI procedure 18, noted that it addresses that training needs / goals are determined through performance of employee reviews. All employees are required to be trained in procedures appropriate to their job function. Training can be accomplished by schooling or OJT relevant to skills. For individuals involved in internal auditing, auditor training includes auditing fundamentals. Records are maintained in an established Training Log (computerized). Specific training requirements were noted to be established for the positions / jobs within the company. Training records were reviewed for six individuals in one of the following positions: Calibration Technician, Calibration Manager, Asst. Calibration Manager, and Contract Administrator. All records were found to meet established training requirements and reflected training in: the Quality System, Policies, Safety and OJT as applicable for the individual's assigned function.

This area was determined to be satisfactory.

Section II – Calibration System Description

Verified that Process Instruments has an established and documented Quality System. Noted that Process Instruments Policies and Objectives are defined in the Quality Manual and Quality Management Procedures. All quality documentation was found to be entered into the Process Instruments computer database. The documentation is kept current in the system and is available on line to all personnel at their workstations. The Process Instrument's Organization Charts were noted to be maintained in the Quality Management Procedure

1, section 1.5.1 and the Quality Management Organization Chart in section 1.5.2 (Rev 6 dated 10/02) and were available for review. Process Instruments Documentation provided during the audit was found to address the scope of Process Instruments lab activities. Process Instruments is accredited to A2LA, ISO Guide 17025-1999 and ANSI/ NCSL Z540-1-1994. Process Instruments performs calibrations on various types of equipment/parameters such as Electrical, Time and Frequency, Dimensional, Mechanical, and Thermodynamics. Quality Management procedures were noted to include guidance for personnel training, procedure control, standards maintenance, nonconformance control, internal audits and record control.

The Process instruments Quality system is established to comply with ISO 9001 or ISO 9002 (1994). The program does not address 10CFR50 Appendix B or 10CFR21.

In accordance with section 1.3 of the quality manual, at appropriate intervals, the Quality Manger reviews internal audits to assess the implementation of the quality system. The results of these reviews are used as one of the basis for system improvement. The Quality Manager also performs investigation of non-conforming conditions when warranted. The 2003 Management review was in process during the audit and the status was discussed with the Quality Manager. The 2002 Management Review completed in February 2002. It was noted to address: internal and third part audits, customer survey results, Corrective Action and Preventive Action, Customer Complaint analysis, Suitability of policies and procedures, changes in capabilities and volume of work, work flow and processes, results of MAPs, ILCs and proficiency tests, conformance to quality standards, invoice reviews, and nonconformance reviews.

This area was determined to be satisfactory.

Section III – Contract Requirements

In accordance with Quality Manual section 3, it was noted that process instruments has procedures defining the process for the entry, amendment, and maintenance of customer orders. In accordance with procedure 3 “Contract Review: Quotations – Orders”, quotations can be provided by trained sales personnel. Nothing is to be quoted to a customer before confirming availability. If unsure, order entry personnel are required to contact the appropriate area manager to confirm that Process instruments can supply the product or services.

Order Entry personnel are required to review incoming purchase orders for correct price, quality requirements, and delivery information. Purchase orders for calibration are entered into the “Accounting and Calibration” software tracking system. If necessary, the client is contacted to clarify any calibration requirements and to obtain agreement for any requirement that is beyond the capability of Process Instrument. Amendments to quotes, customer orders and invoices are allowed if a review of the amendment is performed including confirmation that the customer understands and agrees with the amendment. When it is determined that work can be performed as described in the purchase order, the “order review and accepted by” field is initialed by the approver. All non-standard item orders are reviewed and approved by the Calibration Manger.

The order entry process and purchase order examples were reviewed and discussed with the Contract Administrator. It was explained that upon receipt, orders are reviewed to determine if any special requirements exist. Instructions, technical and quality requirements are noted. The scope documents are reviewed to assure that PI can perform the service / provide the product. The applicable lab is then notified of the order. The Contract Administrator enters the purchase order into the “Entry System” software and runs a report. The purchase order examples reviewed were all found to be properly completed and approved.

This section was considered satisfactory.

Section IV – Adequacy of Measurement Standards

In accordance with the Process instruments Quality Manual section 11, all test and measurement standards are controlled by the quality system to assure the integrity of measurements. Calibration is traceable to NIST or to fundamental physical constants. Measurement and test ratios are defined. Calibration environments are controlled to the extent necessary to maintain claimed uncertainties. Where applicable, Process Instruments participates in Measurement Assurance programs and Inter-laboratory comparisons (ILC's) to evaluate and verify claimed uncertainties.

In accordance with procedure 11 "Calibration", Uncertainties (if applicable) are documented on the Calibration / Certification Report. Traceability is maintained by an unbroken chain of comparisons to national or intrinsic standards; by periodic recalibration of calibration assets following approved procedures, generally accepted practices, or original equipment manufacturer (OEM); and by calculating the overall measurement uncertainty based on the uncertainty stated at each step in the chain. If process Instruments does not have the capability to calibrate standards internally, they are sent to NIST or to a qualified laboratory accredited by A2LA or NVLAP. Copies of these laboratory accreditation certificates are maintained in process Instrument's files.

Where appropriate, process instruments maintains a minimum 4:1 Test Uncertainty Ratio (TUR) unless approved by the Calibration Manger or where multiple standards are used and the collective uncertainty is computed using a root sum of squares method.

Verified by review of procedural controls, discussion with responsible personnel and review of M&TE / standards and calibration records during the survey that the uncertainties for calibration standards used to perform resistance calibrations (for Exelon resistance standards, have a minimum 4:1 uncertainty as documented on the calibration records:

Examples reviewed during the survey included: High Precision Thermometer serial 230, asset# 140079, calibrated 2/14/03; Autoimatic Current Comparator Bridge, asset# 140132, calibrated 2/5/03; Resistor Standard 140161 calibrated 5/14/02; Thermistor Probe Asset 140180 calibrated 2/14/03

This area was determined to be satisfactory.

Section V – Calibration Procedures

In accordance with Quality Procedure 8 "Calibration", procedures used for Process Instrument Inc. calibration activities include manufacturer's calibration procedures, DOD calibration procedures and operator's manuals. These manuals are on file and are accessible to technicians. If no procedure is available, a new procedure is developed. The procedure is based on functionally equivalent items or on an outline established in the Quality System. Uncertainty specifications are taken into consideration for all ranges and functions of the unit under test. Prior to putting an in-house procedure into place it is validated. Hard copy procedures are reviewed annually for updated revisions. Any obsolete procedures are removed and destroyed. A list of procedures is maintained showing the date of the procedure, the date of review, and who performed it. Verified by review of resistance standard calibration procedures, the procedures list and other example documentation along with observation of activities in the laboratories that procedures are available and are being used by personnel for

the calibrations performed. The procedures reviewed were noted to address the standards to be used, equipment to be used, as well as the required parameters to perform the calibration.

In accordance with the Process Instrument procedure 11 for Calibration, traceability is established for internally calibrated items by following approved procedures, maintaining a minimum 4:1 uncertainty ration (where applicable and calculated using expanded uncertainties at approximately the 95% confidence level established at $k=2$) expanded uncertainties are calculated following established procedures as outlined in published documents such as ANSI /NCSL Z540-2-1996 or other similar standards. Test uncertainty ratios less than 4:1 are reported out where multiple standards are use in the calibration process. The collective uncertainty is completed using the root sum of the squares method. The guidance of ANSI / NCSL 2-540-2-1996 is also used. Test Uncertainty ratios less than 4:1 may be used only with the approval of the calibration Manager.

In accordance with procedure and based on the type of equipment calibrated by Process Instrument, sampling is not performed on a routine or a prescribed basis. No instances where sampling was employed was noted during the survey.

All resistance standard calibrations are performed by the Calibration Manger. His results are reviewed / and verified by the Assistant Lab Manager. Likewise all calibration certificates are reviewed and approved by an individual (the Calibration Manager or the Quality Manager) other than the person who performed the calibration. The Calibration Manager also reviews results of all Inter-laboratory Comparisons and/or proficiency test for successful participation.

Per discussion with the Calibration Manager and observation of resistance lab activities noted that for resistance standard testing standard Software is part of the test equipment. The test / calibration equipment includes a resistance bridge, a thermal scanner, resistance standards (calibrated by NIST (1 ohm & 10K ohm)), dummy resistance standards, an oil bath, thermometer, and barometer. The standard resistor under test (Unit Under test – UUT) is compared to a calibrated standard resistor using the resistance ratio bridge and a substitution method of calibration. The actual UUT resistance is determined and noted at the time of the test. This equipment is connected to a Measurements International Limited model 6010 Automatic Resistance / Thermometer Bridge Program. The printouts from this program provide a measured run for a customer. A file is maintained on the computer by the device (resistor) serial number to provide a history. The computer data is placed on a hard drive and is backed up on tape through a server on the network once a day. The server is password protected. In addition to the use of resistance standards provided directly from NIST, Process instruments validates their test / calibration results through NCSL & NVLAP inter-laboratory comparisons with other laboratories. Examples of inter-lab comparisons between 1998 and 2002 for various resistor sizes and types were shown during the survey supporting the results and accuracies of the Process instrument calibrations.

This area is considered satisfactory.

Section VI – Environmental Controls

It was observed that Process Instruments ensures that facilities are maintained in a fashion to support correct performance of calibrations in accordance with QAM sections 10 and 11. Processes are in place to ensure that environmental conditions are maintained in a manner so that the quality of measurements is not at risk and can be performed in a manner specified in the technical document for the item supported.

During the audit, observed that all laboratories are clean and environmentally controlled. Noted use of strip chart recorders in each lab to track temperature and humidity in each lab. In accordance with controlling

procedures when M&TE is received for calibration, the units under test are acclimatized in the lab or bath (as appropriate) overnight or at least 12 hours prior to calibration. As required by procedure and as shown during a facility walk down, heating and cooling equipment as well as sensors and controllers are used to control calibration environments to the extent necessary to insure integrity of the calibration results. Access to the labs is controlled to insure the integrity and security of measurements and data. Appropriate housekeeping is performed on a daily and weekly basis. Temperature and Relative Humidity ranges were noted to be established by procedure for each lab and the shop area. As reflected by data taken from the strip chart records in the labs / shop area, the required environments are being maintained.

Calibration reports are required to include the environmental conditions where / when the item was calibrated. If the environmental conditions exceed procedural limits, the Laboratory Manager is notified to determine whether or not to proceed with the calibration before the environment is brought back under control.

This area was determined to be satisfactory.

Section VII – Intervals of Calibration

It was shown that in addition to labeling on the pieces of equipment which shows the calibration due date, Process Instruments uses a customer recall system called "Calibration Manager" that is built into the computer order entry / reporting system. Using this system, customers are notified (via mail / fax) approximately 30 days prior to the calibration due date of the instrument.

For Process Instrument's own calibration equipment, the Asset system is used. Once a month a report is run for equipment due for maintenance and/or calibration. If a piece of equipment becomes overdue for calibration or maintenance it is highlight on the report in yellow for resolution (the Contract Administrator runs the reports)

Verified by review of the databases and various pieces of M&TE and Standards that calibration frequencies are established, documented and maintained for standards / equipment

This area was determined to be satisfactory

Section VIII – Calibration Status

Verified by review of Quality manual section 8 & 12, procedure 11 "Calibration", discussion with responsible personnel and observation that M&TE / standards/ items are identified by the OEM description noted in manuals, parts list, or are grouped together (e.g. Diodes). Instruments are identified by make, model, and serial number. Items in house for repair are identified by Work Order # Customer items in house for calibration are identified by the item's unique make, model, and serial or identification number.

Worksheets are generated and accompany customer-supplied items in the PI facility. The items inspection status is indicated by initials in the appropriate fields of the worksheet. Customer items in for repairs are tagged as such at receiving. Purchased items are segregated to the "incoming Shelf" after an acceptable inspection. Completed calibrated equipment is identified with a calibration sticker per section 15 of the calibration

procedure. M&TE that are not standards are identified with "Reference Only" or Calibration not Required stickers".

Process Instrument's own equipment is also required and was noted to be identified by the Asset number (except for standards that are kept in baths that are controlled by their serial numbers). Asset numbers are assigned using the Asset program that identifies the Work Order number, Asset Manufacturer, serial number, and description.

If an item is found to fail calibration it is removed from service and a determination is made to repair or to retire the item. If an item is repaired it is calibrated before being returned to service. If an item is retired it is assigned a "Do Not Use" sticker, segregated, and discarded or stored for parts.

For equipment requiring adjustments, noted that Process Instruments applies tamper proof seals

This area was determined to be satisfactory

Section IX – Calibration Traceability

Per sect 11 of the Quality Manual, Process Instruments maintains traceability of standards and M&TE to NIST or to fundamental physical constants. The program ensures traceability through an unbroken chain of comparisons to NIST, inter-laboratory comparisons or proficiency testing where available and appropriate. During the survey, certificates of calibration were reviewed for several pieces of equipment and found to include adequate traceability. Also observed that Process Instruments participates in inter laboratory comparisons for resistance standards. The Inter-Comparison results are used by PI to validate their resistance standard measuring system and provides further confidence in the quality and accuracy of their measurement results.

This area was determined to be satisfactory

Section X – Subcontractor Calibration

In accordance with Process Instruments Quality Manual section 6 requirements, suppliers are classified as critical, rated or non-rated. The suppliers are evaluated according to their classification. Critical suppliers are evaluated to Mil Standard 45662 requirements. Process Instruments currently has 19 vendors on their evaluated suppliers list. The vendors were all noted to be qualified by survey (March 2000 / April 2000) or NVLAP. It is Process Instrument's policy not to sub work out if they cannot do it themselves. They will sub out work only if instructed to by a customer.

Process Instruments does not use sub-suppliers (or NVLAP) for resistance measurement activities. Process Instruments performs self-surveys. Their 1 ohm and 10K ohm resistance standards are sent to NIST and the other resistance standards are calibrated using these two standards and by Interlaboratory comparisons.

For that Process Instruments owned equipment standards that they do send out for calibration, certifications were found to be on file that were traceable to NIST / NVLAP.

This area was determined to be satisfactory.

Section XI – Storage and Handling

Verified by review of documentation and observation of activities in the receiving / shipping area and laboratories, M&TE / standards are being handled stored and transported in accordance with established procedures to prevent deterioration or damage.

In accordance with QAM section 15 and implementing procedures, upon receipt, material is inspected to assure correct items / attachments are received and are not damaged. Equipment received in protective cases is retained in those cases except when it is being worked on (calibrated). The items are then placed on shelves and tagged as part of the receipt process. The item(s) are entered into the computer database (tag #, customer number, date sales order #). Calibration items are placed directly onto carts and are given to the Administrator for processing into the database. After processing the items are transferred to the applicable lab. The item is either hand carried or moved via a handcart between locations. Items to be calibrated are temporarily stored in one of the laboratories. The Lab Manager / Product Manager is responsible for the storage / inventory of the item(s) in his possession. All laboratories are environmentally controlled. Customer items are not (permanently) stored.

For out going items, it was indicated that PI must meet the customer's packaging requirements. These requirements are documented on the traveler or in the database. Special handling / packing instructions are also followed for delicate items such as liquids, glass articles, and chemicals. Noted that print out labels are applied to the item showing: Work Order Number, Customer Name, Manufacturer, Model Number, Serial Number and PI Asset number. The shipping containers utilized are primarily corrugated boxes. The items are double boxed with peanuts/ bubble wrap/ foam system for packing / filler to protect the equipment. Observed packing /shipping activities performed for a Bechtel Bettis, Inc order involving a Fluke Digital Multimeter, model 3478A, serial 2545A21384.

This area was determined to be satisfactory.

Section XII – Out-of-Tolerance & Corrective Action

Reviewed Quality Manual section 13 which addresses nonconforming products. Items failing inspection or test, damaged in shipment, or in the Care of Process Instrument Inc are treated as nonconforming and are dispositioned in an appropriate and controlled manner. Examples of nonconforming item tagging and designated nonconformance item segregation shelves/ areas were shown to the auditor during survey activities. The Quality Manager is responsible for initiating corrective action. Once corrected, conformance of an item is verified by processes and inspection.

In accordance with Process Instrument procedure 13 " Nonconforming Items", it is Process Instrument's policy to address and correct all non-conforming items. Personnel performing inspections are responsible for initiating non-conformance reports. For customer items damaged while in Process Instruments care, the area manager is responsible for obtaining customer direct disposition. The Quality Manager is responsible for verifying disposition of non-conforming material.

Nonconforming items are documented on nonconformance item reports. The nonconformance report is kept with the item until it is dispositioned. (Dispositions were noted to be: rework, scrap, return to supplier, use-as-is, other.) Nonconforming items are segregated until disposition. Based on interview of receipt personnel and observation of activities in the receipt area, if any equipment is found to be damaged at the time of receipt, it is place into a segregated area (designated shelf) and the item is documented on a nonconforming form for

identification / tracking of concern. There were no nonconforming items in the receipt area at the time of the survey. In the shop / labs segregation is not required but items are identified as nonconforming. Nonconforming inventory items are considered useless and are discarded as soon as convenient.

Nonconformances are evaluated to determine the appropriate disposition. For customer owned items, the customer is notified and customer approval of the disposition is obtained. (Per discussion with the Quality Manager, it was explained that if equipment is found out of tolerance and PI can't do work. Process Instrument will look for a subcontractor but will not subcontract work without customer approval.) The disposition is documented on the nonconformance report. The item is then processed per the disposition, reworked if applicable, and re-inspected to verify conformance. After corrected action is completed the nonconformance form is initialed by the originator, reviewed/ verified and initialed by the Quality Manager. If any additional corrective action is necessary, it is initiated / taken by the Quality Manager

This area was determined to be satisfactory.

Section XIII – Calibration System Adequacy

Per Quality Manual sect 17, Process Instruments performs periodic internal audits. The company's activities are reviewed for opportunities for continuous improvement and to ensure compliance to quality system implementation. The results of these internal audits are used to form the basis of Management Reviews. If nonconformances are identified during internal audits, the Quality Manager is responsible for investigating causes of the nonconforming practice or product and for initiating corrective and preventive action as appropriate. The corrective and preventive actions are required to be verified. During the survey it was shown that the 2003 internal audit was In-process. Documentation for the previous Internal audit and Management Review that was completed in February 2002 was reviewed and noted to address all elements of the Process instruments Quality System. Twelve (12) Findings that were noted to have been identified in several of the areas were tracked / being tracked to completion in an adequate manner.

Per review of implementation procedures 17 "Internal Audits", it was noted that controls are established for the performance of internal audits to test implementation of the quality system and conformance to ISO 9001 and ISO/IEC 17025. Sections of the quality system are reviewed by a person independent of the functions. Static functions are audited less frequently than dynamic functions. Internal auditors are trained by a qualified system auditor. Records of the training are maintained in the Training Log. Audits are accomplished using checklists. Results are recorded on the checklist or an equivalent document. Audits are planned by the Quality Manager. The frequency of the audits is at least annually (for slowly evolving sections). Nonconforming audit results are documented in part one of the Audit Finding report. Corrective Actions are documented in part two of the finding report. The Quality Manager assigns verification of implementation and effectiveness of corrective actions documented Audit results are distributed to the Area Manager(s) of the function assessed.

The Quality Manager maintains completed Audit Finding reports and Checklists as quality records. The Quality Manager reports the results of audits during Management reviews. He also verifies implementation of any non-conformances during or prior to the Management Review.

In addition to internal audits, Process Instruments also participates in proficiency testing/inter-laboratory comparisons testing to establish the adequacy of the calibration system. Examples of these tests were explained and discussed during the survey as they relate to resistance standards calibration.

This area was determined to be satisfactory.

Section XIV – Records

Verified that record controls are established in section 16 of the Quality Manual. Quality records were found to be indexed, controlled and protected to insure their availability and currency. Customer related quality records are maintained for a minimum of six years. Older procedures and policies are archived. The storage and disposal of quality records are controlled by procedure to protect their integrity. Access to quality records is controlled as appropriate to the record.

In accordance with procedure 16 “Quality Records”, noted that Quality records are identified to include: Vendor packing slips, customer packing slips, instrument orders, part orders, service orders, repair orders, calibration orders, customer purchase orders, PI purchase orders, calibration records, change forms nonconforming item forms, audit forms, audit finding forms, management review forms.

Each person who handles / completes a quality document is responsible for its legibility and integrity. Controls are established for correcting errors to documents. Administrative office personnel are responsible for filing, retrieving, and maintaining records. The Calibration Manager is responsible for the maintenance of calibration records and procedures. Procedure indexes are located at the beginning of each document. Software calibration procedures are indexed in MET/CAL Indexes. Printed calibration procedures are indexed and filed in cabinets.

Record files are required to be stored in a dry location that they won't degrade. Observed records to be filed in locked filing cabinets with limited access. Internal and customer calibration certificates / reports are stored in locked files in the PI office having a security system. Customer calibration records are released only to that customer. Various calibration / certification records for customer and PI standards and M&TE along with personnel qualification and training records were reviewed. In all cases the reports and records were found to be retrievable, legible, properly completed and maintained

This area was determined to be satisfactory

Administrative Details

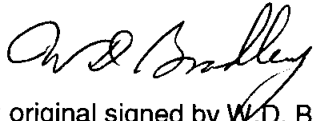
Audit Team Members:

Bill Bradley, Audit Team Leader, Exelon Generation

Personnel Contacted:

Karl Klevens, Calibration Manager	(1)
Jay Klevens, QA Manager	(1) (2)
Julian Taylor, Administrative Assistant	(1)
Anthony Alessio, Calibration Technician	(1)

(1) Attended Pre-Audit meeting
 (2) Attended Post Audit meeting



3/3/04

Audit Prepared by: original signed by W.D. Bradley Date: 03/03/04



3/3/04

Audit Approved by: original signed by W.D. Bradley Date: 03/03/04